

Regulation Review and Impact Analysis Report v. 6.10

as of October 31, 2016

Attachments

- Table A: Listing and Status Report on Regulations Reviewed
- Table B: Summary and Analysis of Agency Notices and Regulations
- Table C: NIHB Recommendations and Evaluation of Agency's Subsequent Actions
- RRIAR Index
- RRIAR Number Reference Guide

NOTE: For regulatory actions taken prior to January 1, 2013, please see the Regulation Review and Impact Analysis Report (RRIAR), v. 2.12 dated December 31, 2012. For regulatory actions taken from January 1, 2013, to December 31, 2013, please see the RRIAR, v. 3.12, dated December 31, 2013. For regulatory actions taken from January 1, 2014, to December 31, 2014, please see the RRIAR, v. 4.12, dated December 31, 2014. For regulatory actions taken from January 1, 2015, to December 31, 2015, please see the RRIAR, v. 5.12, dated December 31, 2015.

The purpose of the Regulation Review and Impact Analysis Report (RRIAR) is to identify and summarize key regulations issued by the Centers for Medicare and Medicaid Services (CMS) pertaining to Medicare, Medicaid, CHIP, and health reform¹ that affect (a) American Indians and Alaska Natives and/or (b) Indian Health Service, Indian Tribe and tribal organization, and urban Indian organization providers. Furthermore, the RRIAR includes a summary of the regulatory analyses prepared by the National Indian Health Board (NIHB)², if any, and indicates the extent to which the recommendations made by NIHB were incorporated into any subsequent CMS actions.

In addition to this cover page, the report consists of three tables as well as an added health reform index and number reference guide –

- Table A provides a status report on the RRIAR itself, listing the regulations included in the RRIAR to date, and the components of the analysis provided under each. The regulations are organized in four sections: I. Medicaid; II. Medicare; III. Health Reform; and IV. Other.
- Table B lists key regulations issued by CMS, due dates for comments, a synopsis of the CMS action, and a summary of the analysis, if any, prepared by NIHB.
- Table C identifies the recommendations made by NIHB pertaining to each regulation, if any, and evaluates the extent to which the recommendations made by NIHB were incorporated into subsequent CMS actions.
- The RRIAR Index: Health Reform lists key terms (further sorted by subtopic, when applicable) found in regulations implementing health reform, with the corresponding RRIAR entry numbers and page numbers shown. The accompanying RRIAR Number Reference Guide: Health Reform provides a listing, by RRIAR entry number, of the notice type, short title, and issuing agency or agencies for each entry.

Regulations with pending due dates for public comments -

- > 48.f. Medical Loss Ratio Report for MA Plans and PDPs (CMS-10476; comments due 11/1/2016)
- 112.y. Dear Tribal Leader Letter (Core Provider Network) (VA/no ref. #; comments due 11/5/2016)
- > 112.z. Dear Tribal Leader Letter (IHS Headquarters Realignment) (IHS/no ref. #; comments due 11/5/2016)
- 13.d. Medicare Quality of Care Complaint Form (CMS-10287; comments due 11/7/2016)
- 72.c. Physician Certification/Recertification in SNFs (CMS-R-5; comments due 11/7/2016)
- 92.III. Health Insurance Enforcement and Consumer Protections Grants (CMS-10605; comments due 11/7/2016)
- 109.b. Notice Requirements of Continuation Coverage (DoL/OMB 1210-0123; comments due 11/7/2016)
- 139.d.Ambulance Transports and Signature Requirements (CMS-10242; comments due 11/7/2016)
- 112.r. Secondary Authorization Request for VA Community Care (VA/OMB 2900-0823; comments due 11/10/2016)
- > 153.t. CMS/OPM Computer Matching Program (CMS/no ref. #; comments due 11/10/2016 approx.)
- > 153.u.CMS/Peace Corps Computer Matching Program (CMS/no ref. #; comments due 11/10/2016 approx.)
- 27.w. Evaluation of Training--Stabilization Programs (CMS-10598; comments due 11/14/2016)
- > 41.g. Revisions to State Medicaid Fraud Control Unit Rules (HHS OIG/RIN 0936-AA07; comments due 11/21/2016)
- 2.e. Part C--Medicare Advantage and 1876 Cost Plan Expansion (CMS-10237; comments due 11/30/2016)
- 2.f. Applications for Medicare Prescription Drug Plan Contracts (CMS-10137; comments due 11/30/2016)
- 25.c. Indirect and Direct Graduate Medical Education Costs (CMS-R-64; comments due 11/30/2016)
- 49.c. Financial Statement of Debtor (CMS-379; comments due 11/30/2016)
- > 52.i. Home Health PPS Rate Update: Physician Narrative Requirement (CMS-10311; comments due 11/30/2016)

National Indian Health Board, Regulation Review and Impact Analysis Report

¹ "Health reform" is inclusive of (1) the Patient Protection and Affordable Care Act (Pub. L. 111-148), incorporating by reference S. 1790 as reported by the Committee on Indian Affairs of the Senate in December 2009 (containing amendments to the Indian Health Care Improvement Act, IHCIA), and as amended by the Health Care and Education Reconciliation Act (HCERA; Pub. L. 111-152) (collectively referred to as "ACA") and (2) the American Recovery and Reinvestment Act of 2009 (ARRA, Pub. L. 111-5)

² The analyses and recommendations may include those made by the Tribal Technical Advisory Group to CMS (TTAG) and other tribal organizations.

- > 60.n. Health Insurance Common Claims Form (CMS-1490S; comments due 11/30/2016)
- 121.c. Medicare Participating Physician or Supplier Agreement (CMS-460; comments due 11/30/2016)
- 134.b.Medicare Provider Cost Report Reimbursement Questionnaire (CMS-339; comments due 11/30/2016)
- 136.j. Reducing Health Care-Acquired Conditions in Nursing Homes (CMS-10622; comments due 11/30/2016)
- > 112.t. Tribal Consultation on Great Plains Area IHS (IHS/no ref. #; comments due 11/30/2016)
- 25.m. Geographic Classification Review Board Procedures (CMS-R-138; comments due 12/12/2016)
- 121.d. Notification of Co-Located Medicare Providers (CMS-10088; comments due 12/12/2016)
- > 3.b. DME Competitive Bidding (CMS-10169; comments due 12/13/2016)
- > 71.f. End Stage Renal Disease Medical Information Facility Survey (CMS-2744; comments due 12/13/2016)
- 114.b. Evaluating a Pilot Mobile Health Program (CMS-10634; comments due 12/13/2016)
- 7.000.CMS Healthcare.gov Site Wide Online Survey (CMS-10597; comments due 12/14/2016)
- 136.h.MIPS and Alternative Payment Model Incentive Under PFS (CMS-5517-FC; comments due 12/19/2016)
- 8.f. Montana HELP Federal Evaluation (CMS-10635; comments due 12/20/2016)
- 7.x. Notice to Employees of Coverage Options (DoL/OMB 1210-0149; comments due 12/27/2016)
- 31.q. Exchange Functions: Eligibility for Exemptions (CMS-10466; comments due 12/27/2016)
- ➤ 11.d. Bid Pricing Tool (CMS-10142; comments due 12/30/2016)
- 11.f. Plan Benefit Package and Formulary Submission (CMS-R-262; comments due 12/30/2016)
- 11.x. Medication Therapy Management Program Improvements (CMS-10396; comments due 12/30/2016)
- 16.c. Home and Community Based Services Waiver (CMS-8003; comments due 12/30/2016)
- > 52.w. Waiver (CMS-8003; comments due 12/30/2016)
- > 176. Waiver Application for Providers Subject to Moratorium (CMS-10629; comments due 12/30/2016)

Comments recently submitted by NIHB, TTAG, and/or other tribal organizations -

- 7.III. 2017 Letter to Issuers in FFMs (CCIIO/no ref. #; comments submitted 1/17/2016 by TSGAC)
- 136.e. Requirements for Reporting Quality Measures (CMS-3323-NC; comments submitted 2/1/2016)
- 14.c. Waivers for State Innovation (CMS-9936-N; comments submitted 2/23/2016 by TSGAC)
- 83.a. Medicaid/Transformed-Medicaid Statistical Information Systems (CMS-R-284; comments submitted 2/29/2016 by TTAG)
- > 136.c. PQRS and the eRx Incentive Program Data Assessment (CMS-10519; comments submitted 2/29/2016 by TTAG)
- 206. Measures of Quality Improvement Activities (AHRQ/no ref. #; comments submitted 3/4/2016)
- 31.III. Indian-Specific CSV SBC Sample Templates (CCIIO/no ref. #; comments submitted 3/18/2016 by TTAG)
- 136.g.CMS Quality Measure Development Plan (CMS-10519; comments submitted 3/18/2016 by TTAG)
- 60.l. Expanding Uses of Medicare Data by Qualified Entities (CMS-5061-P; comments submitted 3/29/2016)
- 8.d. Oklahoma 1115 Waiver Amendment (11-W-00048/6; comments submitted 4/5/2016 by TSGAC)
- 112.g. Recognition of Tribal Groups for Representation of VA Claimants (VA/no ref. #; comments submitted 4/11/2016)
- 43. Medicaid Reimbursement for Outpatient Drugs (CMS-2345-FC; comments submitted 4/21/2016)
- > 31.III. Indian-Specific CSV SBC Sample Templates (CCIIO/no ref. #; comments submitted 5/4/2016 by TTAG)
- ➤ 112.n.Catastrophic Health Emergency Fund (CMS-359/360; comments submitted 5/10/2016 by TSGAC)
- 31.iii. Tribal Consultation on ACA Employer Shared Responsibility (IRS/no ref. #; comments submitted 5/13/2016 by TSGAC)
- 212. Enhancing Retailer Standards in SNAP (USDA FNS/RIN 0584-AE27; comments submitted 5/16/2016)
- 112.d.I/T/U Payment for Physician and Non-Hospital-Based Services (IHS/RIN 0917-AA12; comments submitted 5/20/2016 by TSGAC)
- > 112.p.FDA Tribal Consultation Policy (FDA/no ref. #; comments submitted 5/31/2016)

- > 112.m. Dear Tribal Leader Letter (Contract Support Costs Policy) (IHS/no ref. #; comments submitted 6/10/2016)
- 25.ii. PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. (CMS-1655-P; comments submitted 6/17/2016)
- 136.h.MIPS and Alternative Payment Model Incentive Under PFS (CMS-5517-P; comments submitted 6/27/2016 by TTAG)
- 216. HHS Grants Regulation (HHS/RIN 0991-AC06; comments submitted 8/11/2016)
- 4.o. Hospital OPPS and ASC Payment System for CY 2017, et al. (CMS-1656-FC; comments submitted 9/6/2016)
- 70.g. Revisions to PFS and Other Changes to Part B for CY 2017 (CMS-1654-P; comments submitted 9/6/2016)
- 46.f. Treatment of Third Party Payers in Calculating DSH (CMS-2399-P; comments submitted 9/14/2016)
- > 112.x. Dear Tribal Leader Letter (IHS Draft Quality Framework) (IHS/no ref. #; comments submitted 10/3/2016)
- 89.t. Notice of Benefit and Payment Parameters for 2018 (CMS-9934-P; comments submitted 10/5/2016 by TSGAC)
- 112.v. Dear Tribal Leader Letter (Consultation on Tribal Priorities) (VA/no ref. #; comments submitted 10/7/2016)
- > 112.s. Dear Tribal Leader Letter (Community Health Aides) (IHS/no ref. #; comments submitted 10/27/2016)
- 112.n. Catastrophic Health Emergency Fund (IHS/RIN 0905-AC97; comments submitted 10/28/2016 by TSGAC)
- > 112.u. Dear Tribal Leader Letter (Tribal Premium Sponsorship) (IHS/no ref. #; comments submitted 10/28/2016 by TSGAC)

Regulations under OMB (Office of Management and Budget) review –

- > 54. ESI Coverage Verification (CMS/RIN 0938-ZB09; approved by OMB 4/26/2012 but not yet published)
- 16.b. Medicaid HCBS Waivers (CMS-2249-F2; approved by OMB 1/14/2014 but not yet published)
- > 180. Flu Vaccination Standard for Certain Providers and Suppliers (CMS-3213-F; approved by OMB 4/18/2014 but not yet published)
- 164.b. Medicare Secondary Payer and "Future Medicals" (CMS-6047-P; approved by OMB 10/9/2014 but not yet published)
- 6.i. Pre-Existing Health Insurance Plan Program Updates (CMS-9995-IFC4; sent to OMB 2/3/2015)
- 3.q. Requirements for Prosthetics Practitioners and Suppliers (CMS-6012-P; sent to OMB 4/27/2015)
- 52.I. Home Health Agency Conditions of Participation (CMS-3819-F; sent to OMB 5/6/2016)
- 214. Medicaid Supplemental Payment and Accountability (CMS-2393-P; sent to OMB 7/19/2016)
- 194.e.340B Drug Pricing Program Omnibus Guidance (HRSA/RIN 0906-AB08; sent to OMB 9/1/2016)
- 136.h.MIPS and Alternative Payment Model Incentive Under PFS (CMS-5517-FC; sent to OMB 9/14/2016)
- 154.c. Use of Pass-Through Payments in Medicaid Managed Care (CMS-2402-P; sent to OMB 10/18/2016)
- 188.c. Fire Safety Requirements for Certain Dialysis Facilities (CMS-3334-P; approved by OMB 10/20/2016)
- > 194.d.340B Ceiling Price and CMPs Regulation (HRSA/RIN 0906-AA89; sent to OMB 10/21/2016)
- 52.u. Home Health PPS Rate Update for CY 2017, et al. (CMS-1648-F; approved by OMB 10/26/2016)
- 71.p. Medicare ESRD PPS for 2017, et al. (CMS-1651-F; approved by OMB 10/26/2016)
- 4.o. Hospital OPPS and ASC Payment System for CY 2017, et al. (CMS-1656-FC; approved by OMB 10/28/2016)

Recent (final) rules issued -

- 31.ddd. 2017 Actuarial Value Calculator (CCIIO/no ref. #; issued 1/21/2016)
- 43. Medicaid Reimbursement for Outpatient Drugs (CMS-2345-FC; issued 2/1/2016)
- ➤ 26. Medicaid Home Health (CMS-2348-F; issued 2/2/2016)
- 49.a. Reporting and Returns of Medicare Overpayments (CMS-6037-F; issued 2/12/2016)
- 204. Medicaid Services "Received Through" an IHS/Tribal Facility (SHO #16-002; issued 2/26/2016)
- 7.III. 2017 Letter to Issuers in FFMs (CCIIO/no ref. #; issued 2/29/2016)
- 39.f. Basic Health Program: Federal Funding Methodology for 2017 (CMS-2396-FN; issued 2/29/2016)
- > 89.m. Notice of Benefit and Payment Parameters for 2017 (CMS-9937-F; issued 3/8/2016)

- 89.n. Manual for Reconciliation of Advance Payment of CSRs (CCIIO/no ref. #; issued 3/16/2016)
- 112.d.I/T/U Payment for Physician and Non-Hospital-Based Services (IHS/RIN 0917-AA12; issued 3/21/2016)
- 200. Mental Health Parity Rules for Medicaid and CHIP (CMS-2333-F; issued 3/30/2016)
- 31.III. Indian-Specific CSV SBC Sample Templates (CCIIO/no ref. #; issued 4/28/2016)
- 136.g.CMS Quality Measure Development Plan (CMS/no ref. #; issued 5/2/2016)
- > 188.b. Fire Safety Requirements for Certain Health Care Facilities (CMS-3277-F; issued 5/4/2016)
- > 154.b.Medicaid/CHIP Managed Care (CMS-2390-F; issued 5/6/2016)
- 164.c. Medicare Secondary Payer Conditional Payment Amounts (CMS-6054-F; issued 5/17/2016)
- 181.b. Nondiscrimination Under ACA (HHS OCR/RIN 0945-AA02; issued 5/18/2016)
- 104.b. State Health Insurance Assistance Program (CMS/RIN 0985-AA11; issued 6/3/2016)
- 10.g. Medicare Shared Savings Program: ACO Benchmarking (CMS-1644-F; issued 6/10/2016)
- 48.j. Modification of Treatment of Certain Health Organizations (TD 9772; issued 6/18/2016)
- 184.j. Clinical Diagnostic Laboratory Tests Payment System (CMS-1621-F; issued 6/23/2016)
- 31.III. Indian-Specific CSV SBC Sample Templates (CCIIO/no ref. #; issued 7/13/2016)
- 60.l. Expanding Uses of Medicare Data by Qualified Entities (CMS-5061-F; issued 7/27/2016)
- 25.II. Inpatient Rehabilitation Facility PPS for FY 2017 (CMS-1647-F; issued 8/5/2016)
- 72.g. PPS and Consolidated Billing for SNFs for FY 2017, et al. (CMS-1645-F; issued 8/5/2016)
- 78.I. Hospice Wage Index and Payment Rate Update for FY 2017 (CMS-1652-F; issued 8/5/2016)
- 25.jj. PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. (CMS-1655-F/CMS-1664-F/CMS-1632-F2; issued 8/22/2016)
- 188a. Emergency Preparedness Requirements (CMS-3178-F; issued 9/16/2016)
- 135.e. Reform of Requirements for Long-Term Care Facilities (CMS-3260-F; issued 10/4/2016)
- 1.p. Health IT Certification Program: Enhanced Oversight (HHS ONC/RIN 0955-AA00; issued 10/19/2016)
- 92.kkk. Rules for Expatriate Health Plans, et al. (TD 9791, DoL/RIN 1210-AB75, CMS-9932-F; issued 10/31/2016)
- > 136.h.MIPS and Alternative Payment Model Incentive Under PFS (CMS-5517-FC; issued 11/4/2016)

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Comments submitted by NIHB, TTAG, and other organizations may be accessed at http://www.nihb.org/tribalhealthreform/mmpc-regulation-comments/.

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|--|--|---|--|
| | | | SECTION I: MEDICAID (AND DUAL MEDICAID AND MEDICARE) | Beginning on page 1 of 126 | |
| | | | Section II: Medicare | Beginning on page 20 of 126 | |
| | | | Section III: Health Reform | Beginning on page 68 of 126 | |
| | | | Section IV: Other | Beginning on page 113 of 126 | |
| | | | Section I: Medicaid (and dual Medicaid and Medicare) | | |
| 1.I. | EHR Incentive ProgramStage 3 ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Electronic Health Record Incentive ProgramStage 3 and Modifications to Meaningful Use in 2015 through 2017 AGENCY: CMS | CMS-3310- PFC CMS-3311-FC See also 1.n. | Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: 5/29/2015; TTAG also filed comments 5/29/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 10/16/2015; issued correction 3/4/2016, 6/1/2016 Due Date: 12/15/2015 NIHB File Date: 12/15/2015 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

¹ For regulations issued over the September 2010 through December 2012 period, please refer to the archived RRIAR v.2.12 dated December 31, 2012. For regulations issued over the January 2013 through December 2013 period, please refer to the archived RRIAR v.3.12 dated December 31, 2013. For regulations issued over the January 2014 through December 2014 period, please refer to the archived RRIAR v.4.12 dated December 31, 2014. For regulations issued over the January 2015 through December 2015 period, please refer to the archived RRIAR v.5.12 dated December 31, 2015.

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|--------------------|--|-------------------------------|--|---|--|
| 1.p. | Health IT Certification Program: Enhanced Oversight ACTION: Proposed Final Rule NOTICE: ONC Health IT Certification Program: Enhanced Oversight and Accountability AGENCY: HHS ONC | HHS ONC RIN 0955- AA00 | Issue Date: 3/2/2016 Due Date: 5/2/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 10/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 1.q. | 2015 Test Tools and Procedures for Health IT Certification ACTION: Notice NOTICE: Notice of Availability: 2015 Edition Test Tools and Test Procedures Approved by the National Coordinator for the ONC Health IT Certification Program AGENCY: HHS ONC | HHS ONC (no reference number) | Issue Date: 2/4/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 1.r. | Voluntary Personal Health Record Model Privacy Notice ACTION: Request for Information NOTICE: Request for Information on Updates to the ONC Voluntary Personal Health Record Model Privacy Notice AGENCY: HHS ONC | HHS ONC (no reference number) | Issue Date: 3/1/2016 <u>Due Date:</u> 4/15/2016 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-------------------------------|--|---|--|
| 1.s. | Assessing Interoperability for MACRA ACTION: Request for Information NOTICE: Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015; Request for Information Regarding Assessing Interoperability for MACRA AGENCY: HHS ONC | HHS ONC (no reference number) | Issue Date: 4/8/2016 Due Date: 6/3/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 4/27/2016 | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 1.t. | PHR User Survey ACTION: Request for Comment NOTICE: Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey AGENCY: CMS | CMS-10623 | Issue Date: 6/13/2016 Due Date: 8/12/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/26/2016 Due Date: 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 1.u. | Test Tools and Procedures for Health IT Certification ACTION: Notice NOTICE: Notice of Availability: Test Tools and Test Procedures Approved by the National Coordinator for the ONC Health IT Certification Program AGENCY: HHS ONC | HHS ONC (no reference number) | Issue Date: 8/15/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|--------------|---|---|--|
| 8.d. | Oklahoma 1115 Waiver Amendment ACTION: Request for Comment NOTICE: §1115(a) SoonerCare Research and Demonstration Waiver Amendment Request AGENCY: N/A | 11-W-00048/6 | Issue Date: 3/4/2016 Due Date: 4/14/2016 TSGAC File Date: 4/5/2016 Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 8.e. | Healthy Indiana Program 2.0 Beneficiaries Survey ACTION: Request for Comment NOTICE: Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey AGENCY: CMS | CMS-10615 | Issue Date: 3/29/2016 Due Date: 4/8/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/4/2016; issued extension 7/22/2016, 9/26/2016 Due Date: 6/3/2016; 9/20/2016; 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 8.f. | Montana HELP Federal Evaluation ACTION: Request for Comment NOTICE: Montana Health and Economic Livelihood Partnership (HELP) Federal Evaluation AGENCY: CMS | CMS-10635 | Issue Date: 10/21/2016 Due Date: 12/20/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| 16.b. | Medicaid HCBS Waivers ACTION: Proposed-Final Rule NOTICE: Medicaid; State Plan Home and Community-Based Services, 5- Year Period for Waivers, Provider Payment Reassignment; Setting Requirements AGENCY: CMS | CMS-2249- P2 F2 | Issue Date: 5/3/2012 Due Date: 6/4/2012 7/2/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 5/3/2012; Final Rule approved by OMB 1/13/2014 | Summary of Agency action: √ NIHB analysis of action: None. | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 16.c. | Home and Community Based Services Waiver ACTION: Request for Comment NOTICE: 1915(c) Home and Community Based Services Waiver AGENCY: CMS | CMS-8003 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/16/2013; issued extension 10/31/2016 Due Date: 9/16/2013; 12/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 20.a. | Assuring Access to Services ACTION: Proposed-Final Rule NOTICE: Medicaid Program; Methods for Assuring Access to Covered Medicaid Services AGENCY: CMS | CMS-2328-PFC | Issue Date: 5/6/2011 Due Date: 7/5/2011 ANTHC File Date: 7/5/2011 Date of Subsequent Agency Action, if any: Issued Final Rule 11/2/2015; issued deadline extension notice 4/12/2016 Due Date: 1/4/2016 | Summary of Agency action: √ ANTHC analysis of action: √ Summary of subsequent Agency action: √ | ANTHC recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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|--------------------|--|---------------------------------|---|--|--|
| 20.b. | Data Metrics and Alternative Processes for Access to Care ACTION: Request for Information NOTICE: Medicaid Program; Request for Information (RFI)Data Metrics and Alternative Processes for Access to Care in the Medicaid Program AGENCY: CMS | CMS-2328-NC | Issue Date: 11/2/2015 <u>Due Date:</u> 1/4/2016 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 20.c. | FAQs on Access Rule Implementation ACTION: Guidance NOTICE: Access Rule Implementation Frequently Asked Questions (FAQs) AGENCY: CMS | CMS (no reference number) | Issue Date: 3/16/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 23.b. | MACPro: New Online System for State Plan Amendments, Waivers, etc. ACTION: Request for Comment NOTICE: Medicaid and CHIP Program (MACPro) AGENCY: CMS | CMS-10434 | Issue Date: 1/2/21/2012 Due Date: 1/22/2013 TSGAC File Date: 1/22/2013 Date of Subsequent Agency Action, if any: Issued revision 11/9/2015, 3/28/2016 Due Date: 1/8/2016, 4/27/2016 | Summary of Agency action: √ TSGAC analysis of action: √ Summary of subsequent Agency action: √ | TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|------------------------------|---|---|--|
| 26. | Medicaid Home Health ACTION: Proposed Final Rule NOTICE: Medicaid Program; Face- to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health AGENCY: CMS | CMS-2348- P F | Issue Date: 7/12/2011 Due Date: 9/12/2011 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/2/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 41.f. | New Safe Harbors ACTION: Notice NOTICE: Solicitation of New Safe Harbors and Special Fraud Alerts AGENCY: HHS OIG | OIG-124-N | Issue Date: 12/23/2015 Due Date: 2/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 41.g. | Revisions to State Medicaid Fraud Control Unit Rules ACTION: Proposed Rule NOTICE: Medicaid; Revisions to State Medicaid Fraud Control Unit Rules AGENCY: HHS OIG | HHS OIG RIN 0936- AA07 | Issue Date: 9/20/2016 Due Date: 11/21/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---------------------------------|--|---|--|
| 43. | Medicaid Reimbursement for Outpatient Drugs ACTION: Proposed-Final Rule NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS | CMS-2345- ₽FC | Issue Date: 2/2/2012 Due Date: 4/2/2012 NIHB File Date: 4/2/2012 Date of Subsequent Agency Action, if any: Issued Final Rule 2/1/2016 Due Date: 4/1/2016 NIHB File Date: 4/21/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 44.h. | Comprehensive Primary Care Plus Model ACTION: Notice NOTICE: Comprehensive Primary Care Plus (CPC+) Model AGENCY: CMS | CMS (no reference number) | Issue Date: 4/11/2016 Due Date: 9/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 46.e. | Final FY 2013 and Preliminary FY 2015 DSH Allotments ACTION: Notice NOTICE: Medicaid Program; Final FY 2013 and Preliminary FY 2015 Disproportionate Share Hospital Allotments, and Final FY 2013 and Preliminary FY 2015 Institutions for Mental Diseases Disproportionate Share Hospital Limits AGENCY: CMS | CMS-2398-N | Issue Date: 2/2/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|------------|--|---|--|
| 46.f. | Treatment of Third Party Payers in Calculating DSH Uncompensated Care Costs ACTION: Proposed Rule NOTICE: Medicaid Program; Disproportionate Share Hospital PaymentsTreatment of Third Party Payers in Calculating Uncompensated Care Costs AGENCY: CMS | CMS-2399-P | Issue Date: 8/15/2016 <u>Due Date:</u> 9/14/2016 <u>NIHB File Date</u> : 9/14/2016 <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 46.g. | Final FY 2014 and Preliminary FY 2016 DSH Allotments ACTION: Notice NOTICE: Medicaid Program; Final FY 2014 and Preliminary FY 2016 Disproportionate Share Hospital Allotments, and Final FY 2014 and Preliminary FY 2016 Institutions for Mental Diseases Disproportionate Share Hospital Limits AGENCY: CMS | CMS-2401-N | Issue Date: 10/26/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|--|---|--|
| 83.a. | Medicaid/Transformed-Medicaid Statistical Information Systems ACTION: Request for Comment NOTICE: Medicaid Statistical Information System (MSIS) and Transformed-Medicaid Statistical Information System (T-MSIS) AGENCY: CMS | CMS-R-284 | Issue Date: 8/15/2012 Due Date: 10/15/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/19/2012; issued revision 12/3/2012, 12/31/2015, 4/12/2016 Due Date: 11/19/2012; 1/2/2013; 2/29/2016; 5/12/2016 TTAG File Date: 2/29/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 103.a. | CHIP Report on Payables and Receivables ACTION: Request for Comment NOTICE: Children's Health Insurance Program (CHIP) Report on Payables and Receivables AGENCY: CMS | CMS-10180 | Issue Date: 11/16/2012 Due Date: 12/17/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 4/26/2013; issued extension 8/18/2016 Due Date: 5/28/2013; 10/17/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 103.b. | Medicaid Report on Payables and Receivables ACTION: Request for Comment NOTICE: Medicaid Report on Payables and Receivables AGENCY: CMS | CMS-R-199 | Issue Date: 11/16/2012 Due Date: 12/17/2012 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 4/26/2013; issued extension 3/1/2016, 7/19/2016 Due Date: 5/28/2013; 5/2/2016; 8/18/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|--------------------------|--|---|--|
| 104.b. | State Health Insurance Assistance Program ACTION: Final Rule NOTICE: State Health Insurance Assistance Program (SHIP) AGENCY: CMS | CMS RIN 0985- AA11 | Issue Date: 6/3/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 140. | Social Security Office Report of State Buy-in Problem ACTION: Request for Comment NOTICE: Social Security Office Report of State Buy-in Problem AGENCY: CMS | CMS-1957 | Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 5/10/2013, 2/10/2016, 4/15/2016 Due Date: 6/10/2013; 4/11/2016; 5/16/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 154.b. | Medicaid/CHIP Managed Care ACTION: Proposed Final Rule NOTICE: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability AGENCY: CMS | CMS-2390- P F | Issue Date: 6/1/2015 Due Date: 7/27/2015 NIHB File Date: 7/27/2015; TTAG also filed comments 7/27/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 5/6/2016; issued correction 7/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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|--------------------|--|------------------------|--|---|--|
| 154.c. | Use of Pass-Through Payments in Medicaid Managed Care ACTION: Proposed Rule NOTICE: The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems AGENCY: CMS | CMS-2402-P | Issue Date: [Pending at OMB as of 10/18/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 158. | Model Employer CHIP Notice ACTION: Request for Comment NOTICE: Model Employer CHIP Notice AGENCY: DoL | DoL (OMB 1210-0137) | Issue Date: 5/22/2013 Due Date: 7/22/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 10/2/2013, 5/26/2016, 9/20/2016 Due Date: 11/1/2013, 7/25/2016; 10/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 161.a. | Payment Error Rate in Medicaid and CHIP ACTION: Request for Comment NOTICE: Payment Error Rate Measurement in Medicaid & Children's Health Insurance Program (CHIP) AGENCY: CMS | CMS-10166 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/30/2013; issued extension 4/8/2016, 7/22/2016 Due Date: 9/30/2013; 6/7/2016; 8/22/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------|--|---|--|
| 161.b. | Eligibility Error Rate in Medicaid and CHIP ACTION: Request for Comment NOTICE: Eligibility Error Rate Measurement in Medicaid and the Children's Health Insurance Program AGENCY: CMS | CMS-10184 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/30/2013; issued extension 4/8/2016, 7/22/2016 Due Date: 9/30/2013; 6/7/2016; 8/22/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 161.d. | State Medicaid Eligibility Quality Control Sample Plans ACTION: Request for Comment NOTICE: State Medicaid Eligibility Quality Control Sample Plans AGENCY: CMS | CMS-317 | Issue Date: 8/16/2013 Due Date: 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/8/2016, 7/22/2016 Due Date: 6/7/2016; 8/22/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 161.e. | State Medicaid Eligibility Quality Control Sample Selection Lists ACTION: Request for Comment NOTICE: State Medicaid Eligibility Quality Control Sample Selection Lists AGENCY: CMS | CMS-319 | Issue Date: 8/16/2013 Due Date: 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/8/2016, 7/22/2016 Due Date: 6/7/2016; 8/22/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|------------|---|---|--|
| 161.f. | Medicaid and CHIP Managed Care Claims ACTION: Request for Comment NOTICE: Medicaid and Children's Health Insurance Managed Care Claims and Related Information AGENCY: CMS | CMS-10178 | Issue Date: 8/16/2013 Due Date: 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/8/2016, 7/22/2016 Due Date: 6/7/2016; 8/22/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 161.h. | Medicaid Eligibility Quality Control and PERM Programs ACTION: Proposed Rule NOTICE: Medicaid/CHIP Program; Medicaid Program and Children's Health Insurance Program (CHIP); Changes to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs in Response to the Affordable Care Act AGENCY: CMS | CMS-6068-P | Issue Date: 6/22/2016 Due Date: 8/22/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------|--|---|--|
| 161.i. | Quality Measures for Medicaid Enrollees in MLTSS ACTION: Notice NOTICE: Quality Measure Development and Maintenance for CMS Programs Serving Medicare-Medicaid Enrollees and Medicaid-Only Enrollees: Measures for Medicaid Enrollees in Managed Long-Term Services and Supports AGENCY: CMS | CMS (no reference number) | Issue Date: 9/15/2016 Due Date: 10/7/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 175.a. | Medicaid Drug Program Monthly and Quarterly Drug Reporting ACTION: Request for Comment NOTICE: Medicaid Drug Program Monthly and Quarterly Drug Reporting Format AGENCY: CMS | CMS-367 | Issue Date: 8/9/2013 Due Date: 9/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014; issued revision 5/2/2016, 7/11/2016 Due Date: 5/12/2014; 7/1/2016, 8/10/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|------------|--|---|--|
| 175.b. | Medicaid Drug Use Review Program ACTION: Request for Comment NOTICE: Medicaid Drug Use Review Program AGENCY: CMS | CMS-R-153 | Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/17/2014, 1/29/2016, 4/12/206 Due Date: 4/16/2014; 3/29/2016; 5/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 176. | EPSDT Participation Report ACTION: Request for Comment NOTICE: Annual EPSDT Participation Report AGENCY: CMS | CMS-416 | Issue Date: 8/9/2013 Due Date: 10/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/6/2013, 10/31/2016 Due Date: 1/6/2014; 12/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 180. | Flu Vaccination Standard for Certain Providers and Suppliers ACTION: Final Rule NOTICE: Influenza Vaccination Standard for Certain Participating Providers and Suppliers AGENCY: CMS | CMS-3213-F | Issue Date: [Approved by OMB on 4/18/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|--------------------------|---|---|--|
| 188.a. | Emergency Preparedness Requirements ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS | CMS-3178- P F | Issue Date: 12/27/2013 Due Date: 2/25/2014 3/31/2014 TTAG File Date: 3/31/2014 Date of Subsequent Agency Action, if any: Issued due date extension 2/21/2014; Issued Final Rule 9/16/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 188.b. | Fire Safety Requirements for Certain Health Care Facilities ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities AGENCY: CMS | CMS-3277- P F | Issue Date: 4/16/2014 Due Date: 6/16/2014 TTAG File Date: 6/16/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 5/4/2016; issued correction 6/30/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 188.c. | Fire Safety Requirements for Certain Dialysis Facilities ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Fire Safety Requirements for Certain Dialysis Facilities AGENCY: CMS | CMS-3334-P | Issue Date: [Approved by OMB 10/20/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

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|--------------------|--|--|---|---|--|
| 200. | Mental Health Parity Rules for Medicaid and CHIP ACTION: Proposed Final Rule NOTICE: Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and ABPs AGENCY: CMS | CMS-2333-PF | Issue Date: 4/10/2015 Due Date: 6/9/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/30/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 204. | Medicaid Services "Received Through" an IHS/Tribal Facility ACTION: Request for Information Final Policy NOTICE: Medicaid Services "Received Through" an Indian Health Service/Tribal Facility: A Request for Comment AGENCY: CMS | CMS (no reference number) SHO #16-002 | Issue Date: 10/27/2015 Due Date: 11/17/2015 TTAG File Date: 11/17/2015; TSGAC also filed comments 11/17/2015 Date of Subsequent Agency Action, if any: Issued Final Policy 2/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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|--------------------|--|---------------------------------|---|---|--|
| 210. | Functional Assessment Standardized Items (CARE Tool) ACTION: Request for Comment NOTICE: Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool AGENCY: CMS | CMS-10243 | Issue Date: 5/2/2016 Due Date: 7/1/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/5/2016 Due Date: 9/6/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 211. | Non-Enforcement of Overtime Rule for Certain Providers ACTION: Guidance NOTICE: Time Limited Non- Enforcement Policy for a Subset of Medicaid-Funded Providers AGENCY: DoL | DoL (no reference number) | Issue Date: 5/19/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 214. | Medicaid Supplemental Payment and Accountability ACTION: Proposed Rule NOTICE: Medicaid Supplemental Payment and Accountability AGENCY: CMS | CMS-2393-P | Issue Date: [Pending at OMB as of 7/19/2016] Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 215. | Initial Request for State Implemented Moratorium Form ACTION: Request for Comment NOTICE: Initial Request for State Implemented Moratorium Form AGENCY: CMS | CMS-10628 | Issue Date: 8/18/2016 Due Date: 10/17/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------|---|---|--|
| 2.e. | Part CMedicare Advantage and 1876 Cost Plan Expansion ACTION: Request for Comment NOTICE: Part CMedicare Advantage and 1876 Cost Plan Expansion Application AGENCY: CMS | CMS-10237 | SECTION II: MEDICARE Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 10/3/2014, 7/7/2015, 9/24/2015, 7/8/2016, 10/31/2016 Due Date: 11/4/2013; 9/9/2014; 11/3/2014; 9/8/2015; 10/26/2015; 9/6/2016; 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 2.f. | Applications for Medicare Prescription Drug Plan Contracts ACTION: Request for Comment NOTICE: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts AGENCY: CMS | CMS-10137 | Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 9/19/2014, 7/7/2015, 9/24/2015, 7/8/2016, 10/31/2016 Due Date: 11/4/2013; 9/9/2014; 10/20/2014; 9/8/2015; 10/26/2015; 9/6/2016; 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---------------------------------------|--|---|--|
| 3.b. | DME Competitive Bidding ACTION: Request for Comment NOTICE: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program AGENCY: CMS | CMS-10169 | Issue Date: 7/27/2012 Due Date: 8/27/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/1/2013, 5/10/2013, 4/18/2014, 7/3/2014, 10/14/2016 Due Date: 4/30/2013; 6/10/2013; 6/17/2014; 8/4/2014; 12/13/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 3.c. | Durable Medical Equipment Certificate of Medical Necessity ACTION: Request for Comment NOTICE: DME Medicare Administrative Contractor CMN and Supporting Documentation Requirements AGENCY: CMS | CMS-846-849, -10125, and -10126 | Issue Date: 9/24/2012 Due Date: 11/23/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/8/2013, issued revision 2/19/2016, 5/11/2016 Due Date: 4/8/2013; 4/19/2016; 6/10/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 3.d. | Certification of Medical Necessity for Home Oxygen Therapy ACTION: Request for Comment NOTICE: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Documentation Requirements AGENCY: CMS | CMS-484 | Issue Date: 3/14/2013 Due Date: 4/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/19/2016, 5/11/2016 Due Date: 4/19/2016; 6/10/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-------------|---|---|--|
| 3.e. | Grandfathering Provisions of the DMEPOS Bidding Program ACTION: Request for Comment NOTICE: Grandfathering Provisions of the Medicare DMEPOS Competitive Bidding Program AGENCY: CMS | CMS-10309 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 6/7/2013; issued extension 4/1/2016, 7/19/2016 Due Date: 7/8/2013; 5/31/2016; 8/18/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 3.q. | Requirements for Prosthetics Practitioners and Suppliers ACTION: Proposed Rule NOTICE: Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics AGENCY: CMS | CMS-6012-P | Issue Date: [Pending at OMB as of 4/27/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 4.n. | CORF Eligibility and Survey Forms ACTION: Request for Comment NOTICE: Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations AGENCY: CMS | CMS-359/360 | Issue Date: 1/4/2016 Due Date: 3/4/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/11/2016 Due Date: 4/11/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|------------------|---|---|--|
| 4.0. | Hospital OPPS and ASC Payment System for CY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program AGENCY: CMS | CMS-1656- ₽FC | Issue Date: 7/24/2016 Due Date: 9/6/2016 NIHB File Date: 9/6/2016; TTAG also filed comments 9/6/2016 Date of Subsequent Agency Action, if any: Final Rule approved by OMB 10/28/2016 | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 5.a. | PACE Information Request ACTION: Request for Comment NOTICE: Medicare and Medicaid; Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS : regulation review complete | CMS-R-244 | Issue Date: 7/30/2010 Due Date: 9/28/2010 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/8/2010, 10/4/2013, 12/20/2013, 12/8/2015, 5/2/2016 Due Date: 11/8/2010; 12/3/2013; 1/21/2014; 2/8/2016; 6/1/2016 : regulation currently under re | Summary of Agency action: √ NIHB analysis of action: None. Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|----------------------------|--|---|--|
| 5.c. | Health Plan Monitoring System Data Entry for PACE ACTION: Request for Comment NOTICE: Health Plan Monitoring System Level I and Level II Data Entry for the Program of All- Inclusive Care for the Elderly AGENCY: CMS | CMS-10525 | Issue Date: 5/23/2014 Due Date: 7/22/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/12/2014; issued revision 6/13/2016 Due Date: 10/14/2014; 8/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 5.d. | PACE Update ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS | CMS-4168-P | Issue Date: 8/16/2016 <u>Due Date</u> : 10/17/2016 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 5.e. | PACE Organization Application Process ACTION: Request for Comment NOTICE: The PACE Organization Application Process in 42 CFR part 460 AGENCY: CMS | CMS-10631 See also 5.a. | Issue Date: 9/12/2016 Due Date: 10/12/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---------------------------------|--|---|--|
| 9.h. | Program Integrity Enhancements to Provider Enrollment Process ACTION: Proposed Rule NOTICE: Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process AGENCY: CMS | CMS-6058-P | Issue Date: 3/1/2016 <u>Due Date</u> : 4/25/2016 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 9.i. | Medicaid Provider Enrollment Compendium ACTION: Guidance NOTICE: Medicaid Provider Enrollment Compendium (MPEC) AGENCY: CMS | CMS (no reference number) | Issue Date: 3/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 10.g. | Medicare Shared Savings Program: ACO Benchmarking ACTION: Proposed Final Rule NOTICE: Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations- Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations AGENCY: CMS | CMS-1644- P F | Issue Date: 2/3/2016 Due Date: 3/28/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 6/10/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|--|---|--|
| 11.d. | Bid Pricing Tool ACTION: Request for Comment NOTICE: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs) AGENCY: CMS | CMS-10142 | Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 10/4/2013, 12/20/2013, 9/26/2014, 12/24/2014, 9/24/2015, 12/18/2015, 10/31/2016 Due Date: 2/19/2013; 12/3/2013; 1/21/2014; 11/25/2014; 1/23/2015; 11/23/2015; 1/19/2016; 12/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.f. | Plan Benefit Package and Formulary Submission ACTION: Request for Comment NOTICE: PBP and Formulary Submission for Medicare Advantage and Prescription Drug Plans AGENCY: CMS | CMS-R-262 | Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 11/1/2013, 1/17/2014, 9/26/2014, 12/19/2014, 9/24/2015, 12/18/2015, 10/31/2016 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 1/20/2015; 11/23/2015; 1/19/2016; 12/30/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|--|---|--|
| 11.g. | Medicare Advantage Reporting Requirements ACTION: Request for Comment NOTICE: Part C Medicare Advantage Reporting Requirements and Supporting Regulations AGENCY: CMS | CMS-10261 | Issue Date: 10/26/2012 Due Date: 12/26/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/21/2013, 10/4/2013, 5/1/2015, 8/24/2015; issued correction and partial withdrawal 9/18/2015; issued revision 5/11/2016, 9/12/2016 Due Date: 8/20/2013; 11/4/2013; 6/30/2015; 9/23/2015; 10/19/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.i. | Medicare Advantage Appeals and Grievance Data Disclosure ACTION: Request for Comment NOTICE: Medicare Advantage Appeals and Grievance Data Disclosure Requirements AGENCY: CMS | CMS-R-282 | Issue Date: 2/22/2013 Due Date: 4/23/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 5/3/2013, 12/14/2015, 6/13/2016 Due Date: 6/17/2013; 1/26/2016; 7/13/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------|--|---|--|
| 11.j. | Medicare Part D Reporting Requirements ACTION: Request for Comment NOTICE: Medicare Part D Reporting Requirements AGENCY: CMS | CMS-10185 | Issue Date: 3/15/2013 Due Date: 5/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/26/2013, 5/1/2015, 8/24/2015, 5/6/2016, 9/12/2016 Due Date: 8/26/2013; 6/30/2015; 9/23/2015; 7/5/2016; 10/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.k. | Medicare PDP and MA Plan Disenrollment Reasons Survey ACTION: Request for Comment NOTICE: Implementation of the Medicare Prescription Drug Plan and Medicare Advantage Plan Disenrollment Reasons Survey AGENCY: CMS | CMS-10316 | Issue Date: 4/19/2013 Due Date: 6/18/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/5/2013, 3/25/2016, 6/30/2016 Due Date: 8/5/2013; 5/24/2016; 8/1/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.m. | Collection of Data from MAOs for Risk Adjusted Payments ACTION: Request for Comment NOTICE: Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments AGENCY: CMS | CMS-10062 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/18/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/19/2013; 9/20/2016; 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|--|---|--|
| 11.w. | Final Marketing Provisions for Medicare Parts C and D ACTION: Request for Comment NOTICE: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions AGENCY: CMS | CMS-10260 | Issue Date: 1/29/2014 Due Date: 2/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/30/2016 Due Date: 8/29/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.x. | Medication Therapy Management Program Improvements ACTION: Request for Comment NOTICE: Medication Therapy Management Program Improvements AGENCY: CMS | CMS-10396 | Issue Date: 1/17/2014 Due Date: 3/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014, 10/31/2016 Due Date: 5/12/2014; 12/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.cc. | Collection of Encounter Data from MA and PACE Organizations ACTION: Request for Comment NOTICE: Collection of Encounter Data from Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and Pace Organizations AGENCY: CMS | CMS-10340 | Issue Date: 6/2/2014 <u>Due Date</u> : 8/1/2014 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : Issued revision 9/8/2014, 8/5/2016 <u>Due Date</u> : 10/6/2014; 10/4/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|---------------------------------|---|---|--|
| 11.hh. | Medicare Part C, Part D, and FFS CAHPS Survey ACTION: Request for Comment NOTICE: Medicare Advantage, Medicare Part D, and Medicare Fee- For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey AGENCY: CMS | CMS-R-246 | Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/8/2015, 6/13/2016 Due Date: 6/8/2015; 8/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.mm. | MA Capitation Rates and Part D Payment Policies for 2017 ACTION: Notice NOTICE: Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter AGENCY: CMS | CMS (no reference number) | Issue Date: 4/4/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 11.nn. | Re-Determination of Part D Low- Income Subsidy Deemed Status ACTION: Guidance NOTICE: Annual Re-Determination of Medicare Part D Low-Income Subsidy Deemed Status (Re- Deeming) AGENCY: CMS | CMS (no reference number) | Issue Date: 7/19/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------|--|---|--|
| 13.b. | Acquisition, Protection, and Disclosure of QIO Information ACTION: Request for Comment NOTICE: Acquisition, Protection, and Disclosure of Peer Review Organization Information and Supporting Regulations AGENCY: CMS | CMS-R-70 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/23/2013; 9/20/2016, 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 13.c. | QIO Reconsiderations and Appeals ACTION: Request for Comment NOTICE: QIO Reconsiderations and Appeals Incentive Program AGENCY: CMS | CMS-R-72 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/23/2013; 9/20/2016, 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 13.d. | Medicare Quality of Care Complaint Form ACTION: Request for Comment NOTICE: Medicare Quality of Care Complaint Form AGENCY: CMS | CMS-10287 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/24/2013, 9/8/2016 Due Date: 8/23/2013; 11/7/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-------------|--|---|--|
| 25.c. | Indirect and Direct Graduate Medical Education Costs ACTION: Request for Comment NOTICE: Indirect Medical Education (IME) and Supporting Regulations; Direct Graduate Medical Education (GME) and Supporting Regulations AGENCY: CMS | CMS-R-64 | Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 5/10/2013; issued extension 7/19/2016, 10/31/2016 Due Date: 6/10/2013; 9/19/2016, 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.m. | Geographic Classification Review Board Procedures ACTION: Request for Comment NOTICE: Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations AGENCY: CMS | CMS-R-138 | Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 12/13/2013; issued extension 10/11/2016 Due Date: 1/13/2014; 12/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.bb. | Comprehensive Care for Joint Replacement Payment Model ACTION: Proposed-Final Rule NOTICE: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services AGENCY: CMS | CMS-5516-PF | Issue Date: 7/14/2015 Due Date: 9/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 8/25/2015; issued Final Rule 11/24/2015; issued correction 3/4/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-------------|--|---|--|
| 25.cc. | Revisions to Requirements for Discharge Planning for Hospitals ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and HHAs AGENCY: CMS | CMS-3317-P | Issue Date: 11/3/2015 Due Date: 1/4/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.dd. | Emergency and Foreign Hospital Services ACTION: Request for Comment NOTICE: Emergency and Foreign Hospital Services AGENCY: CMS | CMS-1771 | Issue Date: 9/21/2015 Due Date: 11/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 11/9/2015, 2/5/2016 Due Date: 12/9/2015, 4/5/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.ee. | Design of Survey on Patient Experiences with Care in LTCHs ACTION: Request for Information NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in LTCHs AGENCY: CMS | CMS-3327-NC | Issue Date: 11/20/2015 Due Date: 1/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-------------|--|---|--|
| 25.ff. | Design of Survey on Patient Experiences with Care in IRFs ACTION: Request for Information NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Inpatient Rehabilitation Facilities AGENCY: CMS | CMS-3328-NC | Issue Date: 11/20/2015 <u>Due Date:</u> 1/19/2016 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.gg. | Inpatient Prospective Payment Systems0.2 Percent Reduction ACTION: Notice NOTICE: Medicare Program; Inpatient Prospective Payment Systems; 0.2 Percent Reduction AGENCY: CMS | CMS-1658-NC | Issue Date: 12/1/2015 Due Date: 2/2/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued update 3/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.hh. | Explanation of FY 2004 Outlier Fixed-Loss Threshold ACTION: Notice NOTICE: Medicare Program; Explanation of FY 2004 Outlier Fixed-Loss Threshold as Required by Court Rulings AGENCY: CMS | CMS-1659-N | Issue Date: 1/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued correction 10/14/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---|--|---|--|
| 25.ii. | Hospital Changes to Promote Innovation, etc. ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs: Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care AGENCY: CMS | CMS-3295-P | Issue Date: 6/16/2016 Due Date: 8/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.jj. | PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and FY 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports AGENCY: CMS | CMS-1655- P F CMS-1664-F CMS-1632-F2 | Issue Date: 4/27/2016 Due Date: 6/17/2016 NIHB File Date: 6/17/2016; TTAG and TSGAC also filed comments 6/17/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 8/22/2016; issued correction 10/5/2016, 10/28/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|--------------------------|--|---|--|
| 25.kk. | Exception for Severe Wound Discharges from LTCHs, et al. ACTION: Interim Final Rule NOTICE: Medicare Program; Temporary Exception for Certain Severe Wound Discharges From Certain Long-Term Care Hospitals Required by the Consolidated Appropriations Act, 2016; Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board AGENCY: CMS | CMS-1664-IFC | Issue Date: 4/21/2016 Due Date: 6/17/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 25.II. | Inpatient Rehabilitation Facility PPS for FY 2017 ACTION: Proposed Final Rule NOTICE: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017 AGENCY: CMS | CMS-1647- P F | Issue Date: 4/25/2016 Due Date: 6/20/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 8/5/2016; issued correction 8/31/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|--------------------------|---|---|--|
| 25.mm. | Inpatient Psychiatric Facility PPS Rate Update for FY 2017 ACTION: Notice NOTICE: Medicare Program; FY 2017 Inpatient Psychiatric Facilities Prospective Payment SystemRate Update AGENCY: CMS | CMS-1650-N | Issue Date: 8/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 49.a. | Reporting and Returns of Medicare Overpayments ACTION: Proposed Final Rule NOTICE: Medicare Program; Reporting and Returning of Overpayments AGENCY: CMS | CMS-6037- P F | Issue Date: 2/16/2012 Due Date: 4/16/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension notice 2/17/2015; issued Final Rule 2/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 49.b. | Medicare Credit Balance Reporting Requirements ACTION: Request for Comment NOTICE: Medicare Credit Balance Reporting Requirements and Supporting Regulations AGENCY: CMS | CMS-838 | Issue Date: 9/17/2010 Due Date: 11/16/2010 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 2/22/2013; issued extension 5/16/2016, 7/19/2016 Due Date: 3/25/2013; 7/15/2016; 8/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|--|---|--|
| 49.c. | Financial Statement of Debtor ACTION: Request for Comment NOTICE: Financial Statement of Debtor and Supporting Regulations AGENCY: CMS | CMS-379 | Issue Date: 6/21/2013 Due Date: 8/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/30/2013; issued extension 7/8/2016, 10/31/2016 Due Date: 9/30/2013; 9/6/2016; 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.d. | Home Health Change of Care Notice ACTION: Request for Comment NOTICE: Home Health Change of Care Notice AGENCY: CMS | CMS-10280 | Issue Date: 12/12/2012 Due Date: 2/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2013; issued extension 10/26/2015, 3/11/2016 Due Date: 3/28/2013; 12/28/2015; 4/11/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.i. | Home Health PPS Rate Update: Physician Narrative Requirement ACTION: Request for Comment NOTICE: Medicare ProgramHome Health Prospective Payment System Rate Update for CY 2010: Physician Narrative Requirement and Supporting Regulation AGENCY: CMS | CMS-10311 | Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/20/2013, 7/29/2016, 10/7/2016, 10/31/2016 Due Date: 1/21/2014; 9/27/2016; 11/7/2016; 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|---|--|---|--|
| 52.j. | Moratoria on Enrollment of Ambulances and HHAs ACTION: Notice NOTICE: Medicare, Medicaid, and CHIP: Announcement of New and Extended Temporary Moratoria on Enrollment of Ambulances and Home Health Agencies in Designated Geographic Locations AGENCY: CMS | CMS-6046-N CMS-6047-N CMS-6059-N2 CMS-6059-N3 CMS-6059-N4 | Issue Date: 2/4/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension notice 8/1/2014, 2/2/2015, 7/27/2015, 2/2/2016, 8/3/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.1. | Home Health Agency Conditions of Participation ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies AGENCY: CMS | CMS-3819-PF | Issue Date: 10/9/2014 Due Date: 12/8/2014 1/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 12/1/2014; sent Final Rule to OMB 5/6/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.n. | OASIS-C2/ICD-10 ACTION: Request for Comment NOTICE: Outcome and Assessment Information Set (OASIS) OASIS-C2/ICD-10 AGENCY: CMS | CMS-10545 | Issue Date: 1/9/2015 Due Date: 3/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/25/2015; issued revision 4/1/2016, 6/30/2016 Due Date: 4/24/2015; 5/31/2016; 8/1/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------|---|---|--|
| 52.q. | Home Health Face-to-Face Encounter Clinical Templates ACTION: Request for Comment NOTICE: Home Health Face-to- Face Encounter Clinical Templates AGENCY: CMS | CMS-10564 | Issue Date: 8/12/2015 Due Date: 10/13/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.r. | Prior Authorization of Home Health Services Demonstration ACTION: Request for Comment NOTICE: Medicare Prior Authorization of Home Health Services Demonstration AGENCY: CMS | CMS-10599 | Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/21/2016 Due Date: 7/21/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.s. | Evaluation of the Medicare Patient IVIG Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration AGENCY: CMS | CMS-10600 See also 52.k. | Issue Date: 2/10/2016 Due Date: 4/11/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/22/2016 Due Date: 5/23/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|--------------------------|---|---|--|
| 52.t. | Pre-Claim Review Demonstration for Home Health Services ACTION: Notice NOTICE: Medicare Program; Pre- Claim Review Demonstration for Home Health Services AGENCY: CMS | CMS-6069-N | Issue Date: 6/10/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.u. | Home Health PPS Rate Update for CY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements AGENCY: CMS | CMS-1648- P F | Issue Date: 7/5/2016 Due Date: 8/26/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|------------|---|---|--|
| 52.v. | Access Waiver for Part B Ambulance Suppliers and HHAs ACTION: Notice NOTICE: Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Provider Enrollment Moratoria Access Waiver Demonstration of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Moratoria- Designated Geographic Locations AGENCY: CMS | CMS-6073-N | Issue Date: 8/3/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 52.w. | Waiver Application for Providers Subject to Moratorium ACTION: Request for Comment NOTICE: Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium AGENCY: CMS | CMS-10629 | Issue Date: 10/31/2016 Due Date: 12/30/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|--------------------------|--|---|--|
| 60.f. | Medicare Data Validation ACTION: Request for Comment NOTICE: Medicare Part C and Part D Data Validation AGENCY: CMS | CMS-10305 | Issue Date: 12/5/2012 Due Date: 1/4/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 11/1/2013; issued revision 6/13/2014, 9/19/2014, 6/30/2016 Due Date: 12/2/2013; 8/12/2014; 10/20/2014; 8/29/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 60.1. | Expanding Uses of Medicare Data by Qualified Entities ACTION: Proposed Final Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities AGENCY: CMS | CMS-5061- P F | Issue Date: 2/2/2016 Due Date: 3/29/2016 NIHB File Date: 3/29/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 7/7/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 60.m. | Reapplication Submission for Qualified Entities ACTION: Request for Comment NOTICE: Reapplication Submission Requirement for Qualified Entities Under ACA Section 10332 AGENCY: CMS | CMS-10596 | Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------------------------|---|---|--|
| 60.n. | Patient Request for Medicare Payment ACTION: Request for Comment NOTICE: Patient's Request for Medicare Payment AGENCY: CMS | CMS-1490S See also 60.c. | Issue Date: 4/22/2016 Due Date: 6/21/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 10/31/2016 Due Date: 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 70.e. | Revisions to PFS and Other Changes to Part B for CY 2016 ACTION: Proposed Final Rule NOTICE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 AGENCY: CMS | CMS-1631- PFC | Issue Date: 7/15/2015 Due Date: 9/8/2015 TTAG File Date: 9/8/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 11/16/2015; issued correction 3/8/2016, 6/1/2016 Due Date: 12/29/2015 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 70.f. | Part B Drug Payment Model ACTION: Proposed Rule NOTICE: Medicare Program; Part B Drug Payment Model AGENCY: CMS | CMS-1670-P | Issue Date: 3/11/2016 Due Date: 5/9/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|--------------------------|--|---|--|
| 70.g. | Revisions to PFS and Other Changes to Part B for CY 2017 ACTION: Proposed Final Rule NOTICE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model AGENCY: CMS | CMS-1654- P F | Issue Date: 7/14/2016 Due Date: 9/6/2016 NIHB File Date: 9/6/2016; TTAG also filed comments 9/6/2016 Date of Subsequent Agency Action, if any: Issued correction 8/10/2016; sent Final Rule to OMB 10/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 71.d. | ESRD Network Semi-Annual Cost Report Forms ACTION: Request for Comment NOTICE: End Stage Renal Disease Network Semi-Annual Cost Report Forms and Supporting Regulations AGENCY: CMS | CMS-685 | Issue Date: 2/12/2013 Due Date: 4/15/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 4/26/2013, 3/1/2016, 5/6/2016 Due Date: 5/28/2013; 5/2/2016; 6/6/2016 : regulation currently under re | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|--------------------------|---|---|--|
| 71.e. | Renal Operations in a Web Enabled Network ACTION: Request for Comment NOTICE: Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization Form AGENCY: CMS | CMS-10268 | Issue Date: 4/19/2013 Due Date: 6/18/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/23/2013; 9/20/2016; 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 71.f. | End Stage Renal Disease Medical Information Facility Survey ACTION: Request for Comment NOTICE: End Stage Renal Disease Medical Information Facility Survey AGENCY: CMS | CMS-2744 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 8/16/2013; issued extension 10/14/2016 Due Date: 9/16/2013; 12/13/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 71.n. | Medicare ESRD PPS and Quality Incentive Program ACTION: Proposed Final Rule NOTICE: Medicare Program; End- Stage Renal Disease Prospective Payment System, and Quality Incentive Program AGENCY: CMS | CMS-1628- P F | Issue Date: 7/1/2015 Due Date: 8/25/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 9/2/2015; issued Final Rule 11/6/2015; issued correction 12/31/2015 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|--------------------------|--|---|--|
| 71.0. | esrd Application and Survey and Certification Report ACTION: Request for Comment NOTICE: End Stage Renal Disease Application and Survey and Certification Report AGENCY: CMS | CMS-3427 | Issue Date: 11/16/2015 Due Date: 1/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/1/2016 Due Date: 3/31/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 71.p. | Medicare ESRD PPS for 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; ESRD PPS, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, ESRD Quality Incentive Program, DMEPOS Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, DMEPOS Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive ESRD Care Model AGENCY: CMS | CMS-1651- P F | Issue Date: 6/30/2016 Due Date: 8/23/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------|--|---|--|
| 72.c. | Physician Certification/ Recertification in SNFs ACTION: Request for Comment NOTICE: Physician Certification/ Recertification in Skilled Nursing Facilities Manual Instructions and Supporting Regulation AGENCY: CMS | CMS-R-5 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 6/7/2013; issued extension 7/22/2016, 10/7/2016 Due Date: 7/8/2013; 9/20/2016; 11/7/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 72.f. | Skilled Nursing Facility PPS and Consolidated Billing ACTION: Request for Comment NOTICE: Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing AGENCY: CMS | CMS-10387 | Issue Date: 7/21/2015 Due Date: 9/21/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 10/2/2015, 3/4/2016 Due Date: 11/2/2015; 4/4/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|--------------------------|--|---|--|
| 72.g. | PPS and Consolidated Billing for SNFs for FY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities Proposed Rule for FY 2017, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and SNF Payment Models Research AGENCY: CMS | CMS-1645- P F | Issue Date: 4/25/2016 <u>Due Date</u> : 6/20/2016 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : Issued Final Rule 8/5/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 78.I. | Hospice Wage Index and Payment Rate Update for FY 2017 ACTION: Proposed Final Rule NOTICE: Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements AGENCY: CMS | CMS-1652- P F | Issue Date: 4/28/2016 Due Date: 6/20/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 8/5/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|--|---|--|
| 79. | Fiscal Soundness Reporting Requirements ACTION: Request for Comment NOTICE: Fiscal Soundness Reporting Requirements AGENCY: CMS | CMS-906 | Issue Date: 9/4/2012 <u>Due Date</u> : 11/5/2012 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : Issued revision 12/21/2012; issued extension 10/2/2015; 11/9/2015, 2/5/2016 <u>Due Date</u> : 1/22/2013; 12/1/2015; 12/9/2015, 4/5/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 80.a. | Notice of Denial of Medical Coverage (or Payment) ACTION: Request for Comment NOTICE: Notice of Denial of Medical Coverage (or Payment) AGENCY: CMS | CMS-10003 | Issue Date: 9/7/2012 Due Date: 11/6/2012 TTAG/NIHB File Date: 11/6/2012 (ANTHC also filed comments 11/6/2012) Date of Subsequent Agency Action, if any: Issued revision 4/12/2013, 10/16/2015, 3/11/2016 Due Date: 5/13/2013; 12/15/2015; 4/11/2016 | | TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------|---|---|--|
| 80.b. | Advanced Beneficiary Notice of Noncoverage ACTION: Request for Comment NOTICE: Advance Beneficiary Notice of Noncoverage AGENCY: CMS | CMS-R-131 | Issue Date: 12/12/2012 Due Date: 2/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2013; issued extension 11/9/2015, 5/2/2016 Due Date: 3/28/2013; 1/8/2016; 6/1/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 80.c. | Notice of Denial of Medicare Prescription Drug Coverage ACTION: Request for Comment NOTICE: Notice of Denial of Medicare Prescription Drug Coverage AGENCY: CMS | CMS-10146 | Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/18/2013, 3/11/2016, 9/12/2016 Due Date: 8/19/2013; 5/10/2016; 10/12/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 106.b. | Hospital Death Reports ACTION: Request for Comment NOTICE: Report of a Hospital Death Associated with Restraint or Seclusion AGENCY: CMS | CMS-10455 | Issue Date: 1/30/2013 Due Date: 3/1/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/24/2016, 8/24/2016 Due Date: 8/23/2016; 9/23/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|------------------------|---|---|--|
| 110.i. | Self-Referral Disclosure Protocol ACTION: Request for Comment NOTICE: Self-Referral Disclosure Protocol AGENCY: CMS | CMS-10328 | Issue Date: 2/24/2014 Due Date: 4/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/2/2014, 5/6/2016, 9/9/2916 Due Date: 6/2/2014; 7/5/2016; 10/11/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 117.b. | National In-Center Hemodialysis CAHPS Survey ACTION: Request for Comment NOTICE: National Implementation of In-Center Hemodialysis CAHPS Survey AGENCY: CMS | CMS 10478 CMS-10105 | Issue Date: 4/19/2013 Due Date: 6/18/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement (of CMS-10105) 6/28/2013; issued revision 6/13/2016, 9/23/2016 Due Date: 7/29/2013; 8/12/2016; 10/24/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 118. | Hospital Wage Index Occupational Mix Survey ACTION: Request for Comment NOTICE: Hospital Wage Index Occupational Mix Survey and Supporting Regulations AGENCY: CMS | CMS-10079 | Issue Date: 12/7/2012 Due Date: 2/5/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/28/2013; issued extension 10/9/2015, 12/28/2015 Due Date: 4/1/2013; 12/8/2015; 1/27/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------|--|---|--|
| 121.c. | Medicare Participating Physician or Supplier Agreement ACTION: Request for Comment NOTICE: Medicare Participating Physician or Supplier Agreement AGENCY: CMS | CMS-460 | Issue Date: 4/12/2013 Due Date: 6/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/21/2013, 7/15/2016, 10/31/2016 Due Date: 7/22/2013; 9/13/2016; 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 121.d. | Notification of Co-Located Medicare Providers ACTION: Request for Comment NOTICE: Notification of Fiscal Intermediaries (FIs) and CMS of Co-Located Medicare Providers and Supporting Regulations AGENCY: CMS | CMS-10088 | Issue Date: 5/17/2013 Due Date: 7/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/26/2013; issued reinstatement 10/11/2016 Due Date: 8/26/2013; 12/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 121.m. | Medicare Enrollment Application DMEPOS Suppliers ACTION: Request for Comment NOTICE: Medicare Enrollment ApplicationDurable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers AGENCY: CMS | CMS-855S | Issue Date: 9/11/2015 Due Date: 11/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/18/2015 Due Date: 1/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|--|---|---|--|
| 121.n. | Medicare Registration Application ACTION: Request for Comment NOTICE: Medicare Registration Application AGENCY: CMS | CMS-855O | Issue Date: 12/11/2015 Due Date: 2/9/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/25/2016 Due Date: 4/25/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 121.0. | New Use for System of Records (Part A Enrollment Data) ACTION: Notice NOTICE: Privacy Act of 1974; Report of a New Routine Use for a CMS System of Records AGENCY: CMS | CMS (no reference number) | Issue Date: 2/18/2016 Due Date: 30 days (approx. 3/21/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 121.p. | Medicare Enrollment Application ACTION: Request for Comment NOTICE: Medicare Registration Application AGENCY: CMS | CMS-855(A, B, and I) See also 121.a. and 121.h. | Issue Date: 4/1/2016 Due Date: 5/31/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/31/2016 Due Date: 6/30/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-------------------------|---|---|--|
| 126.a. | Medicare Rural Hospital Flexibility Grant Program ACTION: Request for Comment NOTICE: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination AGENCY: HRSA | HRSA (OMB 0915-0363) | Issue Date: 12/28/2012 Due Date: 60 days (approx. 3/1/2013) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/26/2013; issued revision 5/27/2015, 2/12/2016 Due Date: 30 days (approx. 5/28/2013); 7/27/2015; 3/17/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 129.b. | Awarding and Administration of MAC Contracts ACTION: Notice NOTICE: Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts AGENCY: CMS | CMS-1653-NC | Issue Date: 12/21/2015 <u>Due Date</u> : 2/19/2016 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 131.a. | Medicare Parts C and D Audit Guide ACTION: Request for Comment NOTICE: Medicare Parts C and D Universal Audit Guide AGENCY: CMS | CMS-10191 | Issue Date: 1/22/2013 Due Date: 3/25/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/18/2013; issued revision 6/13/2016 Due Date: 8/19/2013; 8/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------|---|---|--|
| 131.b. | PACE Organization Monitoring and Audit Process ACTION: Request for Comment NOTICE: The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460 AGENCY: CMS | CMS-10630 | Issue Date: 8/5/2016 Due Date: 10/4/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 134.a. | Prepaid Health Plan Cost Report ACTION: Request for Comment NOTICE: Prepaid Health Plan Cost Report AGENCY: CMS | CMS-276 | Issue Date: 1/30/2013 Due Date: 4/1/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 5/3/2013; issued revision 2/10/2016, 4/15/2016 Due Date: 6/3/2013; 4/11/2016; 5/16/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 134.b. | Medicare Provider Cost Report Reimbursement Questionnaire ACTION: Request for Comment NOTICE: Medicare Provider Cost Report Reimbursement Questionnaire AGENCY: CMS | CMS-339 | Issue Date: 1/30/2013 Due Date: 4/1/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 5/3/2013; issued extension 7/15/2016, 10/31/2016 Due Date: 6/3/2013; 9/13/2016; 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-------------|---|---|--|
| 134.e. | Home Health Agency Cost Report ACTION: Request for Comment NOTICE: Home Health Agency Cost Report AGENCY: CMS | CMS-1728-94 | Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 9/17/2013; issued revision 9/4/2015, 2/10/2016 Due Date: 10/17/2013; 11/3/2015; 3/11/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 135.a. | LTCH Continuity Assessment Record and Evaluation ACTION: Request for Comment NOTICE: Long Term Care Hospital Continuity Assessment Record and Evaluation Data Set AGENCY: CMS | CMS-10409 | Issue Date: 2/1/2013 Due Date: 4/2/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 4/12/2013; issued extension 3/11/2016, 5/16/2016 Due Date: 5/13/2013; 5/10/2016, 6/15/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 135.e. | Reform of Requirements for Long-Term Care Facilities ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities AGENCY: CMS | CMS-3260-PF | Issue Date: 7/16/2015 Due Date: 9/14/2015 10/15/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued notice of reopening of comment period 9/15/2015; issued Final Rule 10/4/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-------------|---|---|--|
| 136.c. | PQRS and the eRx Incentive Program Data Assessment ACTION: Request for Comment NOTICE: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support AGENCY: CMS | CMS-10519 | Issue Date: 3/17/2014 Due Date: 5/16/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/8/2014; issued revision 9/25/2015, 1/29/2016 Due Date: 10/6/2014; 11/24/2015; 2/29/2016 TTAG File Date: 2/29/2016 | subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 136.e. | Requirements for Reporting Quality Measures ACTION: Request for Information NOTICE: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs AGENCY: CMS | CMS-3323-NC | Issue Date: 12/31/2016 Due Date: 2/1/2016 2/16/2016 NIHB File Date: 2/1/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/2/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 136.f. | CMS Innovation Partners Program Applications ACTION: Request for Comment NOTICE: CMS Innovation Partners Program Applications and Surveys AGENCY: CMS | CMS-10601 | Issue Date: 3/1/2016 Due Date: 5/2/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 5/6/2016 Due Date: 6/6/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|---------------------------------|---|---|--|
| 136.g. | CMS Quality Measure Development Plan ACTION: Guidance NOTICE: CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) (DRAFT) AGENCY: CMS | CMS (no reference number) | Issue Date: 12/18/2016 Due Date: 3/1/2016 NIHB File Date: 3/18/2016 Date of Subsequent Agency Action, if any: Issued Final Guidance 5/2/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 136.h. | MIPS and Alternative Payment Model Incentive Under PFS ACTION: Proposed-Final Rule NOTICE: Medicare Program; Merit- Based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician- Focused Payment Models AGENCY: CMS | CMS-5517- ₽FC | Issue Date: 5/9/2016 Due Date: 6/27/2016 NIHB File Date: 6/27/2016; TTAG also filed comments 6/27/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 11/4/2016 Due Date: 12/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|---------------------------------|---|---|--|
| 136.i. | Advancing Care Coordination ACTION: Proposed Rule NOTICE: Medicare Program; Advancing Care Coordination Through Episode Payment Models; Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model AGENCY: CMS | CMS-5519-P | Issue Date: 8/2/2016 Due Date: 10/3/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action |
| 136.j. | Reducing Health Care-Acquired Conditions in Nursing Homes ACTION: Request for Comment NOTICE: Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes AGENCY: CMS | CMS-10622 | Issue Date: 6/30/2016 Due Date: 8/29/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/31/2016 Due Date: 11/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 136.k. | State Innovation Model Concepts ACTION: Request for Information NOTICE: Request for Information on State Innovation Model Concepts AGENCY: CMS | CMS (no reference number) | Issue Date: 9/8/2016 Due Date: 10/28/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|-----------|---|---|--|
| 137.a. | Procedures for Making Medicare National Coverage Decisions ACTION: Request for Comment NOTICE: Procedures for Making National Coverage Decisions AGENCY: CMS | CMS-R-290 | Issue Date: 2/12/2013 Due Date: 4/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 5/31/2013; issued extension 6/24/2016, 8/24/2016 Due Date: 7/1/2013; 8/23/2016; 9/23/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 137.d. | Data Collection for Beneficiaries Receiving Beta Amyloid PET ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease AGENCY: CMS | CMS-10583 | Issue Date: 9/25/2015 Due Date: 11/24/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/8/2015 Due Date: 1/7/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 137.e. | Transcatheter Valve Therapy Registry and KCCQ-10 ACTION: Request for Comment NOTICE: Transcatheter Valve Therapy Registry and KCCQ-10 AGENCY: CMS | CMS-10443 | Issue Date: 3/18/2016 Due Date: 5/17/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/17/2016 Due Date: 7/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|---|---|--|
| 139.a. | Examination and Treatment for Emergency Medical Conditions ACTION: Request for Comment NOTICE: Examination and Treatment for Emergency Medical Conditions and Women in Labor AGENCY: CMS | CMS-R-142 | Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 6/13/2016, 9/2/2016 Due Date: 6/17/2013; 8/9/2016; 10/3/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 139.d. | Ambulance Transports and Signature Requirements ACTION: Request for Comment NOTICE: Emergency and Non-Emergency Ambulance Transports and Beneficiary Signature Requirements AGENCY: CMS | CMS-10242 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 8/16/2013; issued extension 7/29/2016, 10/7/2016 Due Date: 9/16/2013; 9/27/2016; 11/7/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 142.a. | Detailed Notice of Discharge ACTION: Request for Comment NOTICE: Detailed Notice of Discharge (DND) AGENCY: CMS | CMS-10066 | Issue Date: 3/6/2013 Due Date: 5/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 11/27/2015, 6/13/2016 Due Date: 6/17/2013; 1/26/2016; 7/13/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------|--|---|--|
| 142.b. | Important Message from Medicare ACTION: Request for Comment NOTICE: Important Message from Medicare (IM) AGENCY: CMS | CMS-R-193 | Issue Date: 3/6/2013 Due Date: 5/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 12/8/2015, 6/13/2016 Due Date: 6/17/2013; 1/26/2016; 7/13/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 146.a. | Data for Medicare Beneficiaries Receiving NaF-18 PET Scans ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries Receiving NaF-18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer AGENCY: CMS | CMS-10152 | Issue Date: 3/14/2013 Due Date: 4/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/4/2016, 5/11/2016 Due Date: 5/3/2016; 6/10/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 146.b. | Data for Medicare Beneficiaries Receiving ICDs ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter Defibrillators for Primary Prevention of Sudden Cardiac Death AGENCY: CMS | CMS-10151 | Issue Date: 4/22/2013 Due Date: 6/21/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016 Due Date: 8/23/2013; 9/20/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|-----------|--|---|--|
| 148.a. | Acceptable Off-Label Uses of Certain Drugs and Biologicals ACTION: Request for Comment NOTICE: Collection Requirements for Compendia for Determination of Medically Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen AGENCY: CMS | CMS-10302 | Issue Date: 3/14/2013 Due Date: 5/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/31/2013, 5/26/2016, 7/29/2016 Due Date: 7/1/2013; 7/25/2016; 8/29/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 148.b. | Data for Medicare Part B Drugs and Biologicals ACTION: Request for Comment NOTICE: Data for Medicare Part B Drugs and Biologicals AGENCY: CMS | CMS-10110 | Issue Date: 7/21/2015 <u>Due Date:</u> 9/21/2015 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : Issued reinstatement 10/2/2015, 3/4/2016 <u>Due Date</u> : 11/2/2015; 4/4/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-------------------------|---|---|--|
| 151.a. | Request for Employment Information ACTION: Request for Comment NOTICE: Request for Employment Information AGENCY: CMS | CMS-R-297 (CMS-L564) | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/26/2013; issued revision 1/2/2014; issued extension 7/25/2016, 9/29/2016 Due Date: 8/26/2013; 2/3/2014; 9/23/2016; 10/31/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 156. | Coverage for Diabetes Outpatient Self-Management Training ACTION: Request for Comment NOTICE: Expanded Coverage for Diabetes Outpatient Self- Management Training Services and Supporting Regulations AGENCY: CMS | CMS-R-247 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/23/2013; 9/20/2016; 10/26/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 164.b. | Medicare Secondary Payer and "Future Medicals" ACTION: Proposed Rule NOTICE: Medicare Secondary Payer and "Future Medicals" AGENCY: CMS | CMS-6047-P | Issue Date: [Approved by OMB 10/9/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action |

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|--------------------|---|-------------------|---|---|--|
| 164.c. | Medicare Secondary Payer Conditional Payment Amounts ACTION: Interim Final Rule NOTICE: Medicare Program; Obtaining Final Medicare Secondary Payer Conditional Payment Amounts via Web Portal AGENCY: CMS | CMS-6054- IFCF | Issue Date: 9/20/2013 Due Date: 11/19/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 5/17/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 172.a. | Medicare Current Beneficiary Survey ACTION: Request for Comment NOTICE: Medicare Current Beneficiary Survey AGENCY: CMS | CMS-P-0015A | Issue Date: 7/26/2013 Due Date: 9/24/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 10/4/2013; issued revision 2/24/2016, 4/29/2016 Due Date: 11/4/2013; 4/25/2016; 5/31/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-------------|--|---|--|
| 179.d. | Changes to Medicare Appeals Procedures ACTION: Proposed Rule NOTICE: Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures AGENCY: HHS | HHS-2015-49 | Issue Date: 7/5/2016 <u>Due Date:</u> 8/29/2016 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action |
| 179.e. | CY 2017 Amount in Controversy Thresholds for Medicare Appeals ACTION: Notice NOTICE: Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2017 AGENCY: CMS | CMS-4179-N | Issue Date: 9/23/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 195.c. | Collection of Customer Satisfaction Surveys ACTION: Request for Comment NOTICE: Generic Clearance for the Collection of Customer Satisfaction Surveys AGENCY: CMS | CMS-10415 | Issue Date: 10/30/2015 Due Date: 12/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/30/2015 Due Date: 1/29/2015 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---------------------------------|--|---|--|
| 208. | Medicare Probable Fraud Measurement Pilot ACTION: Request for Comment NOTICE: Medicare Probable Fraud Measurement Pilot AGENCY: CMS | CMS-10406 | Issue Date: 2/5/2016 <u>Due Date:</u> 4/5/2016 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any:</u> Issued extension 4/29/2016 <u>Due Date:</u> 5/31/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| /: | Pre-Existing Health Insurance | | Section III: Health Reform Issue Date: [Pending at OMB as | Summary of Agency | NIHB recommendations included: |
| 6.i. | Plan Program Updates ACTION: Interim Final Rule NOTICE: Pre-Existing Condition Insurance Plan Program Updates AGENCY: CMS | CMS-9995- IFC4 | of 2/3/2015] <u>Due Date:</u> <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | action: NIHB analysis of action: | Subsequent Agency action: Analysis of Agency action: |
| 7.1. | Stand-Alone Dental Plans in Federally-Facilitated Exchanges ACTION: Guidance NOTICE: Issuers of Stand-Alone Dental Plans: Intent to Offer in FFE States AGENCY: HHS | HHS (no reference number) | Issue Date: 1/28/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 5/6/2014, 2/19/2015, 3/8/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|------------------------|---|---|--|
| 7.q. | Cooperative Agreement to Support Navigators in FFE ACTION: Request for Comment NOTICE: Cooperative Agreement to Support Navigators in Federally- Facilitated and State Partnership Exchanges AGENCY: CMS | CMS-10463 | Issue Date: 4/12/2013 Due Date: 6/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/26/2013; issued revision 4/11/2014, 7/25/2014, 3/30/2015; issued extension 6/26/2015; issued revision 5/11/2016, 8/10/2016 Due Date: 8/26/2013; 6/10/2014; 8/25/2014; 5/29/2015; 7/27/2015; 7/11/2016; 9/9/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.x. | Notice to Employees of Coverage Options ACTION: Request for Comment NOTICE: Notice to Employees of Coverage Options Under Fair Labor Standards Act Section 18B AGENCY: DoL | DoL (OMB 1210-0149) | Issue Date: 8/15/2013 Due Date: 10/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/28/2016 Due Date: 12/27/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------------------------------|--|---|--|
| 7.hhh. | FFM and Federally-Facilitated SHOP Enrollment Manual ACTION: Guidance NOTICE: Federally-Facilitated Marketplace and Federally- Facilitated Small Business Health Options Program Enrollment Manual AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 10/1/2015 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> Issued updated manual 7/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.jjj. | Establishment of QHPs and Exchanges ACTION: Request for Comment NOTICE: Establishment of Qualified Health Plans and American Health Benefit Exchanges AGENCY: CMS | CMS-10400 | Issue Date: 11/23/2015 Due Date: 1/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/4/2016 Due Date: 4/4/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.kkk. | ECP Petition for 2017 ACTION: Notice NOTICE: Essential Community Provider Petition for the 2017 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 12/9/2015 Due Date: 1/8/2016 1/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension | Summary of Agency action: √ TSGAC analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|-----------------------------------|--|---|--|
| 7.111. | 2017 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft 2017 Letter to Issuers in the Federally-Facilitated Marketplaces AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 12/23/2015 Due Date: 1/17/2016 TSGAC File Date: 1/17/2016 Date of Subsequent Agency Action, if any: Issued Final Letter 2/29/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TSGAC recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 7.mmm. | Establishment of an Exchange by a State and QHPs ACTION: Request for Comment NOTICE: Establishment of an Exchange by a State and Qualified Health Plans AGENCY: CMS | CMS-10593 | Issue Date: 12/2/2015 Due Date: 2/1/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/4/2016 Due Date: 4/4/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.nnn. | Establishment of Exchanges and QHPsStandards for Employers ACTION: Request for Comment NOTICE: Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers AGENCY: CMS | CMS-10592 | Issue Date: 12/2/2015 Due Date: 2/1/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/18/2016 Due Date: 4/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 7.000. | CMS Healthcare.gov Site Wide Online Survey ACTION: Request for Comment NOTICE: CMS Healthcare.gov Site Wide Online Survey AGENCY: CMS | CMS-10597 | Issue Date: 12/14/2015 Due Date: 2/12/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 10/14/2016 Due Date: 11/14/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.rrr. | Key Dates for CY 2016: QHP Certification in the FFM, et al. ACTION: Guidance NOTICE: Proposed Key Dates for Calendar Year 2016: QHP Certification in the Federally- Facilitated Marketplaces; Rate Review; Risk Adjustment and Reinsurance AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 12/23/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued Final Guidance 2/29/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 7.sss. | April 2016 Transition of Issuers to Policy-Based Payments ACTION: Guidance NOTICE: Policy-Based Payments Bulletin Transition in April 2016 INFORMATION: Policy-Based Payments: April 2016 Transition of All Issuers to Policy-Based Payments and Subsequent Adjustments Only in Cases of Extreme Variation Between Policy- Based Payments and the Manual Payment Process AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 5/2/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.ttt. | Marketplace Eligibility Appeals Paper-Based Processes ACTION: Guidance NOTICE: Marketplace Eligibility AppealsOptions for Paper-Based Processes AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|--|---|--|
| 7.uuu. | Ensuring Meaningful Access by Limited-English Speakers ACTION: Guidance NOTICE: Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web- Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR §155.205(c) and §156.250 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/30/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.vvv. | Ending Special Enrollment Periods for Coverage in 2015 ACTION: Guidance NOTICE: Ending Special Enrollment Periods for Coverage During Calendar Year 2015 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.www. | Amendments to SEPs and the CO-OP Program ACTION: Interim Final Rule NOTICE: Patient Protection and Affordable Care Act: Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program AGENCY: CMS | CMS-9933-IFC | Issue Date: 5/11/2016 Due Date: 7/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 7.xxx. | Display of QRS Star Ratings and QHP Enrollee Survey Results ACTION: Guidance NOTICE: CMS Bulletin on Display of Quality Rating System (QRS) Star Ratings and Qualified Health Plan (QHP) Enrollee Survey Results for QHPs Offered Through Marketplaces AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/29/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> Issued revised Guidance 9/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.yyy. | FAQs on Incarceration and the Marketplace ACTION: Guidance NOTICE: Incarceration and the Marketplace Frequently Asked Questions AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 5/3/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------------------------------|--|---|--|
| 7.222. | Effectuation of 2016 FFM Dental Enrollment Without APTCs ACTION: Guidance NOTICE: Effectuation of 2016 Federally-Facilitated Marketplace Dental EnrollmentINFORMATION: CMS to Effectuate Dental Enrollment for 2016 Policies Without Advance Payments of the Premium Tax Credit AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/1/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.aaaa. | FAQs on Auto Re-Enrollment for QHPs No Longer Available ACTION: Guidance NOTICE: Auto Re-Enrollment for QHPs No Longer Available in the Marketplace: External FAQs AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/24/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.bbbb. | FAQs on Annual Income Threshold Adjustment ACTION: Guidance NOTICE: Annual Income Threshold Adjustment FAQ AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 7/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|--|---|--|
| 7.ccc. | Inappropriate Steering of Individuals to Individual Market ACTION: Notice NOTICE: Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans AGENCY: CMS | CMS-6074-N | Issue Date: 8/23/2016 Due Date: 9/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.dddd. | FAQs on Periodic Data Matching ACTION: Guidance NOTICE: Summer/Fall 2016 Periodic Data MatchingFAQs AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included:Subsequent Agency action:Analysis of Agency action: |
| 7.eeee. | Notice to States Regarding Marketplace Auto Re-Enrollment ACTION: Guidance NOTICE: Notice to States Regarding Marketplace Auto Re- Enrollment AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/8/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.ffff. | FAQs on Language Access Tagline Requirements ACTION: Guidance NOTICE: Language Access Tagline Frequently Asked Questions AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/10/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 7.gggg. | Network Breadth Information for QHPs on Healthcare.gov ACTION: Guidance NOTICE: Network Breadth Pilot: CMS Bulletin on Network Breadth Information for Qualified Health Plans on Healthcare.gov AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/19/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 9/30/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.hhhh. | FAQs on FFM User Fee Adjustment Submissions ACTION: Guidance NOTICE: FAQs for Federally- Facilitated Marketplace (FFM) User Fee Adjustment Submission Requirements AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/22/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> Date of Subsequent Agency <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.iiii. | ECP Petition for 2018 ACTION: Notice NOTICE: Essential Community Provider Petition for the 2018 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/2/2016 Due Date: 10/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------------------------------|--|---|--|
| 7.jjjj. | Agreement Between QHP Issuers and CMS ACTION: Guidance NOTICE: Qualified Health Plan Certification Agreement and Privacy and Security Agreement Between Qualified Health Plan Issuer and the Centers for Medicare & Medicaid Services AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/1/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.kkkk. | FAQs on Crosswalk of Enrollees into the Plans of Other Issuers ACTION: Guidance NOTICE: FAQs Regarding Crosswalk of Enrollees into Plans Offered by Other Issuers AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/2/2016 <u>Due Date:</u> None NIHB File Date: <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.1111. | FAQs on Verification of Special Enrollment Periods ACTION: Guidance NOTICE: Frequently Asked Questions Regarding Verification of Special Enrollment Periods AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/6/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------------------------------|--|---|--|
| 7.mmmm. | FAQ on Safe Harbor for Issuers with Increased Enrollment in 2017 ACTION: Guidance NOTICE: FAQ on Compliance Safe Harbor for Issuers Affected by an Increase in Enrollment for the 2017 Plan Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/16/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 7.nnnn. | FAQ on Health Insurance Marketplace Standards ACTION: Guidance NOTICE: Frequently Asked Questions on Health Insurance Marketplace Standards AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 10/17/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 12.f. | FAQs on the CO-OP Program ACTION: Guidance NOTICE: Frequently Asked Questions on the Consumer Operated and Oriented Plan (CO-OP) Program AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 1/27/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 14.c. | Waivers for State Innovation ACTION: Notice NOTICE: Waivers for State Innovation AGENCY: CMS/Treasury | CMS-9936-N | Issue Date: 12/16/2015 Due Date: Open TSGAC File Date: 2/23/2016 Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 27.u. | Transitional Reinsurance Program Collections for 2015 ACTION: Guidance NOTICE: The Transitional Reinsurance Program's Contribution Collections for the 2015 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 2/12/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 27.v. | New System of Records (Risk Adjustment Data Validation) ACTION: Notice NOTICE: Privacy Act of 1974; Report of New System of Records AGENCY: CMS | CMS (no reference number) | Issue Date: 5/3/2016 <u>Due Date:</u> 30 days (approx. 6/2/2016) <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 27.w. | Evaluation of Training Stabilization Programs ACTION: Request for Comment NOTICE: Clearance for Evaluation of Stakeholder TrainingHealth Insurance Marketplace and Market Stabilization Programs AGENCY: CMS | CMS-10598 | Issue Date: 6/17/2016 Due Date: 8/16/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 10/14/2016 Due Date: 11/14/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|---|---|---|--|
| 27.x. | Q&A on HHS-Operated Risk Adjustment Methodology ACTION: Guidance NOTICE: March 31, 2016, HHS- Operated Risk Adjustment Methodology MeetingQuestions & Answers AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/8/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 29.d. | Minimum Value of Eligible Employer-Sponsored Plans ACTION: Proposed Final Rule NOTICE: Minimum Value of Eligible Employer-Sponsored Plans and Other Rules Regarding the Health Insurance Premium Tax Credit AGENCY: IRS | REG 125398 12 REG 143800 14 TD 9745 | Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued supplement to Proposed Rule 9/1/2015; issued Final Rule 12/18/2015; issued correction 1/15/2016 Due Date: 11/2/2015 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 29.s. | Premium Tax Credit ACTION: Proposed Rule NOTICE: Premium Tax Credit NPRM VI AGENCY: IRS | REG-109086- 15 | Issue Date: 7/8/2016 Due Date: 9/6/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 9/14/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|---|---|---|--|
| 29.t. | Information Reporting of Catastrophic Health Coverage ACTION: Proposed Rule NOTICE: Information Reporting of Catastrophic Health Coverage and Other Issues Under Section 6055 AGENCY: IRS | REG-103058- 16 | Issue Date: 8/2/2016 Due Date: 10/3/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 31.q. | Exchange Functions: Eligibility for Exemptions ACTION: Request for Comment NOTICE: Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions AGENCY: CMS | CMS-10466 See also 31.e. | Issue Date: 10/16/2013 Due Date: 11/15/2013 TTAG File Date: 11/15/2013 Date of Subsequent Agency Action, if any: Issued final applications 12/19/2013; issued revision 10/25/2016 Due Date: 12/27/2016 TTAG File Date: 12/30/2013 | Summary of Agency action: √ TTAG analysis of action: √ Summary of subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 31.tt. | Summary of Benefits and Coverage and Uniform Glossary ACTION: Request for Comment NOTICE: Summary of Benefits and Coverage and Uniform Glossary Required Under the Affordable Care Act AGENCY: DoL | DoL (OMB 1210-0147) See also 92.kk. | Issue Date: 2/27/2015 <u>Due Date:</u> 3/30/2015 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any:</u> Issued revision 2/26/2016 <u>Due Date:</u> 3/28/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|--|---|--|
| 31.ddd. | 2017 Actuarial Value Calculator ACTION: Guidance NOTICE: Draft-2017 Actuarial Value Calculator AGENCY: CCIIO | CCIIO (no reference number | Issue Date: 11/20/2015 Due Date: 12/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 1/21/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 31.fff. | Minimum Essential Coverage Calculation Report and Notices ACTION: Request for Comment NOTICE: Minimum Essential Coverage AGENCY: CMS | CMS-10465 | Issue Date: 3/11/2016 Due Date: 5/10/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/17/2016 Due Date: 7/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 31.ggg. | FAQs on ACA Implementation (SBC) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation (Part 30) AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/11/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------------------------------|--|---|--|
| 31.hhh. | FAQs on SBC Related to Rate Filing and QHP Certification ACTION: Guidance NOTICE: Additional Frequently Asked Questions on the Summary of Benefits and Coverage (SBC) Related to Rate Filing and QHP Certification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/11/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 31.iii. | Tribal Consultation on ACA Employer Shared Responsibility ACTION: Notice NOTICE: Tribal Consultation on the ACA Employer Shared Responsibility Provisions AGENCY: IRS | IRS (no reference number) | Issue Date: 4/20/2016 Due Date: None TSGAC File Date: 5/13/2016 Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 31.jjj. | et al. ACTION: Request for Comment NOTICE: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment AGENCY: CMS | CMS-10468 | Issue Date: 4/1/2016 Due Date: 5/31/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/29/2016 Due Date: 8/29/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---|--|---|--|
| 31.kkk. | FAQs on Health Insurance Market Reforms (EHBs) ACTION: Guidance NOTICE: Frequently Asked Questions on Health Insurance Market Reforms and Marketplace Standards AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 5/26/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 31.III. | Indian-Specific CSV Sample SBC Templates ACTION: Guidance NOTICE: Sample Summary of Benefits and Coverage (SBC) Templates; Zero Cost-Sharing Variation (Z-CSV) and Limited Cost-Sharing Variation (L-CSV) AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/16/2016 Due Date: 3/18/2016 TTAG File Date: 3/18/2016 Date of Subsequent Agency Action, if any: Issued template(s) 4/6/2016 (general), 4/28/2016 (draft Indian-specific); issued final Indian-specific templates 7/13/2016 Due Date: 5/4/2016 TTAG File Date: 5/4/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 31.mmm. | Coverage for Contraceptive Services ACTION: Notice NOTICE: Coverage for Contraceptive Services AGENCY: IRS/DoL/CMS | IRS (no reference number) DoL (no reference number) CMS-9931-NC | Issue Date: 7/22/2016 Due Date: 9/20/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 31.nnn. | 2018 Actuarial Value Calculator ACTION: Guidance NOTICE: Draft 2018 Actuarial Value Calculator AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/29/2016 Due Date: 9/30/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 31.000. | Health Coverage Tax Credit Hardship Exemption ACTION: Guidance NOTICE: Guidance on Health Coverage Tax Credit Hardship Exemption AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/12/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 39.f. | Basic Health Program: Federal Funding Methodology for 2017 ACTION: Proposed Final Methodology NOTICE: Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018 AGENCY: CMS | CMS-2396- ₽FN | Issue Date: 10/22/2015 Due Date: 11/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Methodology 2/29/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|--|---|--|
| 48.b. | Medical Loss Ratio Rebate Calculation Report and Notices ACTION: Request for Comment NOTICE: Annual MLR and Rebate Calculation Report and MLR Rebate Notices AGENCY: CMS | CMS-10418 | Issue Date: 12/4/2012 Due Date: 2/4/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/22/2013, 11/22/2013, 1/31/2014, 1/30/2015, 4/24/2015, 2/19/2016, 5/25/2016 Due Date: 3/25/2013; 1/21/2014; 3/5/2014; 3/31/2015; 5/26/2015; 4/19/2016; 6/24/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 48.f. | Medical Loss Ratio Report for MA Plans and PDPs ACTION: Request for Comment NOTICE: Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) AGENCY: CMS | CMS-10476 | Issue Date: 7/5/2013 Due Date: 9/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 11/8/2013; issued revision 9/2/2016 Due Date: 12/9/2013; 11/1/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 48.j. | Modification of Treatment of Certain Health Organizations ACTION: Final Rule NOTICE: Modification of Treatment of Certain Health Organizations AGENCY: IRS | TD 9772 | Issue Date: 6/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 48.k. | FAQ on MLR and Risk Corridors Data Submission Deadline ACTION: Guidance NOTICE: Medical Loss Ratio and Risk Corridors Data Submission Deadline for the 2015 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 7/26/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 50.f. | Eligibility and Enrollment for Employees in SHOP ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Employees in SHOP AGENCY: CMS | CMS-10438 See also 50.m. | Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: Issued revision 12/11/2015, 3/25/2016 Due Date: 2/9/2016; 4/25/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 50.g. | Eligibility and Enrollment for Small Businesses in SHOP ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in SHOP AGENCY: CMS | CMS-10439 See also 50.m. | Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: Issued revision 12/11/2015, 3/25/2016 Due Date: 2/9/2016; 4/25/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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|--------------------|--|-----------------------------------|---|---|--|
| 50.h. | Eligibility for Insurance Affordability Programs and Enrollment ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment Through Affordable Insurance Exchanges, Medicaid and CHIP Agencies AGENCY: CMS | CMS-10440 | Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: 4/30/2013; issued revision 12/2/2015, 3/25/2016 Due Date: 2/1/2016; 4/25/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 50.aa. | SHOP Effective Date and Termination Notice Requirements ACTION: Request for Comment NOTICE: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements AGENCY: CMS | CMS-10555 | Issue Date: 3/9/2015 Due Date: 5/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/14/2015 Due Date: 1/13/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 50.ff. | State-Based SHOP Direct Enrollment Transition ACTION: Guidance NOTICE: Extension of State-Based SHOP Direct Enrollment Transition AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/18/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|--|---|--|
| 50.gg. | SBM No Cost Extensions in 2017 ACTION: Guidance NOTICE: Guidance for SBM No Cost Extensions in 2017 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/29/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> Date of Subsequent Agency <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 51.c. | Application of Market Reforms to Student Health Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin SeriesINFORMATION: Application of the Market Reforms and Other Provisions of the Affordable Care Act to Student Health Coverage AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 2/5/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 51.d. | Student Health Insurance Coverage ACTION: Request for Comment NOTICE: Student Health Insurance Coverage AGENCY: CMS | CMS-10377 | Issue Date: 3/11/2016 Due Date: 5/10/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/17/2016 Due Date: 7/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|-----------------------------------|---|---|--|
| 51.e. | FAQ on ACA Implementation (Student Health Insurance) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation (Part 33) AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 10/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 54. | ESI Coverage Verification ACTION: Notice NOTICE: Employer-Sponsored Coverage Verification: Preliminary Informational Statement AGENCY: CMS | CMS RIN 0938- ZB09 | Issue Date: [Approved by OMB 4/26/2012] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 63.b. | Electronic Funds Transfers Authorization Agreement ACTION: Request for Comment NOTICE: Electronic Funds Transfers Authorization Agreement AGENCY: CMS | CMS-588 | Issue Date: 3/1/2013 Due Date: 4/30/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/17/2013, 6/13/2016, 9/12/2016 Due Date: 6/17/2013; 8/9/2016; 10/12/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------|---|---|--|
| 67.a. | State Consumer Assistance Grants ACTION: Request for Comment NOTICE: Consumer Assistance Program Grants AGENCY: CMS | CMS-10333 | Issue Date: 7/27/2012 Due Date: 9/25/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/7/2012; issued extension 11/2/2015, 1/20/2016 Due Date: 2/7/2013; 1/4/2016; 2/19/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 67.b. | Research on Outreach for Health Insurance Marketplace ACTION: Request for Comment NOTICE: Consumer Research Supporting Outreach for Health Insurance Marketplace AGENCY: CMS | CMS-10458 | Issue Date: 1/11/2013 Due Date: 3/12/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/4/2013; issued extension 4/22/2016, 6/24/2016 Due date: 5/6/2013; 6/21/2016; 7/25/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 89.d. | Cost-Sharing Reductions Reconciliation Methodology ACTION: Request for Comment NOTICE: Issuer Reporting Requirements for Selecting a Cost- Sharing Reductions Reconciliation Methodology AGENCY: CMS | CMS-10469 | Issue Date: 4/12/2013 Due Date: 6/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/28/2013; issued extension 5/16/2016, 8/10/2016 Due Date: 7/29/2013; 7/15/2016, 9/9/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|---|---|--|
| 89.g. | Cost Sharing Reduction Reconciliation ACTION: Request for Comment NOTICE: Cost Sharing Reduction Reconciliation AGENCY: CMS | CMS-10526 | Issue Date: 6/27/2014 Due Date: 8/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/26/2014; issued revision 9/14/2015, 1/20/2016 Due Date: 10/27/2014; 11/13/2015; 2/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 89.m. | Notice of Benefit and Payment Parameters for 2017 ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 AGENCY: CMS | CMS-9937- P F | Issue Date: 12/2/2015 Due Date: 12/21/2015 TTAG File Date: 12/21/2015; TSGAC also filed comments 12/21/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 3/8/2016; issued correction 8/11/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 89.n. | Manual for Reconciliation of Advance Payment of CSRs ACTION: Guidance NOTICE: Draft-Manual for Reconciliation of Advance Payment of Cost-Sharing Reductions for Benefit Years 2014 and 2015 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 1/15/2016 Due Date: 2/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 3/16/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------------------------------|---|---|--|
| 89.o. | CSR Reconciliation Issuer to MIDAS Attestation ACTION: Guidance NOTICE: CSR Reconciliation Issuer to MIDAS Attestation Inbound Specification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/9/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 89.p. | CSR Reconciliation Issuer to MIDAS Inbound Specification ACTION: Guidance NOTICE: CSR Reconciliation Issuer to MIDAS Inbound Specification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/9/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 89.q. | Data Submission Deadline for CSR Reconciliation ACTION: Guidance NOTICE: Data Submission Deadline for Cost-Sharing Reduction Reconciliation AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/15/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|-----------------------------------|--|---|--|
| 89.r. | Alternative Schedule for Payment for Reconciliation of CSRs ACTION: Guidance NOTICE: Alternative Schedule for Payment of Charges for Reconciliation of the Cost-sharing Reduction Portion of Advance Payments for the 2014 and 2015 Benefit Years AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/17/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> Issued clarification 6/27/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 89.s. | Discrepancy Resolution Process Inbound Specification (CSRs) ACTION: Guidance NOTICE: Discrepancy Resolution Process Inbound Specification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/23/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 89.t. | Notice of Benefit and Payment Parameters for 2018 ACTION: Proposed Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 AGENCY: CMS | CMS-9934-P | Issue Date: 9/6/2016 Due Date: 10/6/2016 TSGAC File Date: 10/5/2016 Date of Subsequent Agency Action, if any: | Summary of Agency action: √ TSGAC analysis of action: √ | TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------------------------------|--|---|--|
| 89.s. | Reporting CSR Amounts for 2015 MLR and Risk Corridors ACTION: Guidance NOTICE: Reporting Cost-Sharing Reduction Amounts for 2015 MLR and Risk Corridors AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/5/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.b. | Compliance with Individual and Group Market Reforms ACTION: Request for Comment NOTICE: Information Collection Requirements for Compliance with Individual and Group Market Reforms AGENCY: CMS | CMS-10430 | Issue Date: 11/21/2012 Due Date: 1/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 2/22/2013; issued revision 12/2/2015, 3/1/2016 Due Date: 3/25/2013; 2/1/2016; 3/31/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.d. | Patient Protection Notices and Disclosure Requirements ACTION: Request for Comment NOTICE: Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection Under the Affordable Care Act AGENCY: CMS | CMS-10330 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------|---|---|--|
| 92.e. | Disclosure and Recordkeeping for Grandfathered Health Plans ACTION: Request for Comment NOTICE: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care Act AGENCY: CMS | CMS-10325 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.s. | Rate Increase Disclosure and Review Reporting Requirements ACTION: Request for Comment NOTICE: Rate Increase Disclosure and Review Reporting Requirements AGENCY: CMS | CMS-10379 | Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 4/2/2014; issued revision 2/19/2016 Due Date: 5/2/2014; 4/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.hh. | Annual Eligibility Redetermination Notices, et al. ACTION: Request for Comment NOTICE: Annual Eligibility Redetermination, Product Discontinuation, and Renewal Notices AGENCY: CMS | CMS-10527 | Issue Date: 11/4/2014 Due Date: 1/5/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/23/2015; issued revision 4/28/2016, 9/16/2016 Due Date: 2/23/2015; 6/27/2016; 10/17/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|-----------------------------------|--|---|--|
| 92.kk. | Summary of Benefits and Coverage and Uniform Glossary ACTION: Request for Comment NOTICE: Summary of Benefits and Coverage and Uniform Glossary AGENCY: CMS | CMS-10407 See also 31.tt. | Issue Date: 11/24/2014 Due Date: 1/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/24/2015; issued revision 2/26/2016 Due Date: 3/26/2015; 3/28/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.yy. | Transparency in Coverage Reporting by QHP Issuers ACTION: Request for Comment NOTICE: Transparency in Coverage Reporting by Qualified Health Plan Issuers AGENCY: CMS | CMS-10572 | Issue Date: 8/12/2015 Due Date: 10/13/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/29/2016 Due Date: 5/31/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.ccc. | Rate Filing Justifications for 2016 for Single Risk Pool Coverage ACTION: Guidance NOTICE: DRAFT Insurance Standards Bulletin SeriesINFORMATIONBulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 1/22/2015 Due Date: 1/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 2/29/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------------------------------|--|---|--|
| 92.ddd. | Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data BulletinINFORMATION: Evaluation of EDGE Data Submissions for 2015 Benefit Year for Interim Reinsurance Payments and Interim Risk Adjustment Summary Report AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 1/21/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> Issued clarification 3/16/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92 .eee. | Extension of Transitional Policy Through CY 2017 ACTION: Guidance NOTICE: Insurance Standards Bulletin SeriesINFORMATION Extension of Transitional Policy Through Calendar Year 2017: Extended Transition to Affordable Care Act-Compliant Policies AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 2/29/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.fff. | FAQs on the 2017 Moratorium on Health Insurance Provider Fee ACTION: Guidance NOTICE: Frequently Asked Questions on the 2017 Moratorium on Health Insurance Provider Fee AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 2/29/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|--|-----------------------------------|--|---|--|
| 92.ggg. | Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data BulletinINFORMATION: Evaluation of EDGE Data Submissions for 2015 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/18/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.hhh. | Updated Renewal and Product Discontinuation Notices ACTION: Guidance NOTICE: Draft Updated Federal Standard Renewal and Product Discontinuation Notices AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/21/2016 Due Date: 6/27/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.iii. | FAQs on ACA Implementation (Parity and Women's Health) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation and Women's Health And Cancer Rights Act Implementation AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/20/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---|--|---|--|
| 92.jjj. | Marketplace Eligibility Redetermination for 2017 ACTION: Guidance NOTICE: Guidance on Annual Eligibility Redetermination and Re- Enrollment for Marketplace Coverage for 2017 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 5/10/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.kkk. | Rules for Expatriate Health Plans, et al. ACTION: Proposed Final Rule NOTICE: Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance AGENCY: CMS | REG 135702 15 TD 9791 DoL (RIN 1210- AB75) CMS-9932-PF | Issue Date: 6/10/2016 Due Date: 8/9/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 10/31/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.111. | Health Insurance Enforcement and Consumer Protections Grants ACTION: Request for Comment NOTICE: The Health Insurance Enforcement and Consumer Protections Grant Program AGENCY: CMS | CMS-10605 | Issue Date: 6/17/2016 Due Date: 8/16/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 10/7/2016 Due Date: 11/7/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------------------------------|---|---|--|
| 92.mmm. | NQTLs Requiring Analysis to Determine Parity Compliance ACTION: Guidance NOTICE: Warning SignsPlan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.nnn. | FAQs on ACA Implementation (COBRA Model Election Notice) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation (Part 32) AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.000. | Netting of Payments and Charges ACTION: Guidance NOTICE: Netting of Payments and Charges Under 45 CFR 156.1215 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 7/15/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|-----------------------------------|--|---|--|
| 92.ppp. | Issuer Posting of Rate Filing Information ACTION: Guidance NOTICE: Insurance Standards Bulletin SeriesINFORMATION: CCIIO Sub-Regulatory Guidance: Issuer Posting of Rate Filing Information AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/26/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 92.qqq. | FAQs on ACA Implementation (Market Reforms and Parity) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 10/27/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 111.f. | Mental Health Parity Rules: External Review for MSPP ACTION: Request for Comment NOTICE: Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008: Technical Amendment to External Review for MSPP AGENCY: IRS | TD 9640 (OMB 1545-2165) | Issue Date: 11/27/2015 Due Date: 1/26/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|--------------------------|--|---|--|
| 112.d. | I/T/U Payment for Physician and Non-Hospital-Based Services ACTION: Proposed Final Rule NOTICE: Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated with Non- Hospital-Based Care AGENCY: IHS | IHS RIN 0917- AA12 | Issue Date: 12/5/2014 Due Date: 1/20/2015 NIHB File Date: 2/4/2015 Date of Subsequent Agency Action, if any: Issued due date extension 1/14/2015; issued Final Rule 3/21/2016 Due Date: 5/20/2016 TSGAC File Date: 5/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB/TSGAC recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 112.g. | Receipt of Non-VA Care Under Veterans Choice Program ACTION: Request for Comment NOTICE: Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program AGENCY: VA | VA (OMB 2900-0823) | Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 7/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 112.h. | Health Care Plan Information for Veterans Choice Program ACTION: Request for Comment NOTICE: Health Care Plan Information for the Veterans Choice Program AGENCY: VA | VA (OMB 2900-0823) | Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 7/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-------------------------|---|---|--|
| 112.i. | Submission of Medical Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program AGENCY: VA | VA (OMB 2900-0823) | Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 7/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 112.j. | Submission of Credentials by Eligible Entities or Providers ACTION: Request for Comment NOTICE: Submission of Information on Credentials and Licenses by Eligible Entities or Providers AGENCY: VA | VA (OMB 2900-0823) | Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 7/26/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 112.I. | Expanded Access to Non-VA Care Through Veterans Choice ACTION: Interim Final Rule NOTICE: Expanded Access to Non-VA Care Through the Veterans Choice Program AGENCY: VA | VA RIN 2900- AP60 | Issue Date: 12/1/2015 Due Date: 3/30/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 4/25/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C **UPDATED THROUGH 10/31/2016**

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------------|---|---|--|
| 112.m. | Dear Tribal Leader Letter (Contract Support Costs Policy) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 1/7/2016 Due Date: Open NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revised policy 4/11/2016 Due Date: 60 days (approx. 6/10/2016) NIHB File Date: 6/10/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 112.n. | Catastrophic Health Emergency Fund ACTION: Proposed Rule NOTICE: Catastrophic Health Emergency Fund AGENCY: IHS | IHS RIN 0905- AC97 | Issue Date: 1/26/2016 Due Date: 3/11/2016 4/11/2016 5/10/2016 Open (until at least 10/24/2016) TSGAC File Date: 5/10/2016, 10/28/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/25/2016, 3/11/3016; issued tribal consultation notice 6/1/2016, 7/29/2016 (comment period reopened) | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TSGAC recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 112.0. | IHS Reimbursement Rates for CY 2016 ACTION: Notice NOTICE: Reimbursement Rates for Calendar Year 2016 AGENCY: IHS | IHS RIN 0917- ZA30 | Issue Date: 3/8/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------------|--|---|--|
| 112.p. | FDA Tribal Consultation Policy ACTION: Notice NOTICE: U.S. Department Of Health And Human Services Food And Drug Administration Tribal Consultation Policy (Draft) AGENCY: FDA | FDA (no reference number) | Issue Date: 2/29/2016 Due Date: 5/31/2016 NIHB File Date: 5/31/2016 Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 112.q. | Recognition of Tribal Groups for Representation of VA Claimants ACTION: Request for Information Proposed Rule NOTICE: Recognition of Tribal Organizations for Representation of VA Claimants AGENCY: VA | VA RIN 2900- AP51 | Issue Date: 3/10/2016 Due Date: 4/11/2016 NIHB File Date: 4/11/2016 Date of Subsequent Agency Action, if any: Issued Proposed Rule 7/15/2016 Due Date: 9/13/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |
| 112.r. | Secondary Authorization Request for VA Community Care ACTION: Request for Comment NOTICE: Secondary Authorization Request for VA Community Care AGENCY: VA | VA (OMB 2900-0823) | Issue Date: 5/27/2016 Due Date: 7/26/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/11/2016 Due Date: 11/10/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---------------------------------|---|---|--|
| 112.s. | Dear Tribal Leader Letter (Community Health Aides) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 6/1/2016 Due Date: 7/29/2016 10/27/2016 NIHB File Date: 10/27/2016 Date of Subsequent Agency Action, if any: Issued due date extension 7/29/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 112.t. | Tribal Consultation on Great Plains Area IHS ACTION: Notice NOTICE: Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service AGENCY: IHS | IHS (no reference number) | Issue Date: 6/3/2016 Due Date: 90 days (approx. 9/3/2016) 11/30/2016 NIHB File Date: Date of Subsequent Agency Action, if any: Issued correction 6/15/2016, 7/7/2016; issued due date extension 9/23/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 112.u. | Dear Tribal Leader Letter (Tribal Premium Sponsorship) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 7/18/2016 Due Date: 8/17/2016 10/31/2016 TSGAC File Date: 10/28/2016 Date of Subsequent Agency Action, if any: Issued due date extension 7/29/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action: |

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|--------------------|---|---------------------------------|---|---|--|
| 112.v. | Dear Tribal Leader Letter (Consultation on Tribal Priorities) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: VA | VA (no reference number) | Issue Date: 5/19/2016 <u>Due Date</u> : 10/7/2016 <u>NIHB File Date</u> : 10/7/2016 <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 112.w. | Dear Tribal Leader Letter (FY 2015 Self-Governance Program Report) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 8/22/2016 Due Date: 9/30/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 112.x. | Dear Tribal Leader Letter (IHS Draft Quality Framework) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 7/20/2016 Due Date: 9/19/2016 10/3/2016 NIHB File Date: 10/3/2016 Date of Subsequent Agency Action, if any: Issued due date extension 9/15/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |
| 112.y. | Dear Tribal Leader Letter (Core Provider Network) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: VA | VA (no reference number) | Issue Date: 9/12/2016 Due Date: 11/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any: Issued Notice 9/29/2016 | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|--------------------------------|--|---|--|
| 112.z. | Dear Tribal Leader Letter (IHS Headquarters Realignment) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | VA (no reference number) | Issue Date: 10/5/2016 Due Date: 11/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 122.a. | Special Enrollment Rights Under Group Health Plans ACTION: Request for Comment NOTICE: Notice of Special Enrollment Rights Under Group Health Plans AGENCY: DoL | DoL (OMB 1210-0101) | Issue Date: 12/26/2012 Due Date: 1/23/2013 2/25/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 1/24/2013; issued extension 11/23/2015, 3/4/2016 Due Date: 1/22/2016; 4/4/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 128.a. | ACA Internal Claims and Appeals and External Review Procedures ACTION: Request for Comment NOTICE: ACA Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers AGENCY: CMS | CMS-10338 | Issue Date: 1/11/2013 Due Date: 2/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/17/2016 Due Date: 7/18/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|-----------|---|---|--|
| 149. | Evaluation of the Graduate Nurse Education Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Graduate Nurse Education Demonstration Program AGENCY: CMS | CMS-10467 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/28/2013; issued revision 10/16/2015, 1/19/2016 Due Date: 7/29/2013; 12/15/2015; 2/28/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 168. | Enrollee Satisfaction Survey Data Collection ACTION: Request for Comment NOTICE: Enrollee Satisfaction Survey Data Collection AGENCY: CMS | CMS-10488 | Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 11/1/2013; issued revision 4/28/2015, 7/24/2015, 4/29/2016, 7/12/2016 Due Date: 12/2/2013; 6/29/2015; 8/24/2015; 6/28/2016; 8/11/2016 NIHB File Date: 12/2/2013; TTAG also filed comments 12/2/2013 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency FEHBP: Access for Employees of | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ Issue Date: 8/31/2016 | In Table B Is the summary of Agency action included? Is the NIHB analysis included? Summary of Agency | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? NIHB recommendations included: |
|--------------------|---|------------------------|--|---|--|
| 174.g. | Certain Indian Tribal Employers ACTION: Proposed Rule NOTICE: Access to Federal Employees Health Benefits (FEHB) for Employees of Certain Indian Tribal Employers AGENCY: OPM | OPM (RIN 3206-AM40) | <u>Due Date:</u> 10/31/2016 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | action: √ NIHB analysis of action: √ | Subsequent Agency action: Analysis of Agency action: |
| | | | Section IV: Other | | |
| 36. | Reporting Under Transitional Medical Assistance Provisions ACTION: Request for Comment NOTICE: Reporting Requirements for States Under Transitional Medical Assistance Provisions AGENCY: CMS | CMS-10295 | Issue Date: 3/15/2013 Due Date: 5/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/24/2013; issued extension 5/11/2016, 7/19/2018 Due Date: 6/24/2013; 7/11/2016; 8/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 82.h. | HIPAA Eligibility Transaction System Partner Agreement ACTION: Request for Comment NOTICE: HIPAA Eligibility Transaction System (HETS) Trading Partner Agreement (TPA) AGENCY: CMS | CMS-10157 | Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 1/31/2014; issued extension 5/16/2016, 7/19/2016 Due Date: 3/5/2014; 7/15/2016; 8/18/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|--|--|---|--|
| 82.j. | Complaint Forms for Health Information Privacy Issues ACTION: Request for Comment NOTICE: Complaint Forms for Discrimination; Health Information Privacy Complaints AGENCY: HHS OCR | HHS-OS-0945- 0002-60D HHS-OS-0945- 0002-30D | Issue Date: 10/20/2015 Due Date: 12/21/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 82.k. | Health Insurance Reform Security Standards ACTION: Request for Comment NOTICE: Health Insurance Reform Security Standards AGENCY: HHS | HHS-OS-0945- 0004-60D HHS-OS-0945- 0004-30D | Issue Date: 3/15/2016 Due Date: 5/16/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/19/2016 Due Date: 6/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 82.I. | HIPAA Privacy, Security, and Breach Notification Rules ACTION: Request for Comment NOTICE: HIPAA Privacy, Security, and Breach Notification Rules AGENCY: HHS | HHS-OS-0945- 0003-60D HHS-OS-0945- 0003-30D | Issue Date: 3/17/2016 Due Date: 5/16/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/19/2016 Due Date: 6/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|--|--|---|--|
| 82.m. | HIPAA Administrative Simplification Complaint Form ACTION: Request for Comment NOTICE: HIPAA Administrative Simplification Complaint Form AGENCY: CMS | CMS-10148 | Issue Date: 6/6/2016 Due Date: 8/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 9/2/2016 Due Date: 10/3/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 95. | IHS Forms to Implement the Privacy Rule ACTION: Request for Comment NOTICE: IHS Forms to Implement Privacy Rule (45 CFR Parts 160; 164) AGENCY: IHS | IHS-810, -912- 1, -912-2, -913, and -917 | Issue Date: 10/2/2012 Due Date: 60 days (approx. 11/30/2012) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/22/2016, 3/22/2016 Due Date: 3/22/2016; 4/21/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 109.b. | Notice Requirements of Continuation Coverage ACTION: Request for Comment NOTICE: Notice Requirements of the Health Care Continuation Coverage Provisions AGENCY: DoL | DoL (OMB 1210-0123) | Issue Date: 5/22/2013 Due Date: 7/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 9/25/2013, 5/26/2016, 10/7/2016 Due Date: 10/25/2013; 7/25/2016; 11/7/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------------|---|---|--|
| 114.b. | Evaluating a Pilot Mobile Health Program ACTION: Request for Comment NOTICE: Evaluating a Pilot Mobile Health Program AGENCY: CMS | CMS-10634 | Issue Date: 10/14/2016 Due Date: 12/13/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 125. | Interest Rate on Overdue Debts ACTION: Notice NOTICE: Notice of Interest Rate on Overdue Debts AGENCY: HHS | HHS (no reference number) | Issue Date: 12/28/2012 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 3/5/2013, 4/23/2013, 7/23/2013, 11/12/2013, 9/2/2014, 10/27/2014, 1/27/2015, 8/17/2015, 11/3/2015, 1/27/2016, 4/27/2016, 8/10/2016; 10/21/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 138.a. | Organ Procurement Organization Health Insurance Agreement ACTION: Request for Comment NOTICE: Organ Procurement Organization's (OPOs) Health Insurance Benefits Agreement and Supporting Regulations AGENCY: CMS | CMS-576A | Issue Date: 2/14/2013 <u>Due Date</u> : 4/15/2013 <u>NIHB File Date</u> : <u>Date of Subsequent Agency Action, if any</u> : Issued extension 4/19/2013, 3/1/2016, 5/6/2016 <u>Due Date</u> : 6/20/2013; 5/2/2016; 6/6/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------|---|---|--|
| 143. | Paid Feeding Assistants in Long- Term Care Facilities ACTION: Request for Comment NOTICE: Paid Feeding Assistants in Long-Term Care Facilities and Supporting Regulations AGENCY: CMS | CMS-10053 | Issue Date: 3/8/2013 Due Date: 5/7/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 5/26/2016, 7/29/2016 Due Date: 6/17/2013; 7/25/2016, 8/29/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 153.m. | CMS/SSA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974: CMS Computer Match No. 2016-12; HHS Computer Match No. 1604; SSA Computer Match No. 1097-1899 AGENCY: CMS | CMS (no reference number) | Issue Date: 2/9/2016 Due Date: 30 days (approx. 3/10/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 153.n. | CMS/Homeland Security Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-10; HHS Computer Match No. 1607 AGENCY: CMS | CMS (no reference number) | Issue Date: 2/17/2016 Due Date: 30 days (approx. 3/18/2016) NIHB File Date: Date of Subsequent Agency Action, if any: Issued correction 9/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------------|---|---|--|
| 153.0. | CMS/IRS Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-08; HHS Computer Match No. 1606 AGENCY: CMS | CMS (no reference number) | Issue Date: 2/17/2016 Due Date: 30 days (approx. 3/18/2016) NIHB File Date: Date of Subsequent Agency Action, if any: Issued correction 9/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 153.p. | CMS/Administering Entities Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-11; HHS Computer Match No. 1601 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/3/2016 Due Date: 30 days (approx. 4/1/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 153.q. | CMS/VA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-07; HHS Computer Match No. 1605 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/3/2016 Due Date: 30 days (approx. 4/1/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? | |
|--------------------|--|---------------------------------|--|---|--|--|
| 153.r. | CMS/DoD Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-07; HHS Computer Match No. 1602 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/3/2016 Due Date: 30 days (approx. 4/1/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |
| 153.s. | CMS/DoD Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-02; HHS Computer Match No. 1603; DoD- DMDC Match No. 12 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/18/2016 Due Date: 30 days (approx. 4/18/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |
| 153.t. | CMS/OPM Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-14, HHS Computer Match No. 1608 AGENCY: CMS | CMS (no reference number) | Issue Date: 10/11/2016 Due Date: 30 days (approx. 11/10/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|---------------------------------|--|---|--|
| 153.u. | CMS/Peace Corps Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-15, HHS Computer Match No. 1609 AGENCY: CMS | CMS (no reference number) | Issue Date: 10/11/2016 Due Date: 30 days (approx. 11/10/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 155.a. | Research Exception Under GINA ACTION: Request for Comment NOTICE: Notice of Research Exception Under the Genetic Information Nondiscrimination Act AGENCY: CMS | CMS-10286 | Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 4/29/2016, 7/12/2016 Due Date: 8/23/2013; 6/28/2016; 8/11/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 181.b. | Nondiscrimination Under ACA ACTION: Proposed-Final Rule NOTICE: Nondiscrimination in Health Programs and Activities AGENCY: HHS OCR | HHS OCR RIN 0945- AA02 | Issue Date: 9/8/2015 Due Date: 11/9/2015 TSGAC File Date: 11/9/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 5/18/2016; issued correction 7/18/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | TSGAC recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ |

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | In Table B Is the summary of Dates (Issue Due File Agency action | | action? | |
|--------------------|--|-----------------------------------|---|---|---|--|
| 184.j. | Clinical Diagnostic Laboratory Tests Payment System ACTION: Proposed Final Rule NOTICE: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System AGENCY: CMS | | Issue Date: 10/1/2015 Due Date: 11/24/2015 NIHB File Date: 11/24/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 6/23/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √ | |
| 187.b. | Program for Parallel Review of Medical Products ACTION: Notice NOTICE: Program for Parallel Review of Medical Devices AGENCY: CMS/FDA | CMS-3180-N FDA-2010-N- 0308 | Issue Date: 10/21/2016 <u>Due Date</u> : None <u>NIHB File Date</u> : <u>Date of Subsequent Agency</u> <u>Action, if any</u> : | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |
| 189.c. | Annual Update of the HHS Poverty Guidelines ACTION: Notice NOTICE: Annual Update of the HHS Poverty Guidelines AGENCY: HHS | HHS (no reference number) | Issue Date: 1/25/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------|---|---|--|
| 194.c. | Enrollment and Re-Certification of Entities in the 340B Program ACTION: Request for Comment NOTICE: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations AGENCY: HRSA | HRSA (OMB 0915-0327) | Issue Date: 9/30/2014 Due Date: 12/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 4/21/2015, 4/8/2016 Due Date: 5/21/2015; 5/9/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 194.d. | 340B Ceiling Price and CMPs Regulation ACTION: Proposed Final Rule NOTICE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation AGENCY: HRSA | HRSA RIN 0906- AA89 | Issue Date: 6/17/2015 Due Date: 8/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued notice of 30-day comment period 4/19/2016; sent Final Rule to OMB 10/21/2016 Due Date: 5/19/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 194.e. | 340B Drug Pricing Program Omnibus Guidance ACTION: Notice NOTICE: 340B Drug Pricing Program Omnibus Guidance AGENCY: HRSA | HRSA RIN 0906- AB08 | Issue Date: 8/28/2015 Due Date: 10/27/2015 NIHB File Date: 10/27/2015 Date of Subsequent Agency Action, if any: Sent Final Notice to OMB 9/1/2016 | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? | |
|--------------------|--|-----------------------------------|---|---|--|--|
| 194.f. | 340B Drug Pricing Program Reporting Requirements ACTION: Request for Comment NOTICE: 340B Drug Pricing Program Reporting Requirements AGENCY: HRSA | HRSA (OMB 0915-0176) | Issue Date: 12/23/2015 Due Date: 2/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/20/2016 Due Date: 6/20/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |
| 194.g. | 340B Administrative Dispute Resolution Process ACTION: Proposed Rule NOTICE: 340B Drug Pricing Program; Administrative Dispute Resolution AGENCY: HRSA | HRSA RIN 0906- AA90 | Issue Date: 8/12/2016 Due Date: 10/11/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |
| 199.b. | CLAS County Data ACTION: Guidance NOTICE: CLAS County Data AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 12/12/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 1/7/2015, 2/9/2015, 1/27/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |

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| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|---|----------------------------------|---|---|--|
| 202. | Health Needs of the AI/AN LGBT Community ACTION: Request for Information NOTICE: Notice of Request for Information AGENCY: IHS | IHS (no reference number) | Issue Date: 6/5/2015 Due Date: 7/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued meeting notice 7/22/2015, 8/26/2015, 4/7/2016 | Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 205. | Sharing What WorksBPPPLE Form ACTION: Request for Comment NOTICE: IHS Sharing What WorksBest Practice, Promising Practice, and Local Effort (BPPPLE) Form AGENCY: IHS | IHS (OMB 0917-0034) | Issue Date: 10/9/2015 Due Date: 12/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 11/17/2015; issued due date extension 12/15/2015 Due Date: 12/17/2015 1/9/2016 | Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 206. | Measures of Quality Improvement Activities ACTION: Request for Information NOTICE: Request for Measures Assessing Health Care Organization Quality Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self- Management AGENCY: AHRQ | AHRQ (no reference number) | Issue Date: 2/10/2016 Due Date: 3/4/2016 NIHB File Date: 3/4/2016 Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |

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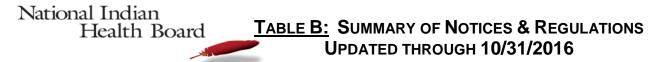
National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 10/31/2016

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? | |
|--------------------|---|-------------------------------|--|---|--|--|
| 207. | Confidentiality of Substance Use Disorder Patient Records ACTION: Proposed Rule NOTICE: Confidentiality of Substance Use Disorder Patient Records AGENCY: SAMHSA | SAMHSA- 4162-20 | Issue Date: 2/9/2016 Due Date: 4/11/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |
| 209. | Reassignment of Personnel in a Public Health Emergency ACTION: Notice NOTICE: Temporary Reassignment of State, Tribal, and Local Personnel During a Public Health Emergency AGENCY: HHS | HHS (no reference number) | Issue Date: 4/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued correction 4/12/2016 | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: | |
| 212. | Enhancing Retailer Standards in SNAP ACTION: Proposed Rule NOTICE: Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP) AGENCY: USDA FNS | USDA FNS RIN 0584- AE27 | Issue Date: 2/17/2016 Due Date: 4/18/2016 5/19/2016 NIHB File Date: 5/16/2016 Date of Subsequent Agency Action, if any: Issued due date extension/clarification 4/5/2016 | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: | |

: regulation review complete

: regulation currently under review

| RRIAR Ref. # | Short Title/ Current Status of Regulation/ Title/ Agency | File Code | Dates (Issue, Due, File, Subsequent Action) ¹ | In Table B Is the summary of Agency action included? Is the NIHB analysis included? | In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? |
|--------------------|--|---------------------------|---|---|--|
| 213.a. | Civil Monetary Penalties Inflation ACTION: Interim Final Rule NOTICE: Civil Monetary Penalties Inflation Adjustment AGENCY: DoJ | AG Order No. 3690-2016 | Issue Date: 6/30/2016 Due Date: 8/29/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included:Subsequent Agency action:Analysis of Agency action: |
| 213.b. | Adjustment of Civil Monetary Penalties for Inflation ACTION: Interim Final Rule NOTICE: Adjustment of Civil Monetary Penalties for Inflation AGENCY: HHS | HHS RIN 0991-AC0 | Issue Date: 9/6/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: | NIHB recommendations included: Subsequent Agency action: Analysis of Agency action: |
| 216. | HHS Grants Regulation ACTION: Proposed Rule NOTICE: Health and Human Services Grants Regulation AGENCY: HHS | HHS (RIN 0991-AC06) | Issue Date: 7/13/2016 Due Date: 8/12/2016 NIHB File Date: 8/11/2016 Date of Subsequent Agency Action, if any: | Summary of Agency action: √ NIHB analysis of action: √ | NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action: |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 1.1. | EHR Incentive Program-Stage 3 ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Electronic Health Record Incentive ProgramStage 3 and Modifications to Meaningful Use in 2015 through 2017 AGENCY: CMS | CMS-3310- PFC CMS-3311- FC See also 1.n. | Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: 5/29/2015; TTAG also filed comments 5/29/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 10/16/2015; issued correction 3/4/2016, 6/1/2016 Due Date: 12/15/2015 NIHB File Date: 12/15/2015 | NIHB response: TTAG response: NIHB response: | SUMMARY OF AGENCY ACTION: This Stage 3 proposed rule would specify the meaningful use criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under Medicare for Stage 3 of the EHR Incentive Programs. It would continue to encourage electronic submission of clinical quality measure (CQM) data for all providers where feasible in 2017, propose to require the electronic submission of CQMs where feasible in 2018, and establish requirements to transition the program to a single stage for meaningful use. Finally, this Stage 3 proposed rule would change the EHR reporting period so that all providers would report under a full calendar year timeline with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time. These changes together support broader CMS efforts to increase simplicity and flexibility in the program while driving interoperability and a focus on patient outcomes in the meaningful use program. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-06685.pdf SUMMARY OF NIHB ANALYSIS: The proposed rule includes a number of provisions supported by tribal organizations, particularly those that help simplify and align reporting periods (calendar year for EPs and eligible hospitals), as well as those that allow for a 90-day reporting period. In addition, tribal organizations support the exceptions for the lack of availability of Internet access or barriers to obtain IT infrastructure. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule with comment period specifies the requirements that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the Medicare EHR Incentive Program. In addition, it changes t | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | (CQM) data, establishes requirements to transition the program to a single stage, and aligns reporting for providers in the Medicare and Medicaid EHR Incentive Programs. CMS seeks comments on sections II.B.1.b.(3).(iii), II.B.1.b.(4).(a), II.B.2.b, II.D.1.e, and II.G.2 of preamble to this final rule with comment period; paragraphs (1)(ii)(C)(3), (1)(iii), (2)(ii)(C)(3) and 2(iii) of the definition of an EHR reporting period at §495.4; and paragraphs (2)(ii)(C)(2) and (2)(iii) of the definition of an EHR reporting period for a payment adjustment year at §495.4. http://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25595.pdf A Health Care Client Memo from Hobbs, Straus, Dean & Walker is embedded below. CMS on 3/4/2016 issued a document (CMS-3310 & 3311-F2) to correct certain technical and typographical errors that appeared in the final rule with comment period published in the 10/16/2015 FR (80 FR 62762) and titled "Medicare and Medicaid Programs; Electronic Health Record Incentive ProgramStage 3 and Modifications to Meaningful Use in 2015 through 2017." https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04785.pdf CMS on 6/1/2016 issued a document (CMS-3310 & 3311-F3) to correct certain technical and typographical errors that appeared in the final rule with comment period published in the 10/16/2015 FR (80 FR 62762) and titled "Medicare and Medicaid Programs; Electronic Health Record Incentive ProgramStage 3 and Modifications to Meaningful Use in 2015 through 2017." https://www.gpo.gov/fdsys/pkg/FR-2016-06-01/pdf/2016-12853.pdf | |
| 1.p. | Health IT Certification Program: Enhanced Oversight ACTION: Proposed Final Rule | HHS ONC RIN 0955- AA00 | <u>Issue Date:</u> 3/2/2016 <u>Due Date:</u> 5/2/2016 <u>NIHB File</u> | | SUMMARY OF AGENCY ACTION: This proposed rule introduces modifications and new requirements under the HHS ONC Health IT Certification Program (Program), including provisions related to the HHS ONC role in the Program. This rule proposes to establish processes for HHS ONC to directly review health IT certified under the Program and take action when necessary, including requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. This proposed rule includes processes | |

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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | NOTICE: ONC Health IT Certification Program: Enhanced Oversight and Accountability AGENCY: HHS ONC | | Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 10/19/2016 | | for HHS ONC to authorize and oversee accredited testing laboratories under the Program. It also includes a provision for the increased transparency and availability of surveillance results. SUMMARY OF NIHB ANALYSIS: This proposed rule might warrant review by tribal health care technology experts. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule finalizes modifications and new requirements under the ONC Health IT Certification Program ("Program"), including provisions related to the role of HHS ONC in the Program. This final rule creates a regulatory framework for direct HHS ONC review of health information technology (health IT) certified under the Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. This final rule also sets forth processes for HHS ONC to authorize and oversee accredited testing laboratories under the Program. In addition, it includes provisions for expanded public availability of certified health IT surveillance results. https://www.gpo.gov/fdsys/pkg/FR-2016-10-19/pdf/2016-24908.pdf | |
| 1.q. | 2015 Test Tools and Procedures for Health IT Certification ACTION: Notice NOTICE: Notice of Availability: 2015 Edition Test Tools and Test Procedures Approved by the National Coordinator for the ONC Health IT Certification Program AGENCY: HHS ONC | HHS ONC (no reference number) | Issue Date: 2/4/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; Use: The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where a vulnerability to the Medicare program might exist. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those which bill for the items) complete the administrative information (e.g., patient name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinician (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the medical condition of the beneficiary and signs the CMN. The physician or other clinician returns the CMN to the supplier, which then submits the CMN (paper or electronic) to CMS with a claim for reimbursement. | |

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. | | |
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| | | | | | SUMMARY OF NIHB ANALYSIS: CMS requires submission of DME CMNs and Informational Forms to ensure the integrity of the Medicare program. The information collection in this PRA request will impose no changes to the current burden on suppliers and providers. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/8/2013 issued a restatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-03-08/pdf/2013-05388.pdf | | | |
| 1.r. | Voluntary Personal Health Record Model Privacy Notice ACTION: Request for Information NOTICE: Request for Information on Updates to the ONC Voluntary Personal Health Record Model Privacy Notice AGENCY: HHS ONC | HHS ONC (no reference number) | Issue Date: 3/1/2016 Due Date: 4/15/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: HHS ONC seeks comments on the scope and content of the voluntary Personal Health Record Model Privacy Notice (MPN) developed by HHS ONC and published in 2011. In response to stakeholder requests for an electronic means to inform consumers about how health technology products store, use, and share health information (especially products of health technology developers not covered by HIPAA), HHS ONC has initiated a process to update the MPN to better align with the current consumer health technology landscape. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04239.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule might warrant review by tribal health care technology experts. | | | |
| 1.s. | Assessing Interoperability for MACRA ACTION: Request for Information NOTICE: Office of the National Coordinator for Health Information Technology; Medicare | HHS ONC (no reference number) | Issue Date: 4/8/2016 Due Date: 6/3/2016 NIHB File Date: None Date of | | SUMMARY OF AGENCY ACTION: In section 106(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress declares it a national objective to achieve widespread exchange of health information through interoperable certified electronic health record (EHR) technology nationwide by December 31, 2018. Section 106(b)(1)(C) of MACRA provides that by 7/1/2016 and in consultation with stakeholders, the HHS Secretary must establish metrics to for use in determining if and to the extent this objective is met. HHS ONC intends to consider metrics that address the specific populations and aspects of interoperable health information described in section 106(b)(1)(B) of MACRA. This | | | |

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Access and CHIP Reauthorization Act of 2015; Request for Information Regarding Assessing Interoperability for MACRA AGENCY: HHS ONC | | Subsequent Agency Action, if any: Issued correction 4/27/2016 | | request for information solicits input on the following three topics: (1) Measurement population and key components of interoperability that should get measured; (2) current data sources and potential metrics that address section 106(b)(1) of MACRA; and (3) other data sources and metrics ONC should consider with respect to section 106(b)(1) of MACRA or interoperability measurement more broadly. https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08134.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: HHS ONC on 4/27/2016 issued a document to correct an error in the request for information titled "Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Request for Information (RFI) Regarding Assessing Interoperability for MACRA" and published in the 4/8/2016 FR (81 FR 20651). In the RFI, HHS ONC failed to identify the file code necessary for submission of comments. This document makes the following correction: on page 20651, "refer to file code ONC xxxx" should read "refer to file code ONC 2016-08134." https://www.gpo.gov/fdsys/pkg/FR-2016-04-27/pdf/2016-09842.pdf | |
| 1.t. | PHR User Survey ACTION: Request for Comment NOTICE: Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey AGENCY: CMS | CMS-10623 | Issue Date: 6/13/2016 Due Date: 8/12/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey; Use: The PHR user survey helps in the TEFT Program Evaluation and understanding the impact of the TEFT PHR on Medicaid CB-LTSS beneficiaries. The TEFT evaluation team approach includes monitoring state PHR implementation efforts and fielding a follow-up questionnaire to CB-LTSS program participants that asks about their experiences using the PHR. The evaluation seeks to measure the degree to which the PHR is implemented in an accessible manner for Medicaid beneficiaries of CB-LTSS. The survey also seeks to assess the user experience of the PHR, including access and usability, as well as some measures of user satisfaction and perceived impacts of PHR use. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13917.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | 9/26/2016 <u>Due Date:</u> 10/26/2016 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/26/2016 issued a new version of this PRA request. CMS has revised this information collection request subsequent to the publication of the 60-day notice in the 6/13/2016 FR (81 FR 38187). The 60-day notice inadvertently had set out the number of burden hours at 192,113 hours, rather than 206 hours. https://www.gpo.gov/fdsys/pkg/FR-2016-09-26/pdf/2016-23157.pdf No comments recommended. | |
| 1.u. | Test Tools and Procedures for Health IT Certification ACTION: Notice NOTICE: Notice of Availability: Test Tools and Test Procedures Approved by the National Coordinator for the ONC Health IT Certification Program AGENCY: HHS ONC | HHS ONC (no reference number) | Issue Date: 8/15/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This notice announces the availability of test procedures and the Cypress version 3.0 test tool approved by the National Coordinator for Health Information Technology (National Coordinator) for the testing of Health IT Modules to four 2015 Edition health information technology (health IT) certification criteria under the ONC Health IT Certification Program. SUMMARY OF NIHB ANALYSIS: | |
| 2.e. | Part CMedicare Advantage and 1876 Cost Plan Expansion ACTION: Request for Comment NOTICE: Part CMedicare Advantage and 1876 Cost Plan Expansion Application AGENCY: CMS | CMS-10237 | Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Part CMedicare Advantage and 1876 Cost Plan Expansion Application; Use: Organizations wishing to provide healthcare services under Medicare Advantage (MA) and/or MA organizations that offer integrated prescription drug and health care products must complete an application, file a bid, and receive final approval from CMS. Existing MA plans can request to expand their contracted service area by completing the Service Area Expansion application. Any current 1876 Cost Plan Contractor that wants to expand its Medicare cost-based contract with CMS can complete the application. CMS collects information to ensure applicant compliance with requirements and gather data to support its determination of contract awards. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | if any: Issued revision 10/4/2013, 7/11/2014, 10/3/2014, 7/7/2015, 9/24/2015, 7/8/2016, 10/31/2016 Due Date: 11/4/2013; 9/9/2014; 11/3/2014; 9/8/2015; 10/26/2015; 9/6/2016; 11/30/2016 | | http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 7/11/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-16076.pdf This PRA request includes no reference to the Indian Addendum. No comments recommended. CMS on 10/3/2014 issued a revision of this PRA request. CMS has revised this PRA request subsequent to the publication of the 30-day notice in 7/11/2014 FR (79 FR 40105). http://www.gpo.gov/fdsys/pkg/FR-2014-10-03/pdf/2014-23614.pdf CMS on 7/7/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-07/pdf/2015-16608.pdf No comments recommended. CMS on 9/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-24/pdf/2015-24262.pdf No comments recommended. CMS on 7/8/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-16220.pdf No comments recommended. | |



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| Agency | | The Bate | | No comments recommended. | |
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| Applications for Medicare Prescription Drug Plan Contracts ACTION: Request for Comment NOTICE: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts AGENCY: CMS | CMS-10137 | Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 9/19/2014, 7/7/2015, 9/24/2015, 7/8/2016, 10/31/2016 Due Date: 11/4/2013; 9/9/2014; 10/20/2014; 9/8/2015; 10/26/2015; 9/6/2016; 11/30/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection: Title: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts; Use: CMS will collect the information under the solicitation of proposals from prescription drug plans, Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage, Cost Plans, PACE, and EGWP applicants. CMS will use the information collected to ensure that applicants meet requirements and to support the determination of contract awards. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf SUMMARY OF NIHB ANALYSIS: This PRA request provides a potential opportunity to comment on language used to communicate the requirement to offer contracts, using an Indian Addendum, to I/T/U facilities. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 7/11/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-16076.pdf This PRA request includes no reference to the Indian Addendum. No comments recommended. CMS on 9/19/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22379.pdf CMS on 7/7/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-07/pdf/2015-16608.pdf No comments recommended. | |
| | of Regulation/Title/ Agency Applications for Medicare Prescription Drug Plan Contracts ACTION: Request for Comment NOTICE: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts | Applications for Medicare Prescription Drug Plan Contracts ACTION: Request for Comment NOTICE: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts | Applications for Medicare Prescription Drug Plan Contracts ACTION: Request for Comment NOTICE: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts AGENCY: CMS File Code Due Date & File Date 6/28/2013 CMS-10137 Ssue Date: 6/28/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 9/19/2014, 7/7/2015, 9/24/2015, 7/8/2016, 10/31/2016 Due Date: 11/4/2013; 9/9/2014; 10/20/2014; 9/8/2015; 10/26/2015; 9/6/2016; | of Regulation/Title/ Agency File Code Due Date & File Date Applications for Medicare Prescription Drug Plan Contracts ACTION: Request for Comment NOTICE: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts AGENCY: CMS CMS-10137 Lssue Date: 6/28/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 9/19/2014, 7/7/2015, 9/24/2015, 7/8/2016, 10/31/2016 Due Date: 11/4/2013; 9/9/2014; 10/20/2014; 9/8/2015; 10/26/2015; 9/6/2016; | Applications for Medicare Prescription Drug Plan Contracts ACTION: Request for Comment NOTICE: Solicitation for Medicare Prescription Drug Plan 2015 Contracts AGENCY: CMS CMS-10137 AGENCY: CMS CMS-10137 Issue Date: 6/28/2013 Issue Date: 6/28/2013 Issue Date: 6/28/2013 Issue Date: 6/28/2013 Issue Date: 8/27/2013 Issue Date: 8/27/2013 Issue Date: 8/27/2013 Issue Date: 9/28/2015 Issue Date: 11/4/2013 Issue Date: 11/4/2013 Issue Date: 6/28/2013 Issue Date: 6/28/2013 Issue Date: 8/27/2013 Issue Date: 11/4/2013 Issue Date: 6/28/2013 Issue Date: 11/4/2013 Issue Date: 6/28/2013 Issue Date: 6/28/2015 Issue Date: 6 |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | No comments recommended. CMS on 7/8/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-16220.pdf No comments recommended. CMS on 10/31/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | |
| 3.b. | DME Competitive Bidding ACTION: Request for Comment NOTICE: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program AGENCY: CMS | CMS-10169 | Issue Date: 7/27/2012 Due Date: 8/27/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/1/2013, 5/10/2013, 4/18/2014, 7/3/2014, 10/14/2016 Due Date: 4/30/2013; 6/10/2013; | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Medicare DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program; <i>Use</i> : CMS will conduct competitive bidding programs in which certain suppliers will receive contracts to provide competitively bid DMEPOS items to Medicare beneficiaries in a competitive bidding area (CBA). In 2007, CMS conducted its first round of bidding, which was implemented on 7/1/2008. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contract and prices became effective on 1/1/2011. The Medicare Modernization Act (MMA) requires the HHS Secretary to recomplete contracts not less often than once every 3 years; CMS has begun preparing to re-compete competitive bidding contracts in the Round 1 Rebid areas. In response to comments on the 60-day FR notice published on 5/7/2012 (77 FR 26763), CMS has revised the Application for Suppliers/Networks collection instrument by clarifying, removing, and renumbering a few questions. SUMMARY OF NIHB ANALYSIS: None. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/1/2013 issued a revision of this PRA request. The most recent approval for this information collection request (ICR) occurred on 10/10/2012. Since then, CMS has decided to update sequentially the paperwork burden necessary to administer the program as it expands nationally and cycles through multiple rounds of competition. Specifically, CMS seeks to update burden | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| # | Agency | | File Date 6/17/2014; 8/4/2014; 12/13/2016 | Response | estimates for certain contract maintenance forms for Round 2 and the national mail-order competition. These include Form C and the Contract Supplier's Disclosure of Subcontractors form. CMS also requests approval of two additional forms: the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, which the agency will use in all rounds of competition. Finally, CMS has retained without changes Forms A, B, and D and their associated burden under this ICR. CMS has completed collection for Forms A and B. CMS plans to continue to use these forms in future rounds of competition. http://www.gpo.gov/fdsys/pkg/FR-2013-03-01/pdf/2013-04752.pdf CMS on 5/10/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11033.pdf CMS on 4/18/2014 issued a revision of this PRA request. OMB issued the most recent approval for this information collection request (ICR) on 6/10/2013. That ICR included the estimated burden to collect the information in bidding Forms A and B for the Round 1 Recompete. In this ICR, CMS seeks approval to collect the information in Forms A and B for competitions that will occur before 2017. For these upcoming competitions, CMS will publish a slightly modified version of the Request for Bids (RFB) instructions and accompanying Forms A and B to allow suppliers to identify and understand the requirements of the program better. CMS decided to modify the RFB instructions and forms based on its experience from the last round of competition. The end result will produce more complete and accurate information to evaluate suppliers. CMS has added no new collection requirements to the modified RFB instructions or Form A or B. Finally, CMS has retained without change the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, the Subcontracting Disclosure Form, and Forms C and D, as well as their associated burden under this ICR. CMS intends to continue use of these forms on an ongoing basis. http://www.g | |
| | | | | | CMS on 10/14/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24910.pdf | |



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| 3.c. | Durable Medical Equipment Certificate of Medical Necessity ACTION: Request for Comment NOTICE: DME Medicare Administrative Contractor CMN and Supporting Documentation Requirements AGENCY: CMS | CMS-846- 849, -10125, and -10126 | Issue Date: 9/24/2012 Due Date: 11/23/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/8/2013, issued revision 2/19/2016, 5/11/2016 Due Date: 4/8/2013; 4/19/2016; 6/10/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection: Title: Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; Use: The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where a vulnerability to the Medicare program might exist. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those which bill for the items) complete the administrative information (e.g., patient name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinician (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the medical condition of the beneficiary and signs the CMN. The physician or other clinician returns the CMN to the supplier, which then submits the CMN (paper or electronic) to CMS with a claim for reimbursement. SUMMARY OF NIHB ANALYSIS: CMS requires submission of DME CMNs and Informational Forms to ensure the integrity of the Medicare program. The information collection in this PRA request will impose no changes to the current burden on suppliers and providers. SUMMARY OF AGENCY ACTION: CMS on 3/8/2013 issued a restatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-03-08/pdf/2013-05388.pdf CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-03474.pdf No comments recommended. | |



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| 3.d. | Certification of Medical Necessity for Home Oxygen Therapy ACTION: Request for Comment NOTICE: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Documentation Requirements AGENCY: CMS | CMS-484 | Issue Date: 3/14/2013 Due Date: 4/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/19/2016, 5/11/2016 Due Date: 4/19/2016; 6/10/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Reinstatement of a previously approved collection; <i>Title</i> : Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Documentation Requirements; <i>Use</i> : Under Section 1862(a)(1)(A) of the Social Security Act, the HHS Secretary may pay only for items and services considered "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." The certificate of medical necessity (CMN) provides a mechanism for suppliers of Durable Medical Equipment (DME) to demonstrate that an item provided meets the criteria for Medicare coverage. No payment to any provider of services, or other individual, can occur unless that individual has furnished the information necessary for Medicare or its contractor to determine the payment amount. Certain individuals can use CMN to furnish this information, rather than producing large quantities of medical records for every claim they submit for payment. Suppliers of DME items cannot provide medical information to physicians for completion of a CMN. The physician who orders the item must provide the information necessary to demonstrate that it is reasonable and necessary, and the supplier must list on the CMN the fee schedule amount and charge for the medical equipment or supplies furnished prior to distribution of such a certificate to the physician. Medicare has the legal authority to collect sufficient information to determine payment for oxygen and oxygen equipment, which account for the largest single total charge of all items paid under DME coverage authority. For Medicare to consider any item for coverage and payment, the information submitted by the supplier (e.g., claims and CMNs), including documentation in patient medical records, must corroborate that the patient meets Medicare coverage criteria. http://www.gpo.gov/fdsys/pkg/FR-2013-03-14/pdf/2013-05802.pdf SUMMARY OF AGENCY ACTION: CMS on 2/19/2016 i | |



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| | of Regulation/Title/ | File Code CMS-10309 | Due Date & | | | NIHB Recs. |
| | | | 6/7/2013; issued extension 4/1/2016, 7/19/2016 <u>Due Date</u> : 7/8/2013; 5/31/2016; 8/18/2016 | | The competitive bidding program will require some beneficiaries to change their suppliers. To ensure that beneficiaries do not lose access to medically necessary equipment, CMS established this notification process. The notification will inform beneficiaries about whether they can continue to rent an item from their current supplier or must go to a contract supplier. The notification also will provide information to beneficiaries about finding a contract supplier in their CBA. In the event that beneficiaries must go to a contract supplier, the notification will identify the procedure for collection of their current equipment and delivery of new equipment. http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07800.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/7/2013 issued a reinstatement of this PRA request with changes. | |



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| 3.q. | Requirements for | CMS-6012-P | Issue Date: | | http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13577.pdf CMS on 4/1/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-01/pdf/2016-07423.pdf No comments recommended. CMS on 7/19/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-19/pdf/2016-17059.pdf No comments recommended. SUMMARY OF AGENCY ACTION: This proposed rule would specify the qualifications | |
| J.4. | Prosthetics Practitioners and Suppliers ACTION: Proposed Rule NOTICE: Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics AGENCY: CMS | GIVIO-0012-1 | [Pending at OMB as of 4/27/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | | needed for qualified practitioners to furnish prosthetics and custom-fabricated orthotics; the accreditation requirements that qualified suppliers must meet to bill for prosthetics and custom-fabricated orthotics; the requirements that an organization must meet to accredit qualified suppliers to bill for prosthetics and custom-fabricated orthotics; and the timeframe by which qualified practitioners and qualified suppliers must meet the applicable licensure, certification, and accreditation requirements. In addition, this rule proposes to remove the current exemption for certain practitioners and suppliers. SUMMARY OF NIHB ANALYSIS: | |
| 4.n. | CORF Eligibility and Survey Forms ACTION: Request for Comment NOTICE: Comprehensive | CMS- 359/360 | <u>Issue Date:</u> 1/4/2016 <u>Due Date:</u> 3/4/2016 <u>NIHB File</u> | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations; <i>Use</i> : CMS-359 serves as the application for health care providers seeking to participate in the Medicare program as a Comprehensive Outpatient Rehabilitation Facility (CORF). This form initiates the process for facilities to become certified as a CORF and provides the CMS Regional Office State Survey Agency staff identifying information regarding the applicant | |

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| | Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations AGENCY: CMS | | Date: None Date of Subsequent Agency Action, if any: Issued extension 3/11/2016 Due Date: 4/11/2016 | | that is stored in the Automated Survey Processing Environment (ASPEN) system. CMS-360 serves as a survey tool used by the State Survey Agencies to record information to determine provider compliance with the CORF Conditions of Participation (CoPs) and to report this information to the federal government. This form includes basic information on the CoP requirements, check boxes to indicate the level of compliance, and a section for recording notes. CMS has the responsibility and authority for certification decisions based on provider compliance with the CoPs, and this form supports that process. https://www.gpo.gov/fdsys/pkg/FR-2016-01-04/pdf/2015-32965.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/11/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05472.pdf No comments recommended. | |
| | | | | | | |
| 4.0. | Hospital OPPS and ASC Payment System for CY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and | CMS-1656- PFC | Issue Date: 7/24/2016 Due Date: 9/6/2016 NIHB File Date: 9/6/2016; TTAG also filed comments 9/6/2016 Date of Subsequent | NIHB response: TTAG response: | SUMMARY OF AGENCY ACTION: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2017 to implement applicable statutory requirements and changes arising from continuing CMS experience with these systems. In this proposed rule, CMS describes the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. Further, in this proposed rule, CMS proposes to make changes to tolerance thresholds for clinical outcomes for solid organ transplant programs; to Organ Procurement Organizations (OPOs) definitions, outcome measures, and organ transport documentation; and to the Medicare and Medicaid Electronic Health Record Incentive Programs. CMS also proposes to remove the HCAHPS Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program. In addition, CMS proposes to | See Table C. |



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| | Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off- Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program AGENCY: CMS | | Agency Action, if any: Final Rule approved by OMB 10/28/2016 | | implement section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain items and services furnished by certain off-campus outpatient departments of a provider. A CMS press release on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-06.html . A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-06.html . https://www.gpo.gov/fdsys/pkg/FR-2016-07-14/pdf/2016-16098.pdf SUMMARY OF NIHB ANALYSIS: A summary of the major provisions of this proposed rule appears below. Summary of Major Provisions 1. OPPS Update: For CY 2017, this proposed rule would increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.55 percent. This proposed rule would continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a proposed reporting factor of 0.980 to the OPPS payments and copayments for all applicable services. 2. Rural Adjustment: This proposed rule would continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost. 3. Cancer Hospital Payment Adjustment: For CY 2017, this proposed rule would continue to provide additional payments equa | |



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| | | | | | proposed rule would not make extensive changes to the already established methodology used for C-APCs. However, this proposed rule would create 25 new C-APCs that meet the previously established criteria, bringing the total number to 62 C-APCs as of January 1, 2017. 5. Chronic Care Management (CCM): For CY 2017, this proposed rule would make minor changes to certain CCM scope of service elements. These changes also would apply to CCM furnished to hospital outpatients. 6. Device-Intensive Procedures: For CY 2017, this proposed rule would base the payment rate for any device-intensive procedure assigned to an APC with fewer than 100 total claims for all procedures in the APC on the median cost instead of the geometric mean cost. In addition, this proposed rule would revise the device intensive calculation methodology and calculate the device offset amount at the HCPCS code level rather than at the APC level. 7. Outpatient Laboratory Tests: For CY 2017, this proposed rule would discontinue the use of the "1." modifier to identify unrelated laboratory tests on claims. In addition, this proposed rule would expand the laboratory tests on claims. In addition, this proposed rule would expand the laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) meeting the criteria of section 1834A(d)(5)(A) of the Act. 8. Packaging Policies: The OPPS currently packages many categories of items and services typically provided as part of the outpatient hospital service (e.g., operating and recovery room, anesthesia, among others). For CY 2017, this proposed rule would align the packaging logic for all of the conditional packaging status indicators so that packaging would occur at the claim level (instead of based on the date of service). 9. Payment Modifier for X-Ray Films: Section 502(b) of Division O, Title V of the Consolidated Appropriations Act amended section 1833(l)(16) of the Act by adding new subparagraph (F). New section 1833(l)(16)(F)(i) of the Act provides that, effective for services furnished | |



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| | | | | | Bipartisan Budget Act of 2015. This provision requires that, beginning January 1, 2017, payment for certain items and services furnished in certain off-campus provider-based departments (PBDs) (collectively referenced as nonexcepted items and services) shall occur "under the applicable payment system." This proposed rule includes several policies relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs application of payment changes under this provision might not apply. In addition, under this proposed rule the Medicare Physician Fee Schedule (MPFS) would serve as the "applicable payment system" for the majority of the items and services furnished by nonexcepted off-campus PBDs. 11. Ambulatory Surgical Center Payment Update: For CY 2017, this proposed rule would increase payment rates under the ASC payment system by 1.2 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. 12. Hospital Outpatient Quality Reporting (QQR) Program: For the Hospital OQR Program, this proposed rule includes proposals for the CY 2018 payment determination, the CY 2019 payment determination, and the CY 2020 and subsequent year payment determinations. Under this proposed rule, for CY 2018 and beyond, CMS would publicly display data on the Hospital Compare Web site, or other agency Web site, as soon as possible after receiving measure data. In addition, hospitals generally would have approximately 30 days to preview their data. For CY 2019 and beyond, this proposed rule would change the timeframe for extraordinary circumstances exemptions (ECE) from 45 days to 90 days from the date that the extraordinary circumstance occurred. For CY 2020 and beyond, this proposed rule would add seven new measures: two claims-based measures and five survey-based measures. 13. Ambulatory Surgical Center Quality Reporting (ASCQR) Program: For the ASCQR Program, this proposed rule includes proposals for the CY 2018 payment determination, the 2019 payment determination, and the CY 2 | |



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| | | | | | measures: two measures collected via a CMS Web-based tool and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures. 14. Hospital Value-Based Purchasing (VBP) Program Update: Section 1886(o) of the Act requires the HHS Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. This proposed rule would remove the HCAHPS Pain Management dimension of the Hospital VBP Program, beginning with the FY 2018 program year. 15. Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs: This proposed rule would make changes to the objectives and measures of meaningful use for Modified Stage 2 and Stage 3, starting with the EHR reporting periods in calendar year 2017. Under both Modified Stage 2 in 2017 and Stage 3 in 2017 and 2018, for eligible hospitals and CAHs attesting under the Medicare EHR Incentive Program, this proposed rule would eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and measures, and lower the reporting thresholds for a subset of the remaining objectives and measures, generally to the Modified Stage 2 thresholds. In addition, this proposed rule would make changes to the EHR reporting period in calendar year 2016 for eligible professionals, eligible hospitals, and CAHs that are new participants in 2017; and the policy on measure calculations for actions outside the EHR reporting period. Finally, this proposed rule would relow a one-time significant hardship exception from the 2018 payment adjustment for certain eligible professionals who are new participants in the EHR Incentive Program in 2017 and are transitioning to the Merit-Based Incentive Payment System in 2017. 16. Transplant Performance Thresholds: With respect to solid organ transplant programs, this proposed rule would restore the effect | |



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| | J J | | | | 7/27/2016 e-mail from Melanie Fourkiller: | |
| | | | | | "At Choctaw, we have been battling CMS on our grandfathered provider based status for the Durant Clinic. This was considered provider based under Chickasaw since the Nation's first compact, remained intact as it was transferred to the Choctaw Nation in 2014, and now we are replacing the facility under Joint Venture. In our view, the provider based status has been continuous and therefore there are no changes with the new facility, even though we will expand services. | |
| | | | | | Since the services are expanded to include Outpatient Surgery, it has attracted new attention from CMS. | |
| | | | | | The most recent hiccup seems to be that the Medicare folks at CMS are interpreting the attached Proposed Rule (starting p. 45681) where 'off campus' outpatient facilities are referenced, to apply to us (and presumably to any I/T/U), again ignoring the grandfathering provisions of 42 CFR 413.65 (m). | |
| | | | | | Kitty is meeting with them internally tomorrow, and we should learn more about this. I also want to do a more in depth review to see if I can figure out what they are hanging their hat on. | |
| | | | | | In any event, my thought is that even if we don't comment on other portions of the PR, we may want to comment on this issue to ensure that grandfathered status remains intact and clearly referenced for Tribes as well as IHS." | |
| | | | | | Prior Concerns In October 2015, TTAG sent a letter to CMS regarding a new provision that withdraws grandfathered Medicare provider-based status for certain tribal facilities and instead offers a new grandfathered tribal Federally Qualified Health Center (FQHC) status. The letter raised concerns that the provision will disrupt operations at the affected tribal facilities, dramatically lower their reimbursement rates, and potentially disqualify them from receiving any Medicare payments between the (unidentified) time they lose their grandfathered provider-based status and the time they qualify for the grandfathered tribal FQHC status. | |
| 5.a. I | PACE Information Request | CMS-R-244 | Issue Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| # | Agency ACTION: Request for Comment NOTICE: Medicare and Medicaid; Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS | | File Date 7/30/2010 Due Date: 9/28/2010 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/8/2010, 10/4/2013, 12/20/2013, 12/8/2016, 5/2/2016 Due Date: 11/8/2010; 12/3/2013; 1/21/2014; 2/8/2016; 6/1/2016 | Response | a currently approved collection: Title: Programs for All-inclusive Care of the Elderly (PACE) and Supporting Regulations; Use: The PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their state nursing home eligibility standards using capitated payments from Medicare and the state. The model of care includes as core services the provision of adult day health care and multidisciplinary team case management, with controlled access to and allocation of all health services. Participants receive physician, therapeutic, ancillary, and social support services in their residence or onsite at the adult day health center. The PACE programs must provide all Medicare and Medicaid covered services, including hospital, nursing home, home health, and other specialized services. Financing of this model occurs through prospective capitation of both Medicare and Medicaid payments. The information collection requirements ensure that only appropriate organizations become PACE organizations and that CMS has the information necessary to monitor the care provided to the frail, vulnerable population served. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/8/2010 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf CMS on 12/20/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf CMS on 12/8/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-08/pdf/2015-30891.pdf No comments recommended. CMS on 5/2/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-02/pdf/2016-10231.pdf No comments recommended. | |
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| 5.c. | Health Plan Monitoring System Data Entry for PACE ACTION: Request for Comment NOTICE: Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly AGENCY: CMS | CMS-10525 | Issue Date: 5/23/2014 Due Date: 7/22/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/12/2014; issued revision 6/13/2016 Due Date: 10/14/2014; 8/12/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Existing collection in use without an OMB control number; Title: Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly; Use: This information collection would require Program of All-Inclusive Care for the Elderly (PACE) organizations to enter Level I and Level II data into the CMS Health Plan Monitoring System. CMS will use the collected information to develop a quality improvement strategy for PACE. http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11947.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/12/2014 issued new version of this PRA request, which involves an information collection in use without an OMB control number. http://www.gpo.gov/fdsys/pkg/FR-2014-09-12/pdf/2014-21799.pdf CMS on 6/13/2016 issued a revision of this PRA request. In this PRA package, CMS has made title changes from Level I and Level II to PACE Quality Data. CMS requests to update and implement previously collected PACE data elements known as Level I and Level II into PACE quality data. Additionally, CMS has established three PACE Quality measures adopted from the National Quality Forum (NQF) and modified for PACE use. These modified PACE quarterly measures include Falls, Falls with Injury, and Pressure Injury Prevalence/Prevention. Currently, CMS has not tested the existing Level I and Level II elements for reliability or feasibility. By adopting NQF defined reliable data collection process for these elements, certain existing Level I and Level II elements will then officially meet quality measures collection standards. CMS will use these measures to improve quality of care for participants in PACE. CMS will implement PACE Quality measures via the existing HPMS. POs will receive education on data criteria entry and will report quarterly. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13917.pdf | |
| 5.d. | PACE Update | CMS-4168-P | <u>Issue Date:</u> 8/16/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the | |



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| | AGENCY: CMS AGENCY: CMS | | Due Date: 10/17/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | Medicare and Medicaid programs. This proposed rule addresses application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. The proposed changes would provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice. https://www.gpo.gov/fdsys/pkg/FR-2016-08-16/pdf/2016-19153.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-11.html. A CMS blog post on this proposed rule is available at https://blog.cms.gov/2016/08/11/delivering-on-the-promise-of-better-care-for-older-adults/. Indian-Specific Provisions This proposed rule does not include any Indian-specific provisions. Summary of Key Economic Provisions Compliance Oversight Requirements: This proposed rule would require each PACE organization (PO) to develop compliance oversight requirements that would serve to monitor and audit its organization for compliance with CMS regulations. In addition, this proposed rule would require POs to have measures that prevent, detect and correct non-compliance with CMS program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. According to CMS, POs already must meet these requirements for their Part D operations. Monitoring and Oversight of PACE Organizations: This proposed rule would add flexibilities in connection with the current requirement that POs undergo monitoring for compliance with the PACE program requirement that POs undergo monitoring for compliance with the PACE program requirement that POs undergo monitoring by remotely reviewing PO documents, which to date the agency has reviewed primarily through site visits. CMS would reduce the number of onsite visits | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | File Date | | performance of a PO and its ongoing compliance with CMS and state requirements. However, the risk assessment also would take into account other information that could indicate a PO requires an audit, such as participant complaints or access to care concerns. Other Provisions of Note 1. Strengthening Protections and Improving Care for Beneficiaries: This proposed rule would establish a more flexible approach to the composition of the interdisciplinary team central to the coordinated care participants receive from POs to allow the team to better meet beneficiary needs. Team members would have the ability to participate in more aspects of care than currently allowed (currently, they can participate in only one aspect). In addition, this proposed rule would allow non-physician primary care practitioners to provide some services in the place of primary care physicians. CMS also proposes: | |
| | | | | | Clarifying that PACE organizations offering qualified prescription drug coverage must comply with Medicare Part D prescription drug program requirements; Making changes to sanctions, enforcement actions, and terminations to strengthen the ability of the agency to hold PACE organizations accountable and decrease the risk of harm to beneficiaries; and Adding language to prevent the employment of individuals with convictions for physical, sexual, or drug or alcohol abuse in any capacity where their contact would pose a potential risk to beneficiaries. | |
| | | | | | Providing Administrative Flexibility and Regulatory Relief for PACE Organizations: This proposed rule would modify the PACE Program Agreementthe contract between CMS, state administering agencies (SAAs), and POsto permit more frequent updates of information crucial to POs while streamlining and making more efficient the development of Program Agreements. | |
| | | | | | SUMMARY OF NIHB ANALYSIS: A few tribal health programs might have an interest in the proposed changes. | |
| 5.e. | PACE Organization Application Process | CMS-10631 See also | <u>Issue Date:</u> 9/12/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: The PACE Organization Application Process in 42 CFR part 460; Use: In general, a PACE Organization (PO) provides Programs of All-Inclusive Care for the | |



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| | ACTION: Request for Comment NOTICE: The PACE Organization Application Process in 42 CFR part 460 AGENCY: CMS | 5.a. | Due Date: 10/12/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | Elderly (PACE) services. An entity wishing to become a PO must submit to CMS an application that describes how the entity meets all the requirements in the PACE program. The entity must include with the application an assurance from the State Administering Agency (SAA) of the state in which the PO will operate. Initial application requirements for the PACE program currently appear in 42 CFR 460.12 and in the PACE Manual, Ch. 17. Until recently, the submission of initial and service area expansion (SAE) PACE applications and supporting information relied on a paper format. However, beginning in 2016, the submission of initial PACE applications occurred via a new automated, electronic submission process. As with initial applications, a PO that seeks to expand its service area and/or add a new service site must submit an application, and with OMB approval, submission of these applications also will occur via an automated process. Although CMS has submitted this information collection to OMB as a "new" package, it currently has OMB approval under control number 0938-0790 (CMS-R-244). Based on internal review, CMS intends to remove the application from that package but, before doing so, requires approval of the application under a new OMB control number. This will avoid lapses in OMB approval, along with any violations of PRA. The 60-day notice for this information collection appeared in the 12/8/2015 FR (80 FR 76193), followed by a 30-day notice that appeared in the 5/2/2016 FR (81 FR 26234), both published under CMS-R-244. This PRA notice, published under the new CMS ID number (CMS-10631) and the tentative OMB control number (0938-New), reprises the 30-notice with nonsubstantive changes. https://www.gpo.gov/fdsys/pkg/FR-2016-09-12/pdf/2016-21873.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 6.i. | Pre-Existing Health Insurance Plan Program Updates ACTION: Interim Final Rule | CMS-9995- IFC4 | Issue Date: [Pending at OMB as of 2/3/2015] Due Date: | | SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS: | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: Pre-Existing Condition Insurance Plan Program Updates AGENCY: CMS | | NIHB File Date: Date of Subsequent Agency Action, if any: | | | |
| 7.1. | Stand-Alone Dental Plans in Federally-Facilitated Exchanges ACTION: Guidance NOTICE: Issuers of Stand-Alone Dental Plans: Intent to Offer in FFE States AGENCY: HHS | HHS (no reference number) | Issue Date: 1/28/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 5/6/2014, 2/19/2015, 3/8/2016 | | SUMMARY OF AGENCY ACTION: This document includes attached tables that list the number of issuers planning to offer stand-alone dental plans (SADPs) in states expected to have a Federally-facilitated Exchange (FFE), including State Partnership Exchanges, based on the current Exchange Blueprint Approvals. ACA permits an SADP to participate in an Exchange if the plan provides the pediatric dental benefits that the Secretary has defined as part of the essential health benefits (EHB). ACA also permits a health plan that does not provide the pediatric dental EHB to obtain certification as a qualified health plan (QHP) eligible for Exchange participation, provided that the Exchange offers at least one SADP. http://cciio.cms.gov/resources/files/voluntary-dental-reporting-list-1-28-13.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/26/2013 issued a revision of this document. This document includes a table listing the number of issuers that intend to offer SADPs in states expected to have an FFE, including State Partnership Exchanges, based on the current Exchange Blueprint Approvals. This information is current as of 4/15/2014. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/voluntary-reporting-guidance.pdf CMS on 2/19/2015 issued guidance listing the number of issuers that intend to offer SADPs in states expected to have an FFM, including State Partnership Marketplaces, based on the current Marketplace Blueprint Approvals. This information, current as of 2/10/2015, applies to the 2016 plan year. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Voluntary-ttp://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Voluntary-ttp://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Voluntary- | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SADP-Reporting-Guidance-02182015.pdf CMS on 3/8/2016 issued guidance listing the number of issuers that intend to offer SADPs in states expected to have an FFM, including State Partnership Marketplaces, based on the current Marketplace Blueprint Approvals. This information, current as of 2/25/2016, applies to the 2017 plan year. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Voluntary-SADP-Reporting-Guidance-for-2017.pdf As indicated in this guidance, because of the availability of at least one SADP in each state, QHP issuers can exclude dental benefits from the EHB offering. | |
| 7.q. | Cooperative Agreement to Support Navigators in FFE ACTION: Request for Comment NOTICE: Cooperative Agreement to Support Navigators in Federally-Facilitated and State Partnership Exchanges AGENCY: CMS | CMS-10463 | Issue Date: 4/12/2013 Due Date: 6/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/26/2013; issued revision 4/11/2014, 7/25/2014, 3/30/2015; issued extension | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Cooperative Agreement to Support Navigators in Federally-Facilitated and State Partnership Exchanges; <i>Use</i> : Section 1311(i) of ACA requires Exchanges to establish a Navigator grant program as part of its function to provide consumers with assistance when needed. Navigators will assist consumers by providing education about and facilitating selection of qualified health plans (QHPs) within Exchanges, as well as other required duties. Section 1311(i) requires that an Exchange operating as of 1/12014 must establish a Navigator Program under which it awards grants to eligible individuals or entities that satisfy the requirements to serve as Exchange Navigators. For Federally-Facilitated Exchanges (FFE) and State Partnership Exchanges (SPEs), CMS will award these grants. Navigator awardees must provide quarterly, biannual, and annual progress reports to CMS on the activities performed during the grant period and any sub-awardees receiving funds. SUMMARY OF NIHB ANALYSIS: This PRA request relates to CCIIO CA-NAV-13-001 (see 7.p.). No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/26/2013 issued a reinstatement of this PRA request with changes. In response to a 60-day notice on this information collection published in the 4/12/2013 FR (78 FR 21957), several commenters suggested changes to the reporting requirements, and CMS incorporated them where appropriate. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 6/26/2015, issued revision 5/11/2016, 8/10/2016 Due Date: 8/26/2013; 6/10/2014; 8/25/2014; 5/29/2015; 7/27/2015; 7/11/2016; 9/9/2016 | | CMS on 4/11/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf CMS on 7/25/2014 issued a revision of this PRA request. CMS has modified the data collection requirements for the weekly, monthly, quarterly, and annual reports provided in the 60-day notice in the 4/11/2014 FR. http://www.gpo.gov/fdsys/pkg/FR-2014-07-25/pdf/2014-17555.pdf CMS on 3/30/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-07089.pdf No comments recommended. CMS on 6/26/2015 issued an extension of this PRA request. CMS has modified the data collection requirements for the weekly, monthly, quarterly, and annual reports provided in the 60-day notice in the 5/30/2015 FR (80 FR 16687). http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/pdf/2015-15770.pdf No comments recommended. CMS on 5/11/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11078.pdf No comments recommended. CMS on 8/10/2016 issued a revision of this PRA request. CMS has modified the data collection requirements for the weekly, monthly, quarterly, and annual reports provided in the 60-day notice published in the 5/11/2016 FR (81 FR 29268). https://www.gpo.gov/fdsys/pkg/FR-2016-08-10/pdf/2016-18986.pdf No comments recommended. | |
| 7.x. | Notice to Employees of Coverage Options | DoL (OMB 1210-0149) | <u>Issue Date:</u> 8/15/2013 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved information collection; Title: Notice to Employees of Coverage Options Under Fair Labor Standards Act Section 18B; Use: Beginning 1/1/2014, | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | ACTION: Request for Comment NOTICE: Notice to Employees of Coverage Options Under Fair Labor Standards Act Section 18B AGENCY: DoL | | Due Date: 10/15/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 10/28/2016 Due Date: 12/27/2016 | | individuals and employees of small businesses will have access to affordable coverage through a new competitive private health insurance marketthe Health Insurance Marketplace. Section 1512 of ACA creates a new Fair Labor Standards Act (FLSA) section 18B requiring a notice to employees of coverage options available through the Marketplace. On 5/8/2013, DoL issued Technical Release 2013-2, which provides temporary guidance regarding the notice requirement under FLSA section 18B and announces the availability of the Model Notice to Employees of Coverage Options. http://www.gpo.gov/fdsys/pkg/FR-2013-08-09/pdf/2013-19321.pdf The model notice for employers that offer health plans is available at http://www.dol.gov/ebsa/pdf/FLSAwithplans.pdf. The model notice for employers that do not offer health plans is available at http://www.dol.gov/ebsa/pdf/FLSAwithoutplans.pdf. Technical Release 2013-2 is available at http://www.dol.gov/ebsa/newsroom/tr13-02.html. SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/28/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-28/pdf/2016-26046.pdf No comments recommended. | |
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| 7.hhh. | FFM and Federally- Facilitated SHOP Enrollment Manual ACTION: Guidance NOTICE: Federally-Facilitated Marketplace and Federally- Facilitated Small Business | CCIIO (no reference number) | Issue Date: 10/1/2015 Due Date: None NIHB File Date: | | SUMMARY OF AGENCY ACTION: ACA created new competitive private Health Insurance Exchanges, or Marketplaces, that enable qualified individuals (QIs) to shop for, select, and enroll in high quality, affordable private health plans. Marketplaces also allow individuals to obtain an eligibility determination or eligibility assessment for coverage under Medicaid and/or CHIP. In addition, ACA created Small Business Health Options Program (SHOP) Marketplaces that enable qualified employers to provide health plans to their employees. QIs and qualified employers have obtained coverage from private health insurance companies through the Marketplaces since 1/1/2014. | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency Health Options Program Enrollment Manual AGENCY: CCIIO | | File Date Date of Subsequent Agency Action, if any: Issued updated manual 7/19/2016 | | This manual, which provides guidance on enrollment in Federally-Facilitated Marketplaces and Federally-Facilitated SHOP Marketplaces, will go into effect as of 10/1/2015. Processing of all enrollments made on or after this date should occur in accordance with the operational requirements set forth in this manual. CMS intends to update this manual regularly and publish clarifying bulletins between updates. This manual supersedes all previous versions of any incorporated bulletins into this document. This manual includes several Indian-specific provisions, outlined below. • 2.5.1 Premium Payment Due Date: In this section, regarding third-party premium payments, CCIIO notes, "Under 45 CFR §156.1250, issuers offering individual market QHPs must accept premium and cost-sharing payments made on behalf of QHP enrollees by Indian tribes, tribal organizations, urban Indian organizations, and state and federal government programs or grantees, such as the Ryan White HIV/AIDS programs. If an enrollee notifies the QHP issuer of coordinated premium payment with one of the third party entities described in 45 CFR §156.1250, issuers should allow for timely premium payment to prevent termination of enrollments for non-payment. CMS may take enforcement action against QHP issuers that fail to comply with this requirement." • 4.2 GUIDELINES FOR SPECIFIC QI SCENARIOS: In this section, regarding Marketplace applicants found eligible for enrollment Partner must allow applicants to select the amount of APTCs they want to apply towards the reduction of their share of the premiums in the plan selection process, and should only display the CSRs plan variation for which an applicant is found eligible, for any of the QHP issuer's silver-level plans (or American Indian/Alaskan Native CSRs plan variations, as appropriate)." • 4.4 OHP DISPLAY GUIDANCE: In this section, regarding requirements for the QHP issuer Enrollment Partner Web site, CCIIO states the site must "provide a way for applicants to select their APTC amount up to the maximu | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | Agono) | | | | Native CSRs variations as appropriate." • 5.1 AVAILABILITY AND LENGTH OF SEPS: In section, regarding the eligibility of Ols/enrollees for a special enrollment period, CCIIO states that a Ol/enrollee might qualify if he or she is an "American Indian/Alaska Native, as defined by Section 4 of the Indian Health Care Improvement Act, which permits the enrollee to enroll in a OHP or change from one OHP to another one time per month." CCIIO also notes in a footnote that, in addition to the "eligibility requirements established by 45 CFR §155.420(d), an Indian (as defined by Section 4 of the Indian Health Care Improvement Act) may enroll in a OHP or change from one OHP to another one time per month." https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated_Enrollment_Operations_Policy-and_Guidance_Final_9-30-2015_mb.pdf SUMMARY OF NIHB ANALYSIS: This guidance provides detailed information on CCIIO requirements on the FFM, QHP issuers, and others with regard to enrollment and disenrollment in/from the Marketplace. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/19/2016 issued an updated version of this manual for 2017. This manual takes effect as of 10/1/2016. All processing of enrollments made on or after 10/1/2016 should occur in accordance with the operational requirements set forth in this manual. CMS intends to update this manual regularly and publish clarifying bulletins between updates. This manual supersedes all previous versions of bulletins it incorporates. For questions related to content posted within this manual, please email EnrollmentGuidance@cms.hhs.gov. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR-FFM-SHOP-Manual-071916.pdf | |
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| 7.jjj. | Establishment of QHPs and Exchanges ACTION: Request for Comment | CMS-10400 | <u>Issue Date:</u> 11/23/2015 <u>Due Date:</u> 1/22/2015 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Establishment of Qualified Health Plans and American Health Benefit Exchanges; Use: ACA expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). | |



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| Ref. | of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | NOTICE: Establishment of Qualified Health Plans and American Health Benefit Exchanges AGENCY: CCIIO | | NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 3/4/2016 Due Date: 4/4/2016 | | As directed by the rule titled "Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers" (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of qualified health plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange, a health insurance issuer must have its health plans certification standards, such as network adequacy, inclusion of essential community providers (ECPs), and non-discrimination. The Exchange must ensure that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on ACA, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State-Based or Federally-Facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of ACA. http://www.gpo.gov/fdsys/pkg/FR-2015-11-23/pdf/2015-29725.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 3/4/2016 issued a revision of this PRA request. CMS received no comments in response to the 60-day notice for this information collection published in 11/23/2015 FR (80 FR 72968). https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04841.pdf No comments recommended. | |
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| 7.kkk. | ECP Petition for 2017 ACTION: Notice NOTICE: Essential Community Provider Petition | CCIIO (no reference number) | <u>Due Date:</u> 1/8/2016 1/15/2016 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: In accordance with section 1311(c)(1)(C) of the ACA, qualified health plan (QHP), including stand-alone dental plan (SADP) issuers must include within their network essential community providers (ECPs), where available, that serve predominantly low-income, medically-underserved individuals. Under this same section of ACA, the HHS Secretary must establish criteria for certification of health plans as QHPs, including criteria for issuer satisfaction of the ECP inclusion requirement. | |



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| for the 2017 Benefit Year Date of Subsequent Agency Action, if any: Issued due date extension His has compiled a non-exhaustive list of available ECPs, federal agencies maintain, that has served as an initial sourn non-exhaustive HHS CPR ist for the 2016 benefit year and tensity list of in order for information of include health care providers that qualify for inclusion in issuen additional for the 2016 benefit year is at https://www.cms.gov/cciio/programs-and-initiatives/health-in write-in for a respective issuer that has listed the provider data HHS will allow petitions submitted after 1/8/2016 but no write-in for a respective issuer that has listed the provider that provider cappilation on OHPs is available on the CCIIO Web si https://www.cms.gov/cciio/programs-and-initiatives/health-in marketplaces/qh. PhS data healthcare gov/cciio/ecp. petition More information on QHPs is available on the CCIIO Web si https://www.cms.gov/cciio/programs-and-initiatives/health-in marketplaces/qh. PhS data healthcare. SumMARY OF TSGAC ANALYSIS: A TSGAC briefing mer embedded below. | re available, in the networks and range of such providers for ice areas. To satisfy this ECP template as part of their QHP by have contracted to provide individuals in their service based on data it and other ice of ECP information. The vailable at insurance- to assist issuers with orks toward satisfaction of the less ECPs as health care erserved individuals. They of the Public Health Service ithe Social Security Act (Act). The service is the service is the social Security act (Act). The service is the service is the social Security act (Act). The service is the service is the service is the social Security act (Act). The service is |



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| | | | | | TSGAC-Memo-Action -Needed-to-Retain-St A TSGAC briefing memo that includes the steps to submitting the petition and the final HHS ECP List for 2017 is embedded below. TSGAC Memo - Steps to Update -or | |
| 7.111. | 2017 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft 2017 Letter to Issuers in the Federally-Facilitated Marketplaces AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 12/23/2015 Due Date: 1/17/2016 TSGAC File Date: 1/17/2016 Date of Subsequent Agency Action, if any: Issued Final Letter 2/29/2016 | TSGAC response: | SUMMARY OF AGENCY ACTION: This draft 2017 Letter to Issuers in the Federally-Facilitated Marketplaces (Letter) provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-Facilitated Marketplaces (FFMs) or the Federally-Facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in those Marketplaces in 2017. Unless otherwise specified, references to the FFMs include the FF-SHOPs. Throughout this Letter, CMS identifies the areas in which states performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS also describes how parts of this Letter apply to issuers in State-Based Marketplaces on the Federal Platform (SBM-FPs). CMS notes that the policies articulated in this Letter apply to the certification process for plan years beginning in 2017. Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics appear in 45 CFR Subtitle A, Subchapter B. CMS proposed additional standards in a proposed rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017" (2017 Payment Notice Proposed Rule, CMS 9937-P), which appeared in the 12/2/2015 FR. CMS expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of ACA. Throughout the plan year, QHP issuers might have to correct deficiencies identified in | See Table C. |



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | , igonoj | | i no buto | | CMS post-certification activities, as a result of the investigation of consumer cases, oversight by State regulators or by CMS, or an industry-standard internal compliance and risk management program of the issuer. QHP issuers in the FFMs also might have to meet other requirements for plan years beginning in 2017, as indicated in future rulemaking. | |
| | | | | | CMS welcomes comments on this proposed guidance. To the extent that this guidance summarizes policies proposed through other rulemaking processes not yet finalized, such as the rulemaking process for the 2017 Payment Notice Proposed Rule, stakeholders should comment on those underlying policies through the ongoing rulemaking processes and not through the comment process for this Letter. Please send comments on other aspects of this Letter to FFEcomments@cms.hhs.gov by 1/17/2016. Interested parties should submit comments organized by subsections of this Letter. | |
| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft- 2017-Letter-to-Issuers-12-23-2015 508.pdf | |
| | | | | | SUMMARY OF NIHB ANALYSIS: A related multi-year analysis of the provisions in this annual Letter is embedded below. Matrix- CCIIO Issuer Letters - Select Marke | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This final 2017 Letter to Issuers in the Federally-Facilitated Marketplaces (Letter) provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-Facilitated Marketplaces (FFMs) or the Federally-Facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in any such Marketplace in 2017. Unless otherwise specified, references to the FFMs include the FF-SHOPs. | |
| | | | | | Throughout this Letter, CMS identifies the areas in which states performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS also describes how parts of this Letter apply to issuers in State-Based Marketplaces on the Federal Platform (SBM-FPs). CMS notes that the policies articulated in this Letter apply to the certification process for plan years | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | beginning in 2017. Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics appear in 45 CFR Subtitle A, Subchapter B. CMS provided additional standards in the final rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Final Rule" (2017 Payment Notice, CMS 9937-F), which went on public display on 2/29/2016. CMS expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of ACA. Throughout the plan year, QHP issuers might have to correct deficiencies identified in CMS post-certification activities, as a result of the investigation of consumer cases, oversight by state regulators or by CMS, or the industry-standard internal compliance and risk management program of the issuer. QHP issuers in FFMs also might have to meet other requirements for plan years beginning in 2017, as indicated in future rulemaking. State-Based Marketplaces on the Federal Platform (SBM-FPs) This Marketplace model, newly established in the HHS Notice of Benefit and Payment Parameters for 2017, will enable State-Based Marketplaces (SBMs) to execute certain processes using the federal eligibility enrollment infrastructure. SBM-FPs and HHS will have to enter into a federal platform agreement that will define a set of mutual obligations, including the set of federal services upon which the SBM-FP agrees to rely. Under this model, certain requirements previously only applicable to QHPs offered on FFMs will apply to QHPs offered on SBM-FPs. SBM-FPs must agree to enforce certain QHP and QHP issuer requirements no less strict than those HHS applies to QHPs and QHP issuers in FFMs, as follows: 45 CFR 156.122(d)(2): the standards for QHPs to make available published upto-date, accurate, and complete formulary drug lists on its website in a format and at times determined by HHS; 45 CFR 156.230 | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | downstream entity standards; and • 45 CFR 156.1010: casework standards. The annual CCIIO Letter to Issuers in the FFM will include implementing guidance specific to SBE-FPs. | |
| 7.mmm. | Establishment of an Exchange by a State and OHPs ACTION: Request for Comment NOTICE: Establishment of an Exchange by a State and Qualified Health Plans AGENCY: CMS | CMS-10593 | Issue Date: 12/2/2015 Due Date: 2/1/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/4/2016 Due Date: 4/4/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Establishment of an Exchange by a State and Qualified Health Plans; Use: ACA expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). As directed by the rule Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of qualified health plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange, a A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of essential community providers (ECPs), and nondiscrimination. The Exchange must ensure that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR parts 155 and 156, based on ACA, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State-Based or Federally-Facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of ACA. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf SUMMARY OF NIHB ANALYSIS: This PRA notice might include issues on which tribal organizations want to comments. SUMMARY OF AGENCY ACTION: CMS on 3/4/2016 issued a new version of this PRA request. CMS received comments in response to the 60-day notice for this information collection published in 12/2/2015 FR. However, as none of these c | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | of Regulation/Title/ | File Code CMS-10592 | Due Date & | | | NIHB Recs. |
| | | | <u>Due Date:</u> 4/18/2016 | | SUMMARY OF NIHB ANALYSIS: CMS-10592 seeks OMB approval of the regulatory PRA requirements associated with the minimum requirements that health insurance issuers must meet with respect to participation in the Marketplaces, specifically the following sections of 45 CFR part 156: QHP issuer notice of effective date (§156.260(b)); QHP issuer reconciliation of enrollment files with Exchange (§156.265(f)); QHP issuer termination notice to the enrollee and Exchange (§156.270(b)); QHP issuer notice of enrollee nonpayment of premium (§156.270(d)); QHP issuer notice to providers of the possibility for denied claims(§156.270(d)(3)); QHP issuer notice of payment delinquency to an enrollee (§156.270(e)); QHP issuers maintenance of records of terminations of coverage (§156.270(h)); and QHP issuer notification of plan non-renewal (§156.290). | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | This PRA request does not have any associated forms or templates. A Supporting Statement for this PRA request is available at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10592.html . SUMMARY OF AGENCY ACTION: CMS on 3/18/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-18/pdf/2016-06191.pdf No comments recommended. | |
| 7.000 | CMS Healthcare.gov Site Wide Online Survey ACTION: Request for Comment NOTICE: CMS Healthcare.gov Site Wide Online Survey AGENCY: CMS | CMS-10597 | Issue Date: 12/14/2015 Due Date: 2/12/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 10/14/2016 Due Date: 11/14/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : CMS Healthcare.gov Site Wide Online Survey; <i>Use</i> : This survey seeks to gain an understanding of user experience, comprehension, and satisfaction with using the federal Health Insurance Marketplace Web site established by ACA. The Marketplace provides coverage to uninsured U.S. residents, as well as those already enrolled in Marketplace health insurance. One of the ways to purchase Marketplace insurance involves the use of the online tools on HealthCare.gov. CMS has developed a survey for consumers to take while using the Web site. This survey represents part of a continuing data collection program mandated by ACA. It seeks to support the program goal to provide tools and information to help consumers successfully find health insurance for which they might not otherwise qualify for or might not find. Monitoring usability and the user experience through this ongoing survey provides the Web site developers with valuable information for use in continuous improvement of the Web site. https://www.gpo.gov/fdsys/pkg/FR-2015-12-14/pdf/2015-31399.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/14/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24814.pdf No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
|--------|--|-----------------------------|--|------------------|---|------------|
| 7.rrr. | Key Dates for CY 2016: QHP Certification in the FFM, et al. ACTION: Guidance NOTICE: Proposed Key Dates for Calendar Year 2016: QHP Certification in the Federally-Facilitated Marketplaces; Rate Review; Risk Adjustment and Reinsurance AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 12/23/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued Final Guidance 2/29/2016 | | SUMMARY OF AGENCY ACTION: This guidance provides proposed key dates in 2016 related to qualified health plan (OHP) certification in the Federally-Facilitated Marketplace (FFM): rate review for single risk pool compliant plans; and risk adjustment, reinsurance, and risk corridors for PY 2015. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-key-dates-table-12-23-15-FINAL.pdf SUMMARY OF NIHB ANALYSIS: Some key dates regarding QHP certification appear below. QHP Agreement/Final CertificationCertification Notices Sent to Issuers: 9/15/2016-9/16/2016Agreements Signed by Issuers and Returned to CMS with Final Plan List: 9/19/2016-9/23/2016Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers: 10/3/2016-10/4/2016Open Enrollment: 11/1/2016-1/31/2017 SUMMARY OF SUBSEQUENT AGENCY ACTION: This guidance provides final key dates in 2016 related to qualified health plan (OHP) certification in the Federally-Facilitated Marketplace (FFM): rate review for single risk pool compliant plans; and risk adjustment, reinsurance, and risk corridors for PY 2015. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2016-key-dates-table-2-29-16.pdf Some key dates regarding QHP certification appear below. QHP Agreement/Final CertificationCertification Notices Sent to Issuers: 9/15/2016-9/16/2016Agreements Signed by Issuers and Returned to CMS with Final Plan List: 9/19/2016-9/23/2016Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers: 10/3/2016-10/4/2016 | |



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| | <u> </u> | | | | | |
| 7.sss. | April 2016 Transition of Issuers to Policy-Based Payments ACTION: Guidance NOTICE: Policy-Based Payments Bulletin Transition in April 2016 INFORMATION: Policy-Based Payments: April 2016 Transition of All Issuers to Policy-Based Payments and Subsequent Adjustments Only in Cases of Extreme Variation Between Policy-Based Payments and the Manual Payment Process AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 5/2/2016 | | SUMMARY OF AGENCY ACTION: This bulletin modifies the 12/4/2015 "Policy-Based Payments: Approach to 2016 Marketplace Payment Program Integrity, Withholding for Issuers Delayed on Policy-Based Payments Implementation, and Payment Adjustment for Issuers Deemed Policy-Based Payments Ready" guidance. CMS will transition all issuers to policy-based payments for the April 2016 payment cycle. CMS also will provide an additional month before ending adjustments to the calculated policy-based payment amount to the manual workbook submitted payment amount, ending these adjustments except in cases of extreme (>25%) variation in the May 2016 payment cycle. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/FT_PBPGuidance_5CR_032116.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This bulletin modifies the 3/22/2016 "Policy-Based Payments: April 2016 Transition of All Issuers to Policy-based Payments and Subsequent Adjustments Only in Cases of Extreme Variation Between Policy-based Payments and the Manual Payment Process" guidance. Consistent with the 3/22/2016 guidance, all issuers transitioned to policy-based payments for the April 2016 payment cycle, with adjustments ended to the calculated policy-based payment amount to the manual workbook submitted payment amount (except in cases of extreme (>25%) variation) in the May 2016 payment cycle. This guidance sets forth the approach CMS will take to smooth the cash-flow implications of this transition for issuers that had net-positive total adjustments for January through April. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Policy-Based-PaymentBulletin_050216.pdf | |
| 7.ttt. | Marketplace Eligibility AppealsPaper-Based Processes ACTION: Guidance | CCIIO (no reference number) | Issue Date: 3/22/2016 Due Date: None | | SUMMARY OF AGENCY ACTION: Section 1411(f) of ACA requires the HHS Secretary to establish a federal process for hearing and making decisions with respect to appeals of determinations made under section 1411(e) of ACA related to eligibility for enrollment in a qualified health plan (QHP) through the Marketplace, advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSRs), and exemptions from the individual responsibility requirement. Section 1411(f) also requires the HHS Secretary | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: Marketplace Eligibility AppealsOptions for Paper-Based Processes AGENCY: CCIIO | | NIHB File Date: Date of Subsequent Agency Action, if any: | | to establish a separate appeals process for employers notified that they might have liability for the employer shared responsibility payment. CMS published final regulations on eligibility appeals on 8/30/2013. Among other provisions, the preamble to the final rule provided flexibility for appeals entities to conduct eligibility appeals via a paper-based process for the first year of operation, through 12/31/2014, and on 10/232014, CMS issued guidance to allow for the extension of this flexibility to conduct eligibility appeals via a paper-based process until 12/31/2015. This guidance announces that CMS has determined the flexibility to use a paper-based process to conduct eligibility appeals should continue for an additional year, through 12/31/2016. According to this guidance, the extended flexibility applies to individual market eligibility appeals (45 CFR 155.500-550), employer appeals (§155.555), and SHOP employer and employee appeals (§155.740). Further, the flexibility extends to all the electronic requirements included within these sections of the regulations, including standards for appeal requests, transfers of appeal records between appeals entities and Medicaid or CHIP agencies, and notice requirements. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Extension-for-paper-based-appeals-3-22-2016.pdf SUMMARY OF NIHB ANALYSIS: | |
| 7.uuu. | Ensuring Meaningful Access by Limited-English Speakers ACTION: Guidance NOTICE: Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web- Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR | CCIIO (no reference number) | Issue Date: 3/30/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: The HHS Notice of Benefit and Payment Parameters for 2016 Final Rule (2016 Payment Notice) (80 FR 10750), among other things, amended language access requirements at 45 CFR § 155.205(c) for Exchanges, qualified health plan (QHP) issuers, and agents or brokers subject to § 155.220(c)(3)(i) ("Web-brokers"). The 2016 Payment Notice also amended language access requirements at 45 CFR § 156.250 that apply to QHP issuers. The amended regulation at §155.205(c) also applies to the Basic Health Program (BHP), in accordance with BHP regulations at 42 CFR 600.150(a)(4). The following document provides guidance to Exchanges, QHP issuers, and Web-brokers on how to comply with the amended language access requirements and on how these requirements interact with other language access requirements that might apply to the same entities. While the general standards under § 155.205(c) with respect to oral interpretation, written translations, and taglines continue to apply to all entities subject to § 155.205(c), this guidance will highlight specific requirements related to taglines and Web site translations for | |



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| Ref. | Short Title/Current Status | | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | |
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| # | of Regulation/Title/ Agency | File Code | Due Date & File Date | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | §155.205(c) and §156.250 AGENCY: CCIIO | | | | Exchanges, QHP issuers, and Web-brokers. Additionally, this guidance provides language data and sample taglines in the top 15 languages spoken by the limited English proficient (LEP) population in each state for use by Exchanges, QHP issuers, and Web-brokers, as necessary. Appendix A: Top 15 Non-English Languages by State: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-A-Top-15.pdf Appendix B: Sample Translated TaglinesLanguages Are Listed in Alphabetical Order: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf SUMMARY OF NIHB ANALYSIS: A review of the state-specific top ten lists of languages indicates that Al/AN languages do not appear very often. For example, in Alaska, no AN language appears in in the top ten list. Tribal representatives might wish to comment on the listings. | |
| 7.vvv. | Ending Special Enrollment Periods for Coverage in 2015 ACTION: Guidance NOTICE: Ending Special Enrollment Periods for Coverage During Calendar Year 2015 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Consistent with CMS practice in prior years, this guidance announces that, as of 4/1/2016, the agency will no longer accept new requests that would enable consumers to enroll in a qualified health plan (QHP) with 2015 coverage effective dates through Federally-Facilitated Marketplaces (FFMs), FFMs where states perform plan management functions, or State-Based Marketplaces on the Federal Platform (SBM-FPs) using a special enrollment period (SEP). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR-GuidanceEnding2015-SEPs-FINAL-040116.pdf SUMMARY OF NIHB ANALYSIS: | |
| 7.www. | Amendments to SEPs and | CMS-9933- | Issue Date: | | SUMMARY OF AGENCY ACTION: This interim final rule with comment period (IFC) | |



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| | Agency | .= ^ | File Date | • | | |
| | the CO-OP Program | IFC | 5/11/2016 | | establishes provisions that alter the parameters of select special enrollment periods and | |
| | | | | | that revise certain rules governing consumer operated and oriented plans (CO-OPs). | |
| | ACTION: Interim Final Rule | | <u>Due Date:</u> | | | |
| | | | 7/5/2016 | | Section 1311(c)(6) of ACA establishes enrollment periods, including special enrollment | |
| | NOTICE: Patient Protection | | | | periods for qualified individuals, for enrollment into qualified health plans (QHPs) through | |
| | and Affordable Care Act: | | NIHB File | | an Exchange. This IFC amends the eligibility requirements of the special enrollment | |
| | Amendments to Special | | Date: None | | period for individuals who gain access to new QHPs as a result of a permanent move so | |
| | Enrollment Periods and the | | | | that this special enrollment period is generally available only to those individuals who had | |
| | Consumer Operated and | | Date of | | minimum essential coverage prior to their permanent move. This change aligns the | |
| | Oriented Plan Program | | Subsequent | | eligibility requirements with the intent of this special enrollment period (i.e., to afford | |
| | | | Agency | | individuals the full range of plan options when they relocate) and promotes stability in the | |
| | AGENCY: CMS | | Action, if any: | | health insurance market. This IFC does not alter the eligibility for special enrollment | |
| | 1102.1011 00 | | <u> </u> | | periods for (1) those being released from incarceration; (2) those moving to the United | |
| | | | | | States from abroad; or (3) those making a permanent move to a state where they will | |
| | | | | | newly qualify for advance payments of the premium tax credit, from a non-Medicaid | |
| | | | | | expansion state where they did not qualify for advance payments of the premium tax | |
| | | | | | credit because of a household income less than 100 percent of the federal poverty level | |
| | | | | | (and did not qualify for Medicaid during the same timeframe). | |
| | | | | | tand that quality for inicalcald during the same timename). | |
| | | | | | This IFC also eliminates the 1/1/2017 implementation deadline for an Exchange to offer | |
| | | | | | advanced availability of the special enrollment period for certain individuals who gain | |
| | | | | | access to new QHPs as a result of a permanent move, as well as to offer a new special | |
| | | | | | enrollment period for loss of a dependent or for no longer being considered a dependent | |
| | | | | | due to divorce, legal separation, or death. This change leaves the implementation of both | |
| | | | | | | |
| | | | | | provisions at the option of the Exchange. | |
| | | | | | In addition, this IEC amonds cortain CO OD actionness requirements to provide greater | |
| | | | | | In addition, this IFC amends certain CO-OP governance requirements to provide greater | |
| | | | | | flexibility and facilitate private market transactions that can provide access to needed | |
| | | | | | capital. These amendments will permit a CO-OP to recruit potential directors from a | |
| | | | | | broader pool of qualified candidates. This IFC also provides greater clarity with respect to | |
| | | | | | what constitutes non-compliance with rules governing the business of a CO-OP and the | |
| | | | | | transactions into which it can enter. These changes will provide CO-OPs with flexibility | |
| | | | | | common among private market health insurance issuers and will support the financial | |
| | | | | | viability of CO-OPs, while at the same time maintaining the fundamental member- | |
| | | | | | governed, member-focused nature of the CO-OP program and enabling CO-OPs to | |
| | | | | | continue to benefit their enrollees. | |
| | | | | | | |



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| | | | | | These regulations are effective on 5/11/2016, with the exception of the amendments to 45 CFR 155.420, which are effective on 7/11/2016. https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11017.pdf A CCIIO fact sheet on this IFC rule is available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/IFC-Fact-Sheet-FINAL-5-6-16.pdf. A Modern Healthcare article on this IFC is available at http://www.modernhealthcare.com/article/20160506/NEWS/160509925. SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 7.xxx. | Display of QRS Star Ratings and QHP Enrollee Survey Results ACTION: Guidance NOTICE: CMS Bulletin on Display of Quality Rating System (QRS) Star Ratings and Qualified Health Plan (QHP) Enrollee Survey Results for QHPs Offered Through Marketplaces AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/29/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 9/30/2016 | | SUMMARY OF AGENCY ACTION: This bulletin announces that public reporting of quality rating information by the Federally-Facilitated Marketplaces (FFMs), including FFMs in which the state performs plan management functions and State-Based Marketplaces on the Federal Platform (SBM-FPs), will begin during the open enrollment period for the 2018 plan year, with a limited pilot in place for the 2017 plan year. CMS will use this time to conduct additional testing to inform the public display of quality rating information for qualified health plans (QHPs) on Marketplace Web sites. State-Based Marketplaces (SBMs) whose consumers do not use HealthCare.gov can display QHP quality information for the 2017 open enrollment period or follow the revised timeframe. In January 2016, CMS published the Quality Rating System (QRS) and QHP Enrollee Survey Technical Guidance for 2016 (2016 Technical Guidance), which included details about the content, process, and timing of the required display of QHP quality rating information. This bulletin revises the timeline previously released in the 2016 Technical Guidance. This bulletin also clarifies the continuing QHP certification requirements for issuers to submit QRS clinical measure and QHP Enrollee Survey response data to CMS. Finally, this bulletin outlines the options for public display of the 2016 QHP quality rating information by SBMs whose consumers do not use HealthCare.gov. CMS remains committed to providing information about the quality of health insurance coverage offered through Marketplaces consistent with 45 CFR 155.1400 and 45 CFR 155.1405. The approach described in this bulletin will inform CMS understanding of the impact of QRS star ratings on consumer behavior and about consumer priorities for QHP | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | quality data as they shop for QHPs on HealthCare.gov. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QRS-Bulletin-4-29-2016.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: On 4/19/2016, CCIIO released a bulletin with guidance on the display of Quality Rating System (QRS) star ratings and Qualified Health Plan (QHP) Enrollee Survey results for QHPs offered through Marketplaces. This guidance announced that public reporting of quality rating information by the Federally-Facilitated Marketplaces (FFMs), including FFMs where the State performs plan management functions, and State-Based Marketplaces on the Federal Platform (SBM-FPs), will begin during the open enrollment period for the 2018 plan year, with a limited pilot for the 2017 plan year. This Quality Rating Information Bulletin updates the April 19 guidance to revise the selection of two FFM states for participation in the public reporting of quality rating information pilot: Virginia and Wisconsin. CCIIO has selected Virginia and Wisconsin based on a review of the 2016 QHP quality rating data that showed ample participation of QHP issuers on their respective Marketplaces and relative variation in QRS star ratings. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/UpdatedQualityPilotGuidance09302016FINAL.pdf | |
| 7.yyy. | FAQs on Incarceration and the Marketplace ACTION: Guidance NOTICE: Incarceration and the Marketplace Frequently Asked Questions AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 5/3/2016 Due Date: None NIHB File Date: Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: Section 1312(f)(1)(B) of ACA and 45 CFR 155.305(a)(2) provide that an individual cannot enroll in a qualified health plan (QHP) through the Health Insurance Marketplace if he or she is incarcerated, other than incarceration pending the disposition of charges. This document answers frequently asked questions (FAQs) on the definition of "incarcerated" and "incarceration pending the disposition of charges" for the purposes of eligibility for enrollment in a QHP through the Marketplace. The information in this document applies to all Federally-Facilitated Marketplaces (including State Partnership Marketplaces) and to State-Based Marketplaces (SBMs) that rely on the federal eligibility and enrollment platform. SBMs that do not rely on the federal eligibility and enrollment platform can adopt the policies set forth in this document, or | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date Action, if any: | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis other reasonable ones consistent with applicable law. The information in this document does not apply to eligibility for Medicaid or CHIP. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Incarceration-and-the-Marketplace-FAQs-05-03-2016.pdf SUMMARY OF NIHB ANALYSIS: | NIHB Recs. |
|-----------|--|-----------------------------------|--|------------------|---|------------|
| 7.zzz. | Effectuation of 2016 FFM Dental Enrollment Without APTCs ACTION: Guidance NOTICE: Effectuation of 2016 Federally-Facilitated Marketplace Dental EnrollmentINFORMATION: CMS to Effectuate Dental Enrollment for 2016 Policies Without Advance Payments of the Premium Tax Credit AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This bulletin announces that CMS will effectuate all remaining aged 2016 initial dental enrollment for policies without advance payments of the premium tax credit (APTCs) before the September 2016 payment cycle. This policy will help ensure the accurate capture of all Federally-Facilitated Marketplace (FFM) enrollment. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/FFM_Dental_Effectuation_Bulletin_06012016.pdf SUMMARY OF NIHB ANALYSIS: | |
| 7.aaaa. | FAQs on Auto Re- Enrollment for QHPs No Longer Available ACTION: Guidance NOTICE: Auto Re- Enrollment for QHPs No Longer Available in the | CCIIO (no reference number) | Issue Date: 6/24/2016 Due Date: None NIHB File Date: | | SUMMARY OF AGENCY ACTION: This guidance answers a number of frequently asked questions (FAQs) on auto re-enrollment for qualified health plans (QHPs) no longer available in the Marketplace. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Auto-Re-Enrollment-FAQ-06242016-FINAL.pdf SUMMARY OF NIHB ANALYSIS: | |

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| | Marketplace: External FAQs AGENCY: CCIIO | | Date of Subsequent Agency Action, if any: | | | |
| 7.bbbb. | FAQs on Annual Income Threshold Adjustment ACTION: Guidance NOTICE: Annual Income Threshold Adjustment FAQ AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 7/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: As part of an ongoing effort to improve the consumer experience in the Marketplace, CMS has implemented a change that will allow more consumers to get their household income immediately verified by the Marketplace when they submit an application. The change will reduce the number of consumers who have to follow up and submit documentation to verify their household income while maintaining important program integrity controls. This document provides details about the change in Federally-Facilitated Marketplaces (FFMs), as well as guidance on what this means for State-Based Marketplaces (SBMs). https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FINAL-Income-Datamatching-FAQ-7-21-16.pdf SUMMARY OF NIHB ANALYSIS: CCIIO proposes that an applicant could have household income up to 25% lower than the data on household income available from the internal federal government sources checked (e.g., IRS tax returns) without requiring the applicant to submit documentation. | |
| 7.ccc. | Inappropriate Steering of Individuals to Individual Market ACTION: Notice NOTICE: Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans | CMS-6074-N | Issue Date: 8/23/2016 Due Date: 9/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This request for information seeks public comment regarding concerns about health care providers and provider-affiliated organizations steering people eligible for or receiving Medicare and/or Medicaid benefits to an individual market plan for the purpose of obtaining higher payment rates. CMS has concerns about reports of this practice and requests comments on the frequency and impact of this issue from the public. CMS believes this practice not only could raise overall health system costs, but could potentially prove harmful to patient care and service coordination because of changes to provider networks and drug formularies, result in higher out-of-pocket costs for enrollees, and have a negative impact on the individual market single risk pool (or the combined risk pool in states that have chosen to merge their risk pools). CMS seeks input from stakeholders and the public regarding the frequency and impact of this practice, and options to limit this practice. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | AGENCY: CMS | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-08-23/pdf/2016-20034.pdf A CMS press release on this notice is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-08-18-2.html. SUMMARY OF NIHB ANALYSIS: No comments recommended. This RFI offers an example of CMS exercising its regulatory authority over the Marketplaces, both FFMs and SBMs, and its willingness to use its regulatory authority when deemed necessary to protect the individual market risk pool from excessive adverse selection. | |
| 7.dddd. | FAQs on Periodic Data Matching ACTION: Guidance NOTICE: Summer/Fall 2016 Periodic Data Matching FAQs AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Consumers determined eligible for or enrolled in Medicaid or CHIP coverage that qualifies as minimum essential coverage (MEC) cannot receive advance payments of the premium tax credit (APTC) for themselves or incomebased cost-sharing reductions (CSRs) to help pay for the cost of Marketplace coverage. Federally-Facilitated Marketplaces and State-Based Marketplaces using the federal eligibility and enrollment platform (Marketplaces) have conducted a data match with state Medicaid and CHIP agencies to determine whether consumers who are enrolled in Marketplace coverage with APTC or CSRs (APTC/CSRs) are also enrolled in Medicaid or CHIP. The consumers for whom a data match occurred included those with validated Social Security numbers, in Marketplaces that have capacity to process requests through the non-employer-sponsored insurance (non-ESI) MEC check service. In summer/fall 2016, the Marketplace will implement new functionality to end APTC/CSRs on behalf of a consumer when the consumer is found to have Marketplace coverage with APTC/CSRs and Medicaid or CHIP coverage and fails to respond to an initial warning notice. In August 2016, the Marketplace will send an initial warning notice, both by mail and via the Marketplace account, to the household contact for each affected consumer, requesting that they take immediate action to respond to the notice. The notice will include the names of those consumers identified as dually-enrolled and instructions on how to respond to the notice. | |



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| # | of Regulation/Title/ Agency | File Code | Due Date & File Date | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | | | | | who did not update their Marketplace application by the date on the initial warning notice to reflect that they are not dually-enrolled or end their Marketplace coverage with APTC/CSRs, informing them that the Marketplace will end their financial assistance. This notice also alerts affected consumers that Marketplace coverage for these consumers will continue without financial help and that they will need to end their Marketplace coverage if they no longer wish to remain enrolled in that coverage at full cost. For unaffected household members, Marketplace coverage will continue, and the Marketplace will recalculate their eligibility for APTC/CSRs, if applicable. The Marketplace will send the final notice and a new eligibility determination notice for all consumers in the household, to inform them of the change in financial help. These notices also will appear in the consumer Marketplace accounts. This document serves to inform state Medicaid and CHIP agencies about the technical and operations aspects of periodic data matching. States should refer to this updated document for the latest information regarding periodic data matching (PDM), as it provides updates to the PDM FAQs published in spring 2016. CCIIO will update this document as necessary to reflect changes in this process. The Marketplace will continue to conduct regular periodic data matches with state Medicaid and CHIP agencies, send notices to consumers, and take appropriate action regarding consumer eligibility. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/PDM-Round-3-FAQ-8-1-16.pdf SUMMARY OF NIHB ANALYSIS: | |
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| 7.eeee. | Notice to States Regarding | CCIIO (no | Issue Date: | | SUMMARY OF AGENCY ACTION: This notice seeks to inform state regulatory | |
| | Marketplace Auto Re- Enrollment | reference number) | 8/8/2016 | | authorities regarding the annual auto re-enrollment determinations for the plan year (PY) 2017 in Federally-Facilitated Marketplaces (FFMs) and State-Based Marketplaces on the | |
| | | , | <u>Due Date:</u> | | Federal Platform (SBM-FPs) with respect to individual market qualified health plans | |
| | ACTION: Guidance | | None | | (QHPs) no longer available in the Marketplace. Beginning with PY 2017, 45 CFR 155.335(j)(3) authorizes Marketplaces to determine the auto re-enrollment of enrollees in | |
| | NOTICE: Notice to States | | NIHB File | | QHPs where the issuer will have no Marketplace enrollment option for the upcoming plan | |
| | Regarding Marketplace Auto | | <u>Date:</u> | | year, unless otherwise directed by the state regulatory authority. In FFMs and SBM-FPs, | |
| | Re-Enrollment | | Date of | | this auto re-enrollment will apply to all QHP enrollees where the issuer no longer has a QHP available through the FFMs for the upcoming plan year with a service area that | |
| | AGENCY: CCIIO | | <u>Subsequent</u> | | covers the location of the enrollee, even if the issuer continues to have QHPs available | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | | | Agency Action, if any: | | through that Marketplace that cover other service areas. (The auto re-enrollment will not apply to stand-alone dental plans in the individual market FFMs, SBM-FPs, or SHOPs.) This notice outlines the steps CMS expects state regulatory authorities in all states with an FFM (including State Partnership Marketplaces) or SBM-FP to take if they wish to direct this auto re-enrollment activity for PY 2017, to ensure that the Marketplace will automatically re-enroll enrollees according to state direction. If CMS does not receive notice from a state regarding its intent to direct the auto re-enrollment of its QHPs no longer available in the Marketplace by 5 p.m. ET on 7/24/2016, the agency will proceed to direct auto re-enrollment for applicable QHPs. A CCIIO FAQ document on Marketplace auto re-enrollment is available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/State_Response_Table_FAQ_08AUG2016PDF . https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final_Letter-to-States_Auto-Re-enrollment-of-QHPs_No_Longer_A-8816.pdf SUMMARY OF NIHB ANALYSIS: | |
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| 7.ffff. | FAQs on Language Access Tagline Requirements ACTION: Guidance NOTICE: Language Access Tagline Frequently Asked Questions AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/10/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance answers the following frequently asked questions (FAQs) on language access tagline requirements: • Q1: When may entities subject to 45 C.F.R. § 155.205(c)(2)(iii)(A) and (B) aggregate limited English proficient populations across multiple states to determine the top 15 languages in which they must provide taglines on Web sites and critical documents? A1: We intend to propose amendments to § 155.205(c)(2)(iii) to provide more specificity about when entities subject to § 155.205(c)(2)(iii)(A) and (B) would be permitted to aggregate limited English proficient populations across states to determine the languages in which taglines must be provided, in light of questions that have arisen about this issue since § 155.205(c)(2)(iii)(A) and (B) were finalized. We intend to propose amendments to § 155.205(c)(2)(iii)(B) to specify that individuals, companies, or corporations that are agents or brokers | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | subject to 45 C.F.R. § 155.220(c)(3)(i) ("web-brokers"), and that are licensed in and serving multiple states, would be permitted to aggregate the limited English proficient populations in the states they serve to determine the top 15 languages in which they must provide taglines under § 155.205(c)(2)(iii)(B). With respect to OHP issuers, we likewise intend to propose amendments to § 155.205(c)(2)(iii)(A) to specify that a OHP issuer would be permitted to aggregate the limited English proficient populations across all states served by the health insurance issuers within its issuer control group, whether or not those health insurance issuers offer plans through the Marketplace in each of those states, to determine the top 15 languages in which it must provide taglines In the meanwhile, we will not take enforcement action against web-brokers or QHP issuers that comply with the rule by providing taglines in accordance with this FAO. We also intend to propose amendments to § 155.205(c)(2)(iii)(A) to specify that Marketplaces would be permitted to aggregate the limited English proficient populations of multiple states to determine the top 15 languages in which taglines are required For more information about language access requirements, see our Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR §155.205(c) and §156.250. • Q2: When providing the taglines required by 45 C.F.R. § 155.205(c) (a) (iii) (A) and (B) on Web site content, must Marketplaces, QHP issuers, and agents or brokers subject to 45 C.F.R. § 155.205(c) (a) (iii) (a) and (b) on Web site content, must Marketplaces, QHP issuers, and webbrokers to include taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a OHP for qualified individuals, applicants, qualified employers, qualified employers, or enrollees. 45 C.F.R. § 155.205(c)(2) (iii) | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any standalone document linked to or embedded in the Web site, such as one in portable document format (PDF) or word processing software format, that is critical within the meaning of the rule. In the meanwhile, we will not take enforcement action against QHP issuers or web-brokers that comply with § 155.205(c)(2)(iii)(A) and (B) by providing taglines in accordance with this FAQ. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Tagline-FAQs-7-27-16-clean-letterhead-MM-508.pdf SUMMARY OF NIHB ANALYSIS: | |
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| 7 .gggg. | Network Breadth Information for QHPs on Healthcare.gov ACTION: Guidance NOTICE: Network Breadth Pilot: CMS Bulletin on Network Breadth Information for Qualified Health Plans on Healthcare.gov AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/19/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 9/30/2016 | | SUMMARY OF AGENCY ACTION: This bulletin announces that, during the open enrollment period for the 2017 coverage year, information on the relative size of provider networks will display for plans in a limited number of states on Healthcare.gov. The consumer experience is a priority for CMS, and the goal of the network breadth pilot seeks to help the agency understand how consumers make use of the network breadth information. During open enrollment, consumers will see information classifying the relative breadth of qualified health plan (QHP) provider networks, as compared with other Marketplace plans nationwide. Consumers will have the ability to compare networks for three provider types, including adult primary care providers, pediatricians, and hospitals. QHP issuers in the Marketplaces in the pilot states will receive information about their network breadth classifications from CMS prior to open enrollment. For plan year 2017, network breadth information will display for only the pilot states. The pilot with include approximately six states for the pilot. CMS will consider states that provide a sample of plans in geographic areas with a range of network availability. This pilot applies to QHPs on the FFMs, including FFMs where the state performs plan management functions. Network breadth information will display to consumers shopping for plans in the individual market only in the pilot states. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Network- | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/NA-Pilot-Final-Guidance-Clean-093016.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 7.hhhh. | | CCIIO (no reference number) | Issue Date: 8/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: For the 2015 benefit year, CMS will release a Webbased form through which third-party administrators (TPAs), including pharmacy benefit managers (PBMs), that provide services to a self-insured group health plan offered by an eligible organization and Federally-Facilitated Marketplace (FFM) issuers that have entered into an agreement with these TPAs (including PBMs) can report contraceptive claims costs incurred by plan participants and beneficiaries. Completion of the Web-based form for the 2015 benefit year will allow CMS to: 1) determine the reduction to the FFM user fee for the participating FFM issuer; 2) ensure that these adjustments to the monthly FFM user fee reflect payments for contraceptive services paid for under this accommodation under 45 C.F.R. §§ 147.131(b) and 156.50(d); and 3) ensure that the adjustment, equal to cost of contraceptive claims incurred during the applicable benefit year plus a 15 percent administrative margin, is applied to the appropriate FFM issuer. This document provides answers to related frequently asked questions (FAQs) to assist issuers and TPAs (including PBMs) with navigating the submission requirements and understanding the mechanism through which CMS will apply the FFM user fee adjustment to FFM issuers. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FFM-UF_adjustment_FAQ_2015.pdf SUMMARY OF NIHB ANALYSIS: | |
| 7.1111. | ECP Petition for 2018 ACTION: Notice NOTICE: Essential Community Provider Petition for the 2018 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/2/2016 Due Date: 10/15/2016 NIHB File Date: None Date of Subsequent | | SUMMARY OF AGENCY ACTION: In accordance with section 1311(c)(1)(C) of ACA, qualified health plan (QHP), including Stand-alone Dental Plan (SADP), issuers must include within their network essential community providers (ECPs), where available, that serve predominantly low-income, medically-underserved individuals. Under this same section of ACA, the HHS Secretary has responsibility for establishing criteria for certification of health plans as QHPs, including criteria for issuer satisfaction of the ECP inclusion requirement. Under 45 CFR 156.235, the HHS Secretary has established criteria for inclusion of a sufficient number and geographic distribution of ECPs, where available, in the networks of issuers to ensure reasonable and timely access to a broad range of such providers for low-income, medically-underserved individuals in their service areas. To satisfy this ECP requirement, QHP and SADP issuers must submit an | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | Agency Action, if any: | | ECP template as part of their QHP application, in which they must list the ECPs with which they have contracted to provide health care services to low-income, medically-underserved individuals in their service areas. HHS has compiled a draft non-exhaustive list of available ECPs for plan year (PY) 2018. These providers submitted an ECP petition by 7/11/2016 to get added to the ECP list for PY 2018 and received approval by CMS through the ECP petition review process. HHS updates this ECP list annually to assist issuers with identifying providers that qualify for inclusion in their plan networks toward satisfaction of the ECP standard under 45 CFR 156.235. The ECP petition submission window for the final PY 2018 ECP list closes at 11:59 p.m. ET on 10/15/2016. For ongoing provider updates, the ECP petition submission process will remain open year-round, and updates will appear on the following plan year ECP list. The draft PY 2018 ECP list is embedded within ECP petition and viewable by clicking the button "Check to see if you are on the list" under question 6 of the petition. Providers that need technical assistance with the ECP petition or have general questions can receive assistance by e-mailing their question(s) to EssentialCommunityProviders@cms.hhs.gov. Providers should type "Comments on ECP Petition" in the subject line of the e-mail. https://data.healthcare.gov/cciio/ecp_petition SUMMARY OF NIHB ANALYSIS: TSGAC and other tribal organizations have circulated this notice, which extended the due date for adding an entry to the HHS ECP List for 2018 to 10/15/2016. No response recommended or needed. | |
| 7.jjjj. | Agreement Between QHP Issuers and CMS ACTION: Guidance NOTICE: Qualified Health Plan Certification Agreement | CCIIO (no reference number) | Issue Date: 9/1/2016 Due Date: None NIHB File | | SUMMARY OF AGENCY ACTION: This guidance includes the qualified health plan (QHP) issuer agreement entered into by and between CMS and an issuer that offers health insurance coverage through QHPs offered through the Federally-Facilitated Marketplace. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Plan-Year-2017-QHP-Issuer-Agreement.pdf | |

National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status of Regulation/Title/ Agency and Privacy and Security | File Code | Issue Date; Due Date & File Date Date: | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agreement Between Qualified Health Plan Issuer and the Centers for Medicare & Medicaid Services AGENCY: CCIIO | | Date of Subsequent Agency Action, if any: | | SUMMARY OF NIHB ANALYSIS: | |
| 7.kkkk. | FAQs on Crosswalk of Enrollees into the Plans of Other Issuers ACTION: Guidance NOTICE: FAQs Regarding Crosswalk of Enrollees into Plans Offered by Other Issuers AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/2/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: As part of the HHS Notice of Benefit and Payment Parameters for 2017 Final Rule (2017 Payment Notice), CMS finalized a provision under which 2016 Health Insurance Marketplace consumers who will not have a QHP offered by their current issuer available to them for 2017 will have a suggested alternative plan from a different issuer selected by the Marketplace. CCIIO notes that such an enrollment would generally require a binder payment from a consumer. In general, CCIIO anticipates that this rule will help those consumers that do not make an active plan selection maintain their Marketplace coverage and financial assistance. Younger consumers are at particular risk of losing Marketplace coverage due to not making an active plan selection. For example, during the 2016 Open Enrollment, the median passive re-enrollee was four years younger than the median active re-enrollee. However, CCIIO has heard concerns from some issuers and state Departments of Insurance about how these new procedures might apply in specific circumstances. This guidance answers frequently asked questions addressing these issues. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/FAO-Regarding-Crosswalk-of-Enrollees-into-Plans-Offered-by-Other-Issuers.pdf SUMMARY OF NIHB ANALYSIS: | |
| 7.1111. | FAQs on Verification of Special Enrollment Periods ACTION: Guidance | CCIIO (no reference number) | Issue Date: 9/6/2016 Due Date: None | | SUMMARY OF AGENCY ACTION: In the HHS Notice of Benefit and Payment Parameters for 2018 Proposed Rule (2018 Payment Notice), CMS Indicated its commitment to making sure that special enrollment periods are available to those who qualify and avoiding any misuse or abuse of special enrollment periods. In recent months, CMS has introduced a special enrollment confirmation process under which consumers enrolling through the most common special enrollment periods on a | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency NOTICE: Frequently Asked Questions Regarding Verification of Special Enrollment Periods AGENCY: CCIIO | | File Date NIHB File Date: Date of Subsequent Agency Action, if any: | Nesponse | Federally-Facilitated Marketplace are directed to provide documentation to confirm their eligibility for the special enrollment period. Preliminary data indicate that the confirmation process has resulted in a material decrease in special enrollment period plan selections. In the seven weeks prior to implementation of the confirmation process, special enrollment period plan selections in 2016 were about the same as during the same weeks in 2015. In the seven weeks after implementation, special enrollment period plan selections in 2016 were almost 15 percent lower than during the same weeks last year, although why enrollments are falling in response to the new confirmation process is unclear. In the 2018 Payment Notice, CMS proposed to continue its efforts to clarify and streamline the rules around special enrollment periods by codifying certain special enrollment periods made available through prior guidance. CMS also noted the concerns it has heard about how these actions are affecting the Marketplace risk pools. Some have said that additional changes are needed to prevent individuals from misusing special enrollment periods to sign up for coverage only after they become sick. Others have cautioned that differential costs for the special enrollment period population reflect the already low take-up rates for special enrollment periods among eligible individuals. CMS has receive requests for information on what policy changes it might consider and when and what input would prove most relevant. This guidance provides answers to frequently asked questions addressing these issues. In particular, to further inform policy development, CMS seeks input on a pilot it intends to launch in the months after Open Enrollment in 2017. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/FAQ-Regarding-Verification-of-SEPs.pdf SUMMARY OF NIHB ANALYSIS: | |
| 7.mmmm. | FAQ on Safe Harbor for Issuers with Increased Enrollment in 2017 ACTION: Guidance | CCIIO (no reference number) | Issue Date: 9/16/2016 Due Date: None | | SUMMARY OF AGENCY ACTION: This guidance answers the following frequently asked question (FAQ) on the safe harbor for health insurance issuers affected by an increase in enrollment in 2017: Q. What is CMS's approach to compliance for issuers affected by a substantial increase in enrollment in plan year 2017? | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: FAQ on Compliance Safe Harbor for Issuers Affected by an Increase in Enrollment for the 2017 Plan Year AGENCY: CCIIO | | NIHB File Date: Date of Subsequent Agency Action, if any: | | A. The Centers for Medicare & Medicaid Services (CMS) anticipates that some issuers of qualified health plans (QHPs) on Federally-facilitated Marketplaces (FFMs) may experience a substantial enrollment increase for the 2017 plan year. This may present temporary operational challenges that prevent these issuers from complying with certain FFM standards that have direct impact on consumers, including consumer casework. CMS intends to provide technical assistance to these issuers, including through account manager support and accelerated resolution of issues. Further, to address these concerns and recognize reasonable issuer efforts, CMS is providing a compliance safe harbor for issues attributable to a substantial increase in enrollment. Specifically, for the 2017 plan year, CMS will not use formal enforcement remedies for non-compliance with the casework standards under 45 CFR 156.1010 or other customer service standards when issuers that have experienced a substantial increase in enrollment make reasonable efforts to address concerns in an appropriate time frame. CMS will take into account the QHP issuer's efforts to cooperate with CMS, address and resolve issues in a reasonable amount of time, and report on the progress of resolution. CMS always encourages issuers to work proactively with CMS to resolve potential issues, and appreciates all issuers' efforts to provide excellent service to all QHP enrollees on the FFMs. SUMMARY OF NIHB ANALYSIS: This guidance indicates that some issuers with a large increase in enrollment might not have to meet customer service standards during the initial period of the increase. | |
| 7.nnnn. | FAQ on Health Insurance Marketplace Standards ACTION: Guidance NOTICE: Frequently Asked Questions on Health Insurance Marketplace Standards AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 10/17/2016 Due Date: None NIHB File Date: Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: This guidance answers the following frequently asked question (FAQ) on Health Insurance Marketplace standards: Q: Are Exchange-certified Stand-alone Dental Plans offered Off-Exchange permitted to accept enrollments outside the Exchange enrollment periods? A: Yes. Nothing in CMS regulations prohibits Exchange-certified stand-alone dental plans (SADPs) offered off-Exchange from accepting enrollments outside the Exchange enrollment periods. Under 45 CFR 155.410(a)(2), an Exchange may only permit a qualified individual to enroll in a qualified health plan (QHP) or an enrollee to change QHPs during an enrollment period specified in the Exchange regulations. Therefore, enrollments through an Exchange are limited to these enrollment periods. However, the | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | Action, if any: | | Exchange would not be involved in off-Exchange enrollments. Therefore, we are confirming that neither this regulation, nor any other CMS regulation, would prohibit Exchange-certified SADPs that wish to enroll consumers outside the Exchange outside the enrollment periods specified in the Exchange regulations from doing so, provided they comply with applicable State laws. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-OffMarketplace-Enrollment-Periods-09282016.pdf SUMMARY OF NIHB ANALYSIS: | |
| 8.d. | Oklahoma 1115 Waiver Amendment ACTION: Request for Comment NOTICE: §1115(a) SoonerCare Research and Demonstration Waiver Amendment Request AGENCY: N/A | 11-W- 00048/6 | Issue Date: 3/4/2016 Due Date: 4/14/2016 TSGAC File Date: 4/5/2016 Date of Subsequent Agency Action, if any: | TSGAC response: | SUMMARY OF AGENCY ACTION: The Oklahoma single state Medicaid agency, the Oklahoma Health Care Authority (OHCA), operates the §1115(a) SoonerCare Research and Demonstration Waiver, initially approved in 1995. The waiver authorizes the SoonerCare Choice and Insure Oklahoma (IO) demonstrations. With this amendment request, OHCA seeks approval of the following amendments to the demonstration for the 2016 renewal period: 1. Modify the evaluation design for the existing Insure Oklahoma Employer-Sponsored Insurance (ESI) plan and Individual Plan (IP) to add outcomes reporting; and 2. Incorporate the Insure Oklahoma Sponsor's Choice Option. Under this amendment request, OHCA would add I/T/Us as sponsors under Insure Oklahoma, allowing I/T/Us to sponsor eligible individuals by paying their premiums for health insurance coverage through Insure Oklahoma. OHCA proposes to implement this amendment on 1/1/2017. The federal public comment period on this amendment request will remain open through 11 p.m. on 4/14/2016. Interested parties can submit comments by completing an online questionnaire at https://public.medicaid.gov/connect.ti/public.comments/viewQuestionnaire?qid=1883139 . All responses are anonymous. https://public.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ok/ok-soonercare-pa.pdf | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: In general, Oklahoma Tribes encourage letters of support for CMS approval of this waiver amendment request. | |
| 8.e. | Healthy Indiana Program 2.0 Beneficiaries Survey ACTION: Request for Comment NOTICE: Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey AGENCY: CMS | CMS-10615 | Issue Date: 3/29/2016 Due Date: 4/8/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/4/2016; issued extension 7/22/2016, 9/26/2016 Due Date: 6/3/2016; 9/20/2016; 10/26/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection: Title: Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey: Use: CMS requires approval for testing and developing the survey to inform adequately its decision making regarding section 1115 waivers, in particular the Indiana non-emergency medical transportation (NEMT) waiver due for renewal by 12/1/2016. The NEMT benefit provides transportation for Medicaid beneficiaries who otherwise have no means of transportation to get to and from medical services. The Healthy Indiana Program (HIP) 2.0 demonstration provides authority for the state to not offer NEMT for the new adult group during the first year of the demonstration (except for pregnant women and individuals determined medically frail). CMS might extend this authority, subject to evaluation of the impact of this policy on access to care. https://www.gpo.gov/fdsys/pkg/FR-2016-03-29/pdf/2016-06828.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/4/2016 issued a revision of this PRA request. This PRA request seeks emergency approval to field the surveys and to conduct key informant interviews and focus groups. CMS tested the surveys during the first week of April 2016 and announced a week-long public comment period in the 3/29/2016 FR (81 FR 17460). This PRA request contains the revised surveys based on testing and public comments provided during the survey testing period. https://www.gpo.gov/fdsys/pkg/FR-2016-05-04/pdf/2016-10448.pdf No comments recommended. CMS on 9/20/2016 issued an extension of this PRA request. This PRA request does not propose any new or revised information collection requirements or burden estimates. Rather, it seeks to extend the current expiration date of 9/30/2016 (approved under the emergency PRA process on 3/21/2016). https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17376.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS on 9/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-26/pdf/2016-23157.pdf No comments recommended. | |
| 8.f. | Montana HELP Federal Evaluation ACTION: Request for Comment NOTICE: Montana Health and Economic Livelihood Partnership (HELP) Federal Evaluation AGENCY: CMS | CMS-10635 | Issue Date: 10/21/2016 Due Date: 12/20/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Montana Health and Economic Livelihood Partnership (HELP) Federal Evaluation; Use: CMS approved the Montana Health and Economic Livelihood Partnership (HELP) demonstration in November 2015. The demonstration provides flexibility for the expanded Medicaid population under ACA for individuals in the state of Montana. Montana expects to achieve the following: (1) Premium and copayment liability that will encourage HELP Program enrollees to act as discerning health care purchasers, take personal responsibility for their health care decisions, and develop health-conscious behaviors as consumers of health care services; and (2) 12-month continuous eligibility to improve continuity of care. The state also seeks to demonstrate the following over the life of the demonstration: (1) Premiums will not pose a barrier to accessing care for HELP Program beneficiaries; (2) HELP Program enrollees will exhibit health-conscious health care behaviors without harming beneficiary health; and (3) 12-month continuous eligibility will promote continuity of coverage and reduce churning rates. The demonstration includes the authority to charge premiums of 2 percent of household income to individuals in the new adult group with incomes between 50 and 133 percent of the federal poverty level (FPL). The state will credit such premium obligation for individuals toward copayments due. Non-payment of premiums might result in disenrollment for individuals with incomes above 100 percent FPL after notice and a grace period. Individuals with incomes above 100 percent FPL after notice and a grace period. Individuals with incomes above 100 percent FPL after notice and a grace period. Individuals with incomes above 100 percent FPL after notice and a grace period. Individuals with incomes above 100 percent FPL after notice and a grace period. Individuals at or below 100 percent FPL who stop paying premiums will not get disenrolled. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 9.h. | Program Integrity Enhancements to Provider Enrollment Process ACTION: Proposed Rule NOTICE: Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process AGENCY: CMS | CMS-6058-P | Issue Date: 3/1/2016 Due Date: 4/25/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule would implement sections of ACA that require Medicare, Medicaid, and CHIP providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers. This proposed rule also would provide CMS with additional authority to deny or revoke Medicare enrollment for a provider or supplier. In addition, this proposed rule would require that to order, certify, refer or prescribe any Part A or B service, item or drug, a physician or, when permitted, an eligible professional must have an approved Medicare enrollment status or have validly opted out of the program. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04312.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule might have items of interest to some Indian health care providers. | |
| 9.i. | Medicaid Provider Enrollment Compendium ACTION: Guidance NOTICE: Medicaid Provider Enrollment Compendium (MPEC) AGENCY: CMS | CMS (no reference number) | Issue Date: 3/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This policy manual contains sub-regulatory guidance and clarifications regarding how state Medicaid agencies should comply with the following federal regulations at 42 CFR § 455: • Subpart B "Disclosure of Information by Providers and Fiscal Agents," and • Subpart E "Provider Screening and Enrollment." The federal regulations at 42 CFR Part 455 include Subparts A through F; however, the information in this manual addresses only Part 455 Subparts B and E. All references to the Medicaid program in this manual apply to CHIP. Section 6401(b) of ACA amended section 1902 of the Social Security Act (Act) to require state Medicaid programs to comply with the procedures established by the HHS Secretary for screening providers and suppliers. Section 6401(c) of ACA amended section 2107(e) of the Act to make the provider and supplier screening requirements under section 1902 applicable to CHIP. | |



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| | | | | | Via a final rule published in the 2/2/2011 FR, CMS established and implemented Medicaid provider screening requirements at 42 CFR Part 455, Subpart E. Per 42 CFR § 457.990, these regulations apply to CHIP and became effective on 3/25/2011. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Part-2-EDGE-Q_Q-Guidance_03182016.pdf SUMMARY OF NIHB ANALYSIS: | |
| 10.g. | Medicare Shared Savings Program: ACO Benchmarking ACTION: Proposed Final Rule NOTICE: Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations-Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance- Based Risk, and Administrative Finality of Financial Calculations AGENCY: CMS | CMS-1644- PF | Issue Date: 2/3/2016 Due Date: 3/28/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 6/10/2016 | | SUMMARY OF AGENCY ACTION: Under the Medicare Shared Savings Program (Shared Savings Program), providers of services and suppliers that participate in an accountable care organization (ACO) continue to receive traditional Medicare fee-forservice (FFS) payments under Parts A and B, but the ACO might qualify to receive a shared savings payment if it meets specified quality and savings requirements. This proposed rule addresses changes to the Shared Savings Program that would modify its benchmark rebasing methodology to encourage the continued investment of ACOs in care coordination and quality improvement and identifies publicly available data to support modeling and analysis of these proposed changes. In addition, this proposed rule would streamline the methodology used to adjust the historical benchmark of an ACO for changes in its ACO participant composition, offer an alternative participation option to encourage ACOs to enter performance-based risk arrangements earlier in their participation under the program, and establish policies for reopening of payment determinations to make corrections after the performance of financial calculations and determination of ACO shared savings and shared losses for a performance year. https://www.gpo.gov/fdsys/pkg/FR-2016-02-03/pdf/2016-01748.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: Under the Medicare Shared Savings Program (Shared Savings Program), providers of services and suppliers that participate in an accountable care organization (ACO) continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO might qualify to receive a shared savings payment if it meets specified quality and savings requirements. This final rule addresses changes to the Shared Savings Program, including: modifications to the | |



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| | | | | | benchmarking methodology of the program when resetting (rebasing) the benchmark of an ACO for a second or subsequent agreement period to encourage the continued investment the ACO in care coordination and quality improvement; an alternative participation option to encourage ACOs to enter performance-based risk arrangements earlier in their participation under the program; and policies for reopening of payment determinations to make corrections after financial calculations have determined ACO shared savings and shared losses for a performance year. https://www.gpo.gov/fdsys/pkg/FR-2016-06-10/pdf/2016-13651.pdf A CMS press release on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-06-06.html. A CMS fact sheet on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-06.html. | |
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| 11.d. | Bid Pricing Tool ACTION: Request for Comment NOTICE: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs) AGENCY: CMS | CMS-10142 | Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 10/4/2013, 12/20/2013, 9/26/2014, | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); Use: Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) must submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by the Centers for Medicare & Medicaid Services (CMS). MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid, with the information provided in the BPT used as the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development, administrative expenses, profit levels, and projected plan enrollment information. CMS reviews and analyzes the information provided in the BPT and decides whether to approve the plan pricing proposed by each organization. CMS is requesting to continue its use of the BPT for the collection of information for CY 2014 through CY 2016. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/17/2013 issued a revision of this PRA request. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | rigency | | 12/24/2014, 9/24/2015, 12/18/2015, 10/31/2016 Due Date: 2/19/2013; 12/3/2014; 11/25/2014; 11/23/2015; 11/23/2016; 12/30/2016 | | http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2013-00858.pdf CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf CMS on 12/20/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf CMS on 9/26/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-22990.pdf CMS on 12/24/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-12-24/pdf/2014-30026.pdf CMS on 9/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-24/pdf/2015-24263.pdf No comments recommended. CMS on 12/18/2015 issued a revision of this PRA request. CMS has revised this package subsequent to the publication of the 60-day notice in the 9/24/2015 FR (80 FR 57619). https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31887.pdf No comments recommended. CMS on 10/31/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26246.pdf No comments recommended. | |
| 11.f. | Plan Benefit Package and Formulary Submission ACTION: Request for Comment | CMS-R-262 | <u>Issue Date:</u> 10/5/2012 <u>Due Date:</u> 12/4/2012 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); Use: Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations must submit plan benefit packages—which consist of the Plan Benefit Package (PBP) | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: PBP and Formulary Submission for Medicare Advantage and Prescription Drug Plans AGENCY: CMS | | NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 11/1/2014, 9/26/2014, 12/19/2015, 12/18/2015, 10/31/2016 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 11/25/2014; 11/25/2015; 11/23/2015; 11/9/2016; 12/30/2016 | | software, formulary file, and supporting documentation, as necessary—for all Medicare beneficiaries residing in their service area. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits, as well as generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. In addition, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization. SUMMARY OF NIHB ANALYSIS: A link to a detailed list of changes to the PBP software appears below. In addition, if issues with the current formulary development process or the use of the formulary have occurred, this PRA request might provide an opportunity to comment on them. The changes proposed are to be implemented and effective by CY 2014. http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html SUMMARY OF SUBSEQUENT AGENCY ACTION: Based on operational changes and policy clarifications to Medicare and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2013-00858.pdf CMS on 1/17/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2013-26107.pdf CMS on 9/26/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-22990.pdf CMS on 12/19/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-22990.pdf CMS on 12/19/2014 issued a revision of this PRA request. CMS has revised this package subsequent to the publication of the 60-day notice in the 9/26/2014 FR (79 FR 57931). http://www.gpo.gov/fdsys/pkg/FR-2014-01-19/pdf/2014-29739.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS on 9/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-24/pdf/2015-24263.pdf No comments recommended. CMS on 12/18/2015 issued a revision of this PRA request. CMS has revised this package subsequent to the publication of the 60-day notice in the 9/24/2015 FR (80 FR 57619). https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31887.pdf No comments recommended. CMS on 10/31/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26246.pdf No comments recommended. | |
| 11.g. | Medicare Advantage Reporting Requirements ACTION: Request for Comment NOTICE: Part C Medicare Advantage Reporting Requirements and Supporting Regulations AGENCY: CMS | CMS-10261 | Issue Date: 10/26/2012 Due Date: 12/26/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/21/2013, 10/4/2013, 5/1/2015, 8/24/2015; issued | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); Use: CMS initiated new Medicare Part C reporting requirements in December 2008. The initial requirements involved thirteen measures, two of which CMS has suspended from reporting because the information is available elsewhere: Measurement 10, "Agent Compensation Structure," and Measurement 11, "Agent Training and Testing." CMS added one new measure beginning 2012: "Enrollment and Disenrollment." CMS suspended the "Benefit Utilization" measure in late 2011. CMS requests the suspension of two additional measures, "Procedure Frequency" and "Provider Network Adequacy," because equivalent data are already collected or available through other sources. CMS has added one additional data element"CMS Issues"to its "Grievances" measure, which currently has 10 reporting categories. CMS also proposes to make the Part C measure, "Plan Oversight of Agents," consistent with the corresponding Part D section by requiring reporting of 10, rather than six, data elements. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/21/2013 issued a revision | |



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| # | Agency | | File Date | Response | and Summary of NIHB Analysis | |
| | | | correction and partial withdrawal 9/18/2015; issued revision 5/11/2016, 9/12/2016 | | of this PRA request. According to this PRA request, information users of Part C reporting include CMS central and regional office staff members, who use this information to monitor health plans and to hold them accountable for their performance; researchers; and other government agencies, such as GAO. Health plans can use this information to measure and benchmark their performance. CMS intends to make some of these data available for public reporting as "display measures" in 2013. http://www.gpo.gov/fdsys/pkg/FR-2013-06-21/pdf/2013-14878.pdf | |
| | | | <u>Due Date:</u> 8/20/2013; 11/4/2013; 6/30/2015; 9/23/2015; | | CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 5/1/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10208.pdf | |
| | | | 10/19/2015; 7/11/2016; 10/12/2016 | | No comments recommended. | |
| | | | | | CMS on 8/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-08-24/pdf/2015-20787.pdf | |
| | | | | | No comments recommended. | |
| | | | | | CMS on 9/18/2015 issued a notice of correction and partial withdrawal of this PRA request. According to CMS, based on internal review, this notice withdraws a portion of a prior notice (dated 8/24/2015) concerning the same subject matter and corrects that notice by adding a new requirement inadvertently omitted from that notice. Specifically, CMS proposes to add a new Payments to Providers reporting section to capture data related to value-based payments by MA organizations. Upon OMB approval, the Payments to Providers section would add 10 data elements. | |
| | | | | | http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23482.pdf | |
| | | | | | CMS on 5/11/2016 issued a revision of this PRA request. This revision would add five new data elements to the reporting section Organization Determinations and Reconsiderations. CMS needs these new data elements to obtain more information about case re-openings. This revision also would suspend the Sponsor Oversight of Agents reporting section beginning in 2017 so that CMS can reassess the reporting section based on burden and usage. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11078.pdf No comments recommended. CMS on 9/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-12/pdf/2016-21873.pdf No comments recommended. | |
| 11.i. | Medicare Advantage Appeals and Grievance Data Disclosure ACTION: Request for Comment NOTICE: Medicare Advantage Appeals and Grievance Data Disclosure Requirements AGENCY: CMS | CMS-R-282 | Issue Date: 2/22/2013 Due Date: 4/23/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 5/3/2013, 12/14/2015, 6/13/2016 Due Date: 6/17/2013; 1/26/2016; 7/13/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare Advantage Appeals and Grievance Data Disclosure Requirements (42 CFR 422.111); Use: Section 1852(c)(2)(C) of the Social Security Act and 42 CFR 422.111(c)(3) require that Medicare Advantage (MA) organizations and demonstrations disclose information pertaining to the number of disputes, as well as their disposition in the aggregate, with the categories of grievances and appeals to any individual eligible to elect an MA organization who requests this information. MA organizations and demonstrations remain under a requirement to collect and provide this information to individuals eligible to elect an MA organization, and CMS continues to need the same format and form for reporting. http://www.gpo.gov/fdsys/pkg/FR-2013-02-22/pdf/2013-04120.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/3/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10530.pdf Instructions for information disclosure, a model disclosure form, and a Supporting Statement are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1205062.html . The Instructions do not require identification of specific categories of appeals (other than expedited appeals). | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS on 12/14/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-14/pdf/2015-31399.pdf No comments recommended. | |
| | | | | | CMS on 6/13/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13916.pdf | |
| | | | | | No comments recommended. | |
| 11.j. | Medicare Part D Reporting Requirements ACTION: Request for Comment NOTICE: Medicare Part D Reporting Requirements AGENCY: CMS | CMS-10185 | Issue Date: 3/15/2013 Due Date: 5/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/26/2013, 5/1/2015, 8/24/2015, 5/6/2016, 9/12/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Part D Reporting Requirements; Use: Title I, Part 423, § 423.514 describes the regulatory authority of CMS to establish reporting requirements for Part D sponsors. Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, its enrollees, and the general public, at the times and in the manner that CMS requires, statistics in the following areas: the cost of its operations; the patterns of utilization of its services; the availability, accessibility, and acceptability of its services; information demonstrating that it has a fiscally sound operation; and other matters CMS may require. CMS has identified the appropriate data needed to effectively monitor plan performance. Changes to the currently approved data collection instrument reflect new executive orders and legislation, as well as recent changes to CMS policy and guidance. http://www.gpo.gov/fdsys/pkg/FR-2013-03-15/pdf/2013-06038.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/26/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf No comments recommended. | |
| | | | <u>Due Date</u> : 8/26/2013; 6/30/2015; 9/23/2015; 7/5/2016; | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/1/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10208.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 10/12/2016 | | No comments recommended. CMS on 8/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-08-24/pdf/2015-20787.pdf No comments recommended. CMS on 5/6/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10705.pdf No comments recommended. CMS on 9/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-12/pdf/2016-21873.pdf No comments recommended. | |
| 11.k. | Medicare PDP and MA Plan Disenrollment Reasons Survey ACTION: Request for Comment NOTICE: Implementation of the Medicare Prescription Drug Plan and Medicare Advantage Plan Disenrollment Reasons Survey AGENCY: CMS | CMS-10316 | Issue Date: 4/19/2013 Due Date: 6/18/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/5/2013, 3/25/2016, 6/30/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; <i>Use</i> : This data collection complements the satisfaction data collected through the Medicare Consumer Assessment of Healthcare Providers and Systems survey by providing dissatisfaction data in the form of reasons for disenrollment from a PDP. CMS can use the data collected in this survey to improve the operation of Medicare Advantage (both MA and MA-PD) contracts and standalone PDPs through the identification of beneficiary disenrollment reasons. Plans can use the information to guide quality improvement efforts. Beneficiaries also can use the data to help choose among the different MA and PDP options. To the extent that these data identify areas for improvement at the contract level, CMS can use them to inform contract oversight. http://www.gpo.gov/fdsys/pkg/FR-2013-04-19/pdf/2013-09267.pdf The PDP and MA Plan Disenrollment Reasons Survey and a Supporting Statement for this PRA request are available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1234927.html?DLPage=1&DLFilter=CMS-10316 (reasons for disenrollment questions: nos. 20-52, pp. 11-25 (MA Plan Survey); nos. 18-43, pp. 42-49 (PDP Survey). | |



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| | | | <u>Due Date:</u> 8/5/2013; 5/24/2016; 8/1/2016 | | SUMMARY OF NIHB ANALYSIS: The survey, given to some Medicare beneficiaries who disenroll from either a Medicare PDP or MA plan, includes a list of possible reasons for disenrollment. This list does not include Indian- or I/T/U-specific reasons for disenrollment. NIHB might want to submit comments to suggest an option for "non-availability of I/T/U providers" or something similar as a reason for disenrollment. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/5/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-05/pdf/2013-16084.pdf CMS on 3/25/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-25/pdf/2016-06829.pdf CMS on 6/30/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15549.pdf | |
| 11.m. | Collection of Data from MAOs for Risk Adjusted Payments ACTION: Request for Comment NOTICE: Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments AGENCY: CMS | CMS-10062 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/18/2013; issued extension 7/22/2016, | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments; Use: CMS will use the data to make risk adjusted payment under Part C. MA and MA-PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the output of the CMS- HCC and -RxHCC models and the risk scores and reimbursements for each beneficiary enrolled. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11035.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/18/2013 issued a reinstatement of this PRA request with changes. Previously, CMS received PRA clearance to collect inpatient and outpatient data for Part C using the CMS-HCC model. Currently, CMS seeks renewal of that OMB approval, as well as clearance for | |

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| | rigency | | 9/26/2016 <u>Due Date:</u> 8/19/2013; 9/20/2016; 10/26/2016 | | changes in data collection to fulfill new mandates under the Medicare Prescription Drug Benefit Improvement and Modernization Act of 2003 (MMA). http://www.gpo.gov/fdsys/pkg/FR-2013-07-18/pdf/2013-17317.pdf CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17376.pdf No comments recommended. CMS on 9/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-26/pdf/2016-23157.pdf | |
| | | | | | No comments recommended. | |
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| 11.w. | Final Marketing Provisions for Medicare Parts C and D ACTION: Request for Comment NOTICE: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions AGENCY: CMS | CMS-10260 | Issue Date: 1/29/2014 Due Date: 2/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/30/2016 Due Date: 8/29/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Medicare Advantage and Prescription Drug Program: Final Marketing Provisions; <i>Use</i> : CMS requires Medicare Advantage (MA) organizations and Part D sponsors to use standardized documents to satisfy disclosure requirements mandated by section 1851(d)(3)(A) of the Social Security Act (Act) for MA organizations and section 1860D-1(c) of the Act for Part D sponsors. MA organizations and Part D sponsors must disclose plan information, including: service area, benefits, access, grievance and appeals procedures, and quality improvement and quality assurance requirements by September 30 of each year. MA organizations and Part D sponsors use this information to comply with the disclosure requirements. CMS will use the approved standardized documents to ensure disclosure of correct information to current and potential enrollees. http://www.gpo.gov/fdsys/pkg/FR-2014-01-29/pdf/2014-01775.pdf SUMMARY OF NIHB ANALYSIS: This PRA request involves a revision to current reporting requirements pertaining to marketing materials used by Medicare Advantage and Part D plans. The plans report on service areas, benefits, etc. No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/30/2016 issued a revision | |



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| | | | | | of this PRA request. For 2017, CMS has a total of nine standardized ANOC/EOC documents: Health Maintenance Organization, Cost, Dual Eligible Special Needs, Medicare Medical Savings Account, Private-Fee-For-Service, Preferred Provider Organizations, Preferred Provider Organization with Prescription Drugs, Health Maintenance Organization with Prescription Drug, and Prescription Drug. MA organizations and Part D sponsors will use these standardized documents for the 2018 contract year. In revising the standardized ANOC/EOCs for contract year 2018, CMS did not add to or remove any section from the prior contract year ANOC/EOC models. MA organizations and Part D sponsors still must use the standardized language in the ANOC/EOC models and send this document to current members at least 15 days prior to the start of the annual enrollment period or by 9/30/2017 for the 2018 enrollment season, based on 42 CFR 422.111(a) (3) and 423.128(a)(3). https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15564.pdf | |
| 11.x. | Medication Therapy Management Program Improvements ACTION: Request for Comment NOTICE: Medication Therapy Management Program Improvements AGENCY: CMS | CMS-10396 | Issue Date: 1/17/2014 Due Date: 3/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014, 10/31/2016 Due Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medication Therapy Management Program Improvements; Use: Medicare beneficiaries or their authorized representatives, caregivers, and health care providers will use information collected by Part D medication therapy management programs (as required by the standardized format for the comprehensive medication review summary) to improve medication use and achieve better health care outcomes. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00916.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/11/2014 issued an extension of this PRA request. Subsequent to the publication of the 60-day notice published in the 1/17/2014 FR, CMS has made non-substantive changes to this information collection request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf CMS on 10/31/2016 issued an extension of this PRA request. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 5/12/2014; 12/30/2016 | | https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26246.pdf No comments recommended. | |
| 11.cc. | Collection of Encounter Data from MA and PACE Organizations ACTION: Request for Comment NOTICE: Collection of Encounter Data from Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and Pace Organizations AGENCY: CMS | CMS-10340 | Issue Date: 6/2/2014 Due Date: 8/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 9/8/2014, 8/5/2016 Due Date: 10/6/2014; 10/4/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Collection of Encounter Data from Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and Pace Organizations; Use: CMS collects encounter data or data on each item or service delivered to enrollees of Medicare Advantage (MA) plans offered by MA organizations. MA organizations currently obtain this data from providers. CMS collects this information using standard transaction forms and code sets. CMS will use the data for determining risk adjustment factors for payment, updating the risk adjustment model, calculating Medicare DSH percentages, Medicare coverage purposes, and quality review and improvement activities. CMS also will use the data to verify the accuracy and validity of the costs claimed on cost reports. For PACE organizations, encounter data would serve the same purpose it does related to the MA program and would get submitted in a similar manner. http://www.gpo.gov/fdsys/pkg/FR-2014-06-02/pdf/2014-12664.pdf SUMMARY OF NIHB ANALYSIS: This PRA request applies to MA plans, including PACE. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/8/2014 issued a revision of this PRA request. CMS has revised this information collection request subsequent to the publication of the 60-day notice in the 6/2/2014 FR (79 FR 31336). http://www.gpo.gov/fdsys/pkg/FR-2014-09-05/pdf/2014-21179.pdf CMS on 8/5/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18662.pdf No comments recommended. | |
| 11.hh. | Medicare Part C, Part D, and FFS CAHPS Survey | CMS-R-246 | <u>Issue Date:</u> 12/12/2014 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Advantage, Medicare Part D, and | |



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| | ACTION: Request for Comment NOTICE: Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey AGENCY: CMS | | Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/8/2015, 6/13/2016 Due Date: 6/8/2015; 8/12/2016 | | Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey; <i>Use</i> : The Medicare consumer assessment of healthcare providers and systems (CAHPS) surveys serve to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. The surveys also provide data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. http://www.gpo.gov/fdsys/pkg/FR-2014-12-12/pdf/2014-29172.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/8/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-08/pdf/2015-11208.pdf No comments recommended. CMS on 6/13/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13917.pdf No comments recommended. | |
| 11.mm. | MA Capitation Rates and Part D Payment Policies for 2017 ACTION: Notice NOTICE: Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter | CMS (no reference number) | Issue Date: 4/4/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with section 1853(b)(1) of the Social Security Act (Act), this announcement informs Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2017 and the risk and other factors for use in adjusting such rates. The capitation rate tables for 2017 appear on the CMS Web site at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html under Ratebooks and Supporting Data. The statutory component of the regional benchmarks, transitional phase-in periods for ACA rates, qualifying counties, and the applicable percentage for each county also appear on this Web site. A summary of the attachments to this announcement appears below. | |



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| | AGENCY: CMS | | THE Date | | Attachment I shows the final estimates of the National Per Capita MA Growth Percentage for 2017 and the National Medicare Fee-for-Service (FFS) Growth Percentage for 2017, the factors used to calculate the 2017 capitation rates. As discussed in Attachment I, the final estimate of the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 3.08 percent, and the final estimate of the FFS Growth Percentage is 3.12 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentage. Attachment III presents responses to Part C payment-related comments on the Advance Notice of Methodological Changes for CY 2017 MA Capitation Rates and Part C and Part D Payment Policies (Advance Notice). Attachment IV presents responses to Part D payment-related comments on the Advance Notice. Attachment V shows the final Part D benefit parameters and contains details on how they are updated. Attachment VI shows the CMS-HCC and RxHCC Risk Adjustment Factors. Attachment VII presents the final Call Letter. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf A CMS press release on this announcement is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-04-04.html. A CMS fact sheet on this announcement is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-04.html. | |
| 11.nn. | Re-Determination of Part D Low-Income Subsidy Deemed Status | CMS (no reference number) | <u>Issue Date:</u> 7/19/2016 <u>Due Date:</u> | | SUMMARY OF AGENCY ACTION: CMS has begun preparing for the annual redetermination of Medicare Part D low-income subsidy (LIS) deemed status, also known as "re-deeming." This document provides information to help states understand the process and their role in ensuring that dual eligible beneficiaries have timely, affordable, | |



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| | ACTION: Guidance NOTICE: Annual Re- Determination of Medicare Part D Low-Income Subsidy Deemed Status (Re- Deeming) AGENCY: CMS | | None NIHB File Date: Date of Subsequent Agency Action, if any: | | and comprehensive coverage under the Medicare Part D prescription drug benefit. https://www.medicaid.gov/federal-policy-guidance/downloads/cib071516.pdf SUMMARY OF NIHB ANALYSIS: | |
| 12.f. | FAQs on the CO-OP Program ACTION: Guidance NOTICE: Frequently Asked Questions on the Consumer Operated and Oriented Plan (CO-OP) Program AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 1/27/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance answers several frequently asked questions regarding the Consumer Operated and Oriented Plan (CO-OP) Program. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CO-OP-Questions-Final-1-27-16.pdf SUMMARY OF NIHB ANALYSIS: | |
| 13.b. | Acquisition, Protection, and Disclosure of QIO Information ACTION: Request for Comment NOTICE: Acquisition, Protection, and Disclosure of Peer Review Organization Information and Supporting | CMS-R-70 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Information Collection Requirements in HSQ-110, Acquisition, Protection, and Disclosure of Peer Review Organization Information and Supporting Regulations in 42 CFR, Sections 480.104, 480.105, 480.116, and 480.134; Use: The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs) to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. QIOs must provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. Patients, practitioners and providers use the information provided in these notices to: obtain access to the data maintained and collected on them by QIOs; add | |



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| | Regulations AGENCY: CMS | | Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/23/2013; 9/20/2016, 10/26/2016 | | data or make changes to existing QIO data; and reflect in the QIO record the reasons for the its disagreement with a request for amendment from an individual or provider. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11035.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/24/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-07-24/pdf/2013-17821.pdf CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17376.pdf No comments recommended. CMS on 9/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-26/pdf/2016-23157.pdf No comments recommended. | |
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| 13.c. | QIO Reconsiderations and Appeals ACTION: Request for Comment NOTICE: QIO Reconsiderations and Appeals Incentive Program AGENCY: CMS | CMS-R-72 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title: Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; Use: In the event that beneficiaries, providers, physicians, or other practitioners do not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, they can request reconsideration. The information collection requirements at 42 CFR 478.18, 478.34, 478.36, and 478.42 contain procedures for QIOs to use in reconsideration of initial determinations. CMS imposes the information requirements contained in these regulations on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in cases of actively disputed issues. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11035.pdf SUMMARY OF NIHB ANALYSIS: | |



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| | | | issued extension 7/22/2016, 9/26/2016 <u>Due Date:</u> 8/23/2013; 9/20/2016, 10/26/2016 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/24/2013 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-07-24/pdf/2013-17821.pdf CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17376.pdf No comments recommended. CMS on 9/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-26/pdf/2016-23157.pdf No comments recommended. | |
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| 13.d. | Medicare Quality of Care Complaint Form ACTION: Request for Comment NOTICE: Medicare Quality of Care Complaint Form AGENCY: CMS | CMS-10287 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/24/2013, 9/8/2016 Due Date: 8/23/2013; 11/7/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Medicare Quality of Care Complaint Form; <i>Use</i> : In accordance with Section 1154(a)(14) of the Social Security Act, Quality Improvement Organizations (QIOs) must conduct appropriate reviews of all written complaints submitted by Medicare beneficiaries concerning the quality of care received. Beneficiaries will use the Medicare Quality of Care Complaint Form to submit quality of care complaints. This form will establish a standard form for all beneficiaries to utilize and ensure QIOs receive pertinent information to effectively process these complaints. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11035.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/24/2013 issued a extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-24/pdf/2013-17821.pdf CMS on 9/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-08/pdf/2016-21628.pdf No comments recommended. | |



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| 14.c. | Waivers for State Innovation ACTION: Notice NOTICE: Waivers for State Innovation AGENCY: CMS/Treasury | CMS-9936-N | Issue Date: 12/16/2015 Due Date: Open TSGAC File Date: 2/23/2016 Date of Subsequent Agency Action, if any: | TSGAC response: | SUMMARY OF AGENCY ACTION: This guidance relates to Section 1332 of ACA and its implementing regulations. Section 1332 provides the HHS and Treasury Secretaries with the discretion to approve a state proposal to waive specific provisions of the ACA (a State Innovation Waiver), provided the proposal meets certain requirements. In particular, the Secretaries can only exercise their discretion to approve a waiver if they find that the waiver would provide coverage to a comparable number of residents of the state as would occur absent the waiver, would provide coverage at least as comprehensive and affordable as would occur absent the waiver, and would not increase the federal deficit. If approved for the waiver, the state can receive funding equal to the amount of forgone federal financial assistance that would have occurred pursuant to specified ACA programs, known as pass-through funding. States can obtain State Innovation Waivers for effective dates beginning on or after 1/1/2017, with approvals for periods of as long as 5 years and with the possibility of renewal. HHS and Treasury promulgated implementing regulations in 2012. This document provides additional information about the requirements for State Innovation Waivers, the application review procedures, the amount of pass-through funding, certain analytical requirements, and operational considerations. The Departments welcome comments on this guidance and will consider issuing additional guidance in the future if additional clarifications are necessary. https://www.gpo.gov/fdsys/pkg/FR-2015-12-16/pdf/2015-31563.pdf SUMMARY OF NIHB ANALYSIS: Tribal organizations might want to submit comments asking CMS to address the specific impact of State Innovation Waivers on Al/ANs, as recommended in prior comments. An analysis of this guidance appears below. Coverage: The guidance calls for: "Assessment of whether the proposal covers a comparable number of individuals, and those with serious health issues or who have a greater risk of developing serious health iss | See Table C. |



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| | | | | | Affordability: The guidance states: "Increasing the number of state residents with large health care spending burdens would cause a waiver to fail the affordability requirement, even if the waiver would increase affordability for many other state residents. Assessment of whether the proposal meets the affordability requirement also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues. Reducing affordability for these types of vulnerable groups would cause a waiver to fail this requirement, even if the waiver maintained affordability in the aggregate." But no explicit mention of Al/ANs is included in the guidance. | |
| | | | | | <u>Coverage</u> : "The waiver must not decrease the number of individuals with coverage that satisfies EHB requirements, the number of individuals with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services covered under the state's Medicaid and/or CHIP programs Assessment of whether the proposal meets the comprehensiveness requirement also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues." | |
| | | | | | Deficit Neutrality: "Under the deficit neutrality requirement, the projected Federal spending net of Federal revenues under the State Innovation Waiver must be equal to or lower than projected Federal spending net of Federal revenues in the absence of the waiver. The effect on Federal spending includes all changes in Exchange financial assistance and other direct spending, such as changes in Medicaid spending (while holding the state's Medicaid policies constant) that result from the changes made through the State Innovation Waiver. Projected Federal spending under the waiver proposal also includes all administrative costs to the Federal government, including any changes in Internal Revenue Service administrative costs, Federal Exchange administrative costs, or other administrative costs associated with the waiver. Waivers must not increase the Federal deficit over the period of the waiver (which may not exceed 5 years unless renewed) or in total over the ten-year budget plan The ten-year budget plan must describe for both the period of the waiver and for the ten-year budget the projected Federal spending net of Federal revenues under the State Innovation Waiver and the projected Federal spending net of Federal revenues in the absence of the waiver." The assessment does not consider the impact of policy changes that are contingent on | |



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| | | | | | further state action, such as state legislation that is proposed but not yet enacted. It also does not include the impact of changes contingent on other Federal determinations, including approval of Federal waivers pursuant to statutory provisions other than Section 1332. Therefore, the assessment would not take into account changes to Medicaid or CHIP that require separate Federal approval, such as changes in coverage or Federal Medicaid or CHIP spending that would result from a proposed Section 1115 demonstration, regardless of whether the Section 1115 demonstration proposal is submitted as part of a coordinated waiver application with a State Innovation Waiver The assessment does take into account changes in Medicaid and/or CHIP coverage or in Federal spending on Medicaid and/or CHIP that would result directly from the proposed waiver of provisions pursuant to Section 1332, holding state Medicaid and CHIP policies constant A state may submit a coordinated waiver application as provided in 31 CFR 33.102 and 45 CFR 155.1302; in such a case, each waiver will be evaluated independently according to applicable Federal laws." Internal Revenue Service: "Certain changes that affect Internal Revenue Service (IRS) administrative processes may make a waiver proposal not feasible to implement. At this time, the IRS is not generally able to administer different sets of rules in different states. As a result, while a state may propose to entirely waive the application of one or more of the tax provisions listed in Section 1332 to taxpayers in the state, it is generally not feasible to design a waiver that would require the IRS to administer an alteration to these provisions for taxpayers in the state. For example, it is generally not feasible to have the IRS administer a different set of eligibility rules for the premium tax credit for residents of a particular state." Public Input on Waiver Proposals: "Consistent with the statutory provisions of Section 1332, regulations at 31 CFR 33.112 and 45 CFR 155.1312 req | | | |
| 16.b. | Medicaid HCBS Waivers | CMS-2249- | Issue Date: | | SUMMARY OF AGENCY ACTION: This proposed rule would revise Medicaid | | | |

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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | ACTION: Proposed-Final Rule NOTICE: Medicaid; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment; Setting Requirements AGENCY: CMS | P2 F2 | 5/3/2012 Due Date: 6/4/2012 7/2/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 5/3/2012; Final Rule approved by OMB 1/13/2014 | | regulations to define and describe State plan home and community-based services (HCBS) under the Social Security Act (the Act) as added by the Deficit Reduction Act of 2005 and amended by ACA. This rule would offer States new flexibility in providing necessary and appropriate services to elderly and disabled populations. In particular, this rule would not require the eligibility link between HCBS and institutional care that exists under the Medicaid HCBS waiver program. This rule would describe Medicaid coverage of the optional State plan benefit to furnish HCBS and receive Federal matching funds. This proposed rule also would amend Medicaid regulations consistent with the requirements of ACA, which amended the Act to provide authority for a 5-year duration for certain demonstration projects or waivers, at the discretion of the HHS Secretary, when they involve individuals dually eligible for Medicaid and Medicare benefits. In addition, this rule would provide an additional limited exception to the general requirement that payment for services under a State plan go directly to the individual practitioner providing a service when the Medicaid program serves as the primary source of reimbursement for a class of individual practitioners. This exception would allow payments to other parties to benefit the providers by ensuring health, welfare, and training. Finally, this rule would amend Medicaid regulations to provide home and community-based setting requirements of ACA for the Community First Choice State plan option. SUMMARY OF NIHB ANALYSIS: | |
| 16.c. | Home and Community Based Services Waiver ACTION: Request for Comment NOTICE: 1915(c) Home and Community Based Services Waiver AGENCY: CMS | CMS-8003 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title: 1915(c) Home and Community Based Services (HCBS) Waiver; Use: CMS will use the Web-based application to review and adjudicate individual waiver actions. States will use the Web-based application to submit and revise their waiver requests. http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13578.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/16/2013 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 8/16/2013; issued extension 10/31/2016 <u>Due Date:</u> 9/16/2013; 12/30/2016 | | CMS on 10/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26246.pdf No comments recommended. | |
| 20.a. | Assuring Access to Services ACTION: Proposed-Final Rule NOTICE: Medicaid Program; Methods for Assuring Access to Covered Medicaid Services AGENCY: CMS | CMS-2328- PFC | Issue Date: 5/6/2011 Due Date: 7/5/2011 ANTHC File Date: 7/5/2011 Date of Subsequent Agency Action, if any: Issued Final Rule 11/2/2015; issued deadline extension notice 4/12/2016 Due Date: 1/4/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would create a standardized, transparent process for states to follow as part of their broader efforts to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area" as required by section 1902(a)(30)(A) of the Social Security Act (Act). This proposed rule also would recognize, as states have requested, electronic publication as an optional means of communicating proposed rate-setting policy changes in state plan amendments (SPAs) to the public. SUMMARY OF ANTHC ANALYSIS: Although this proposed rule serves as an excellent first step in efforts to provide clearer standards and more actively monitor compliance with sufficiency and access requirements in section 1902(a)(30)(A), additional attention is needed for areas where access currently is inadequate. ANTHC generally approves of the MACPAC-recommended three-part framework for determining service access data elements: 1) information on enrollee needs, 2) availability of care and providers, and 3) utilization of services. In general, the Indian health system serves a patient population very different from that of the mainstream United States. As a result, if consideration was given to the availability of culturally competent care (and not just "care"), this would help ensure that states consider the unique position of Indian health programs and their patients when evaluating their Medicaid programs. ANTHC supports the proposed requirement that states submit Medicaid access data collected during the prior year in support of state plan amendments that reduce payment rates or restructure provider payments in circumstances when the resulting changes could create access issues, but Medicaid access data could vary tremendously from year to year, resulting in skewed statistics. The propose | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | and tribal organizations. In soliciting comments on whether to delete the word "significant" from §447.205(a) on notice requirements, CMS correctly recognizes that it is extraordinarily difficult to determine a uniform threshold as to what constitutes a "significant" proposed change in the methods and standards for setting state payment rates for services. The proposed rule did not ask for comments on the exceptions to notice requirements contained in §447.205(b), but the exception for "changes made to conform to Medicare methods or levels of reimbursement" could exempt actions extremely disruptive to access. CMS proposes to allow states to substitute publication on a Web site for publication in print media. Although the additional notice avenue is useful, substituting it for other forms of notice could raise concerns unless some additional protections are added and conditions are satisfied. Given the significant challenges facing tribal health programs, as well as the critical role of third-party reimbursement to the very solvency of the tribal health system, virtually any change in state reimbursement rates will have a "direct effect" on tribal health programs. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule with comment period provides for a transparent data-driven process for states to document whether they have sufficient Medicaid payments to enlist providers to assure beneficiary access to covered care and services consistent with section 1902(a)(30)(A) of the Social Security Act (Act) and to address issues raised by that process. This final rule with comment period also recognizes electronic publication as an optional means of providing public notice of proposed changes in rates or rate-setting methodologies that the state intends to include in a Medicaid state plan amendment (SPA). CMS has provided an opportunity for comment on whether it should make future adjustments to the provisions setting forth requirements for ongoing state reviews of beneficiary access. http://www.gpo.gov/fdsys/pkg/FR-201 | |
| 20.b. | Data Metrics and | CMS-2328- | <u>Issue Date:</u> | | SUMMARY OF AGENCY ACTION: In this request for information (RFI), CMS seeks | |



| Ref. of Regula | | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| Alternative Pr Access to Ca ACTION: Req Information NOTICE: Med Request for In (RFI)Data Me Alternative Pro Access to Care Medicaid Prog | ocesses for re uest for icaid Program; formation etrics and ocesses for e in the ram | NC | 11/2/2015 Due Date: 1/4/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | public input to inform the potential development of standards with regard to access to covered services for beneficiaries under the Medicaid program. Specifically, CMS requests information on core access to care measures and metrics that it could use to measure access to care for beneficiaries in the Medicaid program (including in fee-for-service and managed care delivery systems) and to develop local, state, and national thresholds and goals to inform and improve access in the program. CMS also seeks feedback on approaches to using the metrics, possibly including setting access goals and thresholds and creating formal processes for beneficiaries to raise access concerns. http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27696.pdf SUMMARY OF NIHB ANALYSIS: | |
| 20.c. FAQs on Accomplementation ACTION: Guide NOTICE: Accomplementation Asked Question AGENCY: CM | dance ess Rule on Frequently ons (FAQs) | CMS (no reference number) | Issue Date: 3/16/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance provides answers to a number of frequently asked questions (FAQs) on implementation of CMS 2328-FC, Method for Assuring Access to Covered Medicaid Service. https://www.medicaid.gov/medicaid-chip-program-information/by-topics/access-to-care/downloads/faq-31616.pdf This final rule, issued on 11/2/2015, is available at http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27697.pdf. A fact sheet on this final rule issued on 10/29/2015 is available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/access-to-care/downloads/access-fact-sheet.pdf. CMS 2328-NC, a related request for information on data metrics and alternative processes for access to care in the Medicaid program issued on 11/2/2015, is available at http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27696.pdf. SUMMARY OF NIHB ANALYSIS: | |



| Ref. # Short Title/Current Status of Regulation/Title/ Agency File Code Issue Date; Due Date & File Date NIHB Response Response Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | application asks for the name of any Indian Tribe, Tribal organization, or urban Indian organization (I/T/U) consulted, the consultation date, and the method/location of the consultation. The State also must upload any copies of the consultation notices sent to I/T/Us. The State does not have to provide any summary of the Tribal comments received and/or its response (if any). After completion of the initial application, MACPro provides the State with a specific submission form that, unlike the general application, is specifically tailored to the exact action or amendments that the State proposes. MACPro also will send the State a notification reminding it to complete this form. After the State submits its final package to CMS, MACPro will assign a CMS point of contact and review team to the SPA. The package is then "dispositioned" for approval, disapproval, and post-approval. Alternatively, if CMS reviews the package and determines a need for additional information, the review team will notify the State, which must resubmit the package to CMS. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/9/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-11-09/pdf/2015-28449.pdf No comments recommended. CMS on 3/28/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-28/pdf/2016-06922.pdf No comments recommended. | |
| 25.c. | Indirect and Direct Graduate Medical Education Costs ACTION: Request for Comment NOTICE: Indirect Medical Education (IME) and | CMS-R-64 | Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Indirect Medical Education (IME) and Supporting Regulations at 42 CFR 412.105; Direct Graduate Medical Education (GME) and Supporting Regulations at 412 CFR 413.75 through 83; <i>Use</i> : Section 1886(d)(5)(B) of the Social Security Act (the Act) requires additional payments under the Medicare Prospective Payment System (PPS) for the indirect medical educational (IME) costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, Title 42, Part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment of the cost of | |



| Ref. | Short Title/Current Status | | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | |
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| # | of Regulation/Title/ Agency | File Code | Due Date & File Date | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | Supporting Regulations; Direct Graduate Medical Education (GME) and Supporting Regulations AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued reinstatement 5/10/2013; issued extension 7/19/2016, 10/31/2016 Due Date: 6/10/2013; 9/19/2016, 11/30/2016 | | direct graduate medical education (GME) activities. CMS determines these payments, which are adjustments (add-ons) to other payments made to a hospital under the PPS, by the number of full-time equivalent (FTE) IRs who work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2011, the estimated Medicare program payments for IME costs amounted to \$6.59 billion. CMS also bases Medicare program payments for GME on the number of FTE-IRs who work at a hospital. In FY 2011, the estimated Medicare program payments for GME costs amounted to \$2.57 billion. http://www.gpo.gov/fdsys/pkg/FR-2013-02-28/pdf/2013-04551.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/10/2013 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11033.pdf CMS on 7/19/2016 issued an extension of this PRA request. In FY 2015, the estimated Medicare program payments for indirect medical education (IME) costs amounted to \$8.38 billion. Medicare program payments for direct graduate medical education (GME) also are based upon the number of FTE-IRs who work at a hospital. In FY 2015, the estimated Medicare program payments for GME costs amounted to \$3.1 billion. https://www.gpo.gov/fdsys/pkg/FR-2016-07-19/pdf/2016-17070.pdf No comments recommended. CMS on 10/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | |
| 25.m. | Geographic Classification | CMS-R-138 | Issue Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: | |
| | Review Board Procedures | | 10/4/2013 | | Reinstatement without change of a currently approved collection; <i>Title</i> : Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting | |
| | ACTION: Request for Comment | | <u>Due Date:</u> 12/3/2013 | | Regulations; <i>Use</i> : The information submitted by the hospitals serves to determine the validity of the hospital requests and the discretion used by the Medicare Geographic Classification Review Board (MGCRB) in reviewing and making decisions regarding | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations AGENCY: CMS | | NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 12/13/2013; issued extension 10/11/2016 Due Date: 1/13/2014; 12/12/2016 | | hospital requests for geographic reclassification. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/13/2013 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-12-13/pdf/2013-29726.pdf A Supporting Statement for this PRA request is available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-138.html. CMS on 10/11/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-11/pdf/2016-24415.pdf No comments recommended. | |
| 25.bb. | Comprehensive Care for Joint Replacement Payment Model ACTION: Proposed-Final Rule NOTICE: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services | CMS-5516- PF | Issue Date: 7/14/2015 Due Date: 9/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction | | SUMMARY OF AGENCY ACTION: This proposed rule would implement a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care for Joint Replacement (CCJR) model, in which acute care hospitals in certain selected geographic areas would receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. The episode of care would include all related care within 90 days of hospital discharge from the joint replacement procedures. CMS believes this model would further its goals in improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures. http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/pdf/2015-17190.pdf An HHS press release on this proposed rule is available at http://www.hhs.gov/news/press/2015pres/07/20150709.html . | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | AGENCY: CMS | | 8/25/2015; issued Final Rule 11/24/2015; issued correction 3/4/2016 | | An HHS fact sheet on this proposed rule is available at http://cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-07-09.html . More information on the CCJR model is available at http://innovation.cms.gov/initiatives/ccjr/ . SUMMARY OF NIHB ANALYSIS: This proposed rule would implement a limited, but important, payment reform under Medicare. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/25/2015 issued a document (CMS-5516-CN) to correct technical and typographical errors that appeared in the proposed rule titled "Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services" and published in the 7/14/2015 FR (80 FR 41198). The comment due date remains unchanged. http://www.gpo.gov/fdsys/pkg/FR-2015-08-25/pdf/2015-20994.pdf CMS on 11/24/2015 issued a final rule that implements a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care for Joint Replacement (CJR) model, in which acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for episodes of care for lower extremity joint replacement (LEJR) or reattachment of a lower extremity. The episode of care will include all related care within 90 days of hospital discharge from the joint replacement procedure. CMS believes this model will further its goals in improving the efficiency and quality of care for Medicare beneficiaries with these common medical procedures. http://www.gpo.gov/fdsys/pkg/FR-2015-11-24/pdf/2015-29438.pdf CMS on 3/4/2016 issued a correcting amendment (CMS-5516-F2) to correct a limited number of technical a | |
| 25.cc. | Revisions to Requirements for Discharge Planning for | CMS-3317-P | <u>Issue Date:</u> 11/3/2015 | | SUMMARY OF AGENCY ACTION: This proposed rule would revise the discharge planning requirements that hospitals, including long-term care hospitals and inpatient rehabilitation facilities, critical access hospitals, and home health agencies must meet to | |

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| Ref. | Short Title/Current Status | File Code | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | NILID Daga |
| # | of Regulation/Title/ | File Code | Due Date & | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | Agency | | File Date | • | | |
| | Hospitals | | Due Date: | | participate in the Medicare and Medicaid programs. This proposed rule also would | |
| | | | 1/4/2016 | | implement the discharge planning requirements of the Improving Medicare Post-Acute | |
| | ACTION: Proposed Rule | | | | Care Transformation Act of 2014. | |
| | | | NIHB File | | | |
| | NOTICE: Medicare and | | <u>Date:</u> None | | SUMMARY OF NIHB ANALYSIS: | |
| | Medicaid Programs; | | 5 | | | |
| | Revisions to Requirements | | Date of | | | |
| | for Discharge Planning for | | <u>Subsequent</u> | | | |
| | Hospitals, Critical Access | | <u>Agency</u> | | | |
| | Hospitals, and Home Health | | Action, if any: | | | |
| | Agencies | | | | | |
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| | AGENCY: CMS | | | | | |
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| 25.dd. | Emergency and Foreign | CMS-1771 | Issue Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: | |
| zs.uu. | Hospital Services | CIVIS-1771 | 9/21/2015 | | Reinstatement without change of a previously approved collection; <i>Title</i> : Emergency and | |
| | Hospital Scivices | | 7/21/2013 | | Foreign Hospital Services; <i>Use</i> : Section 1866 of the Social Security Act (Act) states that | |
| | ACTION: Request for | | Due Date: | | any provider of services must qualify to participate in the Medicare program and qualify | |
| | Comment | | 11/20/2015 | | for payments under Medicare if it files an agreement with the HHS Secretary to meet the | |
| | Comment | | 11/20/2013 | | conditions outlined in this section of the Act. Section 1814(d)(1) of the Act and 42 CFR | |
| | NOTICE: Emergency and | | NIHB File | | 424.100 allow payment of Medicare benefits for a Medicare beneficiary to a | |
| | Foreign Hospital Services | | Date: None | | nonparticipating hospital that does not have an agreement in effect with CMS. These | |
| | 1 oreign 1 tospital Services | | <u>Date.</u> None | | payments can occur if such services were emergency services and if CMS would have to | |
| | AGENCY: CMS | | Date of | | make the payment if the hospital had an agreement in effect and met the conditions of | |
| | AGENOT. ONIS | | Subsequent | | payment. This form is used in connection with claims for emergency hospital services | |
| | | | Agency | | provided by hospitals that do not have an agreement in effect under Section 1866 of the | |
| | | | Action, if any: | | Act. As specified in 42 CFR 424.103(b), before a non-participating hospital can receive | |
| | | | Issued | | payment for emergency services rendered to a Medicare beneficiary, it must submit a | |
| | | | reinstatement | | statement sufficiently comprehensive to support that an emergency existed. Form CMS- | |
| | | | 11/9/2015, | | 1771 contains a series of questions relating to the medical necessity of the emergency. | |
| | | | 2/5/2016 | | The attending physician must attest to the need for the hospitalization under the | |
| | | | 2/3/2010 | | regulatory emergency definition and give clinical documentation to support the claim. | |
| | | | Due Date: | | Togalatory ornorgancy dominator and give amilian documentation to support the daint. | |
| | | | 12/9/2015, | | http://www.gpo.gov/fdsys/pkg/FR-2015-09-21/pdf/2015-23528.pdf | |
| | | | 4/5/2016 | | intermining polygonia of or principal control of the particular contro | |
| | | | 1,5/2010 | | SUMMARY OF NIHB ANALYSIS: No comments recommended | |
| | | | | | SUMMARY OF NIHB ANALYSIS: No comments recommended. | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/19/2015 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2015-11-09/pdf/2015-28448.pdf No comments recommended. CMS on 2/5/2016 issued a reinstatement of this PRA request with no changes. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02278.pdf No comments recommended. | |
| 25.ee. | Design of Survey on Patient Experiences with Care in LTCHs ACTION: Request for Information NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Long-Term Care Hospitals AGENCY: CMS | CMS-3327- NC | Issue Date: 11/20/2015 Due Date: 1/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This request for information will aid in the design and development of a survey regarding patient and family member experiences with the care received in long-term care hospitals (LTCHs). http://www.gpo.gov/fdsys/pkg/FR-2015-11-20/pdf/2015-29622.pdf SUMMARY OF NIHB ANALYSIS: | |
| 25.ff. | Design of Survey on Patient Experiences with Care in IRFs | CMS-3328- NC | Issue Date: 11/20/2015 Due Date: | | SUMMARY OF AGENCY ACTION: This request for information will aid in the design and development of a survey regarding patient and family member experiences with the care received in inpatient rehabilitation facilities (IRFs). | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | ACTION: Request for Information NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Inpatient Rehabilitation Facilities AGENCY: CMS | | 1/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | http://www.gpo.gov/fdsys/pkg/FR-2015-11-20/pdf/2015-29623.pdf SUMMARY OF NIHB ANALYSIS: | |
| | | | | | | |
| 25.gg. | Inpatient Prospective Payment Systems0.2 Percent Reduction ACTION: Notice NOTICE: Medicare Program; Inpatient Prospective Payment Systems; 0.2 Percent Reduction AGENCY: CMS | CMS-1658- NC | Issue Date: 12/1/2015 Due Date: 2/2/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued update 3/18/2016 | | SUMMARY OF AGENCY ACTION: In accordance with the 10/6/2015 court order in Shands Jacksonville Medical Center, Inc., et al. v. Burwell, No. 14-263 (D.D.C.) and consolidated cases that challenge the 0.2 percent reduction in inpatient prospective payment systems (IPPS) rates to account for the estimated \$220 million in additional FY 2014 expenditures resulting from the 2-midnight policy, this notice discusses the basis for the 0.2 percent reduction and its underlying assumptions and invites comments on the same to facilitate further CMS consideration of the FY 2014 reduction. CMS will consider and respond to the comments received in response to this notice, and to comments already received on this issue in a final notice, which the agency will publish by 3/18/2016. http://www.gpo.gov/fdsys/pkg/FR-2015-12-01/pdf/2015-30486.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/18/2016 issued a document (CMS-1658-N) to announce that it has moved for an extension of the 3/18/2016 court-ordered deadline to issue the final notice until 4/27/2016. CMS anticipates publishing the final notice on or before 4/27/2016. https://www.gpo.gov/fdsys/pkg/FR-2016-03-18/pdf/2016-06297.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 25.hh. | Explanation of FY 2004 Outlier Fixed-Loss Threshold ACTION: Notice NOTICE: Medicare Program; Explanation of FY 2004 Outlier Fixed-Loss Threshold as Required by Court Rulings AGENCY: CMS | CMS-1659-N | Issue Date: 1/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued correction 10/14/2016 | | SUMMARY OF AGENCY ACTION: In accordance with court rulings in cases that challenge the federal fiscal year (FY) 2004 outlier fixed-loss threshold rulemaking, this document provides further explanation of certain methodological choices made in the FY 2004 fixed-loss threshold determination. https://www.gpo.gov/fdsys/pkg/FR-2016-01-22/pdf/2016-01309.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/14/2016 issued a document (CMS-1659-CN) to correct a technical error that appeared in the notice published in the January 22, 2016, Federal Register (81 FR 3727) and titled "Medicare Program; Explanation of FY 2004 Outlier Fixed-Loss Threshold as Required by Court Rulings." This document makes the following correction: On page 3728, second column, first partial paragraph, line 12, the phrase "FY 2004 using actual market basket" is corrected to read "FY 2002 using actual market basket". https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24917.pdf | |
| 25.ii. | Hospital Changes to Promote Innovation, etc. ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs: Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care AGENCY: CMS | CMS-3295-P | Issue Date: 6/16/2016 Due Date: 8/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule would update the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These proposals seek to make the requirements conform to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that might exacerbate workforce shortage concerns. Specifically, this proposed rule would revise the conditions of participation (CoPs) for hospitals and CAHs to address: Discriminatory behavior by health care providers that might create real or perceived barriers to care; Use of the term "licensed independent practitioners" (LIPs) that might inadvertently exacerbate workforce shortage concerns; Requirements that do not fully conform to current standards for infection control; Requirements for antibiotic stewardship programs to help reduce inappropriate antibiotic use and antimicrobial resistance; and | |

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| | | | | | The use of quality reporting program data by hospital Quality Assessment and Performance Improvement (QAPI) programs. https://www.gpo.gov/fdsys/pkg/FR-2016-06-16/pdf/2016-13925.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-13.html. SUMMARY OF NIHB ANALYSIS: | |
| 25.jj. | PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospitals and the Long-Term Care Hospitals Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare | CMS-1655- PF CMS-1664-F CMS-1632- F2 | Issue Date: 4/27/2016 Due Date: 6/17/2016 NIHB File Date: 6/17/2016; TTAG and TSGAC also filed comments 6/17/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 8/22/2016; issued correction 10/5/2016, 10/28/2016 | NIHB response: TTAG response: TSGAC response: | SUMMARY OF AGENCY ACTION: This proposed rule would revise the Medicare hospital inpatient prospective payment system (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from continuing agency experience with these systems for FY 2017. Some of the proposed changes would implement certain statutory provisions contained in the Pathway for Sustainable Growth (SGR) Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Notice of Observation Treatment and Implications for Care Eligibility Act of 2015, and other legislation. This proposed rule also provides the estimated market basket update to apply to the rate-of-increase limits for certain hospitals excluded from the IPPS and paid on a reasonable cost basis subject to these limits for FY 2017. This proposed rule would update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2017. In addition, this proposed rule would make changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments to hospitals with rural track training programs. This proposed rule would establish new requirements or revise requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities) participating in Medicare, including related provisions for eligible hospitals and critical access hospitals (CAHs) participating in the Electronic Health Record (EHR) Incentive Program. This proposed rule would update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. This proposed rule also would implement | See Table C. |



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| | AGENCY: CMS | | | | statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announce the implementation of the Frontier Community Health Integration Project Demonstration; and make technical corrections and changes to regulations relating to costs to organizations and Medicare cost reports. The main policies impacted by this proposed rule include: Proposed Changes to Payment Rates under IPPS IPPS Rate Adjustments for Documentation and Coding and Two Midnight Policy Medicare Uncompensated Care Payments Hospital Acquired Conditions (HAC) Reduction Program Hospital Readmissions Reduction Program (HRRP) Notification Procedures for Outpatients Receiving Observation Services Electronic Health Record Incentive Programs and Quality Reporting Hospital Inpatient Quality Reporting (IQR) Program Hospital Value-Based Purchasing (VBP) Program PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program PPS-Exempt Care Hospital Quality Reporting Quality Reporting (IPFQR) Program Care Hospital Quality Reporting Program (LTCH QRP) Interim Final Rule with Comment (IFC), regarding an IFC to implement section 231 of the Consolidated Appropriations Act, 2016 that establishes a temporary exception for certain wound care discharges from the site neutral payment rate (that is, the relatively lower payment rate for LTCH discharges that do not meet the statutory patient level criteria) for certain LTCHs. | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-04-27/pdf/2016-09120.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-18-2.html. A Modern Healthcare article on this proposed rule is available at | |



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| | | | | | http://www.modernhealthcare.com/article/20160418/NEWS/160419922. SUMMARY OF NIHB ANALYSIS: CMS issues this proposed rule annually to update Medicare inpatient hospital and long-term care hospital payment rates. This proposed rule also would implement several recent changes in federal law. The memo embedded below summarizes key elements of this proposed rule, including a critical access hospital initiative in three states. The memo also includes a CMS fact sheet that provides an overview of the elements of this proposed rule. Tribal organizations might want to comment on this proposed rule. | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from continuing CMS experience with these systems for FY 2017. Some of these changes will implement certain statutory provisions contained in the Pathway for Sustainable Growth Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Notice of Observation Treatment and Implications for Care Eligibility Act of 2015, and other legislation. This final rule also provides the estimated market basket update to apply to the rate-of-increase limits for certain hospitals excluded from the IPPS and paid on a reasonable cost basis subject to these limits for FY 2017. This final rule updates the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2017. | |
| | | | | | In addition, this final rule makes changes relating to direct graduate medical education (GME) and indirect medical education payments; establishes new requirements or revising existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities), including related provisions for eligible hospitals and critical access hospitals (CAHs) participating in the Electronic Health Record Incentive Program; updates policies relating to the Hospital Value-Based Purchasing Program, the Hospital Readmissions Reduction | |



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| | | | | | Program, and the Hospital-Acquired Condition Reduction Program; implements statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announces the implementation of the Frontier Community Health Integration Project Demonstration; and makes technical corrections and changes to regulations relating to costs to related organizations and Medicare cost reports. In addition, this final rule provides notice of the closure of three teaching hospitals and the opportunity to apply for available GME resident slots under section 5506 of ACA. Further, this rule finalizes provisions of interim final rules with comment period that relate to a temporary exception for certain wound care discharges from the application of the site neutral payment rate under the LTCH PPS for certain LTCHs; application of two judicial decisions relating to modifications of limitations on redesignation by the Medicare Geographic Classification Review Board; and legislative extensions of the Medicare-dependent, small rural hospital program and changes to the payment adjustment for low-volume hospitals. | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-08-22/pdf/2016-18476.pdf A CMS fact sheet on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-02.html. CMS on 10/5/2016 issued a document to correct technical and typographical errors in the final rule published in the 8/22/2016 FR (81 FR 56761) and titled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Finalization of Interim Final Rules With Comment Period on LTCH PPS Payments for Severe Wounds, Modifications of Limitations on Redesignation by the Medicare Geographic Classification Review Board, and Extensions of Payments to MDHs and Low-Volume Hospitals." https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-24042.pdf | |

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| | | | | | CMS on 10/28/2016 issued a document (CMS-1655-CN3) to corrects a typographical error in the final rule published in the /22/2016 FR (81 FR 56761) and titled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Finalization of Interim Final Rules With Comment Period on LTCH PPS Payments for Severe Wounds, Modifications of Limitations on Redesignation by the Medicare Geographic Classification Review Board, and Extensions of Payments to MDHs and Low-Volume Hospitals," as well as additional typographical errors in a related correction that appeared in the 10/5/2016 FR. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26182.pdf | |
| 25.kk. | Exception for Severe Wound Discharges from LTCHs, et al. ACTION: Interim Final Rule NOTICE: Medicare Program; Temporary Exception for Certain Severe Wound Discharges From Certain Long-Term Care Hospitals Required by the Consolidated Appropriations Act, 2016; Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board AGENCY: CMS | CMS-1664- IFC | Issue Date: 4/21/2016 Due Date: 6/17/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This interim final rule with comment period (IFC) implements section 231 of the Consolidated Appropriations Act of 2016 (CAA), which provides for a temporary exception for certain wound care discharges from the application of the site neutral payment rate under the long-term care hospital (LTCH) prospective payment system (PPS) for certain LTCHs. This IFC also amends current CMS regulations to allow hospitals nationwide to reclassify based on their acquired rural status, effective for reclassifications beginning with FY 2018. Hospitals with an existing Medicare Geographic Classification Review Board (MGCRB) reclassification also will have the opportunity to seek rural reclassification for IPPS payment and other purposes and keep their existing MGCRB reclassification. CMS also will apply the policy in this IFC when deciding before the agency Administrator timely appeals previously denied by MGCRB due to existing regulations, which do not permit simultaneous rural reclassification for IPPS payment and other purposes and MGCRB reclassification. These regulatory changes implement the decisions in <i>Geisinger Community Medical Center v. Secretary, United States Department of Health and Human Services</i> , 794 F.3d 383 (3d Cir. 2015) and <i>Lawrence + Memorial Hospital v. Burwell</i> , No. 15-164, 2016 WL 423702 (2d Cir. 2/4/2015) in a nationally consistent manner. https://www.gpo.gov/fdsys/pkg/FR-2016-04-21/pdf/2016-09219.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |



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| | Inpatient Rehabilitation Facility PPS for FY 2017 ACTION: Proposed Final Rule NOTICE: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017 AGENCY: CMS | CMS-1647- PF | Issue Date: 4/25/2016 Due Date: 6/20/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 8/5/2016; issued correction 8/31/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal FY 2017 as required by statute. As required by section 1886(j)(5) of the Social Security Act, this proposed rule includes the classification and weighting factors for the IRF prospective payment system (IRF PPS) case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2017. CMS also proposes to revise and update quality measures and reporting requirements under the IRF Quality Reporting Program (QRP). https://www.gpo.gov/fdsys/pkg/FR-2016-04-25/pdf/2016-09397.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-21.html. SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule will update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal FY 2017 as required by the Social Security Act (Act). As required by section 1886(j)(5) of the Act, this final rule includes the classification and weighting factors for the IRF prospective payment system (IRF PPS) case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2017. This final rule also revises and updates quality measures and reporting requirements under the IRF quality reporting program (QRP). https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18196.pdf A CMS fact sheet on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-29-3.html. CMS on 8/31/2016 issued a document (CMS-1647-CN) that corrects typographical errors in the final rule published in the 8/5/2016 FR (81 FR 52056) and titled, "Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017." | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-08-31/pdf/2016-20897.pdf | |
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| 25.mm. | Facility PPS Rate Update for FY 2017 ACTION: Notice NOTICE: Medicare Program; FY 2017 Inpatient Psychiatric Facilities Prospective Payment SystemRate Update | CMS-1650-N | Issue Date: 8/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: This notice updates the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs) (which include freestanding IPFs and psychiatric units of an acute care hospital or critical access hospital). These changes apply to IPF discharges occurring during fiscal year 2017. https://www.gpo.gov/fdsys/pkg/FR-2016-08-01/pdf/2016-17982.pdf A CMS fact sheet on this notice is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-28.html. | |
| | AGENCY: CMS | | Action, if any: | | SUMMARY OF NIHB ANALYSIS: | |
| 26. | Medicaid Home Health ACTION: Proposed Final Rule NOTICE: Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health AGENCY: CMS | CMS-2348- PF | Issue Date: 7/12/2011 Due Date: 9/12/2011 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/2/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would revise the Medicaid home health service definition as required by section 6407 of ACA to add a requirement that physicians document the existence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible individual within reasonable timeframes. This proposal would align the timeframes with similar regulatory requirements for Medicare home health services in accordance with section 6407 of ACA and would reflect the commitment of CMS to the general principles of Executive Order 13563, released on 1/18/2011 and titled "Improving Regulation and Regulatory Review." In addition, this rule proposes to amend home health services regulations to clarify the definitions of included medical supplies, equipment, and appliances, as well as clarify that States cannot limit home health services to services delivered in the home, or to services furnished to individuals who are homebound. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule revises the Medicaid home health service definition consistent with section 6407 of ACA and section 504 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to add requirements that, for home health services, physicians document and, for certain | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | medical equipment, physicians or certain authorized non-physician practitioners (NPP) document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes. This final rule also aligns the timeframes for the face-to-face encounter with similar regulatory requirements for Medicare home health services. In addition, this final rule amends the definitions of medical supplies, equipment, and appliances. CMS expects minimal impact with the implementation of section 6407 of ACA and section 504 of MACRA. CMS recognizes that states might have budgetary implications as a result of the amended definitions of medical supplies, equipment, and appliances. Specifically, this final rule might expand coverage of medical supplies, equipment, and appliances under the home health benefit. Under this final rule, items previously covered only under certain sections of the Social Security Act now will fall under the home health benefit. https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01585.pdf | |
| 27.u. | Transitional Reinsurance Program Collections for 2015 ACTION: Guidance NOTICE: The Transitional Reinsurance Program's Contribution Collections for the 2015 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 2/12/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Section 1341 of ACA established a transitional reinsurance program to help stabilize premiums in the individual market inside and outside of the Marketplaces. The transitional reinsurance program collects contributions from health insurance issuers and certain self-insured group health plans (collectively, "contributing entities") at an annual per capita contribution rate to fund reinsurance payments to issuers of non-grandfathered reinsurance-eligible individual market plans, the administrative costs of operating the reinsurance program, and the general fund of the U.S. Treasury for the 2014, 2015, and 2016 benefit years. To meet the targets for the 2015 benefit year, HHS established an annual per capita contribution rate of \$44.00 in the HHS Notice of Benefit and Payment Parameters for 2015 Final Rule. Contributing entities had the option to pay the 2015 benefit year contribution: (1) in one payment remitted no later than 1/15/2016, reflecting \$44.00 per covered life; or (2) in two separate payments, with the first payment due by 1/15/2016, reflecting \$11.00 per covered life. For the 2015 benefit year, HHS anticipates that it will have \$7.7 billion in reinsurance contributions for use as reinsurance payments. Based on submissions from contributing entities for the 2015 benefit year as of 2/3/2016, HHS estimates that it will collect a total of \$6.5 billion. | |



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| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and- Guidance/Downloads/RIC_2015ContributionsGuidance.pdf SUMMARY OF NIHB ANALYSIS: | |
| 27.v. | New System of Records (Risk Adjustment Data Validation) ACTION: Notice NOTICE: Privacy Act of 1974; Report of New System of Records AGENCY: CMS | CMS (no reference number) | Issue Date: 5/3/2016 Due Date: 30 days (approx. 6/2/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, CMS proposes to establish a new system of records (SOR) titled "CMS Risk Adjustment Data Validation System (RAD-V)," System No. 09-70-0511. Under § 1343 of ACA, and the implementing regulations at 45 CFR part 153, CMS will use data collected and maintained in this system to support the audit functions of the risk adjustment program, including validation activities under the risk adjustment data validation program. The RAD-V system will contain personally identifiable information (PII) about individuals who are current or former enrollees in non-grandfathered health plans, including information obtained through the risk adjustment data validation process to establish the relative deviation from the average. https://www.gpo.gov/fdsys/pkg/FR-2016-05-03/pdf/2016-10253.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 27.w. | Evaluation of Training-Stabilization Programs ACTION: Request for Comment NOTICE: Clearance for Evaluation of Stakeholder TrainingHealth Insurance Marketplace and Market Stabilization Programs AGENCY: CMS | CMS-10598 | Issue Date: 6/17/2016 Due Date: 8/16/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Clearance for Evaluation of Stakeholder TrainingHealth Insurance Marketplace and Market Stabilization Programs; Use: CMS remains strongly committed to providing appropriate education and technical outreach to states, issuers, self-insured group health plans and third-party administrators (TPA) participating in the Marketplace and/or market stabilization programs mandated by ACA. CMS continues to engage with stakeholders in the Marketplace to obtain input through satisfaction surveys following stakeholder training events. The survey results will help determine the level of stakeholder satisfaction with trainings, identify any issues with training and technical assistance delivery, clarify stakeholder needs and preferences, and define best practices for training and technical assistance. CMS has developed forms for the 2017 stakeholder events. CMS will continue to modify, enhance, and develop forms for future years based on feedback from stakeholders. | |



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| | | | request 10/14/2016 <u>Due Date:</u> 11/14/2016 | | https://www.gpo.gov/fdsys/pkg/FR-2016-06-17/pdf/2016-14409.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/14/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24814.pdf No comments recommended. | |
| 27.x. | Q&A on HHS-Operated Risk Adjustment Methodology ACTION: Guidance NOTICE: March 31, 2016, HHS-Operated Risk Adjustment Methodology MeetingQuestions & Answers AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/8/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This document sets forth the major questions asked and answered during the 3/31/2016 HHS-Operated Risk Adjustment Methodology Public Meeting (Risk Adjustment Conference). https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf SUMMARY OF NIHB ANALYSIS: | |
| 29.d. | Minimum Value of Eligible Employer-Sponsored Plans ACTION: Proposed Final Rule NOTICE: Minimum Value of Eligible Employer-Sponsored Plans and Other Rules Regarding the Health | REG- 125398 12 REG- 143800-14 TD 9745 | Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent | | SUMMARY OF AGENCY ACTION: This document contains proposed regulations relating to the health insurance premium tax credit enacted by ACA, as amended by the Medicare and Medicaid Extenders Act of 2010, the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011, and the Department of Defense and Full-Year Continuing Appropriations Act, 2011. These proposed regulations affect individuals who enroll in qualified health plans through Affordable Insurance Exchanges (Exchanges) and claim the premium tax credit and Exchanges that make qualified health plans available to individuals and employers. These proposed regulations also provide guidance on determining whether health coverage under an eligible employer-sponsored plan provides minimum value and affect employers that offer health coverage and their employees. | |



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| https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31866.pdf | Credit | | Action, if any: Issued supplement to Proposed Rule 9/1/2015; issued Final Rule 12/18/2015; issued correction 1/15/2016 | SUMMARY OF NIHB ANALYSIS: This proposed rule includes a number of clarifying amendments to the premium tax credit in addition to the proposed regulations for determining acceptable minimum value for employer-sponsored coverage. No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: IRS on 9/1/2015 issued a document that withdraws, in part, a notice of proposed rulemaking published on 5/3/2013 relating to the health insurance premium tax credit enacted by ACA (including guidance on determining whether health coverage under an eligible employer-sponsored plan provides minimum value) and replaces the withdrawn portion with new proposed regulations providing guidance on determining whether health coverage under an eligible employer-sponsored plan provides minimum value. These proposed regulations affect participants in eligible employer-sponsored health plans and employers that sponsor these plans. http://www.gpo.gov/fdsys/pkg/FR-2015-09-01/pdf/2015-21427.pdf This supplemental notice of proposed rulemaking reviews the IRS-imposed requirement to define "minimum value" of employer-sponsored coverage to include both (1) a requirement to cover at least 60 percent of the average costs of the covered services and (2) a requirement to include hospitalization and physician services, effective pursuant to the dates provided in the proposed rule. IRS on 12/18/2015 issued a document that contains final regulations on the health insurance premium tax credit enacted by ACA, as amended by the Medicare and Medicaid Extenders Act of 2010, the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011, and the Department of Defense and Full-Year Continuing Appropriations Act, 2011. These final regulations affect individuals who enroll in qualified health plans (OHPs) through Affordable Insurance Exchanges (Exchanges, or Marketplaces) and claim the health insurance premium tax credit and Exchanges that make OHPs available to individuals and employers. | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | IRS on 1/15/2016 issued a document that contains corrections to final regulations (TD 9745) published in the 12/18/2015 FR (80 FR 78971). As published, the final regulations contain an error that might prove misleading and needs clarification. Accordingly, this document amends 26 CFR part 1. https://www.gpo.gov/fdsys/pkg/FR-2016-01-15/pdf/2016-00701.pdf | |
| 29.s. | Premium Tax Credit ACTION: Proposed Rule NOTICE: Premium Tax Credit NPRM VI AGENCY: IRS | REG- 109086-15 | Issue Date: 7/8/2016 Due Date: 9/6/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 9/14/2016 | | SUMMARY OF AGENCY ACTION: This document contains proposed regulations relating to the health insurance premium tax credit (premium tax credit) and the individual shared responsibility provision. These proposed regulations affect individuals who enroll in qualified health plans through Health Insurance Exchanges (Exchanges, also called Marketplaces) and claim the premium tax credit and Exchanges that make qualified health plans available to individuals and employers. These proposed regulations also affect individuals who qualify for employer-sponsored health coverage and individuals who seek to claim an exemption from the individual shared responsibility provision because of unaffordable coverage. Although rules governing the premium tax credit do not directly affect employers, these proposed regulations might indirectly affect employers through the employer shared responsibility provisions and the related information reporting provisions. https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-15940.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. A summary of the major provisions of this proposed rule appears below. Indian-Specific Provisions This proposed rule does not include any Indian-specific provisions. Summary of Major Provisions 1. Effective/Applicability Date: Except as otherwise indicated, these proposed regulations would apply for taxable years beginning after December 31, 2016. 2. Eligibility • a. Applicable Taxpayers: To reduce the likelihood that individuals who | |



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| | | | | | recklessly or intentionally provide inaccurate information to an Exchange will benefit from an Exchange determination, these proposed regulations provide that a taxpayer whose household income is below 100 percent of the FPL would not be treated as an applicable taxpayer if, with intentional or reckless disregard for the facts, the taxpayer provided incorrect information to an Exchange for the year of coverage. • b. Exchange Determination of Ineligibility for Medicaid or CHIP: To reduce the likelihood that individuals who recklessly or intentionally provide inaccurate information to an Exchange will benefit from an Exchange determination, these proposed regulations provide that an individual who is determined or considered ineligible for Medicaid, CHIP, or a similar program (such as a Basic Health Program) by an Exchange could be treated as eligible for coverage under the program if, with intentional or reckless disregard for the facts, the individual (or a person claiming a personal exemption for the individual) provided incorrect information to the Exchange. • c. Nonappropriated Fund Health Benefits Program: These proposed regulations would conform the section 36B regulations to the section 5000A regulations to provide that the Nonappropriated Fund Health Benefits Program of DoD would be treated as an eligible employer-sponsored plan for purposes of determining if an individual is eligible for minimum essential coverage under section 36B (a background memo on this provision is embedded below). | |
| | | | | | d. Eligibility for Employer-Sponsored Coverage for Months During a Plan Year: These proposed regulations would clarify that, if an individual declines to enroll in employer-sponsored coverage for a plan year and does not have the opportunity to enroll in that coverage for one or more succeeding plan years, for purposes of section 36B, the individual would be treated as ineligible for that coverage for the succeeding plan year or years for which there is no enrollment opportunity. e. Excepted Benefits: These proposed regulations would clarify that, for purposes of section 36B, an individual would be considered eligible for coverage under an eligible employer-sponsored plan only if that plan is minimum essential coverage. Taxpayers could rely on this rule for all taxable | |



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| | | | | | years beginning after December 31, 2013. • f. Opt-Out Arrangements and an Employee's Required Contribution: Notice 2015-87 requested comments on the proposed treatment of opt-out arrangements. Because forgoing an unconditional opt-out payment is economically equivalent to forgoing salary pursuant to a salary reduction election, and because §§ 1.36B-2(c)(3)(v) and 1.5000A-3(e)(3)(ii)(A) provide that the employee's required contribution includes the amount of any salary reduction, the proposed regulations adopt the approach described in Notice 2015-87 for opt-out payments made available under unconditional opt-out arrangements and provide that the amount of an opt-out payment made available to the employee under an unconditional opt-out arrangement increases the employee's required contribution. [See 81 FR 44561-4 for a full discussion of this provision, including IRS responses to commenters.] • g. Effective Date of Eligibility for Minimum Essential Coverage When Advance Credit Payments Discontinuance Is Delayed: Under these proposed regulations, if an individual who is enrolled in a qualified health plan for which advance credit payments are made informs the Exchange that the individual is or will soon qualify for other minimum essential coverage and that advance credit payments should be discontinued, but the Exchange does not discontinue advance credit payments for the first calendar month beginning after the month the individual notifies the Exchange, the individual would be treated as eligible for the other minimum essential coverage. Similarly, if a determination is made that an individual is eligible for Medicaid or CHIP but advance credit payments are not discontinued for the first calendar month beginning after the eligibility determination, the individual would be treated as eligible for Medicaid or CHIP no earlier than the first day of the second calendar month beginning after the determination. Taxpayers could rely on this rule for all taxable years beginning after December 31, 2013. | |
| | | | | | 3. Premium Assistance Amount | |
| | | | | | a. Payment of Taxpayer's Share of Premiums for Advance Credit Payments Following Appeal Determinations: These proposed regulations provide that a taxpayer who is eligible for advance credit payments pursuant to an eligibility appeal for a member of the taxpayer's coverage family who, based | |



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| | rigency | | | | on the appeals decision, retroactively enrolls in a qualified health plan, would be considered to have met the requirement in § 1.36B-3(c)(1)(ii) for a month if the taxpayer pays the taxpayer's share of the premium for coverage under the plan for the month on or before the 120th day following the date of the appeals decision. Taxpayers could rely on this rule for all taxable years beginning after December 31, 2013. • b. Month That Coverage Is Terminated: To provide consistency for all individuals who have a coverage month that is less than a full calendar month, these proposed regulations provide that the premium assistance amount for a month would be the lesser of the enrollment premium sfor the month (reduced by any amounts that were refunded), or the excess of the benchmark plan premium over the contribution amount for the month. Taxpayers could rely on this rule for all taxable years beginning after December 31, 2013. 4. Benchmark Plan Premium • a. Effective/Applicability Date of Benchmark Plan Rules: The rules relating to the benchmark plan in this section would apply for taxable years beginning after December 31, 2018. • b. Pediatric Dental Benefits: The proposed regulations provide that for taxable years beginning after December 31, 2018, if an Exchange offers one or more silver-level qualified health plans that do not cover pediatric dental benefits, the applicable benchmark plan would be determined by ranking (1) the premiums for the silver-level qualified health plans that include pediatric dental benefits offered by the Exchange and (2) the aggregate of the premium for the silver-level qualified health plans offered by the Exchange. In constructing this ranking, the premium for the lowest-cost silver plan that does not include pediatric dental benefits for the lowest cost stand-alone dental plan, and similarly, the premium for the second lowest-cost silver plan that does not include pediatric dental benefits would be added to the premium allocable to pediatric dental benefits for the second lowes | |



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| | rigency | | | | § 1.36B-3(f)(4) of these proposed regulations, if a taxpayer's coverage family members reside in multiple locations, whether within the same state or in different states, the taxpayer's benchmark plan would be determined based on the cost of available coverage in the locations where members of the taxpayer's coverage family reside. In particular, if members of a taxpayer's coverage family reside in different locations, the taxpayer's benchmark plan premium would be the sum of the premiums for the applicable benchmark plans for each group of coverage family members residing in different locations, based on the plans offered to the group through the Exchange for the rating area where the group resides. If all members of a taxpayer's coverage family reside in a single location that is different from where the taxpayer resides, the taxpayer's benchmark plan premium would be the premium for the applicable benchmark plan for the coverage family, based on the plans offered to the taxpayer's coverage family through the Exchange for the rating area where the coverage family resides. • d. Aggregation of Silver-Level Policies: To clarify and simplify the benchmark premium determination for situations in which a silver-level plan does not cover all the members of a taxpayer's coverage family under one policy, these proposed regulations would delete the existing rule and provide a new rule in its place. Under the proposed regulations, if a silver-level plan offers coverage to all members of a taxpayer's coverage family who reside in the same location under a single policy, the plan premium taken into account for purposes of determining the applicable benchmark plan would be the premium for that policy. In contrast, if a silver-level plan would require multiple policies to cover all members of a taxpayer's coverage family who reside in the same location, the plan premium taken into account for purposes of determining the applicable benchmark plan would be the sum of the premium for self-only policies under the proposed regu | |



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| | | | | | e. Silver-Level Plan Not Available for Enrollment: Because stand-alone dental plans would be considered in determining a taxpayer's applicable benchmark plan under these proposed regulations, they would provide consistency in the treatment of qualified health plans and stand-alone dental plans that are closed to enrollment or that terminate during the taxable year. f. Only One Silver-Level Plan Offered to the Coverage Family: Section 1.36B-3(f)(8) of these proposed regulations would clarify that, if there is only one silver-level qualified health plan offered through the Exchange that would cover all members of the taxpayer's coverage family (whether under one policy or multiple policies), that silver-level plan would be used for purposes of the taxpayer's applicable benchmark plan. Similarly, if there is only one stand-alone dental plan offered through the Exchange that would cover all members of the taxpayer's coverage family (whether under one policy or multiple policies), the portion of the premium of that plan that is allocable to pediatric dental benefits would be used for purposes of determining the taxpayer's applicable benchmark plan. | |
| | | | | | 5. Reconciliation of Advance Credit Payments: These proposed regulations clarify that, if advance credit payments are made for coverage of an individual for whom no taxpayer claims a personal exemption deduction, the taxpayer who attests to the Exchange to the intention to claim a personal exemption deduction for the individual, not the individual for whose coverage the advance credit payments were made, would have to file a tax return and reconcile the advance credit payments. | |
| | | | | | Information Reporting a. Two or More Families Enrolled in Single Qualified Health Plan: These proposed regulations would clarify that, when multiple families enroll in a single qualified health plan and advance credit payments are made for the coverage, the enrollment premiums reported by the Exchange for each family would be the family's allocable share of the enrollment premiums, based on the proportion of each family's applicable benchmark plan premium. b. Partial Months of Enrollment: To ensure that reporting of enrollment premiums and benchmark plan premiums is consistent with the rules for calculating the premium assistance amounts for partial months of coverage, these proposed regulations provide that, if an individual is enrolled in a qualified | |



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| | Agency | | THE DATE | | health plan after the first day of a month, generally no value should be reported for the individual's enrollment premium or benchmark plan premium for that month. However, if an individual's coverage in a qualified health plan is terminated before the last day of a month, or an individual is enrolled in coverage after the first day of a month and the coverage is effective on the date of the individual's birth, adoption, or placement for adoption or in foster care, or on the effective date of a court order, an Exchange would have to report the premium for the applicable benchmark plan for a full month of coverage (excluding the premium allocated to benefits in excess of essential health benefits). In addition, these proposed regulations provide that the Exchange would have to report the enrollment premiums for the month (excluding the premium allocated to benefits in excess of essential health benefits), reduced by any amount that was refunded due to the plan's termination. • c. Use of Electronic Media: These proposed regulations would replace the general reference in § 301.6011-2(b) to the forms in the 1095 series with specific references to Forms 1095-B and 1095-C, but not Form 1095-A, as this is not an information return. SUMMARY OF SUBSEQUENT AGENCY ACTION: IRS on 9/14/2016 issued a document to correct errors in the notice of proposed rulemaking (NPRM) published in the 7/8/2016 FR (81 FR 44557). As published, the NPRM contains errors that require clarification. Accordingly, this document makes the following corrections: 1. On page 44566, in the preamble, second column, the eighth to the tenth line from the top of the column, the language "dental benefits is added to the premium allocable to pediatric dental benefits for the lowest-cost portion of the premium for a stand-alone dental plan that is allocable to pediatric dental benefits". 2. On page 44566, in the preamble, second column, fourteenth to the sixteenth line from the top of column, the language "added to the premium allocable to the pediatric d | |
| | | | | | 5. In § 1.36B-3 entries "(m) [Reserved]." and "(n) Effective/applicability date." are | |



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| | | | | | added. On page 44571, third column, the second line of paragraph (e)(1), the language "Except as provided in paragraph (f)(2) of" is corrected to read "Except as provided in paragraph (e)(2) of". On page 44574, third column, the second line of paragraph (n)(1), the language "Except as provided in paragraph (o)(2)" is corrected to read "Except as provided in paragraph (n)(2)". On page 44574, third column, paragraph (n)(2) of § 1.36B-3 is corrected to read as follows: (n) * * (2) Paragraphs (c)(4), (d)(1) and (2) apply to taxable years beginning after December 31, 2016. Paragraph (f) of this section applies to taxable years beginning after December 31, 2018. Paragraphs (d)(1) and (2) of § 1.36B-3 as contained in 26 CFR part I edition revised as of April 1, 2016, apply to taxable years ending after December 31, 2013, and beginning before January 1, 2017. Paragraph (f) of § 1.36B-3 as contained in 26 CFR part I edition revised as of April 1, 2016, applies to taxable years ending after December 31, 2013, and beginning before January 1, 2019. https://www.gpo.gov/fdsys/pkg/FR-2016-09-14/pdf/2016-22067.pdf | | |
| 29.t. | Information Reporting of Catastrophic Health Coverage ACTION: Proposed Rule NOTICE: Information Reporting of Catastrophic Health Coverage and Other Issues Under Section 6055 AGENCY: IRS | REG- 103058-16 | Issue Date: 8/2/2016 Due Date: 10/3/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This document contains proposed regulations relating to information reporting of minimum essential coverage under section 6055 of the Internal Revenue Code (Code). Health insurance issuers, certain employers, and others that provide minimum essential coverage to individuals must report to the IRS information about the type and period of coverage and furnish related statements to covered individuals. These proposed regulations affect health insurance issuers, employers, governments, and other persons that provide minimum essential coverage to individuals. https://www.gpo.gov/fdsys/pkg/FR-2016-08-02/pdf/2016-18100.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | | |



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| 31.q. | Exchange Functions: Eligibility for Exemptions ACTION: Request for Comment NOTICE: Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions AGENCY: CMS | CMS-10466 See also 31.e. | Issue Date: 10/16/2013 Due Date: 11/15/2013 TTAG File Date: 11/15/2013 Date of Subsequent Agency Action, if any: Issued final applications 12/19/2013; issued revision 10/25/2016 Due Date: 12/27/2016 TTAG File Date: 12/30/2013 | TTAG response: TTAG response: | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New Collection: Title: Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions; Use: The data collection and reporting requirements in the final rule "Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions" (CMS-9958-F) address federal requirements that states must meet with regard to the Exchange minimum function of performing eligibility determinations and issuing certificates of exemption from the shared responsibility payment. CMS-9958-F addresses standards related to eligibility, including the exemptions application, verification and eligibility determination process, eligibility redeterminations, options for states to rely on HHS to make eligibility determinations for certificates of exemption, and reporting. The data collection and reporting requirements will allow Exchanges to determine eligibility for, and issue certificates of, exemption and will assist Exchanges, HHS, and IRS in ensuring program integrity and quality improvement. This information collection request seeks OMB approval of the information collection requirements associated with the application described in 45 CFR 155.610. http://www.gpo.gov/fdsys/pkg/FR-2013-10-16/pdf/2013-24476.pdf Draft exemption applications, including the "Application for Exemption from the Shared Responsibility Payment for Members of Federally Recognized Tribes and Other Individuals Who are Eligible to Receive Services from an Indian Health Care Provider (see attachment below)," as well as a Supporting Statement for this PRA request, are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-lems/CMS%E2%80%9310466.html . SUMMARY OF TTAG | See Table C. |



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| | | | | | confusion regarding exemptions for Al/ANs, rather than resolving them. This form requires changes to help simplify and clarify it to make it understandable and usable by its intended audience: Al/ANs who qualify for an exemption. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/19/2013 issued final exemption applications, including the "Application for Exemption for American Indians and Alaska Natives and Other Individuals who are Eligible to Receive Services from an Indian Health Care Provider." CMS on 10/25/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-25/pdf/2016-25678.pdf No comments recommended. | |
| | | | | | No comments recommended. | |
| 31.tt. | Summary of Benefits and Coverage and Uniform Glossary ACTION: Request for Comment NOTICE: Summary of Benefits and Coverage and Uniform Glossary Required Under the Affordable Care Act AGENCY: DoL | DoL (OMB 1210-0147) See also 92.kk. | Issue Date: 2/27/2015 Due Date: 3/30/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2016 Due Date: 3/28/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Affordable Care Act Section 2715 Summary Disclosures; Use: Public Health Service Act section 2715 directed HHS and the Departments of Labor and the Treasury (collectively, the Departments), in consultation with the National Association of Insurance Commissioners (NAIC) and a working group comprised of stakeholders, to develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, and policyholders and certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. The subject information collection relates to the provision of the following: A summary of benefits and coverage, which includes coverage examples; a uniform glossary of health coverage and medical terms; and notice of modifications. Group health plans and health insurance issuers must use the Summary of Benefits and Coverage template and instructions for completing the template, as authorized by the Departments, to satisfy the section 2715 disclosure requirements. ACA section 2715 authorizes this information collection. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04094.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: DoL on 2/26/2016 issued a revision | |



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| | | | | | of this PRA request. According to DoL, as required by section 2715, the Departments consulted NAIC to provide further input before finalizing revisions to the SBC template and associated documents. The Departments now plan to finalize the templates and glossary and seek OMB approval for the revised information collection, so that plans and issuers can begin using the revised forms for making the disclosures under PHS Act section 2715 and the implementing regulations. https://www.gpo.gov/fdsys/pkg/FR-2016-02-26/pdf/2016-04318.pdf | |
| 31.ddd. | 2017 Actuarial Value Calculator ACTION: Guidance NOTICE: Draft 2017 Actuarial Value Calculator AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 11/20/2015 Due Date: 12/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 1/21/2016 | | SUMMARY OF AGENCY ACTION: Under the Essential Health Benefits, Actuarial Value, and Accreditation final rule (EHB Final Rule) published in the 2/25/2013 FR (78 FR 12834), HHS requires use of an Actuarial Value (AV) Calculator by issuers of nongrandfathered health insurance plans offered in the individual and small group markets, both inside and outside of the Affordable Insurance Exchanges (or Marketplaces) for the purposes of determining levels of coverage. Section 1302(d)(2)(A) of ACA stipulates calculation of AV based on the provision of essential health benefits (EHB) to a standard population. The statute groups health plans into four tiers: bronze, with an AV of 60 percent; silver, with an AV of 70 percent; gold, with an AV of 80 percent; and platinum, with an AV of 90 percent. The EHB Final Rule allows a <i>de minimis</i> variation of +/- 2 percentage points of AV for each tier. The AV Calculator represents an empirical estimate of the AV calculated in a manner that provides a close approximation to the actual average spending by a wide range of consumers in a standard population. This document details the specific methodologies used in the AV calculation. The first part of this document provides background that includes an overview of the regulation allowing HHS to make updates to the AV Calculator, as well as the updates incorporated into the draft 2017 AV Calculator. In the second part of this document, CCIIO provides a detailed description of the development of the standard population and the AV Calculator methodology. The first section details the data and methods used in constructing the continuance tables used to calculate AV in combination with the user inputs. The second section describes the AV Calculator interface and the calculation of actuarial value based on the interface and the continuance tables. The draft 2017 AV Calculator is available at https://www.cms.gov/CCIIO/Resou | |



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| | | | | | CCIIO will accepting comments on the draft 2017 AV Calculator, as well as the draft 2017 AV Calculator User Guide and the draft 2017 AV Calculator Methodology, until 5 p.m. on 12/7/2015. Interested parties should submit comments to the CMS Actuarial Value email at actuarialvalue@cms.hhs.gov . | |
| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft- 2017-AVC-Methodology-111915.pdf | |
| | | | | | SUMMARY OF NIHB ANALYSIS: | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: Under the Essential Health Benefits, Actuarial Value, and Accreditation final rule (EHB Final Rule) published in the February 25, 2013, Federal Register (78 FR 12834), HHS requires use of an Actuarial Value (AV) Calculator by issuers of non-grandfathered health insurance plans offered in the individual and small group markets, both inside and outside of the Affordable Insurance Exchanges (or Marketplaces) for the purposes of determining levels of coverage. Section 1302(d)(2)(A) of ACA stipulates calculation of AV based on the provision of essential health benefits (EHB) to a standard population. The statute groups health plans into four tiers: bronze, with an AV of 60 percent; silver, with an AV of 70 percent; gold, with an AV of 80 percent; and platinum, with an AV of 90 percent. The EHB Final Rule allows a <i>de minimis</i> variation of +/- 2 percentage points of AV for each tier. The AV Calculator represents an empirical estimate of the AV calculated in a manner | |
| | | | | | that provides a close approximation to the actual average spending by a wide range of consumers in a standard population. This document details the specific methodologies used in the AV calculation. | |
| | | | | | CCIIO has revised this document from the 2016 version to incorporate updates in the final 2017 version, released on January 21, 2016. The first part of this document provides background that includes an overview of the regulation allowing HHS to make updates to the AV Calculator, as well as the updates incorporated into the 2017 AV Calculator. For the second part of the document, CCIIO provides a detailed description of the development of the standard population and the AV Calculator methodology. The first section details the data and methods used in constructing the continuance tables used to calculate AV in combination with the user inputs. The second section describes the AV Calculator interface and the calculation of actuarial value based on the interface and the continuance tables. The final 2017 AV Calculator is available at | |



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| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-AV-Calculator-2017.xlsm. CCIIO notes that the final 2017 AV Calculator does not affect any 2016 plans and will only apply for 2017 plans. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-AVC-Methodology-012016.pdf | |
| 31.fff. | Minimum Essential Coverage Calculation Report and Notices ACTION: Request for Comment NOTICE: Minimum Essential Coverage AGENCY: CMS | CMS-10465 | Issue Date: 3/11/2016 Due Date: 5/10/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/17/2016 Due Date: 7/18/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection: Title: Minimum Essential Coverage; Use: The final rule titled "Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions" and published in the 7/1/2013 FR (78 FR 39494), designates certain types of health coverage as minimum essential coverage. The HHS Secretary can recognize other types of coverage, not statutorily designated and not designated as minimum essential coverage in regulation, as minimum essential coverage if certain substantive and procedural requirements are met. To obtain recognition as minimum essential coverage, the coverage must offer substantially the same consumer protections as those enumerated in the Title I of ACA relating to non-grandfathered, individual health insurance coverage to ensure consumers receive adequate coverage. The final rule requires sponsors of other coverage that seek to have such coverage recognized as minimum essential coverage to adhere to certain procedures. Sponsoring organizations must submit to HHS certain information about their coverage and an attestation that the plan substantially complies with the provisions of Title I of ACA applicable to non-grandfathered individual health insurance coverage. Sponsors also must provide notice to enrollees informing them that the plan has received recognition as minimum essential coverage for the purposes of the individual coverage requirement. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05471.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/17/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-17/pdf/2016-14405.pdf | |



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| | | | | | Under this PRA notice, organizations seeking recognition of the health coverage they sponsor as minimum essential coverage must provide the following information to CMS via an application form Organization and contact information, as follows: 1. Name of the organization sponsoring the plan 2. Name and title of the individual who is authorized to make, and makes, the certification below on behalf of the organization 3. Address of individual named above 4. Phone number of individual named above Plan information, as follows: 1. Number of enrollees 2. Eligibility criteria 3. Cost-sharing requirements, including deductible and out-of-pocket maximum limit 4. Whether the coverage provides all of the essential health benefits (as defined in ACA §1302(b) and its implementing regulations) 5. List of attached plan documentation or other information that demonstrates the coverage sponsored by the organization substantially complies with the provisions of Title I of ACA applicable to non-grandfathered individual health insurance coverage In addition, organizations must sign and submit to CMS a certification statement. The application form is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-application xlsx . The certification statement is available at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10465.html . | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 31.ggg. | FAQs on ACA Implementation (SBC) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation (Part 30) AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/11/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance, prepared jointly by HHS and the Departments of Labor and the Treasury (Departments), answers a frequently asked question (FAQ) regarding new summary of benefits and coverage (SBC) requirements. Public Health Service (PHS) Act section 2715, as added by ACA and incorporated by reference into ERISA and the Internal Revenue Code, directs the Departments to develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage in compiling and providing an SBC that "accurately describes the benefits and coverage under the applicable plan or coverage." On 6/16/2015, the Departments published revised joint final regulations regarding the requirements for the SBC. Separately, on 2/26/2016, the Departments published a coordinated information collection request proposing a new SBC template and instructions, an updated uniform glossary, and other associated materials consistent with the requirements of the Paperwork Reduction Act. Q. What is the intended implementation date for SBCs using the new template and associated documents? A. After the close of the public comment period on March 28, 2016, regarding the proposed SBC template and associated documents that were published on February 26, 2016, the Departments intend to review the comments and finalize the new SBC template and associated documents beginning on February 26, 2016, the Departments intend to review the comments and finalize the new SBC template and associated documents beginning on the first day of the first open enrollment period will be required to use the new SBC template and associated documents beginning on the first day of the first plan years (or, in the individual market, policy years) beginning on or after that date. For plans and issuers that do not use an annual open enrollment period, the new SBC template and associated documents would be required beginning on the first day of the first plan year (or, in the individual market, policy years) | |



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| 31.hhh. | FAQs on SBC Related to Rate Filing and QHP Certification ACTION: Guidance NOTICE: Additional Frequently Asked Questions on the Summary of Benefits and Coverage (SBC) Related to Rate Filing and QHP Certification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/11/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance answers two frequently asked questions (FAQs) on new summary of benefits and coverage (SBC) requirements. • Q1. Which SBC template should issuers include in any filings with state regulators for the 2017 benefit year? A1. Issuers should follow directions from state regulators. Generally, for the individual market, regulators should direct issuers to use the 2012 SBC template, as that is the template that is authorized for use for individual market coverage for the 2017 benefit year which starts on January 1, 2017. • Q2. How should FFM issuers complete the Plans and Benefits Template for 2017 plan year certification that is part of the 2017 QHP Application? A: For fields associated with the "simple fracture" coverage example for the updated SBC template, issuers should enter default values of "\$0" for all costsharing fields to satisfy validation requirements for this scenario. For 2017 coverage, fields associated only with the new SBC template (currently out for 30-day comment, which ends on March 28, 2016), including this coverage example, will not appear on Plan Compare or Window Shopping on HealthCare.gov. For the coverage examples that appear on the 2012 SBC template, issuers should continue to use the 2012 calculator. CMS will provide additional guidance on the Plan and Benefits template as the need arises. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQS-30_final-3-11-16.pdf SUMMARY OF NIHB ANALYSIS: For the 2017 coverage year (1/1/2017-12/31/2017), issuers likely will use the SBC template in place since 2014. | |
| 31.iii. | Tribal Consultation on ACA Employer Shared Responsibility | IRS (no reference number) | Issue Date: 4/20/2016 Due Date: | TSGAC response: | SUMMARY OF AGENCY ACTION: This notice announces that the Department of the Treasury will hold a conference call on 5/13/2016 to engage tribal leaders and their representatives in government-to-government consultation on the employer shared responsibility provisions of ACA. The discussion will focus on the application of the | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | ACTION: Notice NOTICE: Tribal Consultation on the ACA Employer Shared Responsibility Provisions AGENCY: IRS | | None TSGAC File Date: 5/13/2016 Date of Subsequent Agency Action, if any: | | employer shared responsibility provisions to tribal employers. Call Information Date: 5/13/2016 Time: 3 p.m. ET Call number: 888-390-0682 Passcode: 6432 https://www.gpo.gov/fdsys/pkg/FR-2016-03-14/pdf/2016-05761.pdf SUMMARY OF NIHB ANALYSIS: Tribal representatives need to provide IRS with a complete message on their priorities and recommendations. | |
| 31.jjj. | EHBs in ABPs, Eligibility Notices, et al. ACTION: Request for Comment NOTICE: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment AGENCY: CMS | CMS-10468 | Issue Date: 4/1/2016 Due Date: 5/31/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/29/2016 Due Date: 8/29/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; <i>Use</i> : ACA expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). The Exchanges, which became operational on 1/1/2014, enhanced competition in the health insurance market, expanded access to affordable health insurance for millions of U.S. residents, and provided consumers with a place to compare and shop for health insurance coverage. The reporting requirements and data collection in Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment (CMS-2334-F) address: (1) standards related to notices, (2) procedures for the verification of enrollment in an eligible employer-sponsored plan; and (3) other eligibility for qualifying coverage in an eligible employer-sponsored plan; and (3) other eligibility and enrollment provisions to provide detail necessary for state implementation. https://www.gpo.gov/fdsys/pkg/FR-2016-04-01/pdf/2016-07423.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17988.pdf | |
| 31.kkk. | FAQs on Health Insurance Market Reforms (EHBs) ACTION: Guidance NOTICE: Frequently Asked Questions on Health Insurance Market Reforms and Marketplace Standards AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 5/26/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance answers a frequently asked question (FAQ) on essential health benefit (EHB) requirements under ACA. • Q1. For plans that must provide coverage of the essential health benefit package under section 1302(a) of the Affordable Care Act, if an issuer imposes a waiting period before an enrollee can access a covered benefit, is that a violation of the EHB requirements? A1. Yes. We are revising our previously released guidance (May 16, 2014, Frequently Asked Questions on Health Insurance Market Reforms and Marketplace Standards) in which we explained the policy in regard to waiting periods for essential health benefits (EHBs) After further consideration of whether pediatric orthodontia should be excepted from this prohibition on waiting periods, we are revising our policy to no longer allow waiting periods for pediatric orthodontia, as we have determined that the same concerns we previously noted also apply to these benefits. This FAQ supersedes the previously noted FAQ, and it is immediately applicable prospectively to all plans subject to the requirement to provide EHB https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Waiting-period-FAQ-05262016-Finalpdf SUMMARY OF NIHB ANALYSIS: | |
| 31.III. | Indian-Specific CSV Sample SBC Templates ACTION: Guidance NOTICE: Sample Summary of Benefits and Coverage | CCIIO (no reference number) | <u>Issue Date:</u> 3/16/2016 <u>Due Date:</u> 3/18/2016 TTAG File | TTAG response: TTAG response: | SUMMARY OF AGENCY ACTION: CCIIO (Lina Rashid) e-mailed draft sample summary of benefit and coverage (SBC) templates for zero cost-sharing variation (Z-CSV) and limited cost-sharing variation (L-CSV) plans. Once finalized, CCIIO will share these templates with QHP issuers as examples of how to correctly populate the Z-CSV and L-CSV SBCs, although the agency will not mandate their use. SUMMARY OF NIHB ANALYSIS: The SBC documentswhich each QHP issuer will | See Table C. |



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| | (SBC) Templates; Zero Cost-Sharing Variation (Z- CSV) and Limited Cost- Sharing Variation (L-CSV) AGENCY: CCIIO | | Date: 3/18/2016 Date of Subsequent Agency Action, if any: Issued template(s) 4/6/2016 (general), 4/28/2016 (draft Indian- specific); issued final Indian- specific templates 7/13/2016 Due Date: 5/4/2016 TTAG File Date: 5/4/2016 | | release for each plan "variation" offered on a Marketplaceare critical for enrollees to understand how the Indian-specific cost-sharing protections apply (a OHP plan "variation" is a OHP plan with a set of distinct cost-sharing protections, such as the Z-CSV and L-CSV). In a 9/14/2014 letter to CCIIO (embedded below), TTAG previously raised concerns about this issue. According to the letter, Al/ANs, with the assistance of Tribes and tribal health organizations (THOs), have worked to enroll in OHPs offered through Marketplaces. However, the letter notes that the limited and sometimes erroneous information made available through the Marketplace and/or from issuers on the OHP offerings available to Al/ANs, specifically in summary of benefits and coverage (SBC) documents, has imposed a significant impediment to achieving greater enrollment levels. SUMMARY OF SUBSEQUENT AGENCY ACTION: On 4/6/2016, HHS, in conjunction with DoL and the Department of the Treasury, announced key updates to the SBC template and uniform glossary. These updates include an additional coverage example and language and terms to improve consumer understanding of their health coverage. These updates do not include the "sample" SBC templates for Z-CSVs and L-CSVs. Although health insurance issuers do not have to use the updated SBC template and supporting materials until April 2017 (effectively, the 2018 coverage year), CMS likely will finalize the sample SBCs using this template structure at some point soon in 2016. "Applicability: Health plans and issuers that maintain an annual open enrollment period will be required to use the April, 2017 edition of the SBC template and associated documents beginning on the first day of the first open enrollment period that begins on or after April 1, 2017 with respect to coverage for plan years (or, in the individual market, policy years) beginning on or after that date. For plans and issuers that do not use an annual open enrollment period, this SBC template and associated documents is required beginn | |
| | | | | | A CMS press release on the updates to the SBC template and uniform glossary is | |



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| | V | | | | available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases-items/2016-04-06.html . Further information regarding the SBC template, uniform glossary, instructions, and | |
| | | | | | supporting materials is available at (scroll down page) https://www.cms.gov/cciio/Resources/Forms-Reports-and-Other-Resources/index.html#Summary%20of%20Benefits%20and%20Coverage%20and%20Uniform%20Glossary . | |
| | | | | | CCIIO on 4/28/2016 issued draft sample SBC templates for Z-CSV and L-CSV plans (embedded below). Along with these templates, CCIIO noted a revision to the instructions to help make the SBC clearer for Al/ANs: | |
| | | | | | FOR QUALIFIED HEALTH PLANS: For an SBC prepared for a qualified health plan (QHP) offered through a Marketplace, that is an Al/AN limited cost sharing plan, plans must include a box below the coverage examples with the following with language: "Note: These numbers assume the patient received care from an IHCP provider or with IHCP referral at a non-IHCP. If you receive care from a non-IHCP provider without a referral from an IHCP your costs may be higher." | |
| | | | | | SBC 2017 Template SBC 2017 Template AI AN zero 041516.drAI AN limited 041516. | |
| | | | | | The revised instructions are available at https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Individual-Instructions-508-MM.pdf . | |
| | | | | | CMS on 7/13/2016 released sample completed SBCs for a limited cost-sharing variation (L-CSV) plan and a zero cost-sharing variation (Z-CSV) plan. CMS will post these documents on the CCIIO Web site and share them with issuers as a reference tool. In particular, CMS notes a number of additions to the sample completed L-CSV SBC. It | |
| | | | | | shows the cost-sharing the consumer would have at an Indian health care provider (IHCP) or a non-IHCP. The sample completed L-CSV SBC also explains under the limitations, exceptions, and other important information section that, if a consumer goes to an out-of-network provider that charges more than the allowed amount, the consumer might have to pay the difference (often referred to as balance billing). | |



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| | | | | | Lastly, the instructions to the new SBC template released on 4/6/2016 direct issuers to include language below the coverage examples in the limited cost-sharing plan variation SBC to explain that the examples assume that the patient is receiving care from an IHCP or with an IHCP referral at a non-IHCP. This language also explains that the consumer might have higher costs if care is received from a non-IHCP provider without a referral from an IHCP. In addition, on 7/1/2016, CMS released the translated SBC and glossary in four additional languages: Chinese, Spanish, Tagalog, and Navajo (oral and written). The sample completed L-CSV SBC is available at http://files.kauffmaninc.com/projects/cms/documents/SBC_2017_Template_Al_AN_zero_6-7-16_508.pdf . A Dear Tribal Leader Letter on the sample completed L-CSV and Z-CSV SBCs is available at http://files.kauffmaninc.com/projects/cms/documents/dear_tribal_leader_letter_7-13-2016.pdf . | |
| 31.mmm. | Coverage for Contraceptive Services ACTION: Notice NOTICE: Coverage for Contraceptive Services AGENCY: IRS/DoL/CMS | IRS (no reference number) DoL (no reference number) CMS-9931-NC | Issue Date: 7/22/2016 Due Date: 9/20/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This request for information seeks comment on possible alternative ways (other than those offered in current regulations) for eligible organizations that object to providing coverage for contraceptive services on religious grounds to obtain an accommodation, while still ensuring that women enrolled in their health plans have access to seamless coverage of the full range of FDA-approved contraceptives without cost-sharing. IRS, DoL, and CMS have made this request for information in light of the Supreme Court opinion in <i>Zubik v. Burwell</i> , 136 S. Ct. 1557 (2016). https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17242.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |



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| 31.nnn. | 2018 Actuarial Value Calculator ACTION: Guidance NOTICE: Draft 2018 Actuarial Value Calculator AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 8/29/2016 Due Date: 9/30/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: HHS generally requires issuers of nongrandfathered health insurance plans offered in the individual and small group markets, both inside and outside of the Marketplace to use an Actuarial Value (AV) Calculator for the purposes of determining levels of coverage, based on the provision of essential health benefits (EHB) to a standard population. The AV Calculator represents an empirical estimate of the AV calculated in a manner that provides a close approximation to the actual average spending by a wide range of consumers in a standard population. This document details the specific methodologies used in the AV calculation. This document updates the 2017 version. The first part of this document provides background that includes an overview of the regulation allowing HHS to make updates to the AV Calculator, as well as the updates incorporated into the draft 2018 AV Calculator. The second part of this document provides a detailed description of the development of the standard population and the AV Calculator methodology. The first section details the data and methods used in constructing the continuance tables used to calculate AV in combination with the user inputs. The second section describes the AV Calculator interface and the calculation of AV based on the interface and the continuance tables. The draft 2018 AV Calculator is available at http://www.cms.gov/cciio/resources/regulations-and-guidance/index.html . CCIIO notes that the draft 2018 AV Calculator, when finalized, will not affect any 2017 plans and will apply only to 2018 plans. CCIIO will accept comments on the draft 2018 AV Calculator, as well as the draft 2018 AV Calculator is available at https://www.cms.gov/cciio/resources/Regulations-and-Guidance/Downloads/Draft-2018-AVC-Methodology.pdf SUMMARY OF NIHB ANALYSIS: No comments | |
| 31.000. | Health Coverage Tax Credit Hardship Exemption | CCIIO (no reference number) | <u>Issue Date:</u> 8/12/2016 | | SUMMARY OF AGENCY ACTION: This guidance provides information about a hardship exemption that individuals who qualify for the Health Coverage Tax Credit (HCTC) but are not enrolled in HCTC-qualifying health insurance coverage can claim through the tax | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | ACTION: Guidance NOTICE: Guidance on Health Coverage Tax Credit Hardship Exemption AGENCY: CCIIO | | Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | filing process. This hardship exemption applies only for certain months in 2016. The HHS Secretary, in coordination with IRS and the Treasury Department, has determined that any individual not enrolled in HCTC-qualifying health insurance coverage for one or more months between July and December 2016, but would have qualified for HCTC if enrolled, will qualify for a hardship exemption from the individual shared responsibility provision for the months during which he or she was HCTC-eligible. IRS and the Treasury Department intend to publish guidance allowing individuals who qualify for this exemption to claim it on their tax returns. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-Guidance-for-5000A-HCTC.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 36. | Reporting Under Transitional Medical Assistance Provisions ACTION: Request for Comment NOTICE: Reporting Requirements for States Under Transitional Medical Assistance Provisions AGENCY: CMS | CMS-10295 | Issue Date: 3/15/2013 Due Date: 5/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/24/2013; issued extension 5/11/2016, 7/19/2018 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Reporting Requirements for States Under Transitional Medical Assistance (TMA) Provisions; Use: The HHS Secretary must submit annual reports to Congress with information collected from states in accordance with section 5004(d) of the American Recovery and Reinvestment Act of 2009. Medicaid agencies in 50 states complete the reports, and CMS reviews the information to determine if each state has met all of the reporting requirements specified under section 5004(d). CMS has revised this package to remove the requirement to report the Medicaid Federal Medical Assistance Percentage since it no longer needs to collect this information from states. http://www.gpo.gov/fdsys/pkg/FR-2013-03-15/pdf/2013-06038.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/24/2013 issued a revision of this PRA request. CMS has revised this package to remove the requirement to report the Medicaid Federal Medical Assistance Percentage because the agency no longer needs to collect this information from states. http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12465.pdf | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date Due Date: 6/24/2013; 7/11/2016; 8/18/2016 | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis CMS on 5/11/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11078.pdf No comments recommended. CMS on 7/19/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-19/pdf/2016-17059.pdf No comments recommended. | NIHB Recs. |
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| 39.f. | Basic Health Program: Federal Funding Methodology for 2017 ACTION: Proposed Final Methodology NOTICE: Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018 AGENCY: CMS | CMS-2396- PFN | Issue Date: 10/22/2015 Due Date: 11/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Methodology 2/29/2016 | | SUMMARY OF AGENCY ACTION: This document provides the methodology and data sources necessary to determine federal payment amounts made in program years 2017 and 2018 to states that elect to establish a Basic Health Program under ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Marketplaces. http://www.gpo.gov/fdsys/pkg/FR-2015-10-22/pdf/2015-26907.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This document provides the methodology and data sources necessary to determine federal payment amounts made in program years 2017 and 2018 to states that elect to establish a Basic Health Program under ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges (Exchanges). https://www.gpo.gov/fdsys/pkg/FR-2016-02-29/pdf/2016-03902.pdf | |
| 41.f. | New Safe Harbors ACTION: Notice NOTICE: Solicitation of New Safe Harbors and Special Fraud Alerts | OIG-124-N | <u>Issue Date:</u> 12/23/2015 <u>Due Date:</u> 2/22/2016 <u>NIHB File</u> | | SUMMARY OF AGENCY ACTION: In accordance with section 205 of HIPAA, this annual document solicits proposals and recommendations for developing new, and modifying existing, safe harbor provisions under the federal anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new HHS OIG Special Fraud Alerts. https://www.gpo.gov/fdsys/pkg/FR-2015-12-23/pdf/2015-32267.pdf | |

National Indian Health Board

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| | AGENCY: HHS OIG | | Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF NIHB ANALYSIS: | |
| 41.g. | Revisions to State Medicaid Fraud Control Unit Rules ACTION: Proposed Rule NOTICE: Medicaid; Revisions to State Medicaid Fraud Control Unit Rules AGENCY: HHS OIG | HHS OIG RIN 0936- AA07 | Issue Date: 9/20/2016 Due Date: 11/21/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule would amend the regulation governing State Medicaid Fraud Control Units (MFCUs or Units). This proposed rule would incorporate statutory changes affecting MFCUs, as well as policy and practice changes that have occurred since the initial issuance of the regulation in 1978. These changes include a codification of HHS OIG delegated authority and MFCU authority, functions, and responsibilities; disallowances; and issues related to organization, prosecutorial authority, staffing, recertification, and the relationship of MFCUs with Medicaid agencies. https://www.gpo.gov/fdsys/pkg/FR-2016-09-20/pdf/2016-22269.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 43. | Medicaid Reimbursement for Outpatient Drugs ACTION: Proposed Final Rule NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS | CMS-2345- PFC | Issue Date: 2/2/2012 Due Date: 4/2/2012 NIHB File Date: 4/2/2012 Date of Subsequent Agency Action, if any: | NIHB response: NIHB response: | SUMMARY OF AGENCY ACTION: This proposed rule would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of ACA. This proposed rule also would revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program. http://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf SUMMARY OF NIHB ANALYSIS: As the Proposed Rule notes, I/T/U pharmacies can purchase drugs through the Federal Supply Source (FSS) or the 340B programs. The Proposed Rule also notes that these I/T/U pharmacies are then reimbursed under Medicaid State Plans. In the Proposed Rule, CMS indicates that it considered alternative methodologies but chose instead to propose no specific methodologies for the I/T/U programs and instead "to invite public comment on Medicaid payment levels for these | See Table C. |



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| | | | Issued Final Rule 2/1/2016 Due Date: 4/1/2016 NIHB File Date: 4/21/2016 | | facilities." The Proposed Rule goes on to state, however, that CMS is proposing "that States that do not have specific methodologies develop such methodologies for these providers consistent with [CMS'] proposed shift from [estimated acquisition cost (EAC)] to [actual acquisition cost (AAC)]." In addition, the Proposed Rule would require States to submit a State Plan Amendment through the formal review process (including all consultation requirements) when submitting plans to change how dispensing is reimbursed. The Proposed Rule notes that States still would have to substantiate "how their dispensing fee reimbursement to pharmacy providers reasonably reflects the cost of dispensing a drug and will ensure access for these drugs to Medicaid beneficiaries." Most importantly, with regard to dispensing fees, the Proposed Rule would require that, "[w]here the professional dispensing fee might differ because of unique circumstances for 340B covered entities or IHS and tribal pharmacies, the State should look at these circumstances to determine if a different professional dispensing fee is warranted for these entities." SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule implements provisions of ACA pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). This final rule also revises other requirements related to CODs, including key aspects of their Medicaid coverage and payment and the Medicaid drug rebate program. CMS will accept comments on the following subject areas discussed in this final rule: the definition and identification of "line extension drug" at § 447.502. https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf A summary of this final rule is embedded below. CMS presentation on this final rule is embedded below. | |



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| | | | | | Request that CMS in a subsequent guidance document (a) clarify the encounter rate is available to all states, regardless of whether the state currently employs an encounter rate and (b) clarify the application of Federal Supply Schedule rates to payments to THOs; and (2) Prepare a summary document for distribution to T/TOs on recommended steps for T/TOs to review this final rule, evaluate impact on tribal health programs, and possibly advocate adoption of the encounter rate in the state for THOs. | |
| 44.h. | Comprehensive Primary Care Plus Model ACTION: Notice NOTICE: Comprehensive Primary Care Plus (CPC+) Model AGENCY: CMS | CMS (no reference number) | Issue Date: 4/11/2016 Due Date: 9/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This notice announces the launch of the Comprehensive Primary Care Plus (CPC+) model. CMS plans to implement CPC+ in as many as 20 regions to accommodate as many as 5,000 primary care practices, which would encompass more than 20,000 physicians and clinicians and the 25 million patients they serve. CPC+ seeks to provide physicians with the freedom to care for their patients the way they think will deliver the best outcomes and to pay them for achieving results and improving care. Building on the Comprehensive Primary Care initiative started in late 2012, CPC+ over five years will benefit patients by helping primary care practices: • Support patients with serious or chronic diseases in their efforts to achieve health goals; • Give patients 24-hour access to care and health information; • Deliver preventive care; • Engage patients and their families in their own care; and • Work together with hospitals and other clinicians, including specialists, to provide better coordinated care. Primary care practices will participate in CPC+ in one of two tracks. Both tracks will require practices to perform the functions and meet the criteria listed above, but practices in Track 2 also will provide more comprehensive services for patients with complex medical and behavioral health needs, including, as appropriate, a systematic assessment of their psychosocial needs and an inventory of resources and supports to meet those needs. | |



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| Ref. | of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| # | _ | THE GOULE | | Response | and Summary of NIHB Analysis To promote high-quality and high-value care, primary care practices in both CPC+ tracks will receive up-front incentive payments that they will either keep or repay based on their performance on quality and utilization metrics. The payments under this model encourage doctors to focus on health outcomes rather than the volume of visits or tests. Practices in both tracks also will receive data on cost and utilization. Optimal use of health IT and a robust learning system will support them in making the necessary care delivery changes and using the data to improve their care of patients. CMS will select regions for CPC+ with sufficient interest from multiple payers to support the participation of primary care practices. CMS will enter into a memorandum of understanding (MOU) with selected payer partners to document a shared commitment to align on payment, data sharing, and quality metrics in CPC+. CMS will accept payer proposals to partner in CPC+ from April 15, 2016, through June 8, 2016. CMS will accept practice applications in the determined regions from August 1, 2016, through September 15, 2016. https://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Plus A request for applications for CPC+ is available at https://innovation.cms.gov/Files/x/cpcplus-rfa.pdf. A fact sheet on CPC+ is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-11.html. The CPC+ practice care delivery requirements are available at https://innovation.cms.gov/Files/x/cpcplus-practicecaredlyreqs.pdf. The CPC+ certified health IT and Track 2 requirements are available at https://innovation.cms.gov/Files/x/cpcplus-hit-track2reqs.pdf. A document that answers frequently asked questions on CPC+ is available at | MILID RCC3. |
| | | | | | https://innovation.cms.gov/Files/x/cpcplus-faqs.pdf. A CMS press release on CPC+ is available at https://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Plus. | |
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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | A Modern Healthcare article on CPC+ is available at http://www.modernhealthcare.com/article/20160411/NEWS/160419999 . An Advisory Board Company analysis on CPC+ is available at https://www.advisory.com/health-policy/health-policy-vitals/2016/04/the-unanswered-questions-that-will-impact-the-success-of-cpc. SUMMARY OF NIHB ANALYSIS: CPC+ might provide THOs with an opportunity to secure additional revenues when serving Medicare beneficiaries. From Sarah Freeman: "The Comprehensive Primary Care Plus (CPC+) Initiative is a current initiative of CMS. CPC+ is the medical home primary care model, which started in the fall of 2011 and is finishing up this year. There are 7 regions that the initial multi-payor model CPC test was launched. The multi-payer component is important because it is a test of care delivery reform. If you want to get to the medical home and provide medical home care it involves building new capabilities in primary care which costs money. The original CPC model was an upfront payment that paid for care management and other activities. An opportunity for shared savings through the practices in each region if they can decrease the total cost of care, which is an ongoing evaluation model. It is not completed but the model evaluation will be completed this year. The second phase of the model will begin in January 2017. It is proposed as an Alternative Payment Model (APM) in the Medicare Access and CHIP Reauthorization Proposed Rule, so it will be a primary care APM. The payment model care management gives flexibility between 35% and 65%. It allows practices to get more money upfront as a population-based payment to shift delivery of care. If you join the CPC+ you would be in the advanced APM from day one, but you have to be in it for a year before they decide that. Unfortunately CPC | |
| | | | | | enhanced management support. Push is to move as much as possible into primary care to expand what primary care does to the patient, which is the Indian Health Service. There is an initial phase of recruiting payors where the payors identify 20 regions to partner with CMS and align with the model. We have to wait and see if our regions are | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | regions in which the model is enrolled out and we will decide whether we want to participate or not. The CPC model is similar to IPCS, private payors do the reform and sign an MOU with CMS that they will align their payment. The care model focuses on a handful of key changes and is impactful on the system with additions of the principles of IPC. | |
| | | | | | NCQA and the other models focus on structure and processing and to certify the processes where CPC differs and it targeted more towards outcome. To be truly successful you want to commit to adapting and adjusting which are better quality and better patient experience and reduced costs, which is measured by other markers for utilization. It is a model where you can be successfully accredited focusing on changing outcomes for patients. | |
| | | | | | QUESTION: If a Tribal health program is reimbursed at an encounter rate for Medicare are they eligible? | |
| | | | | | ANSWER: It depends on how the FQHCs are using the point of service, this is a Medicare Part B payment and they are able to participate. The encounter rate associated with hospitals comes out of Medicare Part A and that doesn't impact directly. | |
| | | | | | TO DO: Request CMS to schedule an all Tribes call once we know the 20 regions or attach the issue onto the agenda of another CMS call." | |
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| 46 .e. | Final FY 2013 and Preliminary FY 2015 DSH Allotments | CMS-2398-N | <u>Issue Date:</u> 2/2/2016 | | SUMMARY OF AGENCY ACTION: This notice announces the final federal share disproportionate share hospital (DSH) allotments for federal FY 2013 and the preliminary federal share DSH allotments for FY 2015. This notice also announces the final FY 2013 and the preliminary FY 2015 imitations an aggregate DSH payments that states are | |
| | ACTION: Notice | | <u>Due Date:</u> None | | and the preliminary FY 2015 limitations on aggregate DSH payments that states can make to institutions for mental disease and other mental health facilities. In addition, this | |
| | NOTICE: Medicaid Program; Final FY 2013 and | | NIHB File Date: | | notice includes background information describing the methodology for determining the amounts of state FY DSH allotments. | |
| | Preliminary FY 2015 | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01836.pdf | |
| | Disproportionate Share | | Date of | | SUMMARY OF NIHB ANALYSIS: | |
| | Hospital Allotments, and Final FY 2013 and | | Subsequent Agency | | SUIVIIVIANT OF IVIND AIVALTSIS: | |
| | Preliminary FY 2015 | | Action, if any: | | | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Diseases Disproportionate Share Hospital Limits | | | | | |
| | AGENCY: CMS | | | | | |
| 46.f. | Treatment of Third Party Payers in Calculating DSH Uncompensated Care Costs ACTION: Proposed Rule NOTICE: Medicaid Program; Disproportionate Share Hospital Payments Treatment of Third Party Payers in Calculating Uncompensated Care Costs AGENCY: CMS | CMS-2399-P | Issue Date: 8/15/2016 Due Date: 9/14/2016 NIHB File Date: 9/14/2016 Date of Subsequent Agency Action, if any: | NIHB response: | SUMMARY OF AGENCY ACTION: This proposed rule addresses the hospital-specific limitation on Medicaid disproportionate share hospital (DSH) payments under section 1923(g)(1)(A) of the Social Security Act (Act), and the application of such limitation in the annual DSH audits required under section 1923(j) of the Act, by clarifying that the hospital-specific DSH limit is based only on uncompensated care costs. Specifically, this proposed rule would make clearer in the text of the regulation an existing interpretation that uncompensated care costs include only those costs for Medicaid eligible individuals remaining after accounting for payments received by hospitals by or on behalf of Medicaid eligible individuals, including Medicare and other third party payments that compensate the hospitals for care furnished to such individuals. As a result, the hospital-specific limit calculation would reflect only the costs for Medicaid eligible individuals for which the hospital has not received payment from any source (other than state or local governmental payments for indigent patients). https://www.gpo.gov/fdsys/pkg/FR-2016-08-15/pdf/2016-19107.pdf SUMMARY OF NIHB ANALYSIS: Summary/analysis on this proposed rule appears below. Indian-Specific Provisions This proposed rule does not include any Indian-specific provisions. Summary of Major Provisions This proposed rule would clarify the hospital-specific limitation on Medicaid DSH payments under section 1923(g) (1)(A) of the Act and annual DSH audit requirements under section 1923(g) of the Act. Specifically, this proposed rule would modify the terms of the current regulation to make it explicit that "costs" for purposes of calculating hospital-specific DSH limits are costs net of third-party payments received. At § 447.299, this proposed rule would clarify the definition of "Total cost of care for | See Table C. |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | | | | | Medicaid IP/OP services" to specify that the total annual costs of inpatient hospital and outpatient hospital (IP/OP) services must account for all third party payments, including, but not limited to payments by Medicare and private insurance. | |
| | | | | | At least one court has concluded that it unreasonable to interpret the statute as allowing third party payments to get taken into account when calculating the uncompensated care costs of treating Medicaid patients. However, CMS disagrees, maintaining that its interpretation—that all third party payments should get taken into account—better reflects the real economic burden of hospitals treating a disproportionate share of low-income patients and, accordingly, better facilitates the congressional directive of section 1923 of the Act in general and the hospital-specific limit in particular. CMS also believes that the statutory language indicating that costs are "as determined by the Secretary" gives the agency the discretion to take Medicare and other third party payments into account when determining hospital costs for the purpose of calculating Medicaid DSH payments. Nevertheless, in light of the opinion of the court, CMS requests comments on this issue. | |
| | | | | | Analysis CMS in 2008 issued a final rule (CMS-2198-F) to implement the annual DSH audit and reporting requirements established or amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Prior to CMS-2198-F, some states and hospitals had engaged in a practice of excluding both costs and payments associated with Medicaid-eligible individuals with third party coverage, including Medicare, when calculating hospital-specific DSH limits (or including costs while not including payments). Section 1923(g) of the Social Security Act stipulates that DSH payments received by a hospital cannot exceed the uncompensated costs of furnishing hospital services to individuals who are Medicaid-eligible or "have no health insurance (or other source of third party coverage) for the services furnished during the year." | |
| | | | | | The practice of excluding costs and payments associated with Medicaid-eligible individuals with third party coverage led to the artificial inflation of uncompensated care costs and, correspondingly, of hospital-specific DSH limits, allowing some hospitals to receive payments based on the same costs by two payersMedicare (or another third party payer) and Medicaid. CMS-2198-F clarified that all costs and payments associated with individuals dually eligible for Medicare and Medicaid (dual-eligibles), including Medicare payments received by the hospital on behalf of the patients, must enter the calculation of the hospital-specific DSH limit. This proposed rule seeks to reiterate that policy and make explicit within the terms of the regulation that all costs and | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | payments associated with dual-eligibles and individuals with a source of third party coverage must enter the calculation of the hospital-specific DSH limit. Additional Analysis The treatment of IHS appropriations in the calculation of DSH payments for IHS and tribal hospitals has had the (potential) effect of eliminating eligibility for DSH payments for IHS and Tribal facilities. This proposed rule does not address (i.e., correct) this issue, but it might provide an opportunity to clarify. Per Melissa Gower, CMS might have worked through with IHS a DSH calculation process that does not negatively impact the total DSH payments available to IHS and tribal facilities. | |
| 46.g. | Final FY 2014 and Preliminary FY 2016 DSH Allotments ACTION: Notice NOTICE: Medicaid Program; Final FY 2014 and Preliminary FY 2016 Disproportionate Share Hospital Allotments, and Final FY 2014 and Preliminary FY 2016 Institutions for Mental Diseases Disproportionate Share Hospital Limits AGENCY: CMS | CMS-2401-N | Issue Date: 10/26/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This notice announces the final federal share disproportionate share hospital (DSH) allotments for federal FY 2014 and the preliminary federal share DSH allotments for FY 2016, as well as corresponding limitations on aggregate state DSH payments to institutions for mental disease and other mental health facilities. In addition, this notice includes background information describing the methodology for determining the amounts of state DSH allotments. https://www.gpo.gov/fdsys/pkg/FR-2016-10-26/pdf/2016-25813.pdf SUMMARY OF NIHB ANALYSIS: | |
| 48.b. | Medical Loss Ratio Rebate Calculation Report and Notices | CMS-10418 | <u>Issue Date:</u> 12/4/2012 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Annual MLR and Rebate Calculation Report and MLR Rebate Notices; Use: Under Section 2718 of the Affordable Care Act and | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| (| ACTION: Request for Comment NOTICE: Annual MLR and Rebate Calculation Report and MLR Rebate Notices AGENCY: CMS | | Due Date: 2/4/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/22/2013, 11/22/2013, 1/31/2014, 1/30/2015, 4/24/2015, 2/19/2016, 5/25/2016 Due Date: 3/25/2013; 1/21/2014; 3/5/2014; 3/31/2015; 5/26/2015; 4/19/2016; 6/24/2016 | | implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, federal and state taxes and licensing and regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding federal and states taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/22/2013 issued a revision of this PRA request. The 60-day Federal Register notice published on 12/4/2012 (77 FR 71801), pertained to the 2012 MLR Annual Reporting Form and Instructions, and the comment period closed on 2/4/2013. CMS received a total of 4 public comments on 25 specific issues regarding the notice of the revised MLR PRA package. Most of the comments addressed clarifying the instructions or correcting typographical errors, the removal of calculated cells and the ability of issuers to copy and paste data onto the form, and the inclusion of a credibility indicator for small issuers to eliminate the need for small issuers to fill out the complete MLR reporting form. CMS have taken into consideration all of the proposed suggestions and has made changes to the 2012 MLR Annual Reporting Form and Instructions. http://www.gpo.gov/fidsys/pkg/FR-2013-02-22/pdf/2013-04015.pdf CMS on 11/22/2013 issued a revision of this PRA request. Based upon experience in the MLR data collection and evaluation process, CMS has updated its annual burden hour estimates to reflect the actual numbers of submissions, rebates, and rebate notices. The 2013 MLR Reporting Form and instructions also reflect changes for the 2013 reporting year and beyond set forth in the March 2012 update to 45 CFR 158.120(d)(5) regarding aggregation of s | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| Ref. # | | File Code | | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis http://www.gpo.gov/fdsys/pkg/FR-2013-11-22/pdf/2013-28049.pdf CMS on 1/31/2014 issued a revision of this PRA request. According to CMS, the 60-day notice published in the 11/22/2013 FR (78 FR 70059) pertained to the 2013 MLR Annual Reporting Form and Instructions, with comments closing on 1/21/2014. CMS received a total of 2 public comments on 12 specific issues regarding the notice of the revised MLR PRA package. Most of the comments addressed clarifying of the instructions, updates for recent guidance issuance, treatment of Student Health Plans, treatment of ACA fees, adjusted MLR standard experience aggregation, annual mini-med multipliers for credibility determination, reporting for both QIA and non-claims costs, and reporting requirements for businesses in run-off. CMS has considered all of the proposed suggestions and has revised the 2013 MLR Annual Reporting Form and Instructions. http://www.gpo.gov/fdsys/pkg/FR-2014-01-31/pdf/2014-02061.pdf CMS on 1/30/2015 issued a revision of this PRA request. Based upon experience in the MLR data collection and evaluation process, CMS has updated its annual burden hour estimates to reflect the actual numbers of submissions, rebates, and rebate notices. In | NIHB Recs. |
| | | | | | estimates to reflect the actual numbers of submissions, redates, and redate notices. In addition, CMS has updated its annual burden hour estimates to reflect the additional burden related to the risk corridors data submission requirements. The 2014 MLR Reporting Form and instructions reflect changes for the 2014 reporting year and beyond set forth in the March 2013 update to 45 CFR part 158 regarding the MLR reporting and rebate distribution deadlines and the accounting for the transitional reinsurance, risk adjustment, and risk corridors. CMS also has revised the 2014 MLR Reporting Form and instructions to include the reporting elements required under the risk corridors data submission requirements in 45 CFR 153.530. In 2015, issuers likely will send fewer notices and rebate checks to policyholders and subscribers, reducing burden for QHP issuers. However, the requirement to report the risk corridors data will increase burden for QHP issuers. CMS estimates a net reduction in total burden from 294,911 to 271,600. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf CMS on 4/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09591.pdf No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | File Date | | CMS on 2/19/2016 issued an extension of this PRA request. According to CMS, the 2015 MLR Reporting Form and instructions reflect changes for the 2015 reporting/benefit year and beyond. In 2016, issuers likely will submit fewer reports and send fewer notices to policyholders and subscribers, reducing burden on issuers. Conversely, issuers likely will send more rebate checks in the mail to individual market policyholders, increasing burden for some issuers. CMS estimates a net reduction in total burden from 271,600 to 235,148. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03474.pdf No comments recommended. CMS on 5/25/2016 issued an extension of this PRA request. CMS received a total of 3 public comments on a number of specific issues regarding the 60-day notice of the revised PRA package. CMS has taken into consideration all of the comments and has modified the information collection instruments and instructions (the 2015 MLR Annual Reporting Form and Instructions and the 2015 Risk Corridors Plan-Level Data Form and Instructions) to correct minor errors and to provide additional clarifications. https://www.gpo.gov/fdsys/pkg/FR-2016-05-25/pdf/2016-12085.pdf No comments recommended. | |
| 48.f. | Medical Loss Ratio Report for MA Plans and PDPs ACTION: Request for Comment NOTICE: Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) AGENCY: CMS | CMS-10476 | Issue Date: 7/5/2013 Due Date: 9/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); <i>Use</i> : CMS will use the data collection of annual reports provided by plan sponsors for each contract to ensure that beneficiaries receive value for their premium dollar by calculating for each contract medical loss ratio (MLR) and any remittances due for the respective MLR reporting year. CMS will use the recordkeeping requirements to determine plan sponsor compliance with the MLR requirements, including compliance with how plan sponsors report their experience and how they calculate their MLR and any remittances. http://www.gpo.gov/fdsys/pkg/FR-2013-07-05/pdf/2013-16085.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/8/2013 issued a new | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date 11/8/2013; issued revision 9/2/2016 Due Date: 12/9/2013; 11/1/2016 | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-11-08/pdf/2013-26822.pdf CMS on 9/2/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-02/pdf/2016-21199.pdf No comments recommended. | NIHB Recs. |
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| 48.j. | Modification of Treatment of Certain Health Organizations ACTION: Final Rule NOTICE: Modification of Treatment of Certain Health Organizations AGENCY: IRS | TD 9772 | Issue Date: 6/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This document contains final regulations that provide guidance to Blue Cross and Blue Shield organizations, and certain other organizations, on computing and applying the medical loss ratio and the consequences for not meeting the medical loss ratio threshold. The final regulations reflect the enactment of a technical correction to section 833(c)(5) of the Internal Revenue Code by the Consolidated and Further Continuing Appropriations Act of 2015. The final regulations affect Blue Cross and Blue Shield organizations and certain other organizations involved in providing health insurance. https://www.gpo.gov/fdsys/pkg/FR-2016-06-22/pdf/2016-14784.pdf SUMMARY OF NIHB ANALYSIS: | |
| 48.k. | FAQ on MLR and Risk Corridors Data Submission Deadline ACTION: Guidance NOTICE: Medical Loss Ratio and Risk Corridors Data Submission Deadline for the 2015 Benefit Year AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 7/26/2016 Due Date: None NIHB File Date: Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: This guidance answers the frequently asked question about the deadline for submission of medical loss ratio and risk corridors data for the 2015 benefit year. According to this guidance, "Pursuant to 45 CFR 158.110(b), the MLR report for each reporting year must be submitted to HHS by July 31 of the year following the end of an MLR reporting year. Similarly, 45 CFR 153.530(d) states that a Qualified Health Plan (QHP) issuer must submit risk corridors data by July 31 of the year following the benefit year. However, July 31, 2016 falls on a Sunday. Therefore, for the 2015 Reporting and Benefit Year, an issuer may submit its MLR and risk corridors data for the 2015 Benefit Year by 11:59 p.m. ET on Monday, August 1, 2016, which is the first business day following the July 31, 2016 regulatory deadline(s)" | |



| # | of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date Action, if any: | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis Income-Datamatching-FAQ-7-21-16.pdf | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: | |
| 49.a. | Reporting and Returns of Medicare Overpayments ACTION: Proposed Final Rule NOTICE: Medicare Program; Reporting and Returning of Overpayments AGENCY: CMS | CMS-6037- PF | Issue Date: 2/16/2012 Due Date: 4/16/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension notice 2/17/2015; issued Final Rule 2/12/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would require providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date which is 60 days after the date on which the overpayment was identified; or any corresponding cost report is due, if applicable. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/17/2015 issued a document (CMS-6037-RCN) to announce the extension of the timeline for publication of the "Medicare Program; Reporting and Returning of Overpayments" final rule. CMS has issued this notice in accordance with the Social Security Act (the Act), which requires provision of notice in the FR if exceptional circumstances cause the agency to publish a final rule more than 3 years after the publication date of the proposed rule. In this case, the complexity of the rule and scope of comments warrants the extension of the timeline for publication. http://www.gpo.gov/fdsys/pkg/FR-2015-02-17/pdf/2015-03072.pdf CMS on 2/2/2016 issued a final rule that requires providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date 60 days after the date on which identification of the overpayment occurred or the due date of any corresponding cost report, if applicable. The requirements in this rule seek to ensure compliance with applicable statutes, promote the furnishing of high quality care, and protect the Medicare Trust Funds against fraud and improper payments. This final rule provides needed clarity and consistency in the reporting and returning of self-identified overpayments. https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02789.pdf A Modern Healthcare article on this final rule is available at http://www.modernhealthcare.com/article/20160211/NEWS/160219982?utm. | |



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | CMS-838 | Issue Date: 9/17/2010 Due Date: 11/16/2010 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title: Medicare Credit Balance Reporting Requirements and Supporting Regulations in 42 CFR 405.371, 405.378 and 413.20; Use: ACA authorizes the Secretary to request information from providers which is necessary to properly administer the Medicare program, and quarterly credit balance reporting is needed to monitor and control the identification and timely collection of improper payments. The information obtained from Medicare credit balance reports will be used by the contractors to identify and recover outstanding Medicare credit balances and by federal enforcement agencies to protect federal funds, as well as identify the causes of credit balances and to take corrective action. SUMMARY OF NIHB ANALYSIS: All Medicare providers must submit credit balance reports quarterly. The information collection in this PRA request will impose no changes to the burden on providers. | NIHB Recs. |
| | | | 2/22/2013; issued extension 5/16/2016, 7/19/2016 <u>Due Date</u> : 3/25/2013; 7/15/2016; 8/18/2016 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/22/2013 issued a restatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-02-22/pdf/2013-04135.pdf CMS on 5/16/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11499.pdf No comments recommended. CMS on 7/19/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-19/pdf/2016-17059.pdf No comments recommended. | |
| 49.c. | Financial Statement of Debtor | CMS-379 | <u>Issue Date:</u> 6/21/2013 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title: Financial | |



| Ref. # Short Title/Current Status of Regulation/Title/ Agency ACTION: Request for Comment NOTICE: Financial Statement of Debtor and Supporting Regulations: Use: Form CMS-379 collects financial information needed to evaluate requests from physicians and suppliers to pay indebtedness under an extended repayment schedule or to compromise a debt less than the full amount. Normally, when a Medicare Administrative Contractor (MAC) overpays a physician or supplier, the overpayment involves a single claim and a moderate amount. In these cases, the physician or supplier refunds the overpaid amount in a lump sum. Alternatively, the MAC makes payment to the physician or supplier raccepts assignment because the MAC makes payment to the physician or supplier only on assigned claims. AGENCY: CMS AGENCY: CMS AGENCY: CMS AGENCY: CMS AGENCY: CMS Brief Summary of Proposed Agency Action and Summary of NIHB Analysis Statement of Debtor and Supporting Regulations: Use: Form CMS-379 collects financial information needed to evaluate requests from physicians and suppliers to pay indebtedness under an extended repayment schedule or to compromise a debt less than the full amount. Normally, when a Medicare Administrative Contractor (MAC) overpays a physician or supplier refunds the overpaid amount in a lump sum. Alternatively, the MAC makes payment to supplier refunds the overpaid amount in a lump sum. Alternatively, the MAC makes payment to repulsion or supplier accepts assignment because the MAC makes payment to the physician or supplier only on assigned claims. Sometimes, however, the overpayment involves a single claim and a moderate amount. In these cases, the physician or supplier refunds the overpaid mount in a lump sum. Alternatively, the MAC makes payment to the physician or supplier accepts assignment because the MAC makes payment to the physician or supplier only on assigned claims. Sometimes, however, the overpayment involves an exceptionally large amount, and the physician or supplier might lack the ability or feu | | | | | |
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| ACTION: Request for Comment NOTICE: Financial Statement of Debtor and Supporting Regulations AGENCY: CMS AGENCY: CMS Date: Mone Subsequent Regulations AGENCY: CMS AGENC | 3 | File Code | | and Summary of NIHB Analysis | NIHB Recs. |
| CMS on 7/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-16220.pdf No comments recommended. CMS on 10/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | NOTICE: Financial Statement of Debtor and Supporting Regulations | | 8/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/30/2013; issued extension 7/8/2016, 10/31/2016 Due Date: 9/30/2013; 9/6/2016; | information needed to evaluate requests from physicians and suppliers to pay indebtedness under an extended repayment schedule or to compromise a debt less than the full amount. Normally, when a Medicare Administrative Contractor (MAC) overpays a physician or supplier, the overpayment involves a single claim and a moderate amount. In these cases, the physician or supplier refunds the overpaid amount in a lump sum. Alternatively, the MAC might recoup the overpaid amount against future payments. The recoupment can occur only if the physician or supplier accepts assignment because the MAC makes payment to the physician or supplier only on assigned claims. Sometimes, however, the overpayment involves an exceptionally large amount, and the physician or supplier might lack the ability to refund it in a single payment. The MAC cannot recover the overpayment by recoupment if the physician or supplier does not accept assignment of future claims or likely will not file future claims because of going out of business, illness, or death. In these unusual circumstances, the MAC has authority to approve or deny extended repayment schedules for 12 months or recommend that CMS approve schedules for 60 months. Before the MAC takes these actions, it requires full documentation of the financial situation of the physician or supplier. Thus, the physician or supplier must complete form CMS-379. http://www.gpo.gov/fdsys/pkg/FR-2013-06-21/pdf/2013-14878.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/30/2013 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-08-30/pdf/2013-21257.pdf CMS on 7/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-08/pdf/2016-16220.pdf No comments recommended. CMS on 10/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 50.f. | Eligibility and Enrollment for Employees in SHOP ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Employees in SHOP AGENCY: CMS | CMS-10438 See also 50.m. | Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: Issued revision 12/11/2015, 3/25/2016 Due Date: 2/9/2016; 4/25/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program; Use: Section 1311(b)(1)(B) of ACA requires that the Small Business health Option Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health programs (OHPs) offered in the small group market. Section 1311(c)(1)(F) of ACA requires HHS to establish criteria for certification of health plans as QHPs and that these criteria must require plans to utilize a uniform enrollment form that qualified employers may use. Further, section 1311(c)(5)(B) requires HHS to develop a model application and Web site that assists employers in determining whether they qualify to participate in SHOP. HHS has developed a single, streamlined form that employees will use apply to SHOP. Section 155.730 of the Exchanges Final Rule (77 FR 18310) provides more detail about this "single employee application," which will determine employee eligibility. Employees will have to provide the information upon initial application, with subsequent information collections for the purposes of confirming accuracy of or updating information from previous submissions. Information collection will begin during initial open enrollment in October 2013, per § 155.410 of the Exchanges Final Rule. Collection of applications for SHOP will occur year round, per the rolling enrollment requirements of § 155.725 of the Exchanges Final Rule. Employees will have the ability to submit an application for SHOP online, via a paper application, over the phone through a call center operated by an Exchange, or in person through an agent, broker, or Navigator, per § 155.730(f) of the Exchanges Final Rule. Applicants also will have to verify their understanding of the application and sign attestations regarding information in the application. The employer's state will receive completed applications. In resp | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | http://www.gpo.gov/fdsys/pkg/FR-2013-01-29/pdf/2013-01770.pdf CMS-10438 is available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10438.html. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/11/2015 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-11/pdf/2015-31302.pdf No comments recommended. CMS on 3/25/2016 issued a revision of this PRA request. CMS received no comments in response to the 60-day notice for this information collection published in the 12/11/2015 FR (80 FR 76994). https://www.gpo.gov/fdsys/pkg/FR-2016-03-25/pdf/2016-06830.pdf No comments recommended. | |
| 50.g. | Eligibility and Enrollment for Small Businesses in SHOP ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in SHOP AGENCY: CMS | CMS-10439 See also 50.m. | Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in the Small Business Health Options Program; <i>Use</i> : Section 1311(b)(1)(B) of ACA requires that the Small Business health Option Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health programs (QHPs) offered in the small group market. Section 1311(c)(1)(F) of ACA mandates that HHS establish criteria for certification of health plans as QHPs and that these criteria require plans to utilize a uniform enrollment form for qualified employers. Further, section 1311(c)(5)(B) requires HHS to develop a model application and web site that assists employers in determining whether they qualify to participate in SHOP. HHS has developed a single, streamlined form that employers will use apply to SHOP. Section 155.730 of the Exchanges Final Rule provides more detail about this "single employer application," which will determine employer eligibility. | See Table C. |



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| | | | Issued revision 12/11/2015, 3/25/2016 <u>Due Date:</u> 2/9/2016; 4/25/2016 | | Employers will have to provide the information upon initial application, with subsequent information collections for the purposes of confirming accuracy of or updating information from previous submissions. Information collection will begin during initial open enrollment in October 2013, per § 155.410 of the Exchanges Final Rule. Collection of applications for SHOP will occur year round, per the rolling enrollment requirements of § 155.725 of the Exchanges Final Rule. Employers will have the ability to submit an application for SHOP online, via a paper application, over the phone through a call center operated by an Exchange, or in person through an agent, broker, or Navigator, per § 155.730(f) of the Exchanges Final Rule. Applicants also will have to verify their understanding of the application and sign attestations regarding information in the application. The employer's state will receive completed applications. In response to the notice published in the 7/6/2012 FR (77 FR 40061), CMS received public comments from more than 20 entities. Some commenters raised concerns about duplicate or overly burdensome data collection as related to the employer application. CMS has worked with States to minimize any required document submission to streamline and reduce duplication, especially in future years. CMS has considered all of the proposed suggestions and has made changes to this collection of information, such as adding a privacy statement, including information on "doing business as" and information on employer type, and making electronic notices the default option. CMS also has removed some information related to the employer choice of plan offerings and contribution because it is not necessary for an eligibility determination. http://www.gpo.gov/fdsys/pkg/FR-2013-01-29/pdf/2013-01770.pdf CMS-10439 is available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10439.html. SUMMARY OF NIHB ANALYSIS: SUMMARY OF NIHB ANALYSIS: SUMMARY OF NIHB ANALYSIS | |



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| | CMS on 3/25/2016 issued a revision of this PRA request. CMS received no comments in response to the 60-day notice for this information collection published in the 12/11/2015 FR (80 FR 76994). https://www.gpo.gov/fdsys/pkg/FR-2016-03-25/pdf/2016-06830.pdf | | | | | |
| | No comments recommended. | | | | | |
| d e ate ry, on as ne ail, e s e d | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection: <i>Title</i> : Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Affordable Insurance Exchanges, Medicaid and Children's Health Insurance Program Agencies; <i>Use</i> : Section 1413 of ACA directs the Secretary of HHS to develop and provide to each State a single, streamlined form for applying for coverage through the Exchange and Insurance Affordability Programs, including Medicaid, CHIP, and the Basic Health Program, as applicable. The application must maximize the ability of applicants to complete the form satisfactorily, taking into account the characteristics of individuals who qualify for the programs. A State may develop and use its own single streamlined application if approved by the Secretary, in accordance with section 1413, and if it meets the standards established by the Secretary. Section 155.405(a) of the Exchange Final Rule (77 FR 18310) provides more detail about the application that the Exchange must use to determine eligibility and to collect information necessary for enrollment. The regulations in § 435.907 and § 457.330 establish the requirements for State Medicaid and CHIP agencies related to the use of the single, streamlined application. CMS has designed the single, streamlined application as a dynamic online application that will tailor the amount of data required from applicants based on their circumstances and responses to particular questions. CMS has designed a paper version of the application to collect only the data required to determine eligibility. Individuals will have the ability to submit an application online, through the mail, over the phone through a call center, or in person, per § 155.405(c)(2) of the Exchange Final Rule, as well as through other commonly available electronic means as noted in § 435.907(a) and § 457.330 of the Medicaid Final Rule. Individuals can submit the application to an Exchange, Medicaid, or CHIP agency. | | Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: 4/30/2013; issued extension 12/2/2015; issued revision 12/2/2015, 3/25/2016 Due Date: 2/1/2016; 4/25/2016 | CMS-10440 | Eligibility for Insurance Affordability Programs and Enrollment ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment Through Affordable Insurance Exchanges, Medicaid and CHIP Agencies AGENCY: CMS | 50.h. |
| (| about the application that the Exchange must use to determine eligibility and to collect information necessary for enrollment. The regulations in § 435.907 and § 457.330 establish the requirements for State Medicaid and CHIP agencies related to the use of the single, streamlined application. CMS has designed the single, streamlined application as a dynamic online application that will tailor the amount of data required from applicants based on their circumstances and responses to particular questions. CMS hadesigned a paper version of the application to collect only the data required to determine eligibility. Individuals will have the ability to submit an application online, through the majover the phone through a call center, or in person, per § 155.405(c)(2) of the Exchange Final Rule, as well as through other commonly available electronic means as noted in § 435.907(a) and § 457.330 of the Medicaid Final Rule. Individuals can submit the application to an Exchange, Medicaid, or CHIP agency. | | Action, if any: 4/30/2013; issued extension 12/2/2015; issued revision 12/2/2015, 3/25/2016 Due Date: 2/1/2016; | | CHIP Agencies | |



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| | Agency | | File Date | | the application materials, such as moving from categories of data elements to completed draft applications, among others. http://www.gpo.gov/fdsys/pkg/FR-2013-01-29/pdf/2013-01770.pdf CMS-10440 is available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10440.html. Video demonstrations of the online application are available at http://www.youtube.com/user/CMSHHSgov/. SUMMARY OF NIHB ANALYSIS: CMS-10440 contains two Exchange-related paper applications. One of the paper applications is for persons applying for financial assistance (FA). The other paper application is for persons who do not want to apply for financial assistance (non-FA) / do not want to provide information on their finances. There is also a comprehensive list of all questions asked through the online and paper applications. The primary Al/AN-related questions are in Step 4 (page 17) of the FA application and Step 3 (page 5) of the non-FA application. On pages 38 and 41 of the comprehensive list of questions (*508_CMS-10440_Appendix_A_ Individual_Questionnaire*), there are questions pertaining to the identification of persons eligible for Indian-specific benefits. On page 19, there is a question on documenting citizenship status, with the identification of 'Document indicating member of a federally-recognized Indian tribe" as one of the options. On page 22, there is a question on race. On page 24, there is question (Q. 6) on who is Al/AN. On page 31, there are questions on Indian-specific income to be excluded from income calculations for Medicaid and CHIP. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/2/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf No comments recommended. | |
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| | | | | | No comments recommended. | |
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| 50.aa. | SHOP Effective Date and Termination Notice Requirements ACTION: Request for Comment NOTICE: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements AGENCY: CMS | CMS-10555 | Issue Date: 3/9/2015 Due Date: 5/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/14/2015 Due Date: 1/13/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements; Use: CMS requires that, for plan years beginning on or after 1/1/2017, the Small Business Health Options Program (SHOP) must ensure that a qualified health plan (QHP) issuer notifies qualified employees, enrollees, and new enrollees in a QHP through the SHOP of the effective date of coverage. As required by the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameter for 2016 (CMS-9944-F), published on 2/27/2015, if any enrollee has his or her coverage terminated through the SHOP due to non-payment of premiums or a loss of eligibility to participate in the SHOP, the SHOP must notify the enrollee or the qualified employer of the termination of such coverage. In the termination of coverage, the SHOP must include the termination date and reason for termination to the enrollee or qualified employer. http://www.gpo.gov/fdsys/pkg/FR-2015-03-09/pdf/2015-05420.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/14/2015 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-14/pdf/2015-31398.pdf No comments recommended. | |
| 50.ff. | State-Based SHOP Direct | CCIIO (no | Issue Date: | | SUMMARY OF ACENCY ACTION: This guidance extends the entire for state based | |
| 50.11. | ACTION: Guidance NOTICE: Extension of State-Based SHOP Direct Enrollment Transition | reference number) | Issue Date: 4/18/2016 Due Date: None NIHB File Date: | | SUMMARY OF AGENCY ACTION: This guidance extends the option for state-based SHOPs to use direct enrollment as a transitional measure for as long as an additional two yearsfor plan years beginning in 2017 and 2018. This extension only applies to state-based SHOPs that currently utilize direct enrollment. As under prior guidance, state-based Small Business Health Options Programs (SHOPs) interested in continuing the direct enrollment option must submit a plan to CMS. This plan must include a description of how the direct enrollment approach will meet the following three criteria: 1) the employer applies for, and receives, a favorable eligibility | |



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| | AGENCY: CCIIO | | <u>Date of</u> <u>Subsequent</u> <u>Agency</u> <u>Action, if any</u> : | | determination from the SHOP either before or after completion of enrollment; 2) eligible employees and dependents enroll in a SHOP qualified health plan (QHP); and 3) the SHOP QHP issuer conducts enrollment consistent with all SHOP rules and policies. In addition, this plan must include a proposal for implementing SHOP beyond the transitional period. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/1332-and-SHOP-Guidance-508-FINAL.PDF SUMMARY OF NIHB ANALYSIS: | |
| 50.gg. | SBM No Cost Extensions in 2017 ACTION: Guidance NOTICE: Guidance for SBM No Cost Extensions in 2017 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/29/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance provides information for current grantees under section 1311 of ACA on the requirements for requesting a No Cost Extension (NCE). This information supplements the prior CMS guidance titled "FAQs on the Clarification of the Use of 1311 Funds for Establishment Activities" and published in March 2014. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/No-Cost-Extension-Guidance-6-28-16-final.pdf SUMMARY OF NIHB ANALYSIS: | |
| 51.c. | Application of Market Reforms to Student Health Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin Series INFORMATION: Application of the Market Reforms and | CCIIO (no reference number) | Issue Date: 2/5/2016 Due Date: None NIHB File Date: Date of | | SUMMARY OF AGENCY ACTION: This Bulletin provides guidance on the application of certain provisions of the ACA to premium reduction arrangements offered in connection with student health plans and provides temporary transition relief from enforcement by HHS and the Department of Labor (DoL) of the Department of the Treasury (Treasury) (collectively, the Departments) in certain circumstances. On 9/13/2013, DoL published Technical Release 2013-03, addressing the application of the market reforms to health reimbursement arrangements and employer payment plans under the ACA. Treasury and IRS contemporaneously published parallel guidance in Notice 2013-54, and HHS issued guidance stating that it concurs in the application of the | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Other Provisions of the Affordable Care Act to Student Health Coverage AGENCY: CCIIO | | Subsequent Agency Action, if any: | | laws under its jurisdiction as set forth in the guidance issued by DoL and Treasury and IRS. Subsequent guidance reiterated and clarified the application of the market reforms to employer payment plans. This Bulletin provides a transition period for the application of certain market reforms to certain arrangements offered by an institution of higher education to its students designed to reduce the cost of student health coverage (whether insured or self-insured) through a credit, offset, reimbursement, stipend, or similar arrangement (a premium reduction arrangement). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/student-health-bulletin.pdf SUMMARY OF NIHB ANALYSIS: | |
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| 51.d. | Student Health Insurance Coverage ACTION: Request for Comment NOTICE: Student Health Insurance Coverage AGENCY: CMS | CMS-10377 | Issue Date: 3/11/2016 Due Date: 5/10/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/17/2016 Due Date: 7/18/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Student Health Insurance Coverage; <i>Use</i> : Under the Student Health Insurance Coverage Final Rule published 3/21/2012 (77 FR 16453), an issuer that provides student health insurance coverage that does not meet the annual dollar limits requirements under Public Health Service Act (PHS Act) section 2711 must provide notice in the insurance policy or certificate and in any other written materials informing students that the policy being issued does not meet the annual limits requirements under ACA. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule removed outdated provisions in § 147.145(b)(2) and (d) allowing student health insurance issuers to impose restricted annual dollar limits on policies started before 1/1/2014, with an accompanying requirement that student health issuers must provide notice to students. Those provisions, by their own terms, no longer apply, and student health insurance issuers are subject to the prohibition on annual dollar limits under PHS Act section 2711 and § 147.126 for policy years beginning on or after 1/1/2014. Therefore, CMS has discontinued the annual limit notification requirement. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule further provides that, for policy years beginning on or after 7/1/2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of ACA but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage otherwise would satisfy under | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | § 156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05471.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/17/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-17/pdf/2016-14405.pd No comments recommended. | |
| 51.e. | FAQ on ACA Implementation (Student Health Insurance) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation (Part 33) AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 10/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance, prepared jointly by HHS, DoL, and the Department of the Treasury (Departments), answers a frequently asked question (FAQ) regarding student health insurance coverage. Many colleges and universities provide students (typically graduate students) with student health insurance coverage at greatly reduced or no cost as part of their student package, which might include tuition assistance and a stipend for living expenses. For certain students, the school might reduce the cost of coverage through a credit, offset, reimbursement, stipend, or similar arrangement (a premium reduction arrangement). Because the students receiving premium reduction arrangements might perform services for the school providing the premium reduction arrangement, stakeholders have asked whether such an arrangement equates to a group health plan that fails to meet the group market reforms. On 2/5/2016, the Departments issued guidance providing that they will not assert that a premium reduction arrangement fails to satisfy Public Health Service Act (PHS Act) section 2711 or 2713 if the arrangement is offered in connection with other student health insurance coverage (insured or self-insured) for a plan year or policy year beginning before 1/1/2017. Q. Will the Departments' enforcement relief to colleges and universities for certain health care premium reduction arrangements offered in connection with student health plans be extended? A. Yes. Colleges and universities have premium reduction arrangements for graduate | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | student health coverage that are often part of a large and complex admission offer and acceptance process. Additionally, Congress evidenced an intent in the Affordable Care Act to preserve the ability of institutions of higher education to continue offering student health insurance plans otherwise permitted under applicable Federal, State, or local law.10 Accordingly, pending further guidance, the Departments consider it appropriate to further extend the enforcement relief provided in the February 5, 2016 guidance and will not assert that a premium reduction arrangement offered by an institution of higher education fails to satisfy PHS Act section 2711 or 2713 if the arrangement is offered in connection with student health coverage (insured or self-insured). https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQ-Set-33-Final.pdf SUMMARY OF NIHB ANALYSIS: | |
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| 52.d. | Home Health Change of Care Notice ACTION: Request for Comment NOTICE: Home Health Change of Care Notice AGENCY: CMS | CMS-10280 | Issue Date: 12/12/2012 Due Date: 2/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2013; issued extension 10/26/2015, 3/11/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Home Health Change of Care Notice (HHCCN); <i>Use</i> : Home health agencies (HHAs) must provide written notice to original Medicare beneficiaries under various circumstances involving the initiation, reduction, or termination of services, and the Home Health Advance Beneficiary Notice (HHABN) (CMS-R-296) has served as the notice used in these situations. In 2006, CMS added three interchangeable option boxes to HHABN: Option Box 1 addressed liability, Option Box 2 addressed change of care for agency reasons, and Option Box 3 addressed change of care due to provider orders. To streamline, reduce, and simplify notices issued to Medicare beneficiaries, CMS will replace HHABN Option Box 1 with the existing Advanced Beneficiary Notice of Noncoverage (ABN) (CMS-R-131), which providers and suppliers other than HHAs use to inform fee for service (FFS) beneficiaries of potential liability for certain items/services billed to Medicare. CMS will introduce HHCCN (CMS-10280) as a separate, distinct document to provide change of care notice in compliance with HHA conditions of participation. HHCCN will replace both HHABN Option Box 2 and Option Box 3. CMS has designed the single page format of HHCCN to specify whether the change of care results from agency reasons or provider orders. http://www.gpo.gov/fdsys/pkg/FR-2012-12-12/pdf/2012-29951.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | <u>Due Date:</u> 3/28/2013; 12/28/2015; 4/11/2016 | | SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/26/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-02-26/pdf/2013-04313.pdf CMS on 10/26/2015 issued an extension of this PRA request. This iteration contains non-substantive changes that add language informing beneficiaries of their rights under section 504 of the Rehabilitation Act of 1973 by alerting the beneficiary to CMS nondiscrimination practices and the availability of alternate forms of this notice if needed. http://www.gpo.gov/fdsys/pkg/FR-2015-10-26/pdf/2015-27077.pdf No comments recommended. CMS on 3/11/2016 issued an extension of this PRA request. This iteration contains non-substantive changes that add language informing beneficiaries of their rights under section 504 of the Rehabilitation Act of 1973 by alerting the beneficiary to CMS nondiscrimination practices and the availability of alternate forms of this notice if needed. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05472.pdf No comments recommended. | |
| 52.i. | Home Health PPS Rate Update: Physician Narrative Requirement ACTION: Request for Comment NOTICE: Medicare Program- Home Health Prospective Payment System Rate Update for CY 2010: Physician Narrative Requirement and Supporting Regulation | CMS-10311 | Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Medicare ProgramHome Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation; <i>Use</i> : Federal or state surveyors use the conditions of participation and accompanying requirements specified in the regulations as a basis for determining whether a home health agency qualifies for approval or re-approval under Medicare. Contractors and CMS use the physician certification and recertification of the need of the patient for skilled care services and homebound status, clinical justification for skilled nursing management, and evaluation of the care plan specified in the regulations at 42 CFR 424.22 when reviewing the patient medical record as a basis for determining whether the patient qualifies for the Medicare home health benefit and whether the medical record meets the criteria for coverage and Medicare payment. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf | |



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| | AGENCY: CMS | | 12/20/2013, 7/29/2016, 10/7/2016, 10/31/2016 <u>Due Date:</u> 1/21/2014; 9/27/2016; 11/7/2016; 11/30/2016 | | SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/20/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf CMS on 7/29/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17987.pdf CMS on 10/7/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24341.pdf No comments recommended. CMS on 10/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | |
| 52.j. | Moratoria on Enrollment of Ambulances and HHAs ACTION: Notice NOTICE: Medicare, Medicaid, and CHIP: Announcement of New and Extended Temporary Moratoria on Enrollment of Ambulances and Home Health Agencies in Designated Geographic Locations AGENCY: CMS | CMS-6046-N CMS-6047-N CMS-6059- N2 CMS-6059- N3 CMS-6059- N4 CMS-6059- N5 | Issue Date: 2/4/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension notice | | SUMMARY OF AGENCY ACTION: This document announces the imposition of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies in designated geographic locations to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2014-02-04/pdf/2014-02166.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/1/2014 issued a document (CMS-6047-N) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies (HHAs) in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2014-08-01/pdf/2014-18174.pdf CMS on 2/2/2015 issued a document (CMS-6059-N2) to announce the extension of | |



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| | of Regulation/Title/ Agency | File Code | Due Date & File Date 8/1/2014, 2/2/2015, 7/27/2016, 8/3/2016 | | | NIHB Recs. |
| | | | | | of the moratoria on all Part B emergency ground ambulance suppliers. These moratoria, | |
| | | | | | and the changes described in this document, also apply to the enrollment of HHAs and non-emergency ground ambulance suppliers in Medicaid and CHIP. | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-08-03/pdf/2016-18383.pdf | |
| | | | | | A CMS press release on this notice is available at | |



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| | | | | | https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-29-2.html. | |
| 52.1. | Home Health Agency Conditions of Participation ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies AGENCY: CMS | CMS-3819- P F | Issue Date: 10/9/2014 Due Date: 12/8/2014 1/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 12/1/2014; sent Final Rule to OMB 5/6/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would revise the current conditions of participation (CoPs) that home health agencies (HHAs) must meet to participate in the Medicare and Medicaid programs. The proposed requirements would focus on the care delivered to patients by home health agencies, reflect an interdisciplinary view of patient care, allow home health agencies greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes would serve as an integral part of an overall CMS effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while eliminating unnecessary procedural burdens on providers. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/1/2014 issued a notice (CMS-3819-N) that extends the comment period for the proposed rule titled "Conditions of Participation for Home Health Agencies" and published in the 10/9/2014 FR (79 FR 61164). This notice extends the comment period for the proposed rule, which would have ended on 12/8/2014, for 30 days. http://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-28266.pdf | |
| 52.n. | OASIS-C2/ICD-10 ACTION: Request for Comment NOTICE: Outcome and Assessment Information Set (OASIS) OASIS-C2/ICD-10 AGENCY: CMS | CMS-10545 | Issue Date: 1/9/2015 Due Date: 3/10/2015 NIHB File Date: None Date of | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Outcome and Assessment Information Set (OASIS) OASIS-C1/ICD-10; Use: Home health agencies (HHAs) must collect the outcome and assessment information data set (OASIS) to participate in the Medicare program. CMS requests a new OMB control number for the proposed revised OASIS item set, referred to hereafter as OASIS-C1/ICD-10. OMB on 10/7/2014 approved the current version of the OASIS-C1/ICD-9 data set (OMB 0938-0760), which will remain in use until the implementation of the ICD-10 coding system, currently scheduled for 10/1/2015. http://www.gpo.gov/fdsys/pkg/FR-2015-01-09/pdf/2015-00175.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | Subsequent Agency Action, if any: Issued new request 3/25/2015; issued revision 4/1/2016, 6/30/2016 Due Date: 4/24/2015; 5/31/2016; 8/1/2016 | | SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 3/25/2015 issued a new version of this PRA request. Subsequent to the publication of the 60-day notice in the 1/9/2015 FR (80 FR 1419), CMS has made a minor typographical correction to the data set. http://www.gpo.gov/fdsys/pkg/FR-2015-03-25/pdf/2015-06884.pdf CMS on 4/1/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-01/pdf/2016-07423.pdf No comments recommended. CMS on 6/30/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15549.pdf | |
| 52.q. | Home Health Face-to-Face Encounter Clinical Templates ACTION: Request for Comment NOTICE: Home Health Face-to-Face Encounter Clinical Templates AGENCY: CMS | CMS-10564 | Issue Date: 8/12/2015 Due Date: 10/13/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Home Health Face-to-Face Encounter Clinical Templates; Use: CMS requires this collection of data to support the eligibility of Medicare home health services. Home health services are covered under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services consist of part-time, medically necessary skilled care (nursing, physical therapy, occupational therapy, and speech-language therapy) ordered by a physician. CMS has developed a list of clinical elements within a suggested electronic clinical template that would allow electronic health record vendors to create prompts to assist physicians when documenting the home health face-to-face encounter for Medicare purposes. Once completed by the physician, the resulting progress note or clinic note would become part of the medical record. The primary users of these new clinical templates will include physicians and/or allowed non-physician practitioners (NPPs). The templates will help users to capture the necessary information needed to complete the face-to-face encounter documentation. This will help physicians and/or allowed NPPs comply with Medicare policy requirements, thereby reducing the possibility of non-payment of a home health claim because of failure to meet Medicare requirements. http://www.gpo.gov/fdsys/pkg/FR-2015-08-12/pdf/2015-19818.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/28/2015 issued an extension of this PRA request. CMS has revised this information collection request with non-substantive changes since the publication of the 60-day notice in the 8/12/2015 FR (80 FR 48320). https://www.gpo.gov/fdsys/pkg/FR-2015-12-28/pdf/2015-32435.pdf No comments recommended. | |
| 52.r. | Prior Authorization of Home Health Services Demonstration ACTION: Request for Comment NOTICE: Medicare Prior Authorization of Home Health Services Demonstration AGENCY: CMS | CMS-10599 | Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/21/2016 Due Date: 7/21/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Medicare Prior Authorization of Home Health Services Demonstration; Use: Section 402(a)(1)(J) of the Social Security Amendments of 1967 authorizes the HHS Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." In accordance with this authority, CMS seeks to develop and implement a Medicare demonstration project to help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among home health agencies (HHAs) providing services to Medicare beneficiaries. This demonstration will help assure that payments for home health services are appropriate before payment of claims, thereby preventing fraud, waste, and abuse. As part of this demonstration, CMS proposes performing prior authorization before processing claims for home health services in: Florida, Texas, Illinois, Michigan, and Massachusetts. CMS will establish a prior authorization procedure similar to the Prior Authorization of Power Mobility Device (PMD) Demonstration, implemented by CMS the agency in 2012. This demonstration also will follow and adopt prior authorization processes that currently exist in other health care programs, such as TRICARE, certain state Medicaid programs, and in private insurance. The information required under this collection is requested by Medicare contractors to determine proper payment or suspicion of fraud. Medicare contractors will request the information from HHA providers submitting claims for payment from the Medicare program in advance to determine appropriate payment. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02277.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/21/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-21/pdf/2016-14569.pdf | |
| 52.s. | Evaluation of the Medicare Patient IVIG Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration AGENCY: CMS | CMS-10600 See also 52.k. | Issue Date: 2/10/2016 Due Date: 4/11/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/22/2016 Due Date: 5/23/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration; Use: Primary Immune Deficiency Diseases (PIDDs) result from genetic defects that cause a lack of and/or impaired antibody function. Without antibodies, the immune system cannot function effectively. Immunoglobulin (IG) therapy temporarily replaces some of the missing or improperly working antibodies (immunoglobulins) in individuals with PIDD. By special statutory provision, Medicare Part B covers intravenous immunoglobulin (IVIG) for individuals with PIDD who wish to receive the drug in-home, but does not allow for Medicare to cover any of the items and services needed to administer the drug unless the individual is homebound or otherwise receiving services under a Medicare home health episode of care. Therefore, most beneficiaries with PIDD receive treatment at hospital outpatient departments, physician offices, and other outpatient settings. A current alternative to IVIG is subcutaneous immunoglobulin (SCIG), a product that permits some beneficiaries to self-administer the immunoglobulin safely at home without an attending healthcare professional. SCIG at home is reimbursed by Medicare, with limitations. Under the Medicare Patient IVIG Access Demonstration project, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option most appropriate for the beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (e.g., drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration. https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02686.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/22/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-22/pdf/2016-09415.pdf No comments recommended. | |
| 52.t. | Pre-Claim Review Demonstration for Home Health Services ACTION: Notice NOTICE: Medicare Program; Pre-Claim Review Demonstration for Home Health Services AGENCY: CMS | CMS-6069-N | Issue Date: 6/10/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This notice announces a 3-year Medicare pre-claim review demonstration for home health services in the states of Illinois, Florida, Texas, Michigan, and Massachusetts, which have experienced high incidences of fraud and improper payments for these services. https://www.gpo.gov/fdsys/pkg/FR-2016-06-10/pdf/2016-13755.pdf A CMS fact sheet on this notice is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-08-2.html. SUMMARY OF NIHB ANALYSIS: | |
| 52.u. | Home Health PPS Rate Update for CY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based | CMS-1648- PF | Issue Date: 7/5/2016 Due Date: 8/26/2016 NIHB File Date: None Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: This proposed rule would update the home health prospective payment system (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after 1/1/2017. This proposed rule also would: Implement the last year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates; Update the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; Implement the 2nd-year of a 3-year phase-in of a reduction to the national, standardized 60-day episode payment to account for estimated case-mix | |



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| | Purchasing Model; and Home Health Quality Reporting Requirements AGENCY: CMS | | Action, if any: Final Rule approved by OMB 10/26/2016 | | growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014; • Propose changes to the methodology used to calculate outlier payments (with regards to payments made under the HH PPS for high-cost "outlier" episodes of care (i.e., episodes of care with unusual variations in the type or amount of medically necessary care)); and • Propose changes in payment for negative pressure wound therapy (NPWT) performed using a disposable device for patients under a home health plan of care. In addition, this proposed rule discusses CMS efforts to monitor the potential impacts of the rebasing adjustments mandated; includes an update on subsequent research and analysis as a result of the findings from the home health study; solicits comments on a potential process for grouping HH PPS claims centrally during claims processing; and proposes changes to the Home Health Value-Based Purchasing (HHVBP) Model, implemented on 1/1/2016; and proposes updates to the Home Health Quality Reporting Program (HH QRP). | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-07-05/pdf/2016-15448.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-27.html. SUMMARY OF NIHB ANALYSIS: This proposed addresses six HH disciplines: skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services. The Medicare Claims Processing Manual, Chapter 19-Indian Health Services specifically indicates that three of these disciplines (physical therapy, speech-language pathology, occupational therapy) as NOT covered under the all-inclusive rate (AIR). According to 100.11-A/B MAC (A)Physical Therapy, Occupational Therapy, Speech-Language Pathology and Diagnostic Audiology Services-Payment Policy: "Effective January 1, 2006, IHS providers are paid separately from the AIR for physical therapy, OT, speech-language pathology and diagnostic audiology services." On skilled nursing, the manual states, "Effective July 2002, IHS hospital swing-bed services began being paid according to the SNF prospective payment system (PPS) payment methodology," but it remain uncertain whether this policy extends to skilled nursing care provided in the home. The manual does not discuss HH aides and medical | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | social services, and these disciplines do not appear in a list of "Medicare Part B Services Paid Under Various Fee Schedules" (vs. AIR), possibly indicating they are covered under AIR. The manual is available at https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/clm104c19.pdf . | |
| 52.v. | Access Waiver for Part B Ambulance Suppliers and HHAs ACTION: Notice NOTICE: Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Provider Enrollment Moratoria Access Waiver Demonstration of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Moratoria-Designated Geographic Locations AGENCY: CMS | CMS-6073-N | Issue Date: 8/3/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This notice announces the Provider Enrollment Moratoria Access Waiver Demonstration of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in 6 states. Implementation of demonstration will occur in accordance with section 402 of the Social Security Amendments of 1967. Section 402 gives CMS the authority to grant waivers to the statewide enrollment moratoria on a case-by-case basis in response to access to care issues and to subject providers and suppliers enrolling via such waivers to heightened screening, oversight, and investigations. https://www.gpo.gov/fdsys/pkg/FR-2016-08-03/pdf/2016-18381.pdf A CMS press release on this notice is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-29-2.html. SUMMARY OF NIHB ANALYSIS: | |
| 52.w. | Waiver Application for Providers Subject to Moratorium ACTION: Request for Comment | CMS-10629 | Issue Date: 10/31/2016 Due Date: 12/30/2016 NIHB File | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium; Use: This demonstration, in conjunction with an expansion of the existing provider enrollment moratoria, will allow CMS to mitigate known vulnerabilities within the existing moratoria and will lead to increased investigations of fraud. Section 402(a)(l)(J) of the Social Security Amendments of 1967 permits the HHS Secretary to "develop or demonstrate improved methods for the investigation and | |

National Indian Health Board

| Ref. # | Short Title/Current Status of Regulation/Title/ Agency NOTICE: Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium AGENCY: CMS | File Code | Issue Date; Due Date & File Date Date: Date of Subsequent Agency Action, if any: | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act." In addition to the development and demonstration of improved methods for investigations, CMS will utilize this demonstration to address beneficiary access to care issues. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26122.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | NIHB Recs. |
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| 54. | ESI Coverage Verification ACTION: Notice NOTICE: Employer- Sponsored Coverage Verification: Preliminary Informational Statement AGENCY: CMS | CMS RIN 0938- ZB09 | Issue Date: [Approved by OMB 4/26/2012 but not yet published] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS: | |
| 60.f | Medicare Data Validation ACTION: Request for Comment NOTICE: Medicare Part C and Part D Data Validation AGENCY: CMS | CMS-10305 | Issue Date: 12/5/2012 Due Date: 1/4/2013 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Part C and Part D Data Validation (42 CFR 422.516g and 423.514g); Use: CMS established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations (MAOs), Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR 422.516(a) and 423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data (depending on the type of contracts they have in place with CMS). To have use in monitoring and performance measurement, sponsoring | |



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| | | | <u>Date of</u> <u>Subsequent</u> <u>Agency Action, if any</u> : Issued extension 11/1/2013; issued revision 6/13/2014, 9/19/2014, 6/30/2016 <u>Due Date:</u> 12/2/2013; 8/12/2014; 10/20/2014; 8/29/2016 | | organizations must report reliable, valid, complete, and comparable data. In 2009, CMS developed the data validation program as a mechanism to verify the data reported are accurate, valid, and reliable. To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation. Instead, sponsoring organizations must hire external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials. CMS developed standards and data validation criteria for specific Medicare Part C and Part D reporting requirements that the DVCs use in validating sponsoring organization data. These "Data Validation Standards" for each reporting section include standard instructions relating to the types of information that require review and reporting section criteria (MSC) aligned with the "Medicare Part C and Part D Reporting Requirement Technical Specifications." Data collected via "Medicare Part C and Part D Reporting Requirements Technical Specifications." Serve as an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Data Validation Program to substantiate the data collected through the Medicare Data Validation Program to substantiate the data collected via "Medicare Part C and Part D Reporting Requirements Technical Specifications." If CMS detects data anomalies, the CMS division with primary responsibility for the applicable reporting requirement assists with determining a resolution. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/1/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26107.pdf CMS on 6/13/2014 issued a revision of this PRA request. CMS has revised the currently approved information collection to reflect a decrease in the number of reporting sections validated and an increase in the average number of data elements per reporting sections validated and | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS on 6/30/2016 issued a revision of this PRA request. CMS has revised the FDCF for the 2017 and 2018 DV collection periods by changing the scoring of six standards from a binary scale to a five-point Likert-type scale. CMS expects this change to improve the precision of the data validation scores by increasing overall variation in total scores among the MAOs and PDPs. CMS does not expect this revision to alter resource requirements, since it will continue to base the assessment by DV contractors in scoring standards on the percentage of records that meet the standards. https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15564.pdf | |
| 60.1. | Expanding Uses of Medicare Data by Qualified Entities ACTION: Proposed Final Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities AGENCY: CMS | CMS-5061- PF | Issue Date: 2/2/2016 Due Date: 3/29/2016 NIHB File Date: 3/29/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 7/7/2016 | NIHB response: | SUMMARY OF AGENCY ACTION: This proposed rule would implement new statutory requirements that would expand how qualified entities can use and disclose data under the qualified entity program to the extent consistent with applicable program requirements and other applicable laws, including information, privacy, security, and disclosure laws. In doing so, this proposed rule would explain how qualified entities can create non-public analyses and provide or sell such analyses to authorized users, as well as how qualified entities can provide or sell combined data, or provide Medicare claims data alone at no cost, to certain authorized users. This proposed rule also would implement certain privacy and security requirements and impose assessments on qualified entities if the qualified entity or the authorized user violates the terms of a data use agreement (DUA) required by the qualified entity program. https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01790.pdf Background Section 10332 of ACA established the Qualified Entity program, requiring the program to make available standardized extracts of Medicare claims data under parts A, B, and D to "qualified entities" for the evaluation of the performance of providers and suppliers. Qualified entities can use the information for the purpose of evaluating the performance of providers and suppliers, as well as to generate public reports regarding such performance. To become a qualified entity, an organization must submit an application that includes, among other things, a description of the methodologies that the applicant proposes to use to evaluate the performance of providers and suppliers in the geographic area(s) selected. A list of the 13 existing qualified entities is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/QEMedicareData/index.html?redirect=/QEMedicareData. | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 60.m. | Reapplication Submission for Qualified Entities ACTION: Request for Comment NOTICE: Reapplication Submission Requirement for Qualified Entities Under ACA Section 10332 AGENCY: CMS | CMS-10596 | Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Reapplication Submission Requirement for Qualified Entities Under ACA Section 10332; <i>Use</i> : Section 10332 of ACA requires the HHS Secretary to make standardized extracts of Medicare claims data under Parts A, B, and D available to "qualified entities" for the evaluation of the performance of providers of services and suppliers. The statute provides the HHS Secretary with discretion to establish criteria to determine whether an entity qualifies to use claims data to evaluate the performance of providers of services and suppliers. After consideration of comments from a wide variety of stakeholders during the public comment period, CMS established "Medicare Program; Availability of Medicare Data for Performance Measurement" (Final Rule). To implement the requirements outlined in the legislation, the CMS established the Qualified Entity Certification Program (QECP). The Final Rule requires qualified entities to reapply for certification six months prior to the end of their 3-year certification period to remain in good standing. This form serves as the official reapplication that qualified entities must complete to reapply to QECP. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02278.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
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| 60.n. | Patient Request for Medicare Payment ACTION: Request for Comment NOTICE: Patient's Request for Medicare Payment AGENCY: CMS | CMS-1490S See also 60.c. | Issue Date: 4/22/2016 Due Date: 6/21/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 10/31/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Patient's Request for Medicare Payment; <i>Use</i> : CMS-1490S provides beneficiaries with a relatively easy form to use when filing their claims. Without the collection of this information, action on claims for reimbursement relating to the provision of Part B medical services/supplies could not occur. This would result in a nationwide paralysis of the operation of the Medicare Part B and inflict severe physical and financial hardship on beneficiaries. CMS explicitly developed CMS-1490S for easy use by beneficiaries who file their own claims. Beneficiaries can obtain CMS-1490S from any Social Security office, Medicare Administrative Contractors, or CMS. When used, the beneficiary must attach to CMS-1490S his/her bills from physicians or suppliers. The form is, therefore, designed specifically to aid beneficiaries who cannot get assistance from their physicians or suppliers for completing claim forms. OMB currently has approved CMS-1490S under OMB 0938-1197; however, CMS seeks approval for CMS-1490S as a standalone information collection request. Once OMB issues a new control number, CMS will remove the burden for the CMS-1490S currently approved under OMB | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | <u>Due Date</u> : 11/30/2016 | | https://www.gpo.gov/fdsys/pkg/FR-2016-04-22/pdf/2016-09425.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/31/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | |
| 63.b. | Electronic Funds Transfers Authorization Agreement ACTION: Request for Comment NOTICE: Electronic Funds Transfers Authorization Agreement AGENCY: CMS | CMS-588 | Issue Date: 3/1/2013 Due Date: 4/30/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/17/2013, 6/13/2016, 9/12/2016 Due Date: 6/17/2013; 8/9/2016; 10/12/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Electronic Funds Transfers Authorization Agreement; Use: The Electronic Funds Transfer Authorization Agreement (CMS-588) serves to gather information from a provider/supplier to establish an electronic payment process. The legal authority to collect this information appears in Section 1815(a) of the Social Security Act. This section provides authority for the Secretary of HHS to pay providers/suppliers of Medicare services. Under 31 U.S.C. 3332(f)(1), all federal payments, including Medicare payments to providers and suppliers, must occur by electronic funds transfer. 31 U.S.C. 7701 (c) requires any individual or entity engaged in business with the federal government to provide their Tax Identification Number (TIN). This request seeks to renew the information collection. CMS has made only two minor revisions for systems requirements, specifically the additions of a street address line for the location of the financial institution and a second National Provider Identification (NPI) number collection field for those providers/suppliers with more than one NPI. http://www.gpo.gov/fdsys/pkg/FR-2013-03-01/pdf/2013-04752.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/17/2013 issued a revision of this PRA request. This PRA request includes only two minor revisions for systems requirements, specifically the additions of a street address line for the location of the financial institution and a second National Provider Identification (NPI) number collection field for those providers/suppliers with more than one NPI. | |



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| | | | | | http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 6/13/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13800.pdf No comments recommended. CMS on 9/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-12/pdf/2016-21873.pdf No comments recommended. | |
| 67.a. | State Consumer Assistance Grants ACTION: Request for Comment NOTICE: Consumer Assistance Program Grants AGENCY: CMS | CMS-10333 | Issue Date: 7/27/2012 Due Date: 9/25/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/7/2012; issued extension 11/2/2015, 1/20/2016 Due Date: 2/7/2013; 1/4/2016; 2/19/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Consumer Assistance Program Grants; Use: Section 1002 of ACA provides for the establishment of consumer assistance (or ombudsman) programs (CAPs), starting in FY 2010. Federal grants will support CAPs, which will assist consumers with filing complaints and appeals; assist consumers with enrollment into health coverage, collect data on consumer inquiries and complaints to identify problems in the marketplace; educate consumers on their rights and responsibilities; and with the establishment of the new Exchange marketplaces, resolve problems with premium credits for Exchange coverage. ACA requires CAPs to report data to the HHS Secretary "on the types of problems and inquiries encountered by consumers" (section 2793 (d)). Analysis of this data reporting will help identify patterns of practice in the insurance marketplaces and uncover suspected patterns of noncompliance. HHS must share program data reports with the Departments of Labor and Treasury and state regulators. Program data also can offer CMS one indication of the effectiveness of state enforcement, affording opportunities to provide technical assistance and support to state insurance regulators and, in extreme cases, inform the need to trigger federal enforcement. A summary of how each state or territory will use the new resources is available at http://www.healthcare.gov/news/factsheets/2010/10/capgrants_states.html . Awards are made to States, and to qualify to receive a grant, a State must designate an independent office of health insurance consumer assistance, or an ombudsman, that, directly or in coordination with State health insurance regulators and consumer | |



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| π | Agency | | File Date | Response | assistance organizations to collect and report data to the HHS Secretary on the types of problems and inquiries encountered by consumers. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/7/2012 issued a revision of this PRA request. CMS received 21 comments in response to the 60-day notice on this information collection published in the 7/27/2012 FR. The majority of these comments, which CMS has addressed in this notice, involved feedback on providing CAPs with more flexibility in collecting and reporting data. http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29626.pdf CMS on 11/2/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27859.pdf CMS on 1/20/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-20/pdf/2016-00994.pdf No comments recommended. | |
| 67.b. | Research on Outreach for Health Insurance Marketplace ACTION: Request for Comment NOTICE: Consumer Research Supporting Outreach for Health Insurance Marketplace AGENCY: CMS | CMS-10458 | Issue Date: 1/11/2013 Due Date: 3/12/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Consumer Research Supporting Outreach for Health Insurance Marketplace; Use: CMS seeks approval for two surveys to aid in understanding levels of awareness and customer service needs associated with the Health Insurance Marketplace established by ACA. One survey will include individual consumers most likely to use the Marketplace, and another will include small employers most likely to use the Small Business Health Options portion of the Marketplace. These brief surveys, conducted quarterly, will give CMS the ability to obtain a rough indication of the types of outreach and marketing needed to enhance awareness of and knowledge about the Marketplace for individual and business customers. The biggest customer service issue for CMS likely will involve providing education sufficient for consumers to: (a) take advantage of the Marketplace and (b) know how to access CMS customer service channels. The surveys will provide information on media use, concept awareness, and conceptual or content areas where education for customer service delivery needs improvement. Awareness and knowledge gaps are likely to change over time based not | |



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| | | | 4/4/2013; issued extension 4/22/2016, 6/24/2016 <u>Due date:</u> 5/6/2013; 6/21/2016; 7/25/2016 | | only on effectiveness of CMS marketing efforts, but also on those of state, local, private sector, and nongovernmental organizations. http://www.gpo.gov/fdsys/pkg/FR-2013-01-11/pdf/2013-00467.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/4/2013 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07799.pdf CMS on 4/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-22/pdf/2016-09425.pdf No comments recommended CMS on 6/24/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-24/pdf/2016-15021.pdf No comments recommended. | |
| 70.e. | Revisions to PFS and Other Changes to Part B for CY 2016 ACTION: Proposed Final Rule NOTICE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 AGENCY: CMS | CMS-1631- PFC | Issue Date: 7/15/2015 Due Date: 9/8/2015 TTAG File Date: 9/8/2015 Date of Subsequent Agency Action, if any: Issued Final | TTAG response: | SUMMARY OF AGENCY ACTION: This major proposed rule addresses changes to the physician fee schedule (PFS) and other Medicare Part B payment policies to ensure that CMS payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. The Social Security Act (Act) requires CMS to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires CMS to establish RVUs for three categories of resourceswork, practice expense (PE); and malpractice (MP) expense-and each year establish by regulation payment amounts for all physician services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. This proposed rule would establish RVUs for CY 2016 for the PFS and other Medicare Part B payment policies. In addition, this proposed rule includes discussions and proposals regarding: | See Table C. |



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| | Agency | | Rule 11/16/2015; issued correction 3/8/2016, 6/1/2016 Due Date: 12/29/2015 | | Potentially misvalued PFS codes; Telehealth services; Advance care planning services; Establishing values for new, revised, and misvalued codes; Target for relative value adjustments for misvalued services; Phase-In of significant RVU reductions; "Incident to" policy; Portable x-ray transportation fee; Updating the ambulance fee schedule regulations; Changes in geographic area delineations for ambulance payment; Chronic care management services for RHCs and FQHCs; HCPCS coding for RHCs; Payment to grandfathered tribal federally qualified health centers (FQHCs) that existed as provider-based clinics on or before April 7, 2000; Payment for biosimilars under Medicare Part B; Physician Compare Web site; Physician Quality Reporting System; Medicare Shared Savings Program; Electronic Health Record (EHR) Incentive Program; and Value-based payment modifier and the Physician Feedback Program. http://www.gpo.gov/fdsys/pkg/FR-2015-07-15/pdf/2015-16875.pdf SUMMARY OF NIHB ANALYSIS: In response to concerns raised by TTAG, this proposed rule includes a provision under which tribal facilities that were grandfathered in as Medicare provider-based entities on or before 4/7/2000 and that subsequently had a change of status from IHS-operated to tribal-operated, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital such that the organization no longer meets the Medicare conditions of participation to become certified as grandfathered tribal FQHCs. Under the authority in section 1834(o) of ACA to "include adjustments determined appropriate by the HHS Secretary," CMS proposes that these grandfathered tribal FQHCs receive payments of the lesser of their charges or a | |
| | | | | | grandfathered tribal FQHC PPS rate of \$307, which equals the Medicare outpatient per visit payment rate paid to them as a provider-based department, as set | |



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| | | | | | annually by IHS, rather than the FQHC PPS per visit base rate of \$158.85, with coinsurance equal to 20 percent of the lesser of the actual charge or the grandfathered tribal FQHC PPS rate. These grandfathered tribal FQHCs would have to meet all FQHC certification and payment requirements. | |
| | | | | | This FQHC PPS adjustment for grandfathered tribal clinics would not apply to a currently certified tribal FQHC, a tribal clinic that was not provider-based as of April 7, 2000, or an IHS-operated clinic that is no longer provider-based to a tribally-operated hospital. This provision also would not apply in cases in which both the hospital and its provider-based clinic(s) are tribally-operated. | |
| | | | | | CMS recently held a Webinar, titled "2016 PFS Proposed Rule: Medicare Quality Reporting Programs," that provided an overview of this proposed rule. PowerPoint slides, an audio recording, and a transcript of the Webinar are available at https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-07-16-PQRS.html . | |
| | | | | | A recent <i>Modern Healthcare</i> article reported on several key provisions in this proposed rule. A summary appears below. | |
| | | | | | Telehealth: This proposed rule would revise the Medicare telehealth policy to include payments for in-home treatments for end-stage renal disease, although requiring an inperson clinical examination of the catheter-access site by a physician, certified nurse specialist, nurse practitioner, or physician assistant. In addition, this proposed rule would add certified registered nurses anesthetists to the list of qualified telehealth providers for certain services, including evaluation and management. CMS also seeks comments on how to better pay for collaborative care consultations between primary care physicians and specialists requiring "extensive discussion, information-sharing, and planning." CMS rejected requests to include payments for telehealth evaluation and management, telerehabilitation services, palliative care, pain management, and patient-navigation services for cancer patients. | |
| | | | | | Quality incentive programs: This proposed rule would make a number of changes to the Physician Quality Reporting System, the incentive program for the meaningful use of electronic health records, and the value-based payment modifierall of which would become components of a new Merit-Based Incentive Payment System. This proposed rule also would establish several new Medicare Physician Compare Web site | |



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| | V | | | | components, including a green check mark next to the name of providers that received an upward adjustment for cost and quality. In addition, CMS seeks comments on whether to expand the Comprehensive Primary Care Initiative. | |
| | | | | | Advance care planning: This proposed rule includes a provision that would establish two new advance care planning codes in Medicare beginning in 2016. Providers would use the codes when discussing patient choices for advance directives and completing necessary formsone code for the first 30 minutes and a second code for additional 30-minute periods. However, this proposed rule would not set values for these codes, and according to CMS, this provision "does not mean that Medicare has made a national coverage determination regarding the service." CMS also could make advance care planning "an optional element" of the annual beneficiary wellness visit. | |
| | | | | | The complete article is available at http://www.modernhealthcare.com/article/20150708/NEWS/150709923?utm_source=modernhealthcare&utm_medium=email&utm_content=20150708-NEWS-150709923&utm_campaign=mh-alert. | |
| | | | | | SUMMARY OF SUBEQUENT AGENCY ACTION: This major final rule with comment period addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that CMS payment systems reflect changes in medical practice and the relative value of services, as well as changes in the statute. | |
| | | | | | CMS will consider comments submitted on the following subject areas discussed in this final rule with comment period: Interim final work, practice expense (PE), and malpractice (MP) RVUs (including applicable work time, direct PE inputs, and MP crosswalks) for CY 2016; interim final new, revised, potentially misvalued HCPCS codes as indicated in the Preamble text and listed in Addendum C to this final rule with comment period; and the additions and deletions to the physician self-referral list of HCPCS/CPT codes found on tables 50 and 51. | |
| | | | | | http://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf | |
| | | | | | CMS on 3/8/2016 issued a document (CMS-1631-F2) to correct technical and typographical errors that appeared in the final rule with comment period published in the 11/16/2015 FR (80 FR 70886) and titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016." | |



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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-03-08/pdf/2016-05054.pdf CMS on 6/1/2016 issued a document (CMS-1631-F3) to correct technical and typographical errors that appeared in the final rule with comment period published in the 11/16/2015 FR (80 FR 70886) and titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016." https://www.gpo.gov/fdsys/pkg/FR-2016-06-01/pdf/2016-12841.pdf | |
| 70.f. | Part B Drug Payment Model ACTION: Proposed Rule NOTICE: Medicare Program; Part B Drug Payment Model AGENCY: CMS | CMS-1670-P | Issue Date: 3/11/2016 Due Date: 5/9/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule discusses the implementation of a new Medicare payment model under section 1115A of the Social Security Act (Act). CMS propose the Part B Drug Payment Model as a two-phase model that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. The first phase would involve changing the 6 percent add-on to average sales price (ASP) that CMS uses to make drug payments under Part B to 2.5 percent plus a flat fee (in a budget neutral manner). The second phase would implement value-based purchasing tools similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. CMS believes this model will further its goal of more efficient spending on quality care for Medicare beneficiaries. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf Links to several recent news articles on this proposed rule are available below. Associated Press: http://www.nytimes.com/aponline/2016/03/08/us/politics/apus-medicare-drugs.html Kaiser Health News: http://khn.org/news/medicare-to-test-new-payment-approaches-for-some-prescription-medications/ Los Angeles Times: http://www.latimes.com/business/la-fi-drug-prices-20160308-story.html New York Times: http://www.nytimes.com/2016/03/09/us/politics/us-to-test-ways-to-cut-drug-prices-in-medicare.html Wall Street Journal: http://www.wsj.com/articles/u-s-officials-propose-test-program-aimed-at- | |



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| | | | | | lowering-medicare-drug-costs-1457470874 Washington Post: https://www.washingtonpost.com/national/health-science/medicare-considers-overhaul-of-doctors-payments-for-drugs/2016/03/08/90af35e2-e56c-11e5-a6f3-21ccdbc5f74e_story.html SUMMARY OF NIHB ANALYSIS: | |
| 70.g. | Revisions to PFS and Other Changes to Part B for CY 2017 ACTION: Proposed Final Rule NOTICE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model AGENCY: CMS | CMS-1654- PF | Issue Date: 7/14/2016 Due Date: 9/6/2016 NIHB File Date: 9/6/2016; TTAG also filed comments 9/6/2016 Date of Subsequent Agency Action, if any: Issued correction 8/10/2016; sent Final Rule to OMB 10/18/2016 | NIHB response: TTAG response: | SUMMARY OF AGENCY ACTION: This major proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies, such as changes to the Value Modifier, to update CMS payment systems to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes proposals related to the Medicare Shared Saving Program and the release of certain pricing data from Medicare Advantage bids and medical loss ratio reports from Medicare health and drug plans. In addition, this rule proposes to expand the Medicare Diabetes Prevention Program model. https://www.gpo.gov/fdsys/pkg/FR-2016-07-15/pdf/2016-16097.pdf A CMS press release on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-07-1.html. A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-07-2.html. A CMS blog post on this proposed rule is available at https://blog.cms.gov/2016/07/07/focusing-on-primary-care-for-better-health/. SUMMARY OF NIHB ANALYSIS: A summary of the major provisions of this proposed rule appears below. Summary of Major Provisions Under federal statute, CMS must establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. CMS also must establish RVUs for three categories of resources: | See Table C. |



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| | | | | | work, practice expense (PE); and malpractice (MP) expense. In addition, CMS must establish annual payment amounts for all physician services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, CMS proposes to establish RVUs for CY 2017 for the PFS, and other Medicare Part B payment policies, to ensure that agency payment systems reflect changes in medical practice and the relative value of services, as well as changes in statute. This proposed rule also includes discussions and proposals regarding: Potentially Misvalued PFS Codes; Telehealth Services; Establishing Values for New, Revised, and Misvalued Codes; Target for Relative Value Adjustments for Misvalued Services; Phase-in of Significant RVU Reductions; Chronic Care Management (CCM) and Transitional Care Management (TCM); Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs); FQHC-Specific Market Basket; Appropriate Use Criteria for Advanced Diagnostic Imaging Services; Reports of Payments or Other Transfers of Value to Covered Recipients: Solicitation of Public Comments; Release of Part C Medicare Advantage Bid Pricing Data and Part C and Part D Medical Loss Ratio (MLR) Data; Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing; Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number; Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately; Medicare Advantage Provider Enrollment; Proposed Expansion of the Diabetes Prevention Program (DPP) Model; Medicare Shared Savings Program; Value-Based Payment Modifier and the Physician Feedback Program; and Physician Self-referral Updates. | |
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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS proposes changes to physician fee schedule. The Obama administration outlined numerous changes to Medicare reimbursements for providers aimed at improving care for beneficiaries with multiple chronic conditions and mental health issues in a proposed rule released on Thursday. Among the changes: CMS plans to expand its Diabetes Prevention Program into Medicare. Beginning in 2018, providers would be able to bill Medicare for diabetes prevention services for the first time. CMS wants to boost transparency and quality in Medicare Advantage. Specifically, it will require that providers and suppliers that contract with MA plans be screened and enrolled in Medicare. CMS would require physicians to consult a clinical decision support tool for some services. Physicians would need to do so to get paid for certain advanced imaging services, and some doctors may be subject to prior authorization beginning in 2020 if they don't comply. SUMMARY OF SUBSEOUENT AGENCY ACTION: CMS on 8/10/2016 issued a document (CMS-1654-CN) that corrects a technical error in the proposed rule published in the 7/15/2016 FR (81 FR 46162) and titled, "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model." This document makes the following correction: on page 46457, in the first column, in the third paragraph, line 2, the phrase "September 13, 2016" is corrected to read "September 6, 2016". https://www.gpo.gov/fdsys/pkg/FR-2016-08-10/pdf/2016-19012.pdf | |
| 71.d. | ESRD Network Semi- Annual Cost Report Forms ACTION: Request for Comment NOTICE: End Stage Renal | CMS-685 | <u>Issue Date:</u> 2/12/2013 <u>Due Date:</u> 4/15/2013 <u>NIHB File</u> | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a previously approved collection; <i>Title</i> : End Stage Renal Disease (ESRD) Network Semi-Annual Cost Report Forms and Supporting Regulations in 42 CFR section 405.2110 and 42 CFR 405.2112; <i>Use</i> : Section 1881(c) of the Social Security Act establishes End Stage Renal Disease (ESRD) Network contracts. The regulations found at 42 CFR 405.2110 and 405.2112 designated 18 ESRD Networks funded by renewable contracts. These contracts have 3-year cycles. To better administer the program, CMS requires | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Disease Network Semi- Annual Cost Report Forms and Supporting Regulations AGENCY: CMS | | Date: None Date of Subsequent Agency Action, if any: Issued revision 4/26/2013, 3/1/2016, 5/6/2016 Due Date: 5/28/2013; 5/2/2016; 6/6/2016 | | contractors to submit semi-annual cost reports. The cost reports enable the ESRD Networks to report costs in a standardized manner. This allows CMS to review, compare, and project ESRD Network costs during the life of the contract. Since the last information collection, CMS has revised the survey instrument. The burden has not changed. http://www.gpo.gov/fdsys/pkg/FR-2013-02-12/pdf/2013-03059.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/26/2013 issued a revision of this PRA request. Since the last information collection, CMS has revised the survey instrument. The burden has not changed. http://www.gpo.gov/fdsys/pkg/FR-2013-04-26/pdf/2013-09913.pdf CMS on 3/1/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04463.pdf No comments recommended. CMS on 5/6/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10704.pdf No comments recommended. | |
| 71.e. | Renal Operations in a Web Enabled Network ACTION: Request for Comment NOTICE: Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization Form | CMS-10268 | Issue Date: 4/19/2013 Due Date: 6/18/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a currently approved collection; Title: Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization Form; Use: "Facility Administrators" (administrators of CMS-certified dialysis facilities) complete the Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization (CWTPSA) form if they intend to authorize a third party (a business with which the facility is associated, or an independent vendor) to submit data to CMS to comply with the recently revised Conditions for Coverage of dialysis facilities. The CROWNWeb system serves as the collection point of data necessary for entitlement of ESRD patients to Medicare benefits and for Federal monitoring and assessing of the quality and types of care provided to renal patients. The information collected through the CWTPSA form will allow CMS and its contractors to receive data from authorized parties acting on behalf of CMS-certified dialysis facilities. Since | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency AGENCY: CMS | File Code | Issue Date; Due Date & File Date Issued reinstatement 7/24/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/23/2013; 9/20/2016; 10/26/2016 | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis February 2009, CMS has received 4,160 CWTPSA forms and anticipates it will continue to receive no more than 400 new CWTPSA forms annually to address the creation of new facilities under the current participating "third party submitters." http://www.gpo.gov/fdsys/pkg/FR-2013-04-19/pdf/2013-09267.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/24/2013 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-24/pdf/2013-17821.pdf CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17376.pdf No comments recommended. CMS on 9/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-26/pdf/2016-23157.pdf | NIHB Recs. |
|--------|--|-----------|--|------------------|---|------------|
| | | | | | No comments recommended. | |
| 71.f. | End Stage Renal Disease Medical Information Facility Survey ACTION: Request for Comment NOTICE: End Stage Renal Disease Medical Information Facility Survey AGENCY: CMS | CMS-2744 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a previously approved collection; Title: End Stage Renal Disease (ESRD) Medical Information Facility Survey; Use: Medicare-approved providers of dialysis and transplant services complete the End Stage Renal Disease (ESRD) Medical Information Facility Survey form (CMS-2744) annually. CMS-2744 collects information concerning treatment trends, utilization of services, and patterns of practice in treating ESRD patients. CMS uses the information to assess and evaluate the local, regional, and national levels of medical and social impact of ESRD care, and researchers and suppliers of services use the information for trend analysis. The information appears on the CMS Dialysis Facility Compare Web site and enables patients to make informed decisions about their care by comparing dialysis facilities in their area. http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13578.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | revision 8/16/2013; issued extension 10/14/2016 <u>Due Date:</u> 9/16/2013; 12/13/2016 | | SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/16/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf CMS on 10/14/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24813.pdf No comments recommended. | |
| 71.n. | Medicare ESRD PPS and Quality Incentive Program ACTION: Proposed Final Rule NOTICE: Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program AGENCY: CMS | CMS-1628- PF | Issue Date: 7/1/2015 Due Date: 8/25/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 9/2/2015; issued Final Rule 11/6/2015; issued correction 12/31/2015 | | SUMMARY OF AGENCY ACTION: This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2016. The proposals in this rule would ensure that ESRD facilities receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during CY 2016. This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP) for CY 2016. In an effort to incentivize ongoing quality improvement among eligible providers, the ESRD QIP proposes to establish and revise requirements for quality reporting and measurement, including the inclusion of new quality measures for payment year (PY) 2019 and beyond and updates to programmatic policies for the PY 2017 and PY 2018 ESRD QIP. http://www.gpo.gov/fdsys/pkg/FR-2015-07-01/pdf/2015-16074.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule would implement an incentive payment adjustment for ESRD services. SUMMARY OF AGENCY ACTION: CMS on 9/2/2015 issued a document (CMS-1628-CN) to correct a technical error that appeared in the proposed rule titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program" and published in the 7/1/2015 FR (80 FR 37808). This document makes the following correction: on page 37814, second column, second full paragraph, in line 16, the reference to "13A" is corrected to read "11A". http://www.gpo.gov/fdsys/pkg/FR-2015-09-02/pdf/2015-21783.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS on 11/6/2015 issued a final rule that updates and makes revisions to the end-stage renal disease (ESRD) prospective payment system (PPS) for CY 2016. This final rule will ensure that ESRD facilities receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during CY 2016. This final rule also will set forth requirements for the ESRD Quality Incentive Program (QIP), including for PYs 2017 through 2019. http://www.gpo.gov/fdsys/pkg/FR-2015-11-06/pdf/2015-27928.pdf CMS on 12/31/2015 issued a document (CMS-1628-CN2) to correct technical and typographical errors that appeared in the final rule published in the 11/6/2015 FR and titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program." https://www.gpo.gov/fdsys/pkg/FR-2015-12-31/pdf/2015-32967.pdf | |
| 71.0. | ESRD Application and Survey and Certification Report ACTION: Request for Comment NOTICE: End Stage Renal Disease Application and Survey and Certification Report AGENCY: CMS | CMS-3427 | Issue Date: 11/16/2015 Due Date: 1/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/1/2016 Due Date: 3/31/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: End Stage Renal Disease Application and Survey and Certification Report; Use: Part I of this form serves as a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. The Medicare/Medicaid State survey agency completes Part II of this form to determine facility compliance with ESRD conditions for coverage. http://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-29160.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/1/2016 issued a reinstatement of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04462.pdf No comments recommended. | |



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 71.p. | Medicare ESRD PPS for 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model AGENCY: CMS | CMS-1651- PF | Issue Date: 6/30/2016 Due Date: 8/23/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 10/26/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would update and make revisions to the end-stage renal disease (ESRD) prospective payment system (PPS) for calendar year 2017, as well as implement policies for coverage and payment for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP) and to establish and revise requirements for quality reporting and measurement, including the inclusion of new quality measures for payment year (PY) 2020 and beyond and updates to programmatic policies for the PY 2018 and PY 2019 ESRD QIP. This rule also proposes to implement statutory requirements for bid surety bonds and state licensure for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). This rule also proposes to expand supplier appeal rights in the event of a breach of contract action by CMS. In particular, this rule proposes a revision to current regulations to provide that the appeals process applies to all breach of contract actions taken by CMS, rather than just for the termination of a competitive bidding contract. It also proposes changes to the methodologies for adjusting fee schedule amounts for DMEPOS using information from Competitive Bidding Programs and for submitting bids and establishing single payment amounts under the Competitive Bidding Programs for certain groupings of similar items with different features. In addition, this proposed rule would change the methodology for establishing bid limits for items under the DMEPOS Competitive Bidding Programs. Further, this proposed rule solicits comments on the impacts of coordinating Medicare and Medicaid durable medical equipment for dually eligible beneficiaries. Finally, this proposed rule announces a request for information related to the Comprehensive ESRD Care Model and future payment models affecting renal care. https://www.cms.gov/Newsroom/MediaReleaseDatabase/F | |
| 72.c. | Physician Certification/ | CMS-R-5 | <u>Issue Date</u> : | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: | |



| Chart Title/Commant Ctator | | Janua Data | | | |
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| | F". 0 . I | | NIHB | Brief Summary of Proposed Agency Action | NIII D D |
| 9 | File Code | | Response | | NIHB Recs. |
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| Recertification in SNFs | | 4/4/2013 | | | |
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| Comment | | 6/3/2013 | | | |
| | | | | | |
| | | | | requirement. | |
| | | <u>Date</u> : None | | | |
| | | | | http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07800.pdf | |
| | | Date of | | | |
| Instructions and Supporting | | <u>Subsequent</u> | | SUMMARY OF NIHB ANALYSIS: | |
| Regulation | | <u>Agency</u> | | | |
| - | | Action, if any: | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/7/2013 issued a | |
| AGENCY: CMS | | Issued | | reinstatement of this PRA request with no changes. | |
| | | reinstatement | | http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13577.pdf | |
| | | 6/7/2013; | | | |
| | | issued | | CMS on 7/22/2016 issued an extension of this PRA request. | |
| | | extension | | | |
| | | 7/22/2016. | | | |
| | | | | No comments recommended. | |
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| | | Due Date: | | CMS on 10/7/2016 issued an extension of this PRA request. | |
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| | | | | No comments recommended. | |
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| Skilled Nursing Facility | CMS-10387 | Issue Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: | |
| PPS and Consolidated | | 7/21/2015 | | Reinstatement of a previously approved collection; Title: Skilled Nursing Facility (SNF) | |
| Billing | | | | Prospective Payment System and Consolidated Billing; Use: CMS seeks approval of a | |
| | | Due Date: | | | |
| ACTION: Request for | | 9/21/2015 | | described in CMS-1351-F, CMS finalized the assessment effective 10/1/2011. SNFs | |
| Comment | | | | must submit this assessment. The COT OMRA includes a subset of resident assessment | |
| | | NIHB File | | | |
| NOTICE: Skilled Nursina | | | | | |
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| | | Date of | | | |
| | | | | | |
| | Regulation AGENCY: CMS Skilled Nursing Facility PPS and Consolidated Billing ACTION: Request for | of Regulation/Title/ Agency Recertification in SNFs ACTION: Request for Comment NOTICE: Physician Certification/ Recertification in Skilled Nursing Facilities Manual Instructions and Supporting Regulation AGENCY: CMS Skilled Nursing Facility PPS and Consolidated Billing ACTION: Request for Comment NOTICE: Skilled Nursing Facility (SNF) Prospective Payment System and | of Regulation/Title/ Agency Recertification in SNFs ACTION: Request for Comment NOTICE: Physician Certification/ Recertification in Skilled Nursing Facilities Manual Instructions and Supporting Regulation AGENCY: CMS AGENCY: CMS Skilled Nursing Facility PPS and Consolidated Billing ACTION: Request for Comment NOTICE: Physician Certification/ Recertification in Skilled Nursing Facility PPS and Consolidated Billing ACTION: Request for Comment NOTICE: Skilled Nursing Facility (SNF) Prospective Payment System and | of Regulation/Title/ Agency Recertification in SNFs ACTION: Request for Comment NOTICE: Physician Certification/ Recertification in Skilled Nursing Facility PPS and Consolidated Billing ACTION: Request for Comment NOTICE: Physician Certification/ Recertification in Skilled Nursing Facility PPS and Consolidated Billing ACTION: Request for Comment NOTICE: Skilled Nursing Facility PPS and Consolidated Billing NOTICE: Skilled Nursing Facility (SNF) Prospective Payment System and File Code File Date & File Date & File Date: A/4/2013 NIHB File Date: None AU/4/2013 NIHB File Date: None Subsequent Agency Action, if any: Issued reinstatement 6/7/2013; issued extension 7/22/2016, 10/7/2016 Due Date: 7/8/2013; 9/20/2016; 11/7/2015 NIHB File Date: None Date of | File Code Agency Recertification in SNFs ACTION: Request for Comment NOTICE: Physician Certification in Skilled Nursing Facilities Manual Instructions and Supporting Regulation in Skilled Nursing Facilities Manual Instructions and Supporting Regulation in Skilled Nursing Facilities Manual Instructions and Supporting Regulation in Skilled Nursing Facilities Manual Instructions and Supporting Regulation in Skilled Nursing Facilities Manual Instructions and Supporting Regulation in Skilled Nursing Facilities Manual Instructions and Supporting Regulation in Skilled Nursing Facilities Manual Instructions and Supporting Regulation AGENCY: CMS Subsequent Subsequent Subsequent Recertification in Skilled Nursing Facilities Manual Instructions and Supporting Regulation in Skilled Nursing Facility Proposed Nursing Facility (SNF) Prospective Payment System and Conformation Request information Collection Request. NOTICE: Skilled Nursing Facility Proposed Nursing Facility Proposed Nursing Facility (SNF) Prospective Payment System and Conformation Request Information Request Information Request Information Collection Request. NOTICE: Skilled Nursing Facility (SNF) Prospective Payment System and Conformation Request Information Collection Request. NOTICE: Skilled Nursing Facility (SNF) Prospective Payment System and Conformation Request Information Collection Request. NOTICE: Skilled Nursing Facility (SNF) Prospective Payment System and Conformation Request Information Reverse Stall time sperior to complete the COT OMRA, Nor a resident Received a subset of resident assessment Information developed to ruse by SNFs to stallity Medicare payment requirement. The Durdon Adams Nursing Facilities (EMFs), As described in CMFs, 1351-F, CMFs Indicated Balling; User CMFs seeks Symptomated and SNFs st |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB | Brief Summary of Proposed Agency Action | NIHB Recs. |
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| # | Agency | | File Date | Response | and Summary of NIHB Analysis | THIRD TOOC! |
| | AGENCY: CMS | | Agency Action, if any: Issued reinstatement 10/2/2015, 3/4/2016 Due Date: 11/2/2015; 4/4/2016 | | Rehabilitation category and when the intensity of therapy (as indicated by the total reimbursable therapy minutes (RTM) delivered and other therapy qualifiers, such as number of therapy days and disciplines providing therapy) changes to such a degree that it would no longer reflect the RUG-IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. The COT OMRA, a type of required PPS assessment, uses the same item set as the End of Therapy (EOT) OMRA. http://www.gpo.gov/fdsys/pkg/FR-2015-07-21/pdf/2015-17824.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/2/2015 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-25109.pdf CMS on 3/4/2016 issued a reinstatement of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04841.pdf No comments recommended. | |
| | | | | | | |
| 72.g. | Billing for SNFs for FY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Prospective Payment System and | CMS-1645- PF | Issue Date: 4/25/2016 Due Date: 6/20/2016 NIHB File Date: None Date of | | SUMMARY OF AGENCY ACTION: This proposed rule would update the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for FY 2017. In addition, it includes a proposal to specify a potentially preventable readmission measure for the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP) and other proposals for that program aimed at implementing value-based purchasing for SNFs. This rule also proposes additional polices and measures in the Skilled Nursing Facility Quality Reporting Program (SNF QRP). Further, this proposed rule includes an update on the SNF Payment Models Research (PMR) project. https://www.gpo.gov/fdsys/pkg/FR-2016-04-25/pdf/2016-09399.pdf | |
| | Consolidated Billing for Skilled Nursing Facilities Proposed Rule for FY 2017, SNF Value-Based Purchasing Program, SNF | | Subsequent Agency Action, if any: Issued Final Rule 8/5/2016 | | A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-21-2.html . | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | Quality Reporting Program, and SNF Payment Models Research AGENCY: CMS | | | | SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2017. In addition, it specifies a potentially preventable readmission measure for the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP), and implements requirements for that program, including performance standards, a scoring methodology, and a review and correction process for public release of performance information, aimed at implementing value-based purchasing for SNFs. Additionally, this final rule includes additional polices and measures in the Skilled Nursing Facility Quality Reporting Program (SNF QRP). This final rule also responds to comments on the SNF Payment Models Research (PMR) project. https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18113.pdf A CMS fact sheet on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-29.html . | |
| 78.1. | Hospice Wage Index and Payment Rate Update for FY 2017 ACTION: Proposed Final Rule NOTICE: Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements AGENCY: CMS | CMS-1652- PF | Issue Date: 4/28/2016 Due Date: 6/20/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 8/5/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would update the hospice wage index, payment rates, and cap amount for FY 2017. In addition, this rule proposes changes to the hospice quality reporting program, including new quality measures. This proposed rule also solicits feedback on an enhanced data collection instrument and describes plans to publicly display quality measures and other hospice data beginning in the middle of 2017. Finally, this proposed rule includes information regarding the Medicare Care Choices Model (MCCM). https://www.gpo.gov/fdsys/pkg/FR-2016-04-28/pdf/2016-09631.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-21-3.html. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule will update the | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | hospice wage index, payment rates, and cap amount for fiscal year (FY) 2017. In addition, this final rule changes the hospice quality reporting program, including adopting new quality measures. Finally, this final rule includes information regarding the Medicare Care Choices Model (MCCM). https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18221.pdf | |
| | | | | | A CMS fact sheet on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-07-29-2.html . | |
| 79. | Fiscal Soundness Reporting Requirements ACTION: Request for Comment NOTICE: Fiscal Soundness Reporting Requirements AGENCY: CMS | CMS-906 | Issue Date: 9/4/2012 Due Date: 11/5/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/21/2012; issued extension 10/2/2015; 11/9/2015, 2/5/2016 Due Date: 1/22/2013; 12/1/2015; 12/9/2015, | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Fiscal Soundness Reporting Requirements; <i>Use</i> : CMS has responsibility for overseeing the ongoing financial performance for all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors, and Program of All-Inclusive Care for the Elderly (PACE) organizations. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. The revised fiscal soundness reporting form combines MAO, PDP, 1876 Cost Plans, Demonstration Plans, and PACE organizations. Entities contracting in these programs currently submit all documentation requested. Specifically, all contracting organizations must submit annual independently audited financial statements one time per year. The MAOs with a net loss, a negative net worth, or both must file three quarterly statements. Currently, approximately 44 MAOs file quarterly financial statements. The PDPs also must file three unaudited quarterly financial statements. The PACE organizations must file 3 quarterly financial statements for the first three years in the program. Additionally, PACE organizations with a net loss, a negative net worth, or both must file statements. The revised information request includes one additional data element for PACE organizations, Total Subordinated Liabilities. http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/21/2015 issued a | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| π | Agency | | File Date | Response | | |
| | | | 4/5/2016 | | revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf | |
| | | | | | <u> </u> | |
| | | | | | CMS on 10/2/2015 issued an extension of this PRA request. | |
| | | | | | http://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-25108.pdf | |
| | | | | | CMC on 11/0/2015 issued an extension of this DDA request | |
| | | | | | CMS on 11/9/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-25108.pdf | |
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| | | | | | No comments recommended. | |
| | | | | | CMS on 2/5/2016 issued an extension of this PRA request. | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02278.pdf | |
| | | | | | | |
| | | | | | No comments recommended. | |
| | | | | | | |
| 80.a. | Notice of Denial of Medical | CMS-10003 | <u>Issue Date</u> : | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of | |
| | Coverage (or Payment) | | 9/7/2012 | | a currently approved collection; <i>Title</i> : Notice of Denial of Medical Coverage (or Payment); | |
| | ACTION: Request for | | Due Date: | | Use: Section 1852(g)(1)(B) of the Social Security Act (SSA) requires Medicare health plans to provide enrollees with a written notice in understandable language explaining | |
| | Comment | | 11/6/2012 | | the reasons for denying a request for a service or payment for a service the enrollee has | |
| | | | | | already received. This notice also must include a description of the applicable appeals | |
| | NOTICE: Notice of Denial of | | TTAG/NIHB | | processes. Section 1932 of SSA sets forth requirements for Medicaid managed care | |
| | Medical Coverage (or Payment) | | <u>File Date</u> : 11/6/2012 | | plans, including beneficiary protections related to appealing a denial of coverage or payment. This notice combines the existing Notice of Denial of Medicare Coverage with | |
| | i ayineni) | | (ANTHC also | | the Notice of Denial of Payment and includes optional language for use in cases where a | |
| | AGENCY: CMS | | filed | | Medicare health plan enrollee also receives full Medicaid benefits managed by the | |
| | | | comments | | Medicare health plan. | |
| | | | 11/6/2012) | | SUMMARY OF TTAG ANALYSIS: The majority of claims filed by Indian health care | |
| | | | Date of | | providers under Medicare and Medicaid involve direct fee-for-service reimbursement | |
| | | | <u>Subsequent</u> | | from the Federal program and not private managed care plans. However, private plan | |
| | | | Agency Action, | | participation by enrollees, as well as by Indian health care providers, has increased | |
| | | | if any: Issued revision | | under Medicare and Medicaid, and the proposed Notice of Denial of Medical Coverage | |
| | | | 4/12/2013, | | (or Payment) will have increasing importance for Indian health care providers. In addition, the guidance provided by CMS through CMS-10003 also might inform future guidance | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | 10/16/2015, 3/11/2016 <u>Due Date</u> : 5/13/2013; 12/15/2015; 4/11/2016 | | from the HHS Secretary with regard to denials of coverage or payment and any corresponding appeals issued by health plans operating in health insurance exchanges (Exchanges) established under ACA. Indian health care providers have experienced significantly higher coverage and payment denial rates than the average rates cited by CMS. A significant source of these denials is a lack of understanding on the part of private health plans of the applicability of IHCIA § 206. IHCIA § 206 requires health plans to pay Indian health care providers for health services rendered to enrolled individuals, regardless of whether the Indian health care provider is an in-network provider. TTAG recommends changes that will reduce unwarranted denials of coverage and payment and a reduction in the corresponding need for appeals. In addition, TTAG recommends changes to decrease the burden on patients and their providers in filing an appeal, as well as improve compliance with filing required information. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/12/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-04-12/pdf/2013-08677.pdf CMS-10003, Instructions, and a Supporting Statement are available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1235051.html. CMS on 10/16/2015 issued a revision of this PRA request. The revised notice contains bracketed text the plan will insert if the denial notice applies to a full dual eligible. The text in square brackets "[]" reflects the federal protections, the form includes free-text space for inclusion of any state-specific protections that exceed the federal protections. http://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-26390.pdf No comments recommended. CMS on 3/11/2016 issued a revision of this PRA request. CMS has revised this information collection subsequent to the publication of the 60-day notice in the 10/16/2015 FR (80 FR 62534). | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05472.pdf No comments recommended. | |
| 80.b. | Advanced Beneficiary Notice of Noncoverage ACTION: Request for Comment NOTICE: Advance Beneficiary Notice of Noncoverage AGENCY: CMS | CMS-R-131 | Issue Date: 12/12/2012 Due Date: 2/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2013; issued extension 11/9/2015, 5/2/2016 Due Date: 3/28/2013; 1/8/2016; 6/1/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Advance Beneficiary Notice of Noncoverage (ABN); Use: Certain Medicare providers and suppliers use the Advanced Beneficiary Notice of Noncoverage (ABN) (CMS-R-131) to inform fee-for-service (FFS) beneficiaries of potential liability for certain items/services billed to the program. Under section 1879 of the Social Security Act, Medicare beneficiaries can have financially responsibility for items or services usually covered under the program, but denied in an individual case under specific statutory exclusions, if beneficiaries are informed that Medicare likely will deny payment prior to furnishing the items or services. When required, Part B paid physicians, providers (including institutional providers, such as outpatient hospitals), practitioners (such as chiropractors), and suppliers, as well as hospice providers and Religious Non-Medical Health Care Institutions paid under Part A, deliver ABN. The revised ABN in this information collection request incorporates expanded use by Home Health Agencies (HHAs), with no substantive changes to the form or changes that will affect existing ABN users. http://www.gpo.gov/fidsys/pkg/FR-2012-12-12/pdf/2012-29951.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/26/2013 issued a revision of this PRA request. The revised ABN in this information collection request incorporates expanded use by HHAs, with no substantive changes to the form and no changes that will affect existing ABN users. http://www.gpo.gov/fidsys/pkg/FR-2013-02-26/pdf/2013-04313.pdf CMS on 11/9/2015 issued an extension of this PRA request. With this PRA submission, CMS has made minimal formatting changes to the ABN form, including the addition of language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (section 504) by alerting the beneficiary to CMS nondiscrimination practices and the availability of alternate forms of this notice, if needed. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | provider/supplier comprehension and decrease the probability of errors in completing the ABN. CMS has made no substantive changes to the form or to the instructions. http://www.gpo.gov/fdsys/pkg/FR-2015-11-09/pdf/2015-28449.pdf No comments recommended. CMS on 5/2/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-02/pdf/2016-10231.pdf No comments recommended. | |
| 80.c. | Notice of Denial of Medicare Prescription Drug Coverage ACTION: Request for Comment NOTICE: Notice of Denial of Medicare Prescription Drug Coverage AGENCY: CMS | CMS-10146 | Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/18/2013, 3/11/2016, 9/12/2016 Due Date: 8/19/2013; 5/10/2016; 10/12/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Notice of Denial of Medicare Prescription Drug Coverage; <i>Use</i> : Section 1860D-4(g)(1) of the Social Security Act requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process. The Part D denial notice, which CMS has revised for clarity, includes new optional language for Part D plan sponsors to use when explaining their denial rationale. Specifically, CMS has added optional language in the denial rationale section of the notice to allow plans to populate text explaining that enrollees have or might have coverage for a drug denied under Part D under a different benefit, such as Part B. CMS also has changes the instructions to guide plans on when to use this optional text. CMS solicits feedback on this new addition, as well as other situations where another benefit might cover a drug (i.e. employer group benefits) and what changes to the denial notice might help in addressing those situations. CMS also seeks comment regarding the potential viability and usefulness of developing a combined notice for Part C and Part D to allow MA-PD plans that deny a drug under Part D to issue an approval letter under Part B simultaneously. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10522.pdf CMS-10146, Instructions, a list of revisions, and a Supporting Statement are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10146.html. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: CMS-10146 does not include specific categories for denial of drug coverage. No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/18/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-18/pdf/2013-17317.pdf CMS on 3/11/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05471.pdf No comments recommended. No comments recommended. | |
| 82.h. | HIPAA Eligibility Transaction System Partner Agreement ACTION: Request for Comment NOTICE: HIPAA Eligibility Transaction System (HETS) Trading Partner Agreement (TPA) AGENCY: CMS | CMS-10157 | Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 1/31/2014; issued extension 5/16/2016, | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection: Title: HIPAA Eligibility Transaction System (HETS) Trading Partner Agreement (TPA); Use: The HIPAA Eligibility Transaction System (HETS) seeks to allow the release of eligibility data to Medicare providers, suppliers, or their authorized billing agents for the purposes of preparing accurate Medicare claims, determining beneficiary liability, or determining eligibility for specific services. Such information disclosures cannot occur to anyone other than providers, suppliers, or a beneficiary associated with a filed claim. http://www.gpo.gov/fdsys/pkg/FR-2013-11-22/pdf/2013-28049.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/31/2014 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-31/pdf/2014-02061.pdf CMS on 5/16/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11499.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date 7/19/2016 Due Date: 3/5/2014; 7/15/2016; 8/18/2016 | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis No comments recommended. | NIHB Recs. |
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| 82.j. | Complaint Forms for Health Information Privacy Issues ACTION: Request for Comment NOTICE: Complaint Forms for Discrimination; Health Information Privacy Complaints AGENCY: HHS OCR | HHS-OS- 0945-0002- 60D HHS-OS- 0945-0002- 30D | Issue Date: 10/20/2015 Due Date: 12/21/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Complaint Forms for Discrimination; Health Information Privacy Complaints; Use: Individuals can file written complaints with the HHS Office for Civil Rights (OCR) when they believe programs or entities that receive federal financial assistance from HHS have discriminated against them or violated their right to the privacy of protected health information. http://www.gpo.gov/fdsys/pkg/FR-2015-10-20/pdf/2015-26604.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/28/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-28/pdf/2015-32551.pdf No comments recommended. | |
| 82.k. | Health Insurance Reform Security Standards ACTION: Request for Comment NOTICE: Health Insurance Reform Security Standards | HHS-OS- 0945-0004- 60D HHS-OS- 0945-0004- 30D | Issue Date: 3/15/2016 Due Date: 5/16/2016 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Health Insurance Reform Security Standards; Use: HHS OCR requests approval to extend this information collection request (ICR) without change while OMB reviews its request to incorporate the burdens of compliance with the HIPAA Security Rule into another existing ICR (OMB 0945-0003, for the HIPAA Privacy Rule and Supporting Regulations), which is currently under revision to reflect agency experience in administering and enforcing the HIPAA rules. This ICR extends the existing approved information collection for applicable | |



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| Ref. | of Regulation/Title/ | File Code | Due Date & | NIHB | Brief Summary of Proposed Agency Action | NIHB Recs. |
| # | Agency | | File Date | Response | and Summary of NIHB Analysis | |
| | AGENCY: HHS | | Date of Subsequent Agency Action, if any: Issued extension 5/19/2016 Due Date: 6/20/2016 | | compliance activities associated with the HIPAA Security Rule. When the revised version of OMB 0945-0003 receives approval, HHS OCR will request discontinuation of this ICR (OMB 0945-0004). https://www.gpo.gov/fdsys/pkg/FR-2016-03-15/pdf/2016-05806.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: HHS on 5/19/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-19/pdf/2016-11757.pdf | |
| | | | | | No comments recommended. | |
| | | | | | | |
| 82.1. | HIPAA Privacy, Security, and Breach Notification Rules ACTION: Request for Comment NOTICE: HIPAA Privacy, Security, and Breach Notification Rules AGENCY: HHS | HHS-OS- 0945-0003- 60D HHS-OS- 0945-0003- 30D | Issue Date: 3/17/2016 Due Date: 5/16/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/19/2016 Due Date: 6/20/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR parts 160 and 164; <i>Use</i> : The HIPAA Rules require covered entities, and in many respects their business associates, to protect the privacy and security of individually identifiable health information (called "protected health information" or "PHI"); fulfill the rights of individuals under HIPAA with respect to their health information; and provide notification in case of a breach of unsecured protected health information. The information collections associated with these regulatory requirements include documenting and updating policies and procedures for ensuring the privacy and security of the health information of individuals, recording compliance activities, providing individuals with a notice of privacy practices and with access to their information upon request, and notifying affected individuals, the HHS Secretary, and in some cases the media of a breach of protected health information. The revision of this information collection request (ICR) does not change any requirements of the HIPAA Privacy, Security, and Breach Notification Rules. Among other updates, this ICR requests to rename the information collection and incorporate into it the substance of two other information collections (OMB 0945-0004, set to expire on 5/31/2016; and OMB 0945-0001, set to expire on September 9/30/2016), which HHS OCR then would discontinue. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-03-17/pdf/2016-05961.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: HHS on 5/19/2016 issued an revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-19/pdf/2016-11785.pdf No comments recommended. | |
| 82.m. | HIPAA Administrative Simplification Complaint Form ACTION: Request for Comment NOTICE: HIPAA Administrative Simplification Complaint Form AGENCY: CMS | CMS-10148 | Issue Date: 6/6/2016 Due Date: 8/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 9/2/2016 Due Date: 10/3/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: HIPAA Administrative Simplification Complaint Form; Use: Subtitle F of title II of HIPAA, titled "Administrative Simplification" (A.S.), requires the HHS Secretary to adopt national standards for certain information-related activities of the health care industry. The HIPAA provisions, by statute, apply only to "covered entities" referred to in section 1320d-2(a) (1) of this title. CMS has responsibility for administering and enforcing the HIPAA A.S. Transactions, Code Sets, and Identifiers. CMS will use this updated information collection to initiate enforcement actions. This reinstatement request clarifies the removal of the HIPAA Security complaint category. Specifically, the information collection revisions clarify the "Identify the HIPAA Non-Privacy/Security complaint category" section of the complaint form. In this section, complainants have an opportunity to check the "Unique Identifiers" and "Operating Rules" option to categorize additionally the type of HIPAA complaint filed. The revised form now includes an option for identifying Unique Identifier and Operating Rules complaints. It also requests e-mail information about filed-against entities, if available. https://www.gpo.gov/fdsys/pkg/FR-2016-06-06/pdf/2016-13289.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/2/2016 issued a reinstatement of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-02/pdf/2016-21201.pdf No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 83.a. | Medicaid/Transformed-Medicaid Statistical Information System ACTION: Request for Comment NOTICE: Medicaid Statistical Information System (MSIS) and Transformed-Medicaid Statistical Information System (T-MSIS) AGENCY: CMS | CMS-R-284 | Issue Date: 8/15/2012 Due Date: 10/15/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/19/2012; issued revision 12/3/2012, 12/31/2015, 4/12/2016 Due Date: 11/19/2012; 1/2/2013; 2/29/2016; 5/12/2016 TTAG File Date: 2/29/2016 | TTAG response: | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Medicaid Statistical Information System (MSIS); Use: States and other jurisdictions use MSIS to report fundamental statistical data on the operation of their Medicaid program. The data provides the only national-level information available on enrollees, beneficiaries, and expenditures. It also provides the only national-level information available on Medicaid utilization. This information serves as the basis for analyses and for cost savings estimates for HHS cost-sharing legislative initiatives to Congress. The data also plays a crucial role in CMS and HHS actuarial forecasts. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/31/2015 issued a revision of this PRA request. CMS has added the Transformed-Medicaid Statistical Information System (T-MSIS) to this information collection. https://www.gpo.gov/fdsys/pkg/FR-2015-12-31/pdf/2015-32880.pdf T-MSIS has the capacity to capture the status of an individual as an IHS beneficiary, which is important for purposes of ensuring that Al/ANs receive cost-sharing and other Indian-specific protections. Tribal organizations might want to submit comments on this issue. Analysis From Joan O'Connell: This is what I know about T-MSIS and the December notice in the Federal Register. First, we have been asking Kitty/Jim for information on Al/AN Medicaid enrollees and I/T/U providers from T-MSIS for months. I feel it is extremely important to obtain data to see if the new variables are being used correctly. Jim Lyon told us that he is trying to reach out to CMS' Jeff Silverman for information. We asked Jim if Jeff could participate in the January TTAG Data Subcommittee call or Data Subcommittee meeting in February, or if we could schedule a call with Jeff. We have had no word yet on that. In addition, I contacted by phone and by email CMS' Camiel Rowe, who is listed on the T-MSIS December notice in the Federal Register | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | I/T/Us in T-MSIS by this past Tuesday. I followed up with her again since I have had no word back yet I think lack of our having T-MSIS data is an important issue to raise in a response to the notice in the Federal Registereven though the types of T-MSIS measures in not directly addressed in the notice. The changes address monthly reporting and the value of the data. Although the notice is to report hours to be spent on the proposed change for states to report data more frequently to CMS, I think a response to this notice could: Support state Medicaid programs' monthly submissions of data to CMS in order to have timely data on Medicaid enrollees and providers; Describe Al/AN disparities and key Medicaid Al/AN and I/T provider provision; State the importance of having T-MSIS data for Al/AN and I/T/Us to monitor implementation of Al/AN protections and I/T payments to ensure "the proper performance of CMS functions"; T-MSIS is a national database and source for information from all states; Note since its implementation we have not seen reports for Al/AN enrollees or I/T providers; and Request that regular reports be available on a quarterly basis to monitor use of measures, Al/AN protections, and I/T payments from T-MSIS to ensure the "quality, utility, and clarity of the information to be collected." CMS on 4/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-12/pdf/2016-08116.pdf No comments recommended. | |
| 89.d. | Cost-Sharing Reductions Reconciliation Methodology ACTION: Request for Comment | CMS-10469 | <u>Issue Date:</u> 4/12/2013 <u>Due Date:</u> 6/11/2013 <u>NIHB File</u> | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Issuer Reporting Requirements for Selecting a Cost-Sharing Reductions Reconciliation Methodology; <i>Use</i> : Under established HHS regulations (CMS-9964-F), qualified health plan (QHP) issuers will receive advance payments of the cost-sharing reductions throughout the year. Each issuer will then undergo one of two reconciliation processes after the year to ensure that HHS reimbursed each issuer the correct advance cost-sharing amount (pending regulation at CMS-9964-IFC). This information collection | |



| | Short Title/Current Status | | Issue Date; | | | |
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| # | Agency | The odde | File Date | Response | and Summary of NIHB Analysis | WITID RCC3. |
| | NOTICE: Issuer Reporting | | Date: None | | request establishes the data collection requirements for a QHP issuer to report to HHS | |
| | Requirements for Selecting | | | | which reconciliation reporting option the issuer will undergo for a given benefit year. | |
| | a Cost-Sharing Reductions | | Date of | | | |
| | Reconciliation Methodology | | <u>Subsequent</u> | | Sections 1402 and 1412 of ACA provide for reductions in cost sharing on essential health | |
| | | | Agency | | benefits for low- and moderate-income enrollees in silver level QHPs on individual | |
| | AGENCY: CMS | | Action, if any: | | market Exchanges. ACA also provides for reductions in cost sharing for Indians enrolled | |
| | | | Issued new | | in QHPs at any metal level. The law directs QHP issuers to notify the HHS Secretary of cost-sharing reductions made under the statute for qualified individuals and directs the | |
| | | | request 6/28/2013; | | HHS Secretary to make periodic and timely payments to the QHP issuer equal to the | |
| | | | issued | | value of those reductions. Further, the law permits advance payment of the cost-sharing | |
| | | | extension | | reduction amounts to QHP issuers based upon amounts specified by the HHS Secretary. | |
| | | | 5/16/2016, | | Treatment and the term isotative success appearance operation and the contractive | |
| | | | 8/10/2016 | | On 3/11/2013, HHS published a final rule (78 FR 15410) entitled "HHS Notice of Benefit | |
| | | | | | and Payment Parameters for 2014." This rule established a payment approach under | |
| | | | <u>Due Date:</u> | | which CMS would make monthly advance payments to issuers to cover projected cost- | |
| | | | 7/29/2013; | | sharing reduction amounts and then reconcile those advance payments after the end of | |
| | | | 7/15/2016, | | the benefit year to the actual cost-sharing reduction amounts. The reconciliation process | |
| | | | 9/9/2016 | | described in the rule will require that QHP issuers provide CMS the amount of cost sharing paid by each enrollee, as well as the level of cost sharing that each enrollee | |
| | | | | | would have paid under a standard plan without cost-sharing reductions. To determine | |
| | | | | | this amount, QHP issuers must re-adjudicate each claim for these enrollees under a | |
| | | | | | standard plan structure. | |
| | | | | | | |
| | | | | | In response to concerns that the reporting requirements of the reconciliation process for | |
| | | | | | QHP issuers will pose operational challenges for some issuers, CMS on 3/11/2013 also | |
| | | | | | issued an interim final rule (CMS-9964-IFC) with comment period (78 FR 15541), entitled | |
| | | | | | "Amendments to the HHS Notice of Benefit and Payment Parameters for 2014," that laid | |
| | | | | | out an alternative approach that QHP issuers can elect to pursue with respect to the reporting requirements. This alternative approach would allow a QHP issuer to estimate | |
| | | | | | the amount of cost sharing an enrollee receiving cost-sharing reductions would have paid | |
| | | | | | under a standard plan in the Exchange, rather than re-adjudicating each claim for the | |
| | | | | | enrollee. Prior to the start of each coverage year, QHP issuers must notify HHS of the | |
| | | | | | methodology they have selected for the benefit year. QHP issuers will provide | |
| | | | | | information on which option they choose via the Health Insurance Oversight System | |
| | | | | | (HIOS), a Web-based data collection system currently used by issuers to provide | |
| | | | | | information for the healthcare.gov Web site. | |
| | | | | | | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | http://www.gpo.gov/fdsys/pkg/FR-2013-04-12/pdf/2013-08676.pdf A Supporting Statement for this PRA request is available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10469.html. SUMMARY OF NIHB ANALYSIS: This PRA request refers to the pending CMS-9964-IFC. The core issue in the regulation is to provide reimbursement to QHPs for the cost of cost-sharing assistance provided to enrollees. "This alternative approach [in CMS-9964-IFC] would allow a QHP issuer to estimate the amount of cost sharing an enrollee receiving cost-sharing reductions would have paid under a standard plan in the Exchange, rather than re-adjudicating each claim for the enrollee." This option is provided "to permit a reasonable transition period in which QHP issuers will be allowed to choose the methodology that best aligns with their operational practices, which should reduce the administrative burden on issuers in the initial years of the Exchanges All submissions will be made electronically and no paper submissions are required." (78 FR 21957) SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a new version of this PRA request. CMS received no comments in response to a 60-day notice on this information collection published in the 4/12/2013 FR (78 FR 21956). http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15539.pdf CMS on 5/16/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11499.pdf No comments recommended. CMS on 8/10/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-18986.pdf No comments recommended. | |
| 89.g. | Cost Sharing Reduction | CMS-10526 | Issue Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. | | | |
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| | Reconciliation ACTION: Request for Comment NOTICE: Cost Sharing Reduction Reconciliation AGENCY: CMS | | 6/27/2014 Due Date: 8/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/26/2014; issued revision 9/14/2015, 1/20/2016 Due Date: 10/27/2014; 11/13/2015; 2/19/2016 | | collection: Title: Cost Sharing Reduction Reconciliation; Use: Under established HHS regulations, qualified health plan (QHP) issuers will receive estimated advance payments of cost-sharing reductions throughout the year. Each issuer will then undergo a reconciliation process at the end of the benefit year to ensure that HHS reimburses each issuer only for actual cost sharing. This information collection establishes the data elements that a OHP issuer would have to report to HHS to establish the cost-sharing reductions provided on behalf of enrollees for the benefit year. http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15075.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. ACA provides for cost-sharing reductions (CSRs) for eligible individuals who purchase health insurance from a qualified health plan (OHP) through an Exchange. On 3/11/2013, CMS issued a final rule (CMS-9964-F, Payment Notice) that detailed a plan in which HHS would advance monthly payments to issuers for estimated CSRs and then reconcile the advanced amounts against actual CSRs provided by issuers to eligible enrollees during the benefit year. The Payment Notice detailed a methodology for issuers to use when calculating and submitting to HHS the actual CSR amounts provided to enrollees in a benefit year. In response to concerns about the complexity of the methodology, CMS on 10/30/2013 issued a final rule (CMS-9957-F2/CMS-9964-F3) that allows QHP issuers to elect to use a simplified formula during the first three years of the program, from 2014 through 2016, to estimate CSRs provided to enrollees. Under this PRA request, CMS proposes to collect data for both the standard and simplified methodologies through the CSR Reconciliation Data Template. This information collection would allow HHS to gather data necessary to reconcile dollar amounts advanced to QHP issuers by HHS with dollar amounts paid (either actual or reestimated) by the issuer on behalf of an enrollee and recoup or remit the balance. In prior recommendations, TTAG su | | | | |
| | | | | | and not actually provide the cost-sharing reductions due to enrollees. In response, CMS | | | | |



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| | | | | | indicated that issuers will have to use the standard methodology, which relies on actual cost-sharing reduction payments, after 2016. However, CMS stated that CMS "will continue to consider alternative approaches for reimbursing QHP issuers for the future, including a capitated payment system" (See 89.b. and 7.bb. for additional details). | |
| | | | | | TTAG also recommended that CMS ensure the collection of a robust amount of data on the actual payments made by issuers under the Indian-specific cost-sharing variations and ensure the collection of data represents the experiences of all health plans, with consideration to factors such as the service areas of plans, the degree of I/T/U penetration in the service areas, the percentage of Al/ANs enrolled in a plan, plan size and market concentration, and whether plans provided protections under the limited or zero cost-sharing variations. Again, this recommendation sought to ensure any estimated or capitated systems reflect actual payment made on behalf of Al/ANs and not inadvertently create incentives for health plans to deny the cost-sharing protections due to Al/ANs. | |
| | | | | | This PRA request is consistent with the TTAG recommendations in that it is for the purpose of gathering data from health plans to permit CMS to reconcile advance payments made with actual (and re-estimated) payments made and potentially to develop alternative payment approaches for future periods based on a robust set of data. | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/26/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-22980.pdf | |
| | | | | | CMS on 9/14/2015 issued a revision of this PRA request. This revised collection eliminates some data elements and requires summary plan level reporting and reporting in the 2016 reconciliation cycle on the dollar amount of 2014 cost-sharing reductions used in calculations for medical loss ratio and risk corridors programs reporting. http://www.gpo.gov/fdsys/pkg/FR-2015-09-14/pdf/2015-22959.pdf | |
| | | | | | The revised CSR Reconciliation Data Elements form and a Supporting Statement for this PRA request are available at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10526-html . | |
| | | | | | On 4/30/2013, tribal organizations submitted comments in response to CMS-9964-IFC | |



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| | | | | | (see 89.b.), which included an alternative, optional methodology for calculating the value of cost-sharing reductions provided for the purpose of reconciliation of advance payments of cost-sharing reductions and created a transition period permitting the use of this alternative. CMS on 1/20/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-20/pdf/2016-00994.pdf No comments recommended. | |
| 89.m. | Notice of Benefit and Payment Parameters for 2017 ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 AGENCY: CMS | CMS-9937- PF | Issue Date: 12/2/2015 Due Date: 12/21/2015 TTAG File Date: 12/21/2015; TSGAC also filed comments 12/21/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 3/8/2016, issued correction 8/11/2016 | TTAG response: TSGAC response: | SUMMARY OF AGENCY ACTION: This proposed rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost sharing reductions; and user fees for Federally-Facilitated Exchanges. It also provides additional standards for the annual open enrollment period for the individual market for the 2017 benefit year; essential health benefits; cost-sharing requirements; qualified health plans; updated standards for Exchange consumer assistance programs; network adequacy; patient safety standards; the Small Business Health Options Program; stand-alone dental plans; acceptance of third-party payments by qualified health plans; the definitions of large employer and small employer; fair health insurance premiums; guaranteed availability; student health insurance coverage; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions and appeals; and other related topics. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-29884.pdf A fact sheet on this proposed rule is available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CMS-9937-P-Fact-Sheet-final-112015.pdf. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-Facilitated Exchanges. It also provides additional amendments regarding the annual open enrollment period for the individual market for the 2017and 2018 benefit | See Table C. |



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| | | | | | years; essential health benefits; cost sharing; qualified health plans; Exchange consumer assistance programs; network adequacy; patient safety; the Small Business Health Options Program; stand-alone dental plans; third-party payments to qualified health plans; the definitions of large employer and small employer; fair health insurance premiums; student health insurance coverage; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions and appeals; and other related topics. | |
| | | | | | State-Based Marketplaces on the Federal Platform (SBM-FPs) This Marketplace model, newly established in this final rule, will enable State-Based Marketplaces (SBMs) to execute certain processes using the federal eligibility enrollment infrastructure. SBM-FPs and HHS will have to enter into a federal platform agreement that will define a set of mutual obligations, including the set of federal services upon which the SBM-FP agrees to rely. Under this model, certain requirements previously only applicable to QHPs offered on FFMs will apply to QHPs offered on SBM-FPs. SBM-FPs must agree to enforce certain QHP and QHP issuer requirements no less strict than those HHS applies to QHPs and QHP issuers in FFMs, as follows: | |
| | | | | | 45 CFR 156.122(d)(2): the standards for QHPs to make available published upto-date, accurate, and complete formulary drug lists on its website in a format and at times determined by HHS; 45 CFR 156.230: network adequacy standards; 45 CFR 156.235: ECP standards [mandatory "good faith" offer of contracts by QHPs to IHCPs]; 45 CFR 156.298: meaningful difference standards; 45 CFR 156.330: issuer change of ownership standards; 45 CFR 156.340(a)(4): issuer compliance and compliance of delegated and downstream entity standards; and 45 CFR 156.1010: casework standards. | |
| | | | | | The annual CCIIO Letter to Issuers in the FFM will include implementing guidance specific to SBE-FPs. A CMS fact sheet on this final rule is available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CMS-9937-F-Fact-Sheet-Final-2-29-16.pdf . | |



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| | | | | | A Modern Healthcare article about this final rule is available at http://www.modernhealthcare.com/article/20160229/NEWS/160229878 . CMS on 8/11/2016 issued a document (CMS-9937-F2) to correct technical and typographical errors that appeared in the final rule published in the 3/8/2016 FR (81 FR 12204) and titled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017." This document makes the following corrections: 1. On page 12296, in the second column, in the first full paragraph, lines 18 and 19, the phrase "paragraphs (c)(1)(ii), and (c)(2)(iii) of this paragraph, is corrected to read "paragraphs (c)(1)(ii), (c)(2)(iii), and (c)(3)(ii) of this section". 2. On page 12310, a. In the third column, second full paragraph, line 3, the phrase "3-month grace period" is corrected to read "3 consecutive month grace period". b. In the third column, second full paragraph, line 29, the phrase "3-month grace period" is corrected to read "3 consecutive month grace period". c. In the third column, second full paragraph, line 38, the phrase "grace period of 3 months" is corrected to read "grace period of 3 consecutive months". 3. On page 12311, a. In the first column, in the first full paragraph, line 7, the phrase "3-month grace period" is corrected to read "3 consecutive month grace period". c. In the first column, in the first full paragraph, line 24 through 25, the phrase "3-month grace period" is corrected to read "3 consecutive month grace period". d. In the second column, in the first full paragraph, line 8, the phrase "3-month grace period" is corrected to read "3 consecutive month grace period". e. In the second column, in the second full paragraph, line 14, the phrase "3-month grace period" is corrected to read "3 consecutive month grace period". f. In the second column, in the third full paragraph, line 22, the phrase "3-month grace period" is corrected to read "3 consecutive month gr | |



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| | | | | | h. In the third column, in the first partial paragraph, line 12, the phrase "3-month grace period" is corrected to read "3 consecutive month grace period". https://www.gpo.gov/fdsys/pkg/FR-2016-08-11/pdf/2016-19108.pdf | |
| 89.n. | Manual for Reconciliation of Advance Payment of CSRs ACTION: Guidance NOTICE: Draft-Manual for Reconciliation of Advance Payment of Cost-Sharing Reductions for Benefit Years 2014 and 2015 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 1/15/2016 Due Date: 2/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 3/16/2016 | | SUMMARY OF AGENCY ACTION: This draft manual for all issuers offering a qualified health plan (OHP) through a health insurance Marketplace provides information on the process for reconciling advance payment of cost-sharing reduction amounts that QHP issuers have received to reflect the cost-sharing reduction amounts those issuers provided to eligible Marketplace enrollees. This draft manual provides QHP issuers with general instructions on using the standard, simplified, and actuarial value methodologies described at 45 CFR § 156.430 for the purpose of determining the value of cost-sharing reduction amounts provided to eligible Marketplace enrollees and further describes the data elements issuers must submit when the annual cost-sharing reduction reconciliation process begins in spring 2016. CMS requests comment on this draft manual. Please submit comments to CSRreview@cms.hhs.gov by 5 p.m. on 2/15/2016. When submitting comments, please indicate the section of the draft manual to which the comment pertains. After carefully considering comments received, CMS intends to publish a final version of this manual prior to data submission. Collection of these data elements has approval under OMB control number 0938-1266. Technical guidance on actual submission of data will appear in separate documents posted with this manual (see below). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CMS-Guidance-on-CSR-Reconciliation.pdf The document titled "CSR Reconciliation: Issuer to MIDAS Attestation Inbound Specification" is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CSR-Recon-Issuer-to-MIDAS-Inbound-Specification_DRAFT.pdf. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | The document titled "CSR Reconciliation: Sample Pipe Delimited Format" is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CSR-Reconcilation-Sample-Pipe-Delimited-Format-DRAFT-01-13-2016.pdf . | |
| | | | | | SUMMARY OF NIHB ANALYSIS: | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This manual for all issuers offering a qualified health plan (QHP) through a health insurance Marketplace provides information on the process for reconciling advance payment of cost-sharing reduction amounts that QHP issuers have received to reflect the cost-sharing reduction amounts those issuers provided to eligible Marketplace enrollees. This manual provides QHP issuers with general instructions on using the standard, simplified, and actuarial value methodologies described at 45 CFR § 156.430 for the purpose of determining the value of cost-sharing reduction amounts provided to eligible Marketplace enrollees and further describes the data elements issuers must submit when the annual cost-sharing reduction reconciliation process begins in April 2016. | |
| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and- Guidance/Downloads/CMS Guidance on CSR Reconciliation- for_2014_and_2015_benefit_years.pdf | |
| | | | | | The Indian-specific references in this manual appear below. | |
| | | | | | Background/Reduced Cost-Sharing for Eligible Enrollees (page 5): This manual states, "Reduced cost sharing must be available to eligible enrollees who are enrolled in a silver level plan through the Marketplace, or for Indians who are enrolled in any metal level plan through the Marketplace." Background/Timing of the Reconciliation Process (page 6): According to this manual, "On February 13, 2015, CMS announced that advance payments for cost-sharing reductions for the 2014 benefit year would be reconciled in April 2016, rather than in April 2015. The new timetable was established to enhance the accuracy of reconciliation of cost-sharing reduction payments to issuers, and to fully reimburse issuers for reductions in cost sharing provided to eligible low- and moderate-income enrollees and Indian enrollees for the 2014 benefit year." The Standard Methodology/Re-Adjudication of Claims (pages 10-11): On zero and limited cost-sharing plans, this manual notes, "For each of its health | |



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| | ngono y | | | | plans at any level of coverage that an issuer offers, the issuer must submit a zero cost-sharing and limited cost-sharing plan variation. Issuers are required to provide cost sharing reductions for in-network EHB and, provided the standard plan covers it, for out-of-network EHB. If the standard plan does not cover out-of-network EHB, the issuer should not reduce cost sharing for out-of-network EHB. As discussed in QHP Webinar Series FAQs #84 (April 25, 2013), this policy also applies to out-of-network EHB obtained from the Indian Health Service, Tribal or Urban Indian providers, collectively ITU providers. Non-covered services or balance billing for covered out-of-network EHB are not included in the definition of cost sharing; therefore, issuers will not be reimbursed for any CSR on non-covered services or providers or balance billing." In a related footnote, this manual adds, "Enrollee spending for non-covered services is not considered cost sharing. As a result, if a QHP does not cover certain services, (or all services) furnished by a provider outside the network, the spending for these non-covered services would not need to be eliminated for the zero or limited cost sharing plans, even if the service was furnished directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization." • Definitions (page 29): This manual defines cost-sharing reductions as "reductions in cost sharing for an eligible individual enrolled in a Silver level plan in the Exchange or for an individual who is an Indian enrolled in a QHP in the Exchange." | |
| 89.0. | CSR Reconciliation Issuer to MIDAS Attestation ACTION: Guidance NOTICE: CSR Reconciliation Issuer to MIDAS Attestation Inbound Specification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/9/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This document provides the details on cost-sharing reduction (CSR) attestation files received in the Multidimensional Insurance Data Analytics System (MIDAS). The attestation files will appear in Excel document format, with Attestation Forms A, B, and C, as applicable, sent together in a zipped format. All issuers must attest that CSR amounts provided to enrollees and submitted for reimbursement represent only cost-sharing for essential health benefits for which federal reimbursement can occur, as well as amounts paid to fee-for-service providers to the extent issuers passed through the amounts to such providers. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CSR-Reconciliation-Issuer-to-MIDAS-Inbound-Attestation-Specification.pdf A list of attestation error codes for the cost-sharing component of advance payments to | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | issuers is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Cost-Sharing-Reduction-Reconciliation-Attestation-Error-Codes-List-03_25_2016.xlsx . SUMMARY OF NIHB ANALYSIS: This guidance contains no Indian-specific provisions. | |
| 89.p. | CSR Reconciliation Issuer to MIDAS Inbound Specification ACTION: Guidance NOTICE: CSR Reconciliation Issuer to MIDAS Inbound Specification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 3/9/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This document provides the details on cost-sharing reduction (CSR) reconciliation files received in the Multidimensional Insurance Data Analytics System (MIDAS). The issuer will need to submit files to MIDAS in pipe delimited format. Issuers will use ASCII text as the file format and will use a CRLF as the line terminator. The file submitted by issuers should have only ONE HIOS identifier. If the issuer submits data for multiple HIOS IDs, e.g. as the result of an acquisition, the issuer must create a separate file for each HIOS ID. CSRI will serve as the function code for this submission. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CSR-Reconciliation-Issuer-to-MIDAS-Inbound-Specification.pdf A list of error codes for the cost-sharing component of advance payments to issuers is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Part-2-EDGE-Q_O-Guidance_03182016.pdf. SUMMARY OF NIHB ANALYSIS: This guidance contains no Indian-specific provisions. | |
| 89.q. | Data Submission Deadline for CSR Reconciliation ACTION: Guidance NOTICE: Data Submission Deadline for Cost-Sharing Reduction Reconciliation AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/15/2016 Due Date: None NIHB File Date: Date of Subsequent | | SUMMARY OF AGENCY ACTION: Data submission to determine the reconciliation of cost-sharing reductions provided for the 2014 and 2015 benefit years began on 4/1/2016. To ensure the accuracy of data submission, and to accommodate issuers submitting data for both the 2014 and 2015 benefit years for the first time, CMS will extend the final deadline for submission of 2014 and 2015 cost-sharing reduction reconciliation data to 6/3/2016 at 11:59 p.m. ET. Additionally, to help ensure that issuers can submit their CSR reconciliation data successfully by the 6/3/2016 deadline, CMS will establish an interim data submission deadline of 5/2/2016, 11:59 p.m. ET, by which time all issuers must have submitted a data file. If an issuer has submitted a data file by the interim deadline, CMS will consider | |



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| | | | Agency Action, if any: | | the issuer in compliance with the interim deadline, even if the file submitted fails agency validations. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-on-data-submission-deadlline-for-CSR-reconciliation-Final-4_15_16.pdf SUMMARY OF NIHB ANALYSIS: | |
| 89.r. | Alternative Schedule for Payment for Reconciliation of CSRs ACTION: Guidance NOTICE: Alternative Schedule for Payment of Charges for Reconciliation of the Cost-sharing Reduction Portion of Advance Payments for the 2014 and 2015 Benefit Years AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/17/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued clarification 6/27/2016 | | SUMMARY OF AGENCY ACTION: The 3/16/2016 Manual for Reconciliation of the Cost-Sharing Reduction Component of Advance Payments for Benefit Years 2014 and 2015 states, "CMS recognizes that in this first year of reconciliation, a few issuers may not have fully anticipated the results of the reconciliation, and could be charged amounts they did not fully expect and cannot immediately pay. In such an event, if circumstances warrant, CMS is willing to work with the issuer on repayment (but would require that the full amount of these charges eventually be paid) consistent with applicable law." This document answers the question of how an issuer can request such an accommodation. According to this document, CMS will consider providing flexibility on the payment schedule for reconciliation of the cost-sharing reduction component of advance payments to assist issuers with cash flow constraints, to ensure they can continue to provide coverage to enrollees through the end of the benefit year. To request such flexibility, an issuer must e-mail CSRrepayment@cms.hhs.gov no later than 11:59 p.m. ET on 7/5/2016. With that request, the issuer must provide CMS with detailed financial statements and projections and must promptly inform its state Department of Insurance that it has requested this flexibility. If the issuer meets the requirements for this flexibility, it must enter into a payment agreement reflecting the terms of that payment schedule with CMS no later than 11:59 p.m. ET on 7/12/2016. The payment schedule will require the payment of interest, in accordance with 45 CFR 30.18. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CSRFAQ.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/27/2016 issued a document to clarify what information an issuer must provide to request the flexibility on | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | the payment schedule as discussed in the 6/17/2016 guidance. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Auto-Re-Enrollment-FAQ-06242016-FINAL.pdf | |
| 89.s. | Discrepancy Resolution Process Inbound Specification (CSRs) ACTION: Guidance NOTICE: Discrepancy Resolution Process Inbound Specification AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/23/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This document provides details on cost-sharing reduction (CSR) reconciliation discrepancy files submitted by the issuer. The issuer will need to submit files in pipe-delimited format. Issuers will use an ASCII text file format and will use a CRLF as the line terminator. The file submitted by the issuer should have only ONE HIOS issuer ID identifier (Note: One discrepancy file will include records that apply to the 2014 and 2015 benefit years, as applicable). If the issuer is submitting data for multiple HIOS IDs, for example as the result of an acquisition, the issuer must create a separate file for each HIOS ID. CSRDRI will serve as the function code for this submission. CMS will accept only discrepancy files through Enterprise File Transfer (EFT). Accordingly, the file name must adhere to the EFT file name format requirements described in this document. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Cost-Sharing-Reduction-Reconciliation-Discrepancy-Resolution-Inbound-Specification.pdf | |
| 89.t. | Notice of Benefit and Payment Parameters for 2018 ACTION: Proposed Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 AGENCY: CMS | CMS-9934-P | Issue Date: 9/6/2016 Due Date: 10/6/2016 TSGAC File Date: 10/5/2016 Date of Subsequent Agency | TSGAC response: | SUMMARY OF AGENCY ACTION: This proposed rule sets forth payment parameters and provisions related to the risk adjustment program; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform. It also provides additional guidance relating to standardized options; qualified health plans; consumer assistance tools; network adequacy; the Small Business Health Options Program; stand-alone dental plans; fair health insurance premiums; guaranteed renewability; the medical loss ratio program; eligibility and enrollment; appeals; and other related topics. https://www.gpo.gov/fdsys/pkg/FR-2016-09-06/pdf/2016-20896.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAOs/Downloads/CMS-9934-P- | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | Action, if any: | | Fact-Sheet-8-29-16.pdf. A Modern Healthcare article on this proposed rule is available at http://www.modernhealthcare.com/article/20160829/NEWS/160829915 . SUMMARY OF TSGAC ANALYSIS: The proposed rule poses concerns for Tribes, tribal organizations, and Al/ANs in the following areas: • Special Enrollment Periods (§ 155.420); • FFE User Fee for the 2018 Benefit Year (§ 156.50); • Levels of Coverage: Bronze Plans (§ 156.140); and • Network Adequacy Standards (§ 156.230). | |
| 92.b. | Compliance with Individual and Group Market Reforms ACTION: Request for Comment NOTICE: Information Collection Requirements for Compliance with Individual and Group Market Reforms AGENCY: CMS | CMS-10430 | Issue Date: 11/21/2012 Due Date: 1/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 2/22/2013; issued revision 12/2/2015, 3/1/2016 Due Date: 3/25/2013; | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; Use: The provisions of title XXVII of the Public Health Service Act (PHS Act) promote access to health insurance and reduce allowable limitations on coverage. Sections 2723 and 2761 of the PHS Act direct CMS to enforce title XXVII with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the individual and group market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. This collection also pertains to notices issued by individual and group health insurance issuers and self-funded non-Federal governmental plans. This collection includes the issuance of certificates of creditable coverage; notification of preexisting condition exclusions; notification of special enrollment rights; and review of issuer filings of individual and group market products or similar Federal review in cases in which a state is not enforcing a title XXVII individual or group market provision. SUMMARY OF NIHB ANALYSIS: The underlying policies pertaining to individual and group market reforms under ACA (and prior law) are presented in various proposed rules by CMS, with the most recent being CMS-9972: Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review; Proposed Rule. This Paperwork Reduction Act comment request merely identifies the applicable provisions of title XXVII of the PHSA and the estimated number of hours for insurers to file the information that | |



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| | | | 2/1/2016; 3/31/2016 | | may be requested by CMS. CMS-10430 is instructive, though, in identifying the sections of the PHSA for which they will evaluate state enforcement efforts and undertake enforcement actions if determined to be needed. The statutory provisions and implementing regulations that are the subject of this submission implement group and individual market reforms under title XXVII of the PHS Act, as they apply to non-Federal governmental group health plans and group and individual health insurance issuers. The group provisions apply to employment-related group health plans and to the issuers who sell insurance in connection with group health plans. For purposes of title XXVII of the PHS Act, all other health insurance is sold in the individual market. The topics contained in the applicable provisions identified in CMS-10430 include: Certificates and disclosure of prior coverage; Notice of preexisting condition exclusion; Notice to participants regarding special enrollment periods; Notice of impaired financial capability; Federal review of policy forms to ensure guaranteed availability; Federal review of policy forms to ensure guaranteed renewability; Full disclosure by issuers to all small employers of materials on all products and other information; Federal review of policy forms to ensure coverage for the essential health benefits package; Notice to Federal government of self-funded, non-Federal government plan optout; and Notice to non-Federal government plan enrollees of opt-out. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/22/2013 issued a restatement of this PRA request. This information collection includes minimal changes to reflect laws passed since the approval of the previous collection document, which expired 9/30/2012. The OMB control number for this proposed collection will remain the same, but it will receive a new CMS Form Number. http://www.gpo.gov/fdsys/pkg/FR-2013-02-22/pdf/2013-04135.pdf | |



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| | | | | | CMS on 12/2/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf No comments recommended. CMS on 3/1/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04462.pdf No comments recommended. | |
| 92.d. | Patient Protection Notices and Disclosure Requirements ACTION: Request for Comment NOTICE: Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection Under the Affordable Care Act AGENCY: CMS | CMS-10330 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection under the Affordable Care Act; Use: Under section 2711 of the Public Health Service Act (PHS Act) as amended by ACA, health plans used the enrollment opportunity notice to notify certain individuals of their right to re-enroll in their plan. The affected individuals included those whose coverage ended because of reaching a lifetime limit on the dollar value of all benefits for any individual. Use of this notice, a one-time requirement, will not continue. Under section 2712 of the PHS Act as amended by ACA, health plans will use the rescission notice to provide advance notice to certain individuals who might have their coverage rescinded. The affected individuals include those at risk of rescission on their health coverage. Under section 2719A of the PHS Act as amended by ACA, health plans will use the patient protection notification to inform certain individuals of their right to choose a primary care provider or pediatrician and to use obstetrical/gynecological services without prior authorization. http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07798.pdf SUMMARY OF NIHB ANALYSIS: The ability to identify an I/T/U provider as the primary care provider for an enrollee under an Exchange-facilitated plan is important. This plan- issued notice will inform enrollees of the ability to select a primary care provider of choice. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15539.pdf CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03473.pdf No comments recommended. | |
| 92.e. | Disclosure and Recordkeeping for Grandfathered Health Plans ACTION: Request for Comment NOTICE: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care Act AGENCY: CMS | CMS-10325 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care Act; Use: Section 1251 of ACA provides that certain health plans in existence as of March 23, 2010grandfathered health plansdo not have to comply with certain statutory provisions in the law. To maintain grandfathered health plan status, the Interim Final Rule titled "Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act" requires a plan to maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents needed to verify, explain, or clarify its status. The plan must make these records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official. The recordkeeping requirement will allow verification of the grandfathered health plan status of the plan. A plan also must include a statement in any plan materials provided to participants or beneficiaries (in the individual market, primary subscribers) describing the benefits provided under the plan and indicating its grandfathered health plan status. The disclosure requirement will provide participants and beneficiaries with important information, such as that grandfathered health plans do not have to comply with certain consumer protection provisions contained in ACA, as well as contact information that they can use to determine which protections apply and the circumstances under which a plan might lose grandfathered health plan status. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15539.pdf CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03473.pdf No comments recommended. | |
| 92.s. | Rate Increase Disclosure and Review Reporting Requirements ACTION: Request for Comment NOTICE: Rate Increase Disclosure and Review Reporting Requirements AGENCY: CMS | CMS-10379 | Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 4/2/2014; issued revision 2/19/2016 Due Date: 5/2/2014; 4/19/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved information collection: Title: Rate Increase Disclosure and Review Reporting Requirements; Use: Section 1003 of ACA adds a new section 2794 of the Public Health Service Act (PHS Act) directing the HHS Secretary, in conjunction with states, to establish a process for the annual review of "unreasonable increases in premiums for health insurance coverage." The statute provides that health insurance issuers must submit to the HHS Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 also specifies that, beginning with plan years starting in 2014, the HHS Secretary, in conjunction with states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. Section 2794 directs the HHS Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. The regulation therefore develops a process to ensure the public disclosure of all such information and justification. Section 2794 requires that health insurance issuers submit justification for an unreasonable rate increase to both CMS and the relevant state prior to its implementation. Additionally, section 2794 requires the HHS Secretary, in conjunction with states, to monitor rate increases effective in 2014 (submitted for review in 2013). To those ends, the regulation establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined unreasonable by a state or CMS, and a notification requirement for unreasonable rate increases that the issuer will not implement. | |



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| | | | | | On 11/14/ 2013, CMS issued a letter to State Insurance Commissioners outlining transitional policy for non-grandfathered coverage in the small group and individual health insurance markets. If permitted by applicable state authorities, health insurance issuers can continue coverage that would otherwise get terminated or cancelled, and affected individuals and small businesses can re-enroll in such coverage. Under this transitional policy, non-grandfathered health insurance coverage in the individual or small group market renewed for a policy year starting between 1/1/2014 and 10/1/2014 will remain in compliance with certain market reforms if it meets certain specific conditions. These transitional plans remain subject to the requirements of section 2794 but not 2701 (market rating rules), 2702 (guaranteed availability), 2704 (prohibition on health status rating), 2705 (prohibition on health status discrimination), and 2707 (requirements of essential health benefits). In addition, because the single risk pool (1311(e)) depends on all of the aforementioned sections (2701, 2702, 2704, 2705, and 2707), the transitional plans remain exempt from the single risk pool. CMS designed the Unified Rate Review Template and system exclusively for use with the single risk pool plan, and any attempt to include non-single risk pool plans in the Unified Rate Review template or system will create errors, inaccuracies, and limitations that would prevent the effectiveness of reviews of both sets of non-grandfathered plans (single risk pool and transitional). For these many reasons, CMS requires issuers with transitional plans experiencing rate increases subject to review to use the Rate Review Justification system and templates required and utilized prior to 4/1/2013. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30994.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/2/2014 issued a reinstatement of this PRA request establishes reporting requirements for 1) insurance prod | |



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| | | | | | No comments recommended. | |
| 92.hh. | Annual Eligibility Redetermination Notices, et al. ACTION: Request for Comment NOTICE: Annual Eligibility Redetermination, Product Discontinuation, and Renewal Notices AGENCY: CMS | CMS-10527 | Issue Date: 11/4/2014 Due Date: 1/5/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/23/2015; issued revision 4/28/2016, 9/16/2016 Due Date: 2/23/2015; 6/27/2016; 10/17/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Annual Eligibility Redetermination, Product Discontinuation, and Renewal Notices; <i>Use</i> : Section 1411(f)(1)(B) of ACA directs the HHS Secretary to establish procedures to redetermine the eligibility of individuals on a periodic basis in appropriate circumstances. Section 1321(a) of ACA provides authority for the HHS Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, Qualified Health Plans (QHPs), and other components of title I of ACA. Under section 2703 of the Public Health Service Act (PHS Act), as added by ACA, and sections 2712 and 2741 of the PHS Act, enacted by HIPAA, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies. The final rule "Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges" (79 FR 52994) provides that an Exchange can choose to conduct the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the coverage year; or (3) using an alternative proposed by the Exchange and approved by the HHS Secretary. The guidance document "Guidance on Annual Redeterminations for Coverage year, as noted in (2) above. These procedures will apply to the Federally-Facilitated Exchange. Under this option, the Exchange will provide three notices, which the Exchange can combine. The final rule also amends the requirements for product renewal and re-enrollment (or non-renewal) notices sent by OHP issuers in the Exchanges and specifies content for these notices. The accompanying guidance document "Form and Manner o | |



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| | Agency | | FIIE Date | | or Individual Market" or any forms of the notice otherwise permitted by applicable laws and regulations. States enforcing ACA can develop their own standard notices for product discontinuances, renewals, or both, provided the State-developed notices provide at least the same level of protection as the Federal standard notices. http://www.gpo.gov/fdsys/pkg/FR-2014-11-04/pdf/2014-26041.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/23/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01127.pdf No comments recommended. CMS on 4/28/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-28/pdf/2016-09953.pdf CMS on 9/16/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-16/pdf/2016-22342.pdf No comments recommended. | |
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| 92.kk. | Coverage and Uniform | CMS-10407 See also | <u>Issue Date:</u> 11/24/2014 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Summary of Benefits and Coverage and Uniform Glossary; Use: Section 2715 of the Public Health Service Act directs HHS, the | |
| | Glossary | See also 31.tt. | <u>Due Date:</u> | | Department of Labor (DoL), and the Department of the Treasury (collectively, the | |
| | ACTION: Request for Comment | | 1/23/2015 | | Departments), in consultation with the National Association of Insurance Commissioners | |
| | Comment | | NIHB File | | (NAIC) and a working group comprised of stakeholders, to "develop standards for use by a group health plan and a health insurance issuer in compiling and providing to | |
| | NOTICE: Summary of | | Date: None | | applicants, enrollees, and policyholders and certificate holders a summary of benefits | |
| | Benefits and Coverage and Uniform Glossary | | Date of | | and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage." To implement these disclosure requirements, collection of | |
| | j | | Subsequent | | information requests relate to the provision of the following: summary of benefits and | |
| | AGENCY: CMS | | Agency Action, if any: | | coverage, which includes coverage examples; a uniform glossary of health coverage and medical terms; and a notice of modifications. | |



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| | . igonoj | | Issued extension 2/24/2015; issued revision 2/26/2016 Due Date: 3/26/2015; 3/28/2016 | | http://www.gpo.gov/fdsys/pkg/FR-2014-11-24/pdf/2014-27756.pdf Documents associated with this PRA request, including a blank "Summary of Coverage" template, which tribal representatives have requested that CMS require QHPs to provide for Indian-specific cost-sharing variations, are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1251222.html. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/24/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-24/pdf/2015-03650.pdf No comments recommended. CMS on 2/26/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-26/pdf/2016-04318.pdf The proposed revised SBC template, uniform glossary, and other related forms are available at the links below. Proposed SBC Blank Template: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SBC-Template.pdf Proposed SBC Sample Completed Template: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SBC-Sample-Completed.pdf Proposed SBC Sample Completed Template: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SBC-Sample-Completed.pdf Proposed Why This Matters language for SBC "No" Answers: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SNo-Answers.pdf Proposed Why This Matters language for SBC "Yes" Answers: | |
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| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Yes-Answers.pdf Proposed Instructions for Completing the SBCIndividual Health Insurance Coverage: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/cciio-Individual-Instructions.PDF Proposed Instructions for Completing the SBCGroup Health Plan Coverage" https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Group-Instructions.pdf Proposed Guide for Coverage Examples CalculationsMaternity Scenario, Diabetes Scenario, and Foot Fracture: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Coverage examples calculator.pdf Proposed Coverage Examples NarrativeMaternity Scenario: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/maternity-narrative.pdf Proposed Coverage Examples NarrativeDiabetes Scenario: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/diabetes-narrative.pdf Proposed Coverage Examples NarrativeFoot Fracture: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/diabetes-narrative.pdf This PRA request contains revised versions of the SBC documents. The SBC documentswhich each OHP issuer must release for each plan "variation" offered on a Marketplaceare critical for enrollees to understand how the Indian-specific cost-sharing protections apply (a QHP plan "variation" is a plan with a set of distinct cost-sharing protections, such as the "zero" and "limited" cost-sharing variations (CSVs)). Once the template is finalized, CCIIO has agreed to populate the templates to create sample "zero-CSV (Z-CSV)" and "limited-CSV (L-CSV)" versions. CCIIO will share these samples with QHP issuers for use in their development of Z-CSV and L-CSV SBCs. | |
| 92.yy. | Transparency in Coverage Reporting by QHP Issuers | CMS-10572 | <u>Issue Date:</u> 8/12/2015 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Transparency in Coverage Reporting by Qualified Health Plan Issuers; | |



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| ACTION: Request for Comment NOTICE: Transparency in Coverage Reporting by Qualified Health Plan Issuers AGENCY: CMS | | Due Date: 10/13/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/29/2016 Due Date: 5/31/2016 | | Use: Section 1311(e)(3) of ACA requires issuers of qualified health plans (QHPs) to make available and submit transparency in coverage data. This data collection would collect certain information from QHP issuers in Federally-Facilitated Exchanges and State-Based Exchanges that rely on the federal IT platform (i.e., HealthCare.gov). HHS anticipates that consumers might use this information to inform plan selection. Although this proposed data collection remains limited to certain QHP issuers, HHS intends to phase in implementation for other entities over time. As stated in the final rule Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans: Exchange Standards for Employers (77 FR 18310), separate rulemaking issued by HHS and the Departments of Labor and the Treasury (Departments) will continue to address broader implementation. For State-based Exchanges not addressed in the current proposal, the Departments will propose standards later. Consistent with Public Health Service Act (PHS Act) section 2715A, which largely extends the transparency reporting provisions set forth in section 1311(e)(3) to nongrandfathered group health plans (including large group and self-insured health plans) and health insurance issuers offering group and individual health insurance coverage (non-QHP issuers), the Departments intend to propose other transparency reporting requirements at a later time, through a separate rulemaking conducted by the Departments, for non-QHP issuers and non-grandfathered group health plans. These proposed reporting requirements might differ from those prescribed in the HHS proposal under section 1311(e)(3) and will take into account differences in markets, reporting requirements already in existence for non-QHPs (including group health plans), and other relevant factors. The Departments also intend to streamline reporting under multiple reporting provisions and reduce unnecessary duplication. The Departments intend to impl | |



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| | | | | | Issuer D/B/A, if Applicable: Business name(s) under which the issuer offers QHP(s) on the Federally-Facilitated Marketplace (FFM), if different from Issuer Name. Issuer ID: The 5-digit Health Insurance Oversight System (HIOS) ID of the issuer. Contact Name: The issuer staff member who CMS should contact with any questions regarding this data collection. Backup Contact Name: The issuer staff member who CMS should contact with any questions regarding this data collection if the primary contact is unavailable. Contact E-Mail: The e-mail addresses for the primary and backup contacts. Contact Telephone: The telephone numbers for the primary and backup contacts. Claims Payment Policies and Practices and Other Information as Determined Appropriate by the Secretary: URL link to policies on out-of-network liability and balance billing; enrollee claim submission; grace periods and claims pending; retroactive denials; recoupment of overpayments; medical necessity and prior authorization timeframes and enrollee responsibilities; drug exception timeframes and enrollee responsibilities; explanations of benefits (EOBs); and coordination of benefits (COB). | |
| | | | | | Claims Payment Policies and Practices and Other Information as Determined Appropriate by the Secretary: URL link to policies on out-of-network liability and balance billing; enrollee claim submission; grace periods and claims pending; retroactive denials; recoupment of overpayments; medical necessity and prior authorization timeframes and enrollee responsibilities; drug exception timeframes and enrollee responsibilities; EOBs; and COB. Periodic Financial Disclosure: URL link to NAIC Web page listing issuer premium receipts, assets, and liabilities in dollar amounts. Data on Enrollment: Issuer-level enrollment numbers as derived from the FFM (CMS data). Data on Rating Practices: Unified Rate Review data file on Data.HealthCare.gov. Information on Cost Sharing and Payments for Out-of-Network Coverage: | |



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| | rigency | | The Date | | Summary of Benefits and Coverage (SBC) on HealthCare.gov. • Information on Enrollee Rights Under Title I: URL to the enrollee rights and protections information provided on HealthCare.gov. http://www.gpo.gov/fdsys/pkg/FR-2015-08-12/pdf/2015-19818.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/29/2015 issued a new version of this PRA request. CMS received a total of 13 comments in response to the 60-day notice on this information collection published in the 8/12/2015 FR (80 FR 48320). https://www.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-10084.pdf | |
| 92.ccc. | Rate Filing Justifications for 2016 for Single Risk Pool Coverage ACTION: Guidance NOTICE: DRAFT Insurance Standards Bulletin Series-INFORMATIONBulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 12/23/2015 Due Date: 1/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 2/29/2016 | | SUMMARY OF AGENCY ACTION: This draft bulletin seeks comment on the proposed uniform timeline for submission and posting of information about rates for single risk pool coverage, consistent with the proposed amendments to the rate review regulations at 45 CFR Part 154 in the 2017 Payment Notice Proposed Rule. Specifically, this bulletin proposes guidance for purposes of establishing the uniform deadline under 45 CFR 154.220(b) for health insurance issuers to submit the Unified Rate Review Template for proposed rates in the individual and small group markets. It also proposes guidance for purposes of establishing the uniform posting deadline under 45 CFR 154.301(b)(1)(i) for a state with an effective rate review program to provide public access to information regarding proposed rate increases subject to review. The bulletin also identifies the deadline for posting of final rate increases (including those not subject to review) and the CMS Web address for use by states with an effective rate review program that elect to provide public access from their website through a link to the rate information made available on the CMS Web site. The timelines specified in this bulletin would apply to rates filed in 2016 (2016 filing year) for single risk pool coverage (including both qualified health plans (QHPs) and non-QHPs) effective on or after 1/1/2017. In addition, 45 CFR 154.301(b)(3) requires states with an effective rate review program to post the required information on proposed rate increases subject to review and final rate increases (including those not subject to review) at a uniform time and not on a rolling basis. That requirement applies to rate increase information for single risk pool | |



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| | | | | | coverage, including both QHP and non-QHPs, both inside and outside of Marketplaces. The timelines in this bulletin reflect that policy. CMS seeks comments from states, issuers, and other interested parties on how to implement that requirement consistent with state legislative and regulatory requirements. | |
| | | | | | CMS understands that some states that operate a State-Based Marketplace, as well as certain states that utilize the Federally-Facilitated Marketplace platform, faced significant challenges in meeting the timeline specified for the 2015 filing year, due to state legislative or regulatory requirements and the timing of negotiations with issuers. Accordingly, CMS has issued this request for comments so that those states, as well as other interested parties, can provide information to inform future regulations or changes to the timeline. Interested parties should submit comments to RateReview@cms.hhs.gov no later than 1/22/2016. CMS intends to finalize the timeline no later than March 2016. | |
| | | | | | https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Timeline-Bulletin-12-23-15-FINAL.pdf | |
| | | | | | SUMMARY OF NIHB ANALYSIS: | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This bulletin provides the uniform timeline for submission and posting of information about rate filings for single risk pool coverage, consistent with the amendments to the rate review regulations at 45 CFR Part 154 in the HHS Notice of Benefit and Payment Parameters for 2017. Specifically, this bulletin establishes the uniform deadline under 45 CFR 154.220(b) for health insurance issuers to submit the Rate Filing Justification for proposed rates for single risk pool coverage in the individual and small group markets. It also establishes the uniform posting deadline under 45 CFR 154.301(b)(1)(i) for a state with an Effective Rate Review Program to provide public access to information regarding proposed rate increases subject to review. | |
| | | | | | The bulletin also identifies the uniform deadline for a state with an Effective Rate Review Program to post final rate increases (including those not subject to review) and the CMS Web site address for use by states with an Effective Rate Review Program electing to provide public access from their Web site through a link to the CMS Web site. The timelines specified in this bulletin apply to the rate filings issuers will submit in 2016 (2016 filing year) for single risk pool coverage (including both qualified health plans | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 92.ddd. | | CCIIO (no | Issue Date: | | (QHPs) and non-QHPs) with plan or policy years beginning on or after 1/1/2017. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-rate-filing-justification-bulletin-2-29-16.pdf SUMMARY OF AGENCY ACTION: This bulletin provides guidance on the operational | |
| | Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data BulletinINFORMATION: Evaluation of EDGE Data Submissions for 2015 Benefit Year for Interim Reinsurance Payments and Interim Risk Adjustment Summary Report AGENCY: CCIIO | reference number) | 1/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued clarification 3/16/2016 | | processes that CMS will use to evaluate issuer EDGE server data for the 2015 benefit year for the release of interim reinsurance payments and interim risk adjustment summary reports. This analysis will help CMS determine whether an issuer has provided sufficient access to EDGE server data for CMS to calculate interim reinsurance payments and release an interim risk adjustment summary report in a specific state and market. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Evaluation_of_EDGE_Data_Submissions for_2015_Benefit_Year_for_Interim_Reinsurance_Payments_and_Interim_Risk_Adjustment_S.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CCIIO on 3/16/2016 issued a revised bulletin to clarify that, if an issuer of a risk adjustment covered plan (or set of issuers) exceeds 0.5% of the market share, CMS will not issue a risk adjustment interim summary report for that state and market for the 2015 benefit year, as the agency would not consider the state and market credible. The bulletin published 1/20/2016 contained a typographical error, citing a percentage of 0.05%. This change is the only modification from the 1/20/2016 bulletin. As discussed in the 1/20/2016 bulletin, CMS provides guidance on the operational processes that it will use to evaluate issuer EDGE server data for the 2015 benefit year for the release of interim reinsurance payments and interim risk adjustment summary reports. This analysis will help CMS determine whether an issuer has provided access to EDGE server data sufficient for the agency to calculate interim reinsurance payments and release an interim risk adjustment summary report in a specific state and market. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Interim_EDGE- | |



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | Quality Quantity Guidance for 2015 Benefit Year 5CR 031516.pdf | |
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| 92.eee | Extension of Transitional Policy Through CY 2017 ACTION: Guidance NOTICE: Insurance Standards Bulletin Series INFORMATIONExtension of Transitional Policy Through Calendar Year 2017: Extended Transition to Affordable Care Act-Compliant Policies AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 2/29/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF SUBSEQUENT AGENCY ACTION: On 11/14/2013, CMS issued a letter to state insurance commissioners outlining a transitional policy for non-grandfathered coverage in the small group and individual health insurance markets. In this letter, CMS announced that, if permitted by applicable state authorities, health insurance issuers can choose to continue certain coverage that would otherwise get cancelled and that affected individuals and small businesses can choose to re-enroll in such coverage. CMS further stated that, under the transitional policy, it will not consider non-grandfathered health insurance coverage in the individual or small group market renewed for a policy year starting between 1/1/2014 and 10/1/2014 out of compliance with certain market reforms if certain specific conditions are met. On 3/5/2014, CMS extended the transitional policy for two yearsto policy years beginning on or before 10/1/2016in the small group and individual markets. As provided in the 11/14/2013 and 3/5/2014 guidance, CMS does not consider policies subject to the transitional relief are not considered out of compliance with the following provisions of the Public Health Service Act (PHS Act): Section 2701 (relating to guaranteed availability of coverage); Section 2702 (relating to guaranteed renewability of coverage); Section 2703 (relating to the prohibition of pre-existing condition exclusions or other discrimination based on health status), with respect to adults, except with respect to group coverage; Section 2705 (relating to the prohibition of discrimination against individual participants and beneficiaries based on health status), except with respect to group coverage; Section 2706 (relating to comprehensive health insurance coverage); and Section 2709, as codified at 42 U.S.C. § 300gg-8 (relating to coverage for individuals participating in approved clinical trials). | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | In its 3/5/2014 guidance, CMS indicated that it would consider the impact of the two-year extension of the transitional policy in assessing whether an additional one-year extension is appropriate. This guidance extends the transitional policy to policy years beginning on or before 10/1/2017, provided that all policies end by 12/31/2017. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/final-transition-bulletin-2-29-16.pdf SUMMARY OF NIHB ANALYSIS: | |
| 92.fff. | FAQs on the 2017 Moratorium on Health Insurance Provider Fee ACTION: Guidance NOTICE: Frequently Asked Questions on the 2017 Moratorium on Health Insurance Provider Fee AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 2/29/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF SUBSEQUENT AGENCY ACTION: Section 9010 of ACA charges a fee to each covered entity engaged in the business of providing health insurance. The Consolidated Appropriations Act of 2016, Division Q, Title II, § 201, suspends collection of the Health Insurance Provider Fee (Fee) for the 2016 calendar year. Thus, health insurance issuers do not have to pay the Fee in 2017. These FAQs provide guidance on how the moratorium likely will affect 2017 rate fillings for single risk pool plans in the individual and small group market. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FINAL_9010_FAQ_2-29-16.pdf SUMMARY OF NIHB ANALYSIS: | |
| 92.ggg. | Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data BulletinINFORMATION: Evaluation of EDGE Data Submissions for 2015 Benefit | CCIIO (no reference number) | Issue Date: 3/18/2016 Due Date: None NIHB File Date: | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This bulletin provides guidance on the operational processes that CMS will use to evaluate issuer EDGE server data for the 2015 benefit year. This analysis will help CMS determine whether an issuer has provided access to EDGE server data sufficient for the agency to calculate reinsurance payments and apply the HHS risk adjustment methodology. This analysis also will assist CMS with overall program integrity. However, the process set forth below does not alleviate the responsibility of an issuer to ensure the completeness and accuracy of the data submitted to its EDGE server by the applicable deadline. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | AGENCY: CCIIO | | Date of Subsequent Agency Action, if any: | | https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Part-2-EDGE-Q_Q-Guidance_03182016.pdf SUMMARY OF NIHB ANALYSIS: | |
| 92.hhh. | Updated Renewal and Product Discontinuation Notices ACTION: Guidance NOTICE: Draft Updated Federal Standard Renewal and Product Discontinuation Notices AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 4/21/2016 Due Date: 6/27/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This guidance includes draft updated Federal standard notices of product discontinuation and renewal for the individual health insurance market. Once finalized, individual market issuers will use these notices to satisfy the requirement under the guaranteed renewability rules to provide notice of product discontinuation, coverage renewal, and non-renewal or termination based on the movement of enrollees outside the service area of a product. An issuer using these draft updated notices (or the final updated notices, when published) or the existing Federal standard notices would meet the specification of the HHS Secretary under 45 CFR 147.106 regarding the form and manner of the required notices for policy years ending before 12/31/2017, and only an issuer using the final updated notices would meet the specification under 45 CFR 147.106 regarding the form and manner of the required notices for policy years ending on or after 12/31/2017, until the issuance of further guidance. This guidance works in conjunction with previously issued rulemaking and guidance, including the 2015 Market Standards Rule, the Annual Eligibility Redeterminations Rule, the HHS Notice of Benefit and Payment Parameters for 2017, and guidance on the Federal standard notices issued on 9/2/2014. CMS requests comments on the draft updated Federal standard notices in this guidance, consistent with the requirements of the Paperwork Reduction Act. Interested parties should submit comments by 6/27/2016 via e-mail at 2017DiscontinuationandRenewalNotices@cms.hhs.gov. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-Updated-Federal-Standard-Renewal-and-Product-Discontinuation-Notices-042116.pdf | |
| 92.iii. | FAQs on ACA Implementation (Parity and Women's Health) | CCIIO (no reference number) | <u>Issue Date:</u> 4/20/2016 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This guidance, prepared jointly by HHS, DoL, and the Department of the Treasury (Departments), answers a frequently asked question (FAQ) regarding implementation of the market reform provisions of ACA, | |



| Ref. | Short Title/Current Status | | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | |
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| # | of Regulation/Title/ Agency | File Code | Due Date & File Date | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation and Women's Health And Cancer Rights Act Implementation AGENCY: CCIIO | | Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA). https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf SUMMARY OF NIHB ANALYSIS: | |
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| 92.jjj. | Marketplace Eligibility Redetermination for 2017 ACTION: Guidance NOTICE: Guidance on Annual Eligibility Redetermination and Re- Enrollment for Marketplace Coverage for 2017 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 5/10/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: 45 CFR 155.335(a)(2) provides that a Health Insurance Marketplace has three options to redetermine eligibility for enrollment in a qualified health plan (QHP) through the Marketplace and insurance affordability programs on an annual basis. 45 CFR 155.335(a)(2)(ii) provides that one of these options involves a set of alternative procedures specified by the HHS Secretary for the applicable benefit year. This guidance describes these alternative procedures for benefit year 2017. The alternative procedures for benefit year 2017 remain the same as those for benefit year 2016, except that they include a new group for which advance payments of the premium tax credit (APTC) and income-based cost-sharing reductions (CSR) will get discontinued, as highlighted in the guidance describing the alternative procedures for benefit year 2016 and described again in detail in this guidance. As in years past, the alternative procedures for benefit year 2017 preserve a core feature of the annual redetermination and re-enrollment process that, in general, an enrollee can take no action and maintain coverage across benefit years, an important feature in promoting continuity of coverage while limiting administrative burden for enrollees, issuers, and Marketplaces. All Marketplaces using the federal eligibility and enrollment platform will use the procedures specified in this guidance for benefit year 2017. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ARR-2017-Guidance-051016-508.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 92.kkk. | Rules for Expatriate Health Plans, et al. ACTION: Proposed Final Rule NOTICE: Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance AGENCY: CMS | REG 135702- 15 TD 9791 DoL (RIN 1210-AB75) CMS-9932- PF | Issue Date: 6/10/2016 Due Date: 8/9/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 10/31/2016 | | SUMMARY OF AGENCY ACTION: This document contains proposed regulations on the rules for expatriate health plans, expatriate health plan issuers, and qualified expatriates under the Expatriate Health Coverage Clarification Act of 2014 (EHCCA). This document also includes proposed conforming amendments to certain regulations to implement the provisions of EHCCA. Further, this document proposes standards for travel insurance and supplemental health insurance coverage to fall under excepted benefits and revisions to the definition of short-term, limited-duration insurance for purposes of the exclusion from the definition of individual health insurance coverage. These proposed regulations affect expatriates with health coverage under expatriate health plans and sponsors, issuers and administrators of expatriate health plans, individuals with and plan sponsors of travel insurance and supplemental health insurance coverage, and individuals with short-term, limited-duration insurance. In addition, this document proposes to amend a reference in the final regulations relating to prohibitions on lifetime and annual dollar limits and proposes to require the provision of a notice in connection with hospital indemnity and other fixed indemnity insurance in the group health insurance market for it to fall under excepted benefits. https://www.gpo.gov/fdsys/pkg/FR-2016-06-10/pdf/2016-13583.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: This document contains final regulations regarding the definition of short-term, limited-duration insurance for purposes of the exclusion from the definition of individual health insurance coverage and standards for travel insurance and supplemental health insurance coverage considered excepted benefits. This document also amends a reference in the final regulations relating to the prohibition on lifetime and annual dollar limits. | |
| 92.III. | Health Insurance Enforcement and Consumer Protections Grants | CMS-10605 | <u>Issue Date:</u> 6/17/2016 <u>Due Date:</u> | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: The Health Insurance Enforcement and Consumer Protections Grant Program; Use: Section 1003 of ACA adds a new section 2794 to the Public Health Service Act (PHS Act), titled "Ensuring That Consumers Get Value for Their Dollars." | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | ACTION: Request for Comment NOTICE: The Health Insurance Enforcement and Consumer Protections Grant Program AGENCY: CMS | | 8/16/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 10/7/2016 Due Date: 11/7/2016 | | Specifically, section 2794(a) requires the HHS Secretary, in conjunction with states, to establish a process for the annual review of health insurance premiums to protect consumers from unreasonable rate increases. Section 2794(c) directs the HHS Secretary to carry out a program to award grants to states. Section 2794(c)(2)(B) specifies that any appropriated Rate Review Grant funds not fully obligated by the end of FY 2014 shall remain available to the HHS Secretary for grants to states for planning and implementing the insurance market reforms and consumer protections under Part A of title XXVII of the PHS Act. States that apply for funds must complete the grant application. States awarded funds under this funding opportunity must provide CMS with four quarterly reports and one annual report per year (except for the last year of the grant) until the end of the grant period, detailing state progression toward planning and/or implementing the market reforms under Part A of Title XXVII of the PHS Act. States must submit a final report at the end of the grant period. https://www.gpo.gov/fdsys/pkg/FR-2016-06-17/pdf/2016-14409.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/7/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24341.pdf No comments recommended. | |
| 92.mmm. | NQTLs Requiring Analysis to Determine Parity Compliance ACTION: Guidance NOTICE: Warning Signs Plan or Policy Non- Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health | CCIIO (no reference number) | Issue Date: 6/1/2016 Due Date: None NIHB File Date: Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by ACA, generally requires that group health plans and health insurance issuers offering group or individual health insurance coverage ensure that the financial requirements and treatment limitations on mental health or substance use disorder (MH/SUD) benefits they provide are no more restrictive than those on medical or surgical (med/surg) benefits. Requirements exist for determining parity with respect to financial requirements (such as copays) and treatment limitations, which limit the scope or duration of benefits for treatment. Treatment limitations can take the form of quantitative treatment limitations (QTLs), which are numerical in nature (such as visit limits), or non-quantitative treatment limitations (NQTLs), which are non-numerical limits on the scope or duration of benefits | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency Parity Compliance | File Code | Issue Date; Due Date & File Date Action, if any: | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis for treatment (such as preauthorization requirements). The rules for financial requirements and QTLs are different from the rules for NQTLs. This document focuses | NIHB Recs. |
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| | AGENCY: CCIIO | | | | on NQTLs and how to identify provisions that will require inquiry beyond the plan/policy terms to determine compliance with mental health parity requirements. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/MHAPEAChecklistWarningSigns.pdf SUMMARY OF NIHB ANALYSIS: | |
| 92.nnn. | FAQs on ACA Implementation (COBRA Model Election Notice) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation (Part 32) AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 6/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance, prepared jointly by HHS and DoL and the Treasury (Departments), answers a frequently asked question (FAQ) regarding COBRA model election notice requirements. In general, under the COBRA continuation coverage provisions, an individual covered by a group health plan on the day before a qualifying event (such as termination of employment, divorce, or a dependent aging out of a plan, if the event causes a loss of coverage) might have the ability to elect COBRA continuation coverage upon experiencing a qualifying event. Individuals with such a right are called qualified beneficiaries. A group health plan must provide qualified beneficiaries with a COBRA election notice that, among other things, describes their rights to COBRA continuation coverage and how to make a COBRA coverage election. In general, the COBRA election notice must appear in a manner "calculated to be understood by the average plan participant." DoL has a model election notice that plans can use to satisfy the requirement to provide the election notice under COBRA. Q: The COBRA model election notice contains information about enrollment in the Marketplaces. Is it permissible for a group health plan administrator to include additional information about Marketplace coverage in or along with this notice? A: Yes. An individual who experiences a qualifying event and therefore becomes eligible for COBRA continuation coverage (for example, a covered dependent who ages out of her parents' health plan or a covered worker who loses his job), also becomes eligible to apply for Marketplace coverage as a result of the same event. As explained in the COBRA model election notice, for certain qualified beneficiaries, coverage obtained through a Marketplace may be a less expensive healthcare coverage option than enrollment in COBRA continuation coverage | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQS-32_Final-6-21-16.pdf SUMMARY OF NIHB ANALYSIS: | |
| 92.000. | Netting of Payments and Charges ACTION: Guidance NOTICE: Netting of Payments and Charges Under 45 CFR 156.1215 AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 7/15/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Under 45 CFR 156.1215, CMS has the authority to net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the federal or state governments from the issuers and their affiliates under the same taxpayer identification number for: • Advance payments of the premium tax credit and cost-sharing reductions; • Reconciliation of cost-sharing reductions; • Reconciliation of cost-sharing reductions; • Rederally-Facilitated Exchange user fees and fees for State-Based Exchanges utilizing the Federal Platform; and • Risk adjustment, reinsurance, and risk corridors payments and charges. CMS has a policy of netting all of the above payments and charges to efficiently operate these programs and expeditiously support payments under the premium stabilization programs, including risk adjustment. Doing so permits CMS to make timely and complete payments to issuers under the premium stabilization programs, an important step for reducing the incentives for issuers to avoid the sickest enrollees and for increasing the ability of issuers to maintain premium stability. However, circumstances might arise when refraining from netting a particular payment will have no impact on collections for or operations of the premium stabilization programs. In those cases, CMS might elect not to net the payment. A state department of insurance can reasonably notify CMS that an issuer would have to end coverage if the agency nets advance payments and that, if CMS refrains from netting such payments, continued coverage wouldin the view of the stateserve the best interest of the enrollees or the market. In those cases, CMS will refrain from netting advance payments for the months for which the coverage otherwise would have ended. SUMMARY OF NIHB ANALYSIS: In this guidance, CCIIO outlines its authority to delay requiring health plan issuers to make certain payments, such as risk adjustment payments owed, if making the payments would threaten the ability of | |

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| 92.ppp. | Issuer Posting of Rate Filing Information ACTION: Guidance NOTICE: Insurance Standards Bulletin Series INFORMATION: CCIIO Sub- Regulatory Guidance: Issuer Posting of Rate Filing Information AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 9/26/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This Bulletin provides additional guidance on the reporting requirements for health insurance issuers that implement rate increases determined unreasonable by CMS or a state. Specifically, this Bulletin explains the manner in which an issuer must "prominently post" the required rate filing information and its Final Justification for implementing a rate increase deemed "unreasonable" and clarifies the type of information that an issuer must include in its Final Justification. This Bulletin also clarifies that an issuer must prominently display the required rate filing information, including the Final Justification, for at least three years. This information applies to health insurance issuers offering non-grandfathered health insurance coverage in the individual or small group market through or outside of an Exchange (also known as a Marketplace). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Prominent-display-bulletin-final.pdf SUMMARY OF NIHB ANALYSIS: | |
| 92.qqq. | FAQs on ACA Implementation (Market Reforms and Parity) ACTION: Guidance NOTICE: FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation AGENCY: CCIIO | CCIIO (no reference number) | Issue Date: 10/27/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This guidance, prepared jointly by HHS, DoL, and the Department of the Treasury (Departments), answers frequently asked questions (FAQ) regarding implementation of the market reform provisions of ACA and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by ACA. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-part-34_10-26-16_FINAL.PDF SUMMARY OF NIHB ANALYSIS: | |
| 95. | IHS Forms to Implement | IHS-810, - | Issue Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | the Privacy Rule ACTION: Request for Comment NOTICE: IHS Forms to Implement Privacy Rule (45 CFR Parts 160 & 164) | 912-1, -912- 2, -913, and - 917 | 10/2/2012 <u>Due Date:</u> 60 days (approx. 11/30/2012) <u>NIHB File Date:</u> None | | without change of currently approved collection; <i>Title</i> : IHS Forms to Implement the Privacy Rule (45 CFR Parts 160 & 164); <i>Use</i> : The HHS rule titled "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule), which implements the privacy requirements of the Administrative Simplification subtitle of HIPAA, requires this information collection. This rule creates national standards to protect personal health information and gives patients increased access to their medical records. This rule requires the collection of information to implement these protection standards and access requirements. | |
| | AGENCY: IHS | | Date of Subsequent Agency Action, if any: Issued extension 1/22/2016 Due Date: 3/22/2016 4/21/2016 | | SUMMARY OF NIHB ANALYSIS: This PRA request includes no changes to the current forms that IHS uses to implement the Privacy Rule. IHS will use the following data collection instruments to meet the information collection requirements contained in the Privacy Rule: IHS-810: The rule requires covered entities to obtain or receive a valid authorization for its use or disclosure of protected health information other than for treatment, payment, and health care operations. This form, "Authorization for Use or Disclosure of Protected Health Information," is used to document an individual's authorization to use or disclose their protected health information. IHS-912-1: The rule requires a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information, and the covered entity may or may not agree to the restriction. This form, "Request for Restrictions(s)," is used to document an individual's request for restriction of their protected health information and whether IHS agreed or disagreed with the restriction. IHS-912-2: The rule permits a covered entity to terminate its agreement to a restriction if the individual agrees to or requests the termination in writing. This form, "Request for Revocation of Restriction(s)," is used to document the agency or individual request to terminate a formerly agreed to restriction regarding the use and disclosure of protected health information. IHS-913: The rule requires covered entities to permit individuals to request that the covered entity provide an accounting of disclosures of protected health information made by the covered entity. This form, "Request for an Accounting of Disclosures," is used to document an individual's request for an accounting of the request. IHS-917: The rule requires covered entities to permit an individual to request that the covered entity amend protected | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | accepts the requested amendment, in whole or in part, the covered entity must inform the individual that the amendment is accepted. If the covered entity denies the requested amendment, in whole or in part, the covered entity must provide the individual with a written denial. This form, "Request for Correction/Amendment of Protected Health Information," will be used to document an individual's request to amend their protected health information and the agency's decision to accept or deny the request. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-22/pdf/2016-01208.pdf No comments recommended. CMS on 3/22/2016 issued an extension of this PRA request. IHS received no comments in response to the 60-day notice for this information collection published in the 1/22/2016 FR (81 FR 3806). https://www.gpo.gov/fdsys/pkg/FR-2016-03-22/pdf/2016-06445.pdf No comments recommended. | |
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| 103.a. | CHIP Report on Payables and Receivables ACTION: Request for Comment NOTICE: Children's Health Insurance Program (CHIP) Report on Payables and Receivables AGENCY: CMS | CMS-10180 | Issue Date: 11/16/2012 Due Date: 12/17/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a previously approved collection; Title: Children's Health Insurance Program (CHIP) Report on Payables and Receivables; Use: CMS requires the collection of CHIP data and the calculation of the CHIP Incurred But Not Reported (IBNR) estimate for its financial audit. The Chief Financial Officer auditors have reported the lack of an estimate for CHIP IBNR payables and receivables as a reportable condition in the FY 2005 audit of CMS financial statements. CMS needs to collect the necessary data from State agencies in FY 2006 to ensure that it continues to receive an unqualified audit opinion on its financial statements. Program expenditures for CHIP have increased since its inception; as a result, CHIP receivables and payables might materially impact the financial statements. The CHIP Report on Payables and Receivables will provide the information needed to calculate the CHIP IBNR. SUMMARY OF NIHB ANALYSIS: | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 4/26/2013; issued extension 8/18/2016 <u>Due Date:</u> 5/28/2013; 10/17/2016 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/26/2013 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-04-26/pdf/2013-09913.pdf CMS on 8/18/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-08-18/pdf/2016-19656.pdf No comments recommended. | |
| 103.b. | Medicaid Report on Payables and Receivables ACTION: Request for Comment NOTICE: Medicaid Report on Payables and Receivables AGENCY: CMS | CMS-R-199 | Issue Date: 11/16/2012 Due Date: 12/17/2012 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 4/26/2013; issued extension 3/1/2016, 7/19/2016 Due Date: 5/28/2013; 5/2/2016; 8/18/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a previously approved collection; Title: Medicaid Report on Payables and Receivables; Use: The Chief Financial Officers Act of 1990, as amended by the Government Management Reform Act of 1994, requires government agencies to produce auditable financial statements. Because CMS fulfills its mission through its contractors and the States, these entities serve as the primary source of information for the financial statements, which include three basic categories of data: expenses, payables, and receivables. CMS-64 collects data on Medicaid expenses. CMS-R-199 collects Medicaid payable and receivable accounting data from states. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/26/2013 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-04-26/pdf/2013-09913.pdf CMS on 3/1/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04463.pdf No comments recommended. CMS on 7/19/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-19/pdf/2016-17059.pdf No comments recommended. | |
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| 104.b. | State Health Insurance Assistance Program ACTION: Final Rule NOTICE: State Health Insurance Assistance Program (SHIP) AGENCY: CMS | CMS RIN 0985- AA11 | Issue Date: 6/3/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This final rule adopts, without change, the interim final rule (IFR) titled "State Health Insurance Assistance Program (SHIP)." This final rule implements a provision enacted by the Consolidated Appropriations Act of 2014 and reflects the transfer of the State Health Insurance Assistance Program (SHIP) from CMS to the HHS Administration for Community Living (ACL). Prior to the interim final rule, CMS issued regulations under the authority granted by the Omnibus Budget Reconciliation Act of 1990 (OBRA), section 4360. SUMMARY OF NIHB ANALYSIS: | |
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| 106.b. | Hospital Death Reports ACTION: Request for Comment NOTICE: Report of a Hospital Death Associated with Restraint or Seclusion AGENCY: CMS | CMS-10455 | Issue Date: 1/30/2013 Due Date: 3/1/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/24/2016, 8/24/2016 Due Date: 8/23/2016; 9/23/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Report of a Hospital Death Associated with Restraint or Seclusion; Use: The final rule published on 5/16/2012 included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion, § 482.13(g). Hospitals no longer have to report to CMS those deaths where no use of seclusion occurred and the only restraint involved 2-point soft wrist restraints. In addition, the final rule replaced the previous requirement for reporting via telephone to CMS with a requirement that allows submission of reports via telephone, facsimile, or electronically, as determined by CMS. Finally, the final rule reduced the amount of information that CMS needs for each death report to determine the need for further on-site investigation The Child Health Act (CHA) of 2000 established in Title V, Part H, Section 591 of the Public Health Service Act (PHS Act) minimum requirements concerning the use of restraints and seclusion in facilities that receive support with funds appropriated to any federal department or agency. In addition, CHA enacted Section 592 of the PHS Act, which establishes minimum mandatory reporting requirements for deaths in such facilities associated with use of restraint or seclusion. Provisions implementing this statutory reporting requirement for hospitals participating in Medicare appear at 42 CFR 482.13(g), as revised in the final rule. SUMMARY OF NIHB ANALYSIS: | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/24/2016 issued an | NIHB Recs. |
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| | | | | | extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-24/pdf/2016-15029.pdf No comments recommended. CMS on 8/24/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20216.pdf No comments recommended. | |
| 109.b. | Notice Requirements of Continuation Coverage ACTION: Request for Comment NOTICE: Notice Requirements of the Health Care Continuation Coverage Provisions AGENCY: DoL | DoL (OMB 1210-0123) | Issue Date: 5/22/2013 Due Date: 7/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 9/25/2013, 5/26/2016, 10/7/2016 Due Date: 10/25/2013; 7/25/2016; 11/7/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection: Title: Notice Requirements of the Health Care Continuation Coverage Provisions; Use: The continuation coverage provisions of section 601 through 608 of the Employee Retirement Income Security Act of 1974 (ERISA) (and parallel provisions of the Internal Revenue Code (Code)) generally require group health plans to offer qualified beneficiaries the opportunity to elect continuation coverage following certain events that otherwise would result in the loss of coverage. The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) provides the Secretary of Labor (the Secretary) with authority under section 608 of ERISA to carry out the continuation coverage provisions. The Conference Report that accompanied COBRA divided interpretive authority over the COBRA provisions between the Secretary and the Secretary of the Treasury (the Treasury) by providing that the Secretary has the authority to issue regulations implementing the notice and disclosure requirements of COBRA and that the Treasury has the authority to issue regulations defining the required continuation coverage. http://www.gpo.gov/fdsys/pkg/FR-2013-05-22/pdf/2013-12191.pdf A Supporting Statement for this PRA request is available at http://www.reginfo.gov/public/do/DownloadDocument?documentID=391958&version=1. This information collection does not include any associated forms. SUMMARY OF NIHB ANALYSIS: | |



| Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: DoL on 9/25/2013 issued an extension of this PRA request with no changes. A summary of the relevant notice requirements and model notices are available at http://www.dol.gov/ebsa/publications/cobraemployer.html#COBRANoticeandElectionProcedures . No comments recommended. DoL on 5/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-26/pdf/2016-12363.pdf No comments recommended. DoL on 10/7/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24294.pdf | |
| | | | | No comments recommended. | |
| Self-Referral Disclosure Protocol ACTION: Request for Comment NOTICE: Self-Referral Disclosure Protocol AGENCY: CMS | CMS-10328 | Issue Date: 2/24/2014 Due Date: 4/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/2/2014, | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of currently approved collection; <i>Title</i> : Self-Referral Disclosure Protocol; <i>Use</i> : The Self-Referral Disclosure Protocol (SRDP), a voluntary self-disclosure instrument, allows providers of services and suppliers to disclose actual or potential violations of section 1877 of the Social Security Act (the Act). CMS analyzes the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition. In addition, the HHS Secretary, under authority granted by section 6409(b) of ACA and subsequently delegated to CMS, can reduce the amount due and owed for violations. http://www.gpo.gov/fdsys/pkg/FR-2014-02-24/pdf/2014-03874.pdf SUMMARY OF NIHB ANALYSIS: I/T/U providers might have an interest in this PRA request. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/2/2014 issued a revision | |
| | of Regulation/Title/ Agency Self-Referral Disclosure Protocol ACTION: Request for Comment NOTICE: Self-Referral Disclosure Protocol | of Regulation/Title/ Agency Self-Referral Disclosure Protocol ACTION: Request for Comment NOTICE: Self-Referral Disclosure Protocol | of Regulation/Title/ Agency File Code Due Date & File Date File Date CMS-10328 Self-Referral Disclosure Protocol ACTION: Request for Comment NOTICE: Self-Referral Disclosure Protocol AGENCY: CMS Date of Subsequent Agency Action, if any: Issued revision | Self-Referral Disclosure Protocol ACTION: Request for Comment NOTICE: Self-Referral Disclosure Protocol AGENCY: CMS AGENCY: CMS File Code Due Date & File Date INHB Response NIHB Response CMS-10328 Ssue Date: 2/24/2014 | of Regulation/Title/ Agency File Code Due Date & File Date Response Response |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 9/9/2916 <u>Due Date</u> : 6/2/2014; 7/5/2016; 10/11/2016 | | Specifically, CMS proposes: (1) Creating an optional expedited SRDP review process (the "Expedited SRDP Review Process") for disclosures that meet certain eligibility requirements; (2) continuing the established SRDP review process (the "Standard SRDP Review Process") for other disclosures; and (3) revising the estimated burden hours based on agency experience administering the SRDP over the past three years. http://www.gpo.gov/fdsys/pkg/FR-2014-05-02/pdf/2014-10146.pdf CMS on 5/6/2016 issued a revision of this PRA request. CMS seeks approval to revise the current information collection request (ICR). Currently, a party must provide a financial analysis of overpayments arising from actual or potential violations of section 1877 of the Act based on a 4-year lookback period. On 2/12/2016, CMS published a final rule on the reporting and returning of overpayments (final overpayment rule). The final overpayment rule establishes a 6-year lookback period for reporting and returning overpayments. CMS has revised the information collection for SRDP to reflect the 6-year lookback period established by the final overpayment rule. The revision will ensure that parties submitting self-disclosures to the SRDP report overpayments for the entire 6-year lookback period. The 6-year lookback period applies only to submissions to SRDP received on or after 3/14/2016, the effective date of the final overpayment rule; parties submitting self-disclosures to the SRDP prior to 3/14/2016 need only provide a financial analysis of potential overpayments based on a 4-year lookback period. https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10705.pdf No comments recommended. CMS on 9/9/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-09/pdf/2016-21625.pdf No comments recommended. | |
| 111.f. | Mental Health Parity Rules: External Review for MSPP ACTION: Request for Comment | TD 9640 (OMB 1545- 2165) | <u>Issue Date:</u> 11/27/2015 <u>Due Date:</u> 1/26/2016 <u>NIHB File</u> | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008: Technical Amendment to External Review for Multi-State Plan Program; Use: The final regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), which requires parity between mental health or substance use disorder benefits and medical/surgical benefits with respect to financial requirements and | |

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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008: Technical Amendment to External Review for MSPP AGENCY: IRS | | Date: None Date of Subsequent Agency Action, if any: | | treatment limitations under group health plans and group and individual health insurance coverage, includes disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan, included an amendment to the interim final regulations implementing Public Health Service Act (PHS Act) section 2719 to specify that the federal external review process under PHS Act section 2719(b)(2) and paragraph (d) of the internal claims and appeals and external review regulations apply to the Multi-State Plan Program (MSPP) administered by OPM. Section 2719 of the PHS Act and its implementing regulations provide that group health plans and health insurance issuers must comply with either a state external review process or the federal external review process. This information collection request addresses this requirement. http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-30101.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 112.d. | I/T/U Payment for Physician and Non- Hospital-Based Services ACTION: Proposed Final Rule NOTICE: Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated with Non-Hospital-Based Care AGENCY: IHS | IHS RIN 0917- AA12 | Issue Date: 12/5/2014 Due Date: 1/20/2015 2/4/2015 NIHB File Date: 2/4/2015 Date of Subsequent Agency Action, if any: Issued due date extension 1/14/2015; issued Final Rule | NIHB response: TSGAC response: | SUMMARY OF AGENCY ACTION: This proposed rule would amend IHS Purchased and Referred Care (PRC), formally known as Contract Health Services (CHS), regulations to apply Medicare payment methodologies to all physician and other health care professional services and non-hospital based services either authorized under such regulations or purchased by urban Indian organizations (UIOs). Specifically, it proposes that the health programs operated by IHS, Tribes, tribal organizations, or UIOs (collectively, I/T/U programs) will pay the lowest of the amount provided for under the applicable Medicare fee schedule, prospective payment system, or Medicare waiver; the amount negotiated by a repricing agent, if available; or the usual and customary billing rate. IHS might use repricing agents to determine whether it would benefit from savings by utilizing negotiated rates offered through commercial health care networks. This proposed rule seeks comment on how to establish reimbursement that remains consistent across Federal health care programs, aligns payment with inpatient services, and enables IHS to expand beneficiary access to medical care. http://www.gpo.gov/fdsys/pkg/FR-2014-12-05/pdf/2014-28508.pdf SUMMARY OF NIHB ANALYSIS: NIHB strongly supports expanding Medicare-Like Rates beyond hospital-based providers and believes this proposed rule serves as a good step toward achieving that goal. However, as drafted, this proposed rule does not provide the flexibility necessary to ensure continued access to care for Al/ANs through the | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 3/21/2016 <u>Due Date:</u> 5/20/2016 | | Purchased/Referred Care (PRC) programs. Without a mechanism to ensure such flexibility, this proposed rule could operate to deny many Al/ANs access to critically important and life-saving services. This proposed rule requires revisions to provide the flexibility needed to ensure continued access to care while still lowering costs. | |
| | | | TSGAC File Date: 5/20/2016 | | SUMMARY OF SUBSQENT AGENCY ACTION: IHS on 1/14/2015 issued a document that extends the comment period for the Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated with Non-Hospital-Based Care proposed rule published in 12/5/2014 FR (79 FR 72160). This document extends the comment period for the proposed rule, which would have ended on 1/20/2015, to 2/4/2015. http://www.qpo.gov/fdsys/pkg/FR-2015-01-14/pdf/2015-00400.pdf | |
| | | | | | IHS on 3/21/2016 issued a final rule with comment period to implement a methodology and payment rates for IHS Purchased/Referred Care (PRC), formerly known as the Contract Health Services (CHS), to apply Medicare payment methodologies to all physician and other health care professional services and nonhospital-based services. Specifically, it will allow the health programs operated by I/T/Us to negotiate or pay non-I/T/U providers based on the applicable Medicare fee schedule, prospective payment system, Medicare rate, or in the event of a Medicare waiver, the payment amount calculated in accordance with such waiver; the amount negotiated by a repricing agent, if applicable; or the most favored customer (MFC) rate of the provider or supplier. This final rule will establish payment rates consistent across federal health care programs, align payment with inpatient services, and enable I/T/Us to expand beneficiary access to medical care. IHS has included a comment period, in part, to address tribal stakeholder concerns about the opportunity for meaningful consultation on the impact of the rule on tribal health programs. | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-03-21/pdf/2016-06087.pdf An IHS press release on this final rule is available at https://www.ihs.gov/newsroom/index.cfm/pressreleases/2016pressreleases/ihs-implements-new-regulation-for-tribes-to-negotiate-medicare-like-rates/. All Tribes Call On 4/14/2016, IHS announced that Elizabeth Fowler, Deputy Director of Management | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | Operations for the agency, will hold an All Tribes Call on this final rule. IHS will provide an overview of this final rule, with time for questions and answers. Additional information on the call appears below. Date: Thursday, April 21, 2016 Time: 3 p.m4 p.m. ET Dial-in number: 888-323-9705 Passcode: 8647683 Analysis On 3/21/2016, IHS announced that it will implement a new rule that gives IHS, tribal, and urban ladion health programs (I/T/I/Is) the ability to can payment rates at a "Madicare like" | |
| | | | | | urban Indian health programs (I/T/Us) the ability to cap payment rates at a "Medicare-like rate" to physician and other non-hospital providers and suppliers that furnish services through the Purchased/Referred Care (PRC, formally Contract Health Services) program. This new rule states that I/T/Us can negotiate with certain Indian health care providers that furnish services through PRC for payment at Medicare-like rates. This is good news because, for years, IHS and tribal health programs had higher payment rates than private health insurers and other federal programs, such as Medicare and the Veterans Health Administration. This new rule is opt-in and not a requirement, which gives I/Ts more flexibility. This is in recognition of tribal sovereignty and self-determination, as Tribes have the right to negotiate with providers and determine how best to meet the needs of their community when providing health care. This flexibility means that, in some individual cases, it is better for I/Ts to have the ability to negotiate higher rates than what Medicare provides. However, the ability to negotiate higher rates for tribally-operated facilities requires a reasonable pricing arrangement that is in the best interest of the I/T. IHS recognizes that this new rule will have significant tribal implications. Although this | |
| | | | | | new rule is final, to ensure that all concerns are taken into account, IHS will provide another 60 days for the public to submit comments on the rule. In addition, IHS will conduct outreach and education to PRC administrators and participating providers and suppliers. Two issues of concern were discussed at the tribal caucus meeting at the TSGAC conference: (1) the requirement to have a formal AFA modification to indicated "opt-in" or "opt-out" and (2) mixing the issues of an "authorization" and a "referral" (§ 136.202). | |
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| 112.g. | Receipt of Non-VA Care Under Veterans Choice Program ACTION: Request for Comment NOTICE: Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program AGENCY: VA | VA (OMB 2900-0823) | Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 7/26/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program; <i>Use</i> : Section 17.1515 requires eligible veterans to notify VA whether the veteran elects to receive authorized non-VA care through the Veterans Choice Program, get placed on an electronic waiting list, or get scheduled for an appointment with a VA health care provider. Section 17.1515(b)(1) also allows eligible veterans to specify a particular non-VA entity or health care provider, if that entity or provider meets certain requirements. http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf SUMMARY OF NIHB ANALYSIS: How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. SUMMARY OF SUBSQENT AGENCY ACTION: CMS on 5/15/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended. CMS on 5/27/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12574.pdf No comments recommended. | |
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| 112.h. | Health Care Plan Information for Veterans Choice Program ACTION: Request for Comment NOTICE: Health Care Plan Information for the Veterans | VA (OMB 2900-0823) | Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Health Care Plan Information for the Veterans Choice Program; <i>Use</i> : Section 17.1510(d) requires eligible veterans to submit to VA information about their health care plan to participate in the Veterans Choice Program. http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf SUMMARY OF NIHB ANALYSIS: How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS | |



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| AGENCY: VA AGENCY: VA Agency Age | of Regulation/Title/ Agency | File Code | Due Date & File Date | | and Summary of NIHB Analysis | NIHB Recs. |
| Records Under Veterans Choice Program 2900-0823) 2719/2015 ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program; Use: Participating eligible entities and providers must submit a copy of any medical record related to hospital care or medical services furnished under the Veterans Choice Program to an eligible veteran. NOTICE: Submission of Medical Record Information under the Veterans Choice Program to an eligible veteran. NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Date of Summary OF NIHB ANALYSIS: How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. SUMMARY OF SUBSQENT AGENCY ACTION: CMS on 5/15/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended. | | | Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; | | useful. SUMMARY OF SUBSQENT AGENCY ACTION: CMS on 5/15/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended. CMS on 5/27/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12574.pdf | |
| Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program; Use: Participating eligible entities and providers must submit a copy of any medical record related to hospital care or medical services furnished under the Veterans Choice Program to an eligible veteran. NOTICE: Submission of Medical Record Information under the Veterans Choice Program to an eligible veteran. NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Date of Summary OF Subsquent Agency Action. Summary Of Subsquent Agency Action, if any: Issued extension of this PRA request. No comments recommended. | | | | | | |
| 6/15/2015; https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12574.pdf 7/26/2016 | Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program | | 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; | | a currently approved collection; <i>Title</i> : Submission of Medical Record Information under the Veterans Choice Program; <i>Use</i> : Participating eligible entities and providers must submit a copy of any medical record related to hospital care or medical services furnished under the Veterans Choice Program to an eligible veteran. http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf SUMMARY OF NIHB ANALYSIS: How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. SUMMARY OF SUBSQENT AGENCY ACTION: CMS on 5/15/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended. CMS on 5/27/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12574.pdf | |
| | | Agency Choice Program AGENCY: VA Submission of Medical Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program | Choice Program AGENCY: VA Submission of Medical Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program NOTICE: Submission of Medical Record Information under the Veterans Choice Program | of Regulation/Title/ Agency Choice Program AGENCY: VA AGENCY: VA Submission of Medical Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program AGENCY: VA AGENCY: VA Submission of Medical Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program AGENCY: VA AGENCY: VA AGENCY: VA Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 5/27/2016 | Of Regulation/Title/ Agency Choice Program AGENCY: VA Submission of Medical Records Under Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information under the Veterans Choice Program AGENCY: VA Submission of Medical Record Information under the Veterans Choice Program AGENCY: VA AGENCY: VA File Code Due Date & File Date of Subsequent Agency Action, if any: Issue Date: 2/19/2015 Due Date: 4/20/2015 Due Date: 4/20/2015 Due Date: 4/20/2015 Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 5/27/2016 Due Date: 6/15/2015; 5/27/2016 | Of Regulation/Title/ Agency Choice Program AGENCY: VA Date of Subsequent Agency Action, if any: Issued Extension 5/15/2015; 722/2016 Submission of Medical Record Sunder Veterans Choice Program ACTION: Request for Comment NOTICE: Submission of Medical Record Information o |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 112.j. | | VA (OMB 2900-0823) | Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 7/26/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Submission of Information on Credentials and Licenses by Eligible Entities or Providers; <i>Use</i> : Section 17.1530 requires eligible entities and providers to submit verification that the entity or provider maintains at least the same or similar credentials and licenses as those required of VA health care providers, as determined by the VA Secretary. http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf SUMMARY OF NIHB ANALYSIS: How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. SUMMARY OF SUBSQENT AGENCY ACTION: CMS on 5/15/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended. CMS on 5/27/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12574.pdf No comments recommended. | |
| 112.I. | Expanded Access to Non- VA Care Through Veterans Choice ACTION: Interim Final Rule NOTICE: Expanded Access to Non-VA Care Through the Veterans Choice Program | VA RIN 2900- AP60 | Issue Date: 12/1/2015 Due Date: 3/30/2016 NIHB File Date: None Date of | | SUMMARY OF AGENCY ACTION: VA revises its medical regulations that implement section 101 of the Veterans Access, Choice, and Accountability Act of 2014 (Choice Act), which requires VA to establish a program to furnish hospital care and medical services through eligible non-VA health care providers to eligible veterans who either cannot receive care within the wait-time goals of the Veterans Health Administration (VHA) or who qualify based on their place of residence (Veterans Choice Program or Program). The most recent amendments to the Choice Act made by the Construction Authorization and Choice Improvement Act of 2014 and by the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 require these regulatory revisions. The Construction Authorization and Choice Improvement Act of 2014 amended the Choice | |



| | Short Title/Current Status | | Issue Date; | | | |
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| Ref. | of Regulation/Title/ Agency | File Code | Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| # | 9 | File Code | | Response | Act to define additional criteria that VA can use to determine that travel to a VA medical facility constitutes an "unusual or excessive burden," and the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 amended the Choice Act to cover all veterans enrolled in the VA health care system, remove the 60-day limit on an episode of care, modify the wait-time and 40-mile distance eligibility criteria, and expand provider eligibility based on criteria as determined by VA. This interim final rule revises VA regulations consistent with the changes made to the Choice Act as described above. http://www.gpo.gov/fdsys/pkg/FR-2015-12-01/pdf/2015-29865.pdf SUMMARY OF NIHB ANALYSIS: This interim final rule includes no Indian-specific provisions and does not address a previous tribal recommendation that VA use existing sharing agreements with I/T/U facilities, rather than requiring these facilities to negotiate new agreements, when implementing section 101 of the Choice Act. Previously, VA has indicated that it remains "committed to using existing agreements and partnerships where possible." SUMMARY OF SUBSQENT AGENCY ACTION: VA on 4/25/2016 issued a document to correct an error in the interim final rule published in the 12/1/2015 FR (80 FR 74991). In the rule, VA inadvertently omitted two paragraphs, (a)(1) and (a)(2) of 38 CFR 17.1530. | NIHB Recs. |
| | | | | | This document corrects this error. In § 17.1530, paragraphs (a)(1) and (2) should read as follows: | |
| | | | | | § 17.1530 Eligible entities and providers. | |
| | | | | | (a) * * * | |
| | | | | | (1) Not a part of, or an employee of, VA; or(2) If the provider is an employee of VA, is not acting within the scope of such employment while providing hospital care or medical services through the Veterans Choice Program. | |
| | | | | | **** | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-04-25/pdf/2016-09475.pdf | |



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| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| (C) PC | Dear Tribal Leader Letter Contract Support Costs Policy) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 1/7/2016 Due Date: Open NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised policy 4/11/2016 Due Date: 60 days (approx. 6/10/2016) NIHB File Date: 6/10/2016 | NIHB response: | SUMMARY OF AGENCY ACTION: This letter seeks to initiate a consultation on the IHS Contract Support Costs (CSC) policy. IHS plans to update and implement a new policy in 2016. The policy, developed in 1992 and revised several times since then through coordination and consultation with Al/AN Tribes and tribal organizations, aims to provide uniform and equitable guidance on the preparation and negotiation of requests for CSC funds for new and existing awards authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA). The new policy comes in response to a June 2012 Supreme Court decision on CSC claims against the Department of the Interior in the case Salazar v. Ramah Navajo Chapter (Ramah). The impact of this decision generated additional review for IHS, although not a party to the Ramah case, and its CSC policy. The current CSC policy appears in the Indian Health Manual at Part 6, Chapter 3 (2007), available online at https://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p6c3 . IHS last initiated consultation on this policy in October 2011. As IHS updates this policy, please send written input or feedback to Robert G. McSwain by mail at the address below or by e-mail at consultation@ihs.gov . Robert G. McSwain Principal Deputy Director Indian Health Service 5600 Fishers Lane Mail stop: 08E86 Rockville, MD 20857 http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/54891-1_DTLL_CSC_Consultation_to_OD_1-7-16.pdf SUMMARY OF SUBSQENT AGENCY ACTION: IHS on 4/11/2016 issued a subsequent Dear Tribal Leader Letter that opens a tribal consultation for a 60-day period to consult with Al/AN Tribes and tribal organizations on the revised IHS Contract Support Costs (CSC) policy. IHS seeks to goal is | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | File Date | Response | The IHS CSC Workgroup recommended improvements and clarifications that IHS incorporated in the revised policy, including the following significant changes: Introductionincludes Guiding Principles; expands on the definitions Processsection is renamed "Determining CSC Amounts": Assumes full funding instead of addressing how to allocate a limited appropriation 6-3.2.E.1.bDetermination of Final Amount for Indirect CSC Need and Funding: Use the most current and up-to-date information to determine final CSC need at the end of the contract funding period For example, use indirect cost rate not older than two (2) years (note: IHS will use rates up to three (3) years old for FY 2014-FY 2017; these years are considered transitional years). 6-3.2.E.3similar to the 80/20 split used to determine indirect costs funded in Tribal Shares and avoid duplication, IHS provides an option to negotiate indirect costs funded in the Service Unit shares by using a 97/3 split (Tribes still have the option to use the current negotiation of indirect CSC) Throughout the revised CSC policy, footnotes are used to outline differences in interpretation and application of ISDEAA, including which costs are eligible for CSC under the statute Interested parties can submit recommendations by e-mail to consultation@ihs.gov (Subject line: IHS Contract Support Costs Policy) or by mail to the address below. Mary Smith Principal Deputy Director Indian Health Service 5600 Fishers Lane Mail stop: 08E86 Rockville, MD 20857 | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | A template for tribal organization comments on the revised CSC policy and talking points on this policy are embedded below. TEMPLATE Tribal Contract Support Comments on ProposiCosts Talking Points. In-Person Sessions IHS also will hold the following consultation sessions on the newly proposed/revised CSC policy: 1. 2016 U.S. Department of Health & Human Services Region IX Tribal Consultation April 15 from 3 p.m3:45 p.m. Acacia Ballrooms B/C/D Wild Horse Pass Hotel and Casino 5040 Wild Horse Pass Blvd. Chandler, Arizona 85226 2. 2016 Annual Tribal Self-Governance Consultation Conference April 26 from 2:30 p.m4:30 p.m. Great Hall North Buena Vista Palace and Resort 1900 E Buena Vista Drive Lake Buena Vista, Florida 32830 3. 2016 U.S. Department of Health & Human Services Region X Tribal Consultation May 13 from 10:45 a.m12 p.mOpen Tribal Leader Comments session Salmon/Whale Room, 4th Floor Tower Building Suquamish Clearwater Casino Resort 15347 Suquamish Way NE Suquamish, Washington 98392 | |
| 440 | | | | T0040 | OUR MADY OF A OFNOY A OTION HIGH THE STATE OF A STATE OF THE STATE OF | 0 7 11 0 |
| 112.n. | Catastrophic Health Emergency Fund | IHS RIN 0905- AC97 | <u>Issue Date:</u> 1/26/2016 | TSGAC response: | SUMMARY OF AGENCY ACTION: IHS administers the Catastrophic Health Emergency Fund (CHEF), which serves to meet the extraordinary medical costs associated with the treatment of victims of disasters or catastrophic illnesses within the responsibility of the | See Table C. |
| | ACTION: Proposed Rule | | <u>Due Date:</u> | TSGAC | agency. This proposed rule would establish: definitions governing CHEF; a requirement | |



| Ref. | Short Title/Current Status | | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | |
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| # | of Regulation/Title/ | File Code | Due Date & | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | Agency NOTICE: Catastrophic Health Emergency Fund AGENCY: IHS | | File Date 3/11/2016 4/11/2016 5/10/2016 Open (until at least 10/24/2016) TSGAC File Date: 5/10/2016 10/28/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/25/2016, 3/11/3016; issued tribal consultation notice 6/1/2016, 7/29/2016 (comment period reopened) | response: | that a Service Unit shall not qualify for reimbursement for the cost of treatment until the cost of the episode of care has reached a certain threshold; a procedure for reimbursement for certain services exceeding a threshold cost; a procedure for payment for certain cases; and a procedure to ensure payment will occur from CHEF if other sources of payment (federal, state, local, or private) are available. https://www.gpo.gov/fdsys/pkg/FR-2016-01-26/pdf/2016-01138.pdf An IHS press release on this proposed rule is available at https://www.ihs.gov/newsroom/index.cfm/pressreleases/2016pressreleases/ihs-seeks-comment-on-new-regulation-for-catastrophic-health-emergency-fund/. SUMMARY OF NIHB ANALYSIS: A summary of this proposed rule is embedded below. IHS CHEF Proposed Rule raises possible concerns about defining "alternative resources" to include self-insured tribal employer plans and using the term "referral" in relation to an authorization for payment. SUMMARY OF SUBSEQUENT AGENCY ACTION: IHS on 2/25/2016 issued a document that extends the due date to submit comments regarding this proposed rule from 3/11/2016 to 4/11/2016. IHS on 3/11/2016 issued a document that extends the due date to submit comments regarding this proposed rule by 60 days, from 3/11/2016 to 5/102016. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05555.pdf IHS on 6/1/2016 issued a Dear Tribal Leader Letter announcing tribal consultation on this proposed rule. IHS will not move forward with this proposed rule until tribal consultation has occurred, including an in-person consultation session at NCAI on 10/9-14/2016 in Phoenix, AZ. This letter comes in response to numerous requests from Tribes and tribal organizations to conduct tribal consultation before finalizing the rule. https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016 Letters/55766-1-DTLL-CHEF.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | HHS on 7/29/2016 issued a Dear Tribal Leader Letter announcing that IHS will hold telephone and in-person tribal consultation sessions on the proposed rule. Information on the sessions appears below. Telephone Sessions Date: Tuesday, 8/16/2016 Time: 3 p.m. to 4 p.m. ET Call-in number: 1-888-790-3108 Passcode: 4110567 Date: Monday, 10/24/2016 Time: 1 p.m. to 2 p.m. ET Call-in number: 1-888-790-3108 Passcode: 4110567 In-Person Sessions NIHB Annual Consumer Conference in Scottsdale, Arizona, on 9/19/2016, from 9 a.m. to 9:50 a.m. National Congress of American Indians 73rd Annual Convention and Marketplace in Phoenix, Arizona, on 10/9/2016, from 1 p.m. to 2 p.m. A copy of this letter is available at https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/55914-1_CHEF_DTLL_07292016.pdf. | |
| 112.0. | IHS Reimbursement Rates for CY 2016 ACTION: Notice NOTICE: Reimbursement Rates for Calendar Year 2016 | IHS RIN 0917- ZA30 | Issue Date: 3/8/2016 Due Date: None NIHB File Date: | | SUMMARY OF AGENCY ACTION: This notice announces that the IHS Principal Deputy Director, under the authority of sections 321(a) and 322(b) of the Public Health Service Act and the Indian Health Care Improvement Act, has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for CY 2016 for Medicare and Medicaid beneficiaries, beneficiaries of other federal programs, and for recoveries under the federal Medical Care Recovery Act. This notice does not include Medicare Part A inpatient rates, as they are paid based on the prospective payment system. Since the inpatient rates set forth in this notice do not include all physician services and practitioner services, additional payment is available to the extent that those services are provided. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | AGENCY: IHS | | Date of Subsequent Agency Action, if any: | | https://www.gpo.gov/fdsys/pkg/FR-2016-03-09/pdf/2016-05252.pdf CY 2016 Rates Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services) Lower 48 States | |
| 112.p. | FDA Tribal Consultation Policy | FDA (no reference | <u>Issue Date:</u> 2/29/2016 | NIHB response: | SUMMARY OF AGENCY ACTION: FDA adheres to the HHS Tribal Consultation Policy, which serves as a guide for federally recognized Indian Tribes to participate in policy | See Table C. |



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | ACTION: Notice NOTICE: U.S. Department Of Health And Human Services Food And Drug Administration Tribal Consultation Policy (Draft) AGENCY: FDA | number) | Due Date: 5/31/2016 NIHB File Date: 5/31/2016 Date of Subsequent Agency Action, if any: | | development by HHS and its divisions to the greatest extent practicable and permitted by law. The FDA Tribal Consultation Policy seeks to establish clear policies to further the government-to-government relationship between FDA and Tribes and facilitate tribal interaction with FDA. Nothing in the FDA Tribal Consultation Policy diminishes or waives the HHS Tribal Consultation Policy. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. The special government-to-government relationship between the federal government and Tribes is based on the Constitution and has received form and substance by numerous treaties, laws, Executive Orders (EOS), and federal court decisions. The importance of consultation with Tribes was affirmed through Presidential Memoranda in 1994, 2004, and 2009 and EO 13175 in 2000. FDA remains committed to furthering relationships with Tribes by engaging in open, continuous, and meaningful consultation to promote exchange of information, mutual understanding, and informed decision-making. FDA will accept comments on its draft Tribal Consultation Policy (Docket No. FDA-2016-N-0586), as well as suggestions on how to improve communication and outreach with tribal governments until 5/31/2016. Interested parties should submit comments via www.regulations.gov or by mail. http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/TribalAffairs/UCM488351.pdf A Dear Tribal Leader letter on the draft FDA Tribal Consultation Policy is embedded below. FDA Dear Tribal Consultation Policy. SUMMARY OF NIHB ANALYSIS: Tribal representatives might wish to comment on this draft FDA Tribal Consultation Policy. | |
| 112.q. | Recognition of Tribal Groups for Representation of VA Claimants | VA RIN 2900- AP51 | <u>Issue Date:</u> 3/10/2016 | NIHB response: | SUMMARY OF AGENCY ACTION: This request for information seeks tribal consultation on a proposed rule that would amend VA regulations concerning recognition of certain national, state, and regional or local organizations for purposes of VA claims | See Table C. |



| I DOT | rt Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| Inform NOTI Tribal Repre | ION: Request for mation Proposed Rule ICE: Recognition of I Organizations for esentation of VA nants NCY: VA | | Due Date: 4/11/2016 NIHB File Date: 4/11/2016 Date of Subsequent Agency Action, if any: Issued Proposed Rule 7/15/2016 Due Date: 9/13/2016 | | representation. Specifically, the proposed rule would amend VA regulations to provide expressly for VA recognition of tribal organizations so that representatives of tribal organizations can assist Al/AN claimants in the preparation, presentation, and prosecution of their VA benefit claims. In addition, the proposed rule would allow an employee of a tribal government to become accredited through a recognized state organization. https://www.gpo.gov/fdsys/pkg/FR-2016-03-10/pdf/2016-05163.pdf A VA Dear Tribal Leader Letter requesting tribal consultation on this proposed rule is embedded below. VA_DTIL_TRIE38_Par 114_030316.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule requires a response, as it is an important item for tribal organizations and Al/AN veterans. This proposed rule might pose some concerns over the definition of which organizations can register to provide VA claims representation. An analysis of this request for information is embedded below. VA Recognition of Tribal Organizations F SUMMARY OF SUBSEQUENT AGENCY ACTION: VA on 7/15/2016 issued a proposed rule that would amend its regulations concerning recognition of certain national, state, and regional or local organizations for purposes of VA claims representation. Specifically, this proposed rule would allow the VA Secretary to recognize tribal organizations in a similar manner as the VA Secretary recognizes state organizations. This proposed rule would allow a tribal organization established and funded by one or more tribal governments to obtain recognition for the purpose of providing assistance on VA benefit claims. In addition, this proposed rule would allow an employee of a tribal government to become accredited through a recognized state organization in a similar manner as a | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | state organization. This proposed rule seeks to improve access of AI/AN veterans to VA-recognized organizations and VA-accredited individuals who can assist them on their benefit claims. | |
| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-07-15/pdf/2016-16797.pdf | |
| | | | | | This proposed rule incorporates some of the tribal recommendations made in April 2016 (see Table C). This proposed rule also provides an opportunity for tribal representatives to make further comments. | |
| 112.r. | Secondary Authorization Request for VA Community Care ACTION: Request for Comment NOTICE: Secondary Authorization Request for VA Community Care AGENCY: VA | VA (OMB 2900-0823) | Issue Date: 5/27/2016 Due Date: 7/26/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/11/2016 Due Date: 11/10/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Secondary Authorization Request for VA Community Care (VA Form 10-10143e); <i>Use</i> : VA Form 10-10143e would require non-VA health care providers to submit requests for additional services supporting the original authorized plan of care to the agency. Providers must submit to VA a copy of all medical and dental records (including but not limited to images, test results, and notes or other records of what care was provided and why) related to the care of a veteran provided under the Veterans Choice Program for entry into the electronic medical record of the veteran. Providers must submit records produced as a result of care authorized after the beginning of the Veterans Choice Program. https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12574.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: VA on 10/11/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-11/pdf/2016-24482.pdf No comments recommended. | |
| | | | | | | |
| 112.s. | Dear Tribal Leader Letter (Community Health Aides) ACTION: Notice | IHS (no reference number) | Issue Date: 6/1/2016 Due Date: | NIHB response: | SUMMARY OF AGENCY ACTION: This letter seeks to initiate a consultation on a draft policy statement that proposes an expansion in the use of community health aides at IHS facilities nationwide. Facilities operated by Tribes and the IHS could see expanded opportunities under the draft policy for these aides, which also could include dental | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: Dear Tribal Leader Letter AGENCY: IHS | | 7/29/2016 10/27/2016 NIHB File Date: 10/27/2016 Date of Subsequent Agency Action, if any: Issued due date extension 7/29/2016 | | health aide therapists. IHS is proposes to expand its existing community health aide program, including exploring administrative requirements for this expansion. This could include the creation of a national certification board for community health aides in the IHS system. IHS already runs an evaluation system mandated by statute to monitor agency community health aides to assure that patients receive quality health care. Interested parties can submit comments and recommendations by e-mail to consultation@ihs.gov (Subject line: IHS Expansion of Community Health Aide Program Draft Policy Statement Consultation) or by mail to the address below. Alec Thundercloud, MD Director, Office of Clinical and Preventive Services Indian Health Service 5600 Fishers Lane Mail Stop: 08N34-A Rockville, MD 20857 ATTN: IHS Expansion of Community Health Aide Program Draft Policy Statement Consultation https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents /2016_Letters/55744-1_DTLL_CHAP_Expansion.pdf The draft policy statement is available at https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents /2016_Letters/55744-1_IHSPolicyStatementontheExpansionofCHAP.pdf. An NIHB press release on the draft policy statement and related IHS tribal consultation is available at http://www.nihb.org/. SUMMARY OF NIHB ANALYSIS: A background document on the draft policy statement is embedded below. FINAL CHAP and CHAP and CHAP and CHAP Background, p | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | gooj | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: HHS on 7/29/2016 issued a Dear Tribal Leader Letter announcing that IHS will extend the comment period on the draft policy statement to October 27 and hold telephone and in-person Tribal Consultation/Urban Confer sessions. Information on the sessions appears below. Telephone Tribal Consultation/Urban Confer Session Date: Tuesday, 10/4/2016 Time: 3 p.m. to 4:30 p.m. ET Call-in number: 1-888-955-8942 Passcode: 9659843 In-Person Tribal Consultation/Urban Confer Sessions • NIHB Annual Consumer Conference in Scottsdale, Arizona, on 9/19/2016, from 1 p.m. to 2:30 p.m. • National Congress of American Indians 73rd Annual Convention and Marketplace in Phoenix, Arizona, on 10/9/2016, from 2:15 p.m. to 5 p.m. A copy of this letter is available at https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/DTLL_CHAPExtension07292016.pdf. | |
| 112.t. | Tribal Consultation on Great Plains Area IHS ACTION: Notice NOTICE: Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service AGENCY: IHS | IHS (no reference number) | Issue Date: 6/3/2016 Due Date: 90 days (approx. 9/3/2016) 11/30/2016 NIHB File Date: | | SUMMARY OF AGENCY ACTION: This notice announces that IHS will conduct a 90-day tribal consultation and urban confer regarding the State of the Great Plains Area IHS. IHS will conduct two telephone tribal consultation and urban confer sessions on 6/22/2016 and 8/10/2016. IHS also will conduct two on-site tribal consultation and urban confer sessions on 7/13/2016 in Aberdeen, South Dakota and on 8/30/2016 in Rapid City, South Dakota. https://www.gpo.gov/fdsys/pkg/FR-2016-06-03/pdf/2016-13135.pdf An IHS letter on this notice is available at https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/GreatPlainsArea_DTLL_UIOLL_060216.pdf. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | Date of Subsequent Agency Action, if any: Issued correction 6/15/2016, 7/7/2016; issued due date extension 9/23/2016 | | SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: IHS on 6/15/2016 issued a document to correct an error in the notice published in the 6/3/2016 FR and titled "Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service." The notice contained the incorrect U.S. Code regarding consultation. This document makes the following correction: On page 35787, in the first column, under the heading "SUPPLEMENTARY INFORMATION: fourth paragraph," delete "[42 U.S.C. 9835, Section 640(I)(4)(A)]," and insert "2 U.S.C. 1534." https://www.gpo.gov/fdsys/pkg/FR-2016-06-16/pdf/2016-14232.pdf IHS on 7/7/2016 issued a document to correct errors in the notice published in the 6/3/2016 FR and titled "Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service." The notice contained an incorrect date and location of the onsite consultation session. This document makes the following corrections: • On page 35786, in the third column, under the heading SUMMARY, delete "July 13, 2016 in Aberdeen, South Dakota" and insert "July 15, 2016". • On page 35786, in the third column, under the heading DATES, delete both references to Aberdeen, South Dakota, in the first and second paragraphs. • On page 35786, in the third column, under the heading ADDESSES, delete "The Dakota Event Center located at 720 Lamont Street, Aberdeen, South Dakota" and insert "The Best Western Ramkota Hotel located at 2111 N. Lacrosse Street, Rapid City, SD 57701". https://www.gpo.gov/fdsys/pkg/FR-2016-07-07/pdf/2016-16135.pdf IHS on 9/23/2016 issued a document that extends the comment period in the Notice of Tribal Consultation and Urban Confer Sessions on the State of the Great Plains Area Indian Health Service announcement published in the 6/3/2016 FR to 11/30/2016. https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22922.pdf | |
| 112.u. | Dear Tribal Leader Letter (Tribal Premium Sponsorship) | IHS (no reference number) | <u>Issue Date</u> : 7/18/2016 | TSGAC response: | SUMMARY OF AGENCY ACTION: This letter announces that IHS seeks comments and recommendations on a draft Circular addressing the purchase of health care coverage, commonly referred to as Tribal Premium Sponsorship (Sponsorship). Sponsorship | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| ľ | ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | | Due Date: 8/17/2016 10/31/2016 TSGAC File Date: 10/28/2016 Date of Subsequent Agency Action, if any: Issued due date extension 7/29/2016 | | occurs when a Tribe pays health insurance premiums on behalf of IHS beneficiaries. When tribal members enroll in coverage they can improve their access to care through increased options for health care. In turn, revenue collected by tribal and IHS providers goes back into the facility to meet conditions of participation and provide additional funds to hire staff and purchase services and new equipment. In addition, with greater alternate resources, Purchased/Referred Care (PRC) funds go farther as more patients have coverage. This draft Circular seeks to provide further detailed guidance to IHS Area Offices regarding the current IHS policy if an I/T/U wishes to purchase coverage for IHS beneficiaries with Indian Self-Determination and Education Assistance Act (ISDEAA) funding or other IHS-appropriated funds. Per Section 402 of the Indian Health Care Improvement Act, I/T/Us can use federally appropriated funding, to the extent available under law, to purchase health insurance for IHS beneficiaries. A copy of the draft Circular is available at https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/55865-1_Draft_IHSCircularNo2016-08_TribalPremiumSponsorship.pdf Tribal Consultation IHS will consult with tribal leaders on the draft Circular from July 18 through August 17. Tribal leaders or organizations can e-mail written comments to consultation@ihs.gov by COB August 17. IHS also will hold a telephone consultation and Urban Confer Call to provide an overview and discussion of the draft Circular. Information on the call appears below. Date: 7/25/2016 (Monday) Time: 3-4 p.m. ET Call-in number: (888) 323-5260 Passcode: 5432202 SUMMARY OF NIHB ANALYSIS: Tribal representatives might want to request | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | withdraw the draft Circular and (2) rescind the October 2013 letter interpreting section 402(b). SUMMARY OF SUBSEQUENT AGENCY ACTION: HHS on 7/29/2016 issued a Dear Tribal Leader Letter announcing that IHS will extend the comment period on the draft Circular to October 31 and hold two in-person consultation sessions. 1st Session: NIHB Annual Consumer Conference in Scottsdale, Arizona, on 9/19/2016, from 11 a.m. to 11:50 a.m. 2nd Session: National Congress of American Indians 73rd Annual Convention and Marketplace in Phoenix, Arizona, on 10/9/2016, from 3:45 p.m. to 5 p.m. A copy of this letter is available at https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/55865-2_DTLL_PremiumSponsorship.pdf. | |
| 112.v. | Dear Tribal Leader Letter (Consultation on Tribal Priorities) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: VA | VA (no reference number) | Issue Date: 5/19/2016 Due Date: 10/7/2016 NIHB File Date: 10/7/2016 Date of Subsequent Agency Action, if any: | NIHB response: | SUMMARY OF AGENCY ACTION: This Dear Tribal Leader Letter announces that VA seeks input from tribal leaders on the top 3 to 5 priorities that Tribes have for serving veterans in Indian Country. Once identified, VA might use these priorities to assist with the collaborative development of an Indian Country VA policy agenda, which will inform tribal governments, VA, members of Congress, and other Veteran-serving partners in coming years. To gather this input, VA plans to hold two tribal consultation sessions in 2016. The first consultation will take place Wednesday, June 29, 2016, at 5:15 p.m. in the Spokane Convention Center at 334 W. Spokane Falls Blvd., Spokane, WA 99201 (in conjunction with the National Congress of American Indians Mid-Year Conference, taking place June 27-30, 2016, in Spokane, WA). The second consultation will take place later this year (VA will send a second letter to confirm this session when the date and time are finalized). VA also invites written comments on the consultation topics, particularly for tribal leaders and representatives who cannot attend the consultation meetings in person. Interested parties can submit written comments as follows: E-mail: tribalgovernmentconsultation@va.gov | See Table C. |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | | | | | Mail: U.S. Department of Veterans Affairs Office of Intergovernmental Affairs (075F) 810 Vermont Avenue, NW, Suite 915G Washington, DC 20420 A copy of the letter and an associated VA fact sheet are embedded below. DTLL June 2016 VA Fact Sheet Consultation signed, 5-16-16b.pdf SUMMARY OF NIHB ANALYSIS: This DTLL requires a response, as it is an important item for tribal organizations. One topic of concern (previously discussed with VA at the TSGAC meeting on 7/21/2016) is the execution of individual MOUs with tribal health organizations and the continuation of the national MOU. Tribal representatives requested (separate) tribal consultation on this specific topic. Tribal representatives have concerns over VA possibly downplaying MOUs with I/T/Us and transitioning to the CHOICE Act program for reimbursement to Tribes. VA has communicated difficulty in processing payments using the encounter rate vs. the Medicare rate-based payment structure. | |
| 112.w. | Dear Tribal Leader Letter (FY 2015 Self-Governance Program Report) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 8/22/2016 Date: 9/30/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This letter requests comments on the Fiscal Year 2015 Report to Congress on Administration of the Indian Health Service (IHS) Tribal Self-Governance Program. The Indian Self-Determination and Education Assistance Act (ISDEAA) requires that IHS, prior to submitting the report to Congress, seek comments on the methods used to determine individual tribal shares for inclusion in self-governance compacts or funding agreements and the report contents. Interested parties can submit comments by e-mail to sgreport@ihs.gov (Subject line: Tribal Self-Governance ReportFiscal Year 2015 or by mail to the address below. Mary Smith Principal Deputy Director Indian Health Service | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | Mail Stop: 08E86 5600 Fishers Lane Rockville, MD 20857 ATTN: Tribal Self-Governance ReportFiscal Year 2015 https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents /2016_Letters/48202-8_DTLL_FY2015_SG_ReportToCongress.pdf SUMMARY OF NIHB ANALYSIS: | |
| 112.x. | Dear Tribal Leader Letter (IHS Draft Quality Framework) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) | Issue Date: 7/20/2016 Due Date: 9/19/2016 10/3/2016 NIHB File Date: 10/3/2016 Date of Subsequent Agency Action, if any: Issued due date extension 9/15/2016 | | SUMMARY OF AGENCY ACTION: This letter provides an update about IHS efforts to increase access to quality health care for Al/ANs and seeks tribal consultation on a draft Quality Framework (Framework). IHS developed the Framework to outline key priorities and objectives that focus on strengthening the underlying foundation of the direct service health facilities within the IHS system of care. The Framework builds on existing initiatives and programs to drive improvements in service delivery. The Framework focuses on federally operated facilities to align with the following quality priorities: 1) Strengthen organizational capacity to improve quality of care and systems; 2) Meet and maintain accreditation for IHS direct service facilities; 3) Align service delivery processes to improve patient experience; 4) Ensure patient safety; and 5) Improve processes and strengthen communications for early identification of risks. The Framework is available at https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/56010-1_Enclosure_IHSQualityFramework_DRAFT.pdf . Interested parties can submit comments and recommendations by e-mail to consultation@ihs.gov (Subject line: IHS Quality Framework) or by mail to the address below. Ms. Rebecca Spitzgo Indian Health Service 5600 Fishers Lane, Mail Stop 08E86 Rockville, Maryland 20857 ATTN: IHS Expansion of Community Health Aide Program Draft Policy Statement | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | Consultation IHS also will hold telephone and in-person tribal consultation sessions on the proposed rule. Information on the sessions appears below. Telephone Session Date: Tuesday, 8/15/2016 Time: 2 p.m. to 4 p.m. ET Call-in number: 1-800-988-9462 Passcode: 6895736 In-Person Sessions • 13th Annual Direct Service Tribes National Meeting & • 6th Annual Great Plains Tribal Chairmen's Health Board Health Summit in Rapid City, South Dakota, on 8/30/2016. • National Indian Health Board 33rd Annual Tribal Health Conference in Scottsdale, Arizona, on 9/19/2016. https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/56011-1_DTLL_DraftQualityFramework.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/15/2016 issued a DTLL to announce that the agency will extend the comment period on the draft policy statement to 10/3/2016. https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/56011-1_DTLL_QualityFrameworkExtendCommentPeriod.pdf | |
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| 112.y. | Dear Tribal Leader Letter (Core Provider Network) ACTION: Notice NOTICE: Dear Tribal Leader | VA (no reference number) | <u>Issue Date</u> : 9/12/2016 <u>Due Date</u> : 11/5/2016 | | SUMMARY OF AGENCY ACTION: This Dear Tribal Leader Letter announces that VA seeks tribal consultation to assist in developing the core provider network in a manner that would build on existing department relationships with tribal health programs and facilitate future collaboration to improve health care services provided to all eligible, VA-enrolled veterans, regardless of whether they are IHS-eligible. Specifically, VA seeks input from tribal leaders regarding tribal health program participation in the core provider | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency Letter AGENCY: VA | | NIHB File Date: Date of Subsequent Agency Action, if any: Issued Notice 9/29/2016 | | network and a potential transition from the current reimbursement agreement structure to a model under which tribal health programs deliver care to all eligible, VA-enrolled veterans using a standard reimbursement rate. To gather this input, VA plans to hold an in-person tribal consultation session on Wednesday, September 28, 2016, from 9 a.m. to 11 a.m., in the Smithsonian National Museum of the American Indian (NMAI) in Washington, D.C. Interested parties should RSVP to tribalgovernmentconsultation@va.gov. VA also invites written comments at tribalgovernmentconsultation@va.gov. For more information, please contact Majed lbrahim at majed.ibrahim@va.gov. A copy of the letter is embedded below. DTLL Tribal Consultation 09-12-1. SUMMARY OF NIHB ANALYSIS: Tribal organizations in comments should consider asking VA to: Extend the existing Master MOU and individual agreements by 5 years; Approve pending contract proposals from Tribes/THOs; and Create a VA-Tribal work group. A key reason for the request to extend contractsand not fold tribal contracts into the CHOICE programis that the VA-Tribal MOUs have payment protections, as well as important options for implementing innovative delivery options, such as sharing resources between VA and tribal facilities and sharing staff. SUMMARY OF SUBSEQUENT AGENCY ACTION: VA on 9/29/2016 issued notice on this tribal consultation. The comment due date remains unchanged. https://www.gpo.gov/fdsys/pkg/FR-2016-09-29/pdf/2016-23483.pdf | |
| 112.z. | (IHS Headquarters | VA (no reference | <u>Issue Date</u> : 10/5/2016 | | SUMMARY OF AGENCY ACTION: This Dear Tribal Leader Letter announces that IHS seeks tribal consultation on a proposed realignment of IHS Headquarters offices. This | |
| | Realignment) | number) | <u>Due Date</u> : | | realignment seeks to impact how IHS Headquarters operates and accomplishes its oversight responsibilities, with clearer and more transparent lines of accountability. To | |



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status | File Code | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | NILID Doos |
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| # | of Regulation/Title/ Agency | File Code | Due Date & File Date | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | | 11/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | | improve efficiency and effectiveness of program operations, this realignment also moves some IHS Division-level components under different senior staff leadership. In addition to these organizational changes, this realignment makes management process changes, as well improves procurement planning and budget monitoring. IHS will accept comments on this realignment through 11/5/2016. Once IHS finalizes the realignment chart and functional statements, they will appear as a notice in the Federal Register with an effective date 30 days after the publication date. https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/DTLL_HeadquartersRealignment_10052016.pdf SUMMARY OF NIHB ANALYSIS: NIHB on October 17 sent a letter to IHS requesting a due date extension. A copy of the letter appears below. IHS Realignment Letter 10.17.16.pdf | |
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| 114.b. | Evaluating a Pilot Mobile Health Program ACTION: Request for Comment NOTICE: Evaluating a Pilot Mobile Health Program AGENCY: CMS | CMS-10634 | Issue Date: 10/14/2016 Due Date: 12/13/2016 NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Evaluating a Pilot Mobile Health Program; <i>Use</i> : CMS supports a pilot mobile health (mHealth) program in California, Louisiana, Ohio, and Oklahoma. The three-year mHealth project complements existing CMCS measurement, data collection, and reporting activities to monitor, track, and assess state maternal and infant health efforts in Medicaid and CHIP populations. This information collection request supports the evaluation of the pilot mHealth program, and CMS will use it in tracking maternal and infant health outcomes in the Medicaid population. The methods used for collection and analysis of the data might prove useful to states and serve to increase reporting of perinatal core set measures and monitoring and interpretation of state-level maternal and infant health efforts. Results from the evaluation will help CMS understand the usefulness of mobile technology for conveying health information to pregnant women and new mothers enrolled in Medicaid/CHIP, as well as the influence this information has on health behaviors and outcomes. https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24910.pdf | |
| | | | | | SUMMARY OF NIHB ANALYSIS: No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 117.b. | National In-Center Hemodialysis CAHPS Survey ACTION: Request for Comment NOTICE: National Implementation of In-Center Hemodialysis CAHPS Survey AGENCY: CMS | CMS 10478 CMS-10105 | Issue Date: 4/19/2013 Due Date: 6/18/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement (of CMS- 10105) 6/28/2013; issued revision 6/13/2016, 9/23/2016 Due Date: 7/29/2013; 8/12/2016; 10/24/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: National Implementation of In-Center Hemodialysis CAHPS Survey; Use: CMS will use data collected in the national implementation of the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey for the following purposes: (1) To provide a source of information from which they agency can publicly report selected measures to beneficiaries as a decision aid for dialysis facility selection; (2) to aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; (3) to provide the agency with information for monitoring and public reporting purposes; and (4) to support the end-stage renal disease value-based purchasing program. http://www.gpo.gov/fdsys/pkg/FR-2013-04-19/pdf/2013-09267.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a reinstatement of a PRA request for CMS-10478. In the 4/19/2013 FR (78 FR 23566), CMS inadvertently published this information collection request (ICR) as a new collection under CMS-10478. CMS will not continue seeking approval for this ICR under CMS-10478. CMS-10105 was discontinued in 2007, but CMS seeks to have it reinstated. CMS on 6/13/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13917.pdf No comments recommended. CMS on 9/23/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-22967.pdf No comments recommended. | |
| 118. | Hospital Wage Index Occupational Mix Survey | CMS-10079 | <u>Issue Date</u> : 12/7/2012 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Hospital Wage Index Occupational Mix Survey and Supporting Regulations in 42 CFR, Section 412.64; Use: Section 304(c) of Public Law | |



| Ref. | Short Title/Current Status | | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | |
|--------|--|-----------|---|----------|---|------------|
| # | of Regulation/Title/ Agency | File Code | Due Date & File Date | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | ACTION: Request for Comment NOTICE: Hospital Wage Index Occupational Mix Survey and Supporting Regulations AGENCY: CMS | | Due Date: 2/5/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/28/2013; issued extension 10/9/2015, 12/28/2015 Due Date: 4/1/2013; 12/8/2015; 1/27/2016 | | 106-554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in Medicare to construct an occupational mix adjustment to the wage index for application beginning 10/1/2004 (the FY 2005 wage index). The occupational mix adjustment seeks to control for the effect of hospital employment choices on the wage index. http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29627.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/28/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-02-28/pdf/2013-04548.pdf CMS on 10/9/2015 issued an extension of this PRA request. The FY 2016 survey will provide for the collection of hospital-specific wages and hours data for calendar year 2016 (i.e., payroll periods ending between 1/1/2016 and 12/31/2016). The 2016 Medicare occupational mix survey will apply beginning with the FY 2019 wage index. http://www.gpo.gov/fdsys/pkg/FR-2015-10-09/pdf/2015-25809.pdf No comments recommended. CMS on 12/28/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-28/pdf/2015-32435.pdf No comments recommended. | |
| | | | | | | |
| 121.c. | Medicare Participating Physician or Supplier Agreement | CMS-460 | <u>Issue Date</u> : 4/12/2013 <u>Due Date</u> : | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare Participating Physician or Supplier Agreement; Use: Section 1842(h) of the Social Security Act permits physicians and suppliers to participate voluntarily in Medicare Part B by agreeing to take assignment on | |
| | ACTION: Request for Comment | | 6/11/2013 <u>NIHB File</u> | | all claims for services to Medicare beneficiaries. The law also requires that the HHS Secretary provide specific benefits to the physicians, suppliers, and other individuals who choose to participate. The CMS-460 serves as the agreement by which the physician or | |
| | NOTICE: Medicare | | <u>Date</u> : None | | supplier elects to participate in Medicare. The information is used by: Medicare | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Participating Physician or Supplier Agreement AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued extension 6/21/2013, 7/15/2016, 10/31/2016 Due Date: 7/22/2013; 9/13/2016; 11/30/2016 | | contractors to provide the benefits the law provides for participating entities and to enable contractors to enforce the Medicare limiting charge for physicians, suppliers, and other individuals who do not participate; Medicare beneficiaries to assist them in locating physicians who will accept Medicare assignment on claims for services and save them money; and CMS to gauge the effectiveness of its efforts and the efforts of its contractors to increase participation in Medicare. http://www.gpo.gov/fdsys/pkg/FR-2013-04-12/pdf/2013-08676.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/21/2013 issued an extension of this PRA request. CMS on 7/15/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-15/pdf/2016-16797.pdf No comments recommended. CMS on 10/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | |
| 121.d. | Notification of Co-Located Medicare Providers ACTION: Request for Comment NOTICE: Notification of Fiscal Intermediaries (FIs) and CMS of Co-Located Medicare Providers and Supporting Regulations AGENCY: CMS | CMS-10088 | Issue Date: 5/17/2013 Due Date: 7/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension without change of a currently approved collection; <i>Title</i> : Notification of Fiscal Intermediaries (FIs) and CMS of Co-Located Medicare Providers and Supporting Regulations in 42 CFR 412.22 and 412.532; <i>Use</i> : Many long-term care hospitals (LTCHs) are co-located with other Medicare providers (acute care hospitals, inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), and psychiatric facilities), a situation that can lead to gaming of the Medicare system based on patient shifting. CMS requires LTCHs to notify fiscal intermediaries (FIs), Medicare administrative contractors (MACs), and CMS of co-located providers and establish policies to limit payment abuse based on FIs and MACs tracking patient movement among these co-located providers (42 CFR 412.22(e)(6) and (h)(5)). Based on their ability to identify co-located providers, FIs, MACs, and CMS will track | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date Issued extension | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis patient shifting between LTCHs and other in-patient providers to ensure appropriate payments under 42 CFR 412.532. This section limits payments to LTCHs where more | NIHB Recs. |
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| | | | 7/26/2013; issued reinstatement 10/11/2016 <u>Due Date</u> : 8/26/2013; 12/12/2016 | | than 5 percent of admissions represent patients sequentially discharged by the LTCH, admitted to an on-site provider, and subsequently readmitted to the LTCH. Because each discharge triggers a Medicare payment, CMS implemented this policy to discourage payment abuse. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11812.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/26/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf CMS on 10/11/2016 issued a reinstatement of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-11/pdf/2016-24415.pdf No comments recommended. | |
| 121.m. | Medicare Enrollment ApplicationDMEPOS Suppliers ACTION: Request for Comment NOTICE: Medicare Enrollment Application Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers AGENCY: CMS | CMS-855S | Issue Date: 9/11/2015 Due Date: 11/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/18/2015 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Enrollment ApplicationDurable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers; Use: The CMS-855S Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier enrollment application gathers from a supplier information that tells CMS its name, whether it meets certain qualifications of a health care supplier, where it renders its services or supplies, the identity of the owners of the enrolling entity, and information necessary to establish correct claims payment. This revision of CMS-855S seeks to simplify and clarify the current data collection and to remove obsolete and/or redundant questions. CMS has corrected grammar and spelling errors and has added limited informational text within the application form and instructions in conjunction with links to Web sites when greater detail is needed by the supplier. To clarify current data collection differentiations and to comport with accreditation coding, CMS has updated Section 3D ("Products and Services Furnished by This Supplier"). This revision does not offer any new material data collection. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | <u>Due Date</u> : 1/19/2016 | | http://www.gpo.gov/fdsys/pkg/FR-2015-09-11/pdf/2015-22944.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/18/2015 issued a revision of this PRA request. CMS received one comment in response to the 60-day notice. https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31887.pdf No comments recommended. | |
| 121.n. | Medicare Registration Application ACTION: Request for Comment NOTICE: Medicare Registration Application AGENCY: CMS | CMS-855O | Issue Date: 12/11/2015 Due Date: 2/9/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/25/2016 Due Date: 4/25/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Registration Application; Use: CMS-8550 serves to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications for enrollment in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services and/or prescribing Medicare Part D drugs for Medicare beneficiaries. The application allows a physician or other eligible professional to enroll in Medicare without approval for billing privileges. Applicants submit the required information is submitted when requesting enrollment in Medicare for the sole purpose of ordering and certifying certain Medicare items and services or for prescribing Medicare Part D drugs. Medicare contractors use the application to collect data to help ensure that the applicant has the necessary credentials to order and certify certain Medicare items and services or to prescribe Medicare Part D drugs. This includes ensuring that the physician is not excluded from the Medicare program. https://www.gpo.gov/fdsys/pkg/FR-2015-12-11/pdf/2015-31302.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/25/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-25/pdf/2016-06830.pdf No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 121.o. | New Use for System of Records (Part A Enrollment Data) ACTION: Notice NOTICE: Privacy Act of 1974; Report of a New Routine Use for a CMS System of Records AGENCY: CMS | CMS (no reference number) | Issue Date: 2/18/2016 Due Date: 30 days (approx. 3/21/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, this notice announces a new routine use to the existing system of records titled Enrollment Data Base (EDB), System No. 09-70-0502, last modified in the 2/26/2008 FR (73 FR 10249), to assist with transmitting data to IRS for 10958 processing. The new routine use will authorize CMS to disclose information maintained in the system "to the IRS for the purposes of reporting Medicare Part A enrollment information and to provide statements to the individual enrollees with respect to whom information is reported to the IRS." Disclosures made pursuant to the routine use will be coordinated through the CMS Division of Medicare Enrollment Coordination, Medicare Enrollment and Appeals Group, Center for Medicare. SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 121.p. | Medicare Enrollment Application ACTION: Request for Comment NOTICE: Medicare Registration Application AGENCY: CMS | CMS-855(A, B, and I) See also 121.a. and 121.h. | Issue Date: 4/1/2016 Due Date: 5/31/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/31/2016 Due Date: 6/30/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare Enrollment Application; Use: The CMS-855 Medicare enrollment application serves to gather information from a provider or supplier that tells CMS its name, whether it meets certain qualifications as a health care provider or supplier, where it practices or renders its services, the identity of the owners of the enrolling entity, and other information necessary to establish correct claims payments. https://www.gpo.gov/fdsys/pkg/FR-2016-04-01/pdf/2016-07423.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-31/pdf/2016-12694.pdf No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 122.a. | Special Enrollment Rights Under Group Health Plans ACTION: Request for Comment NOTICE: Notice of Special Enrollment Rights Under Group Health Plans AGENCY: DoL | DoL (OMB 1210-0101) | Issue Date: 12/26/2012 Due Date: 1/23/2013 2/25/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 1/24/2013; issued extension 11/23/2015, 3/4/2016 Due Date: 1/22/2016; 4/4/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Notice of Special Enrollment Rights Under Group Health Plans; Use: Under regulations 29 CFR 2590.701-6(c), a group health plan must provide an individual offered coverage under the plan a notice describing its special enrollment rights at or before the time coverage is offered. http://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-30964.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: DoL on 1/24/2013 issued a document that extends the comment period for this PRA request from 1/23/2013 to 2/25/2013. http://www.gpo.gov/fdsys/pkg/FR-2013-01-24/pdf/C1-2012-30878.pdf DOL on 11/23/2015 issued an extension of this PRA request. DOL on 3/4/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04685.pdf No comments recommended. | |
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| 125. | Interest Rate on Overdue Debts ACTION: Notice NOTICE: Notice of Interest Rate on Overdue Debts AGENCY: HHS | HHS (no reference number) | Issue Date: 12/28/2012 Due Date: None NIHB File Date: | | SUMMARY OF AGENCY ACTION: Section 30.18 of HHS claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that HHS becomes entitled to recovery. The rate must equal or exceed the current value of funds rate set by the Department of Treasury or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities," unless the HHS Secretary waives interest in whole or part or a statute, contract, or repayment agreement prescribes a different rate. The Secretary of the Treasury may revise this rate quarterly. HHS publishes this rate in the Fed Reg. | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | | | Date of Subsequent Agency Action, if any: Issued revisions 3/5/2013, 4/23/2013, 7/23/2013, 11/12/2014, 10/27/2014, 1/27/2015, 8/17/2015, 11/3/2015, 1/27/2016, 4/27/2016, 8/10/2016, 10/21/2016 | | The current rate of 10 38%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2012. This interest rate is effective until the Secretary of the Treasury notifies the HHS of any change. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: Under the 3/5/2013 revision, the current rate of 105/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2012. This interest rate will remain effective until the Secretary of the Treasury notifies HHS of any change. http://www.gpo.gov/fdsys/pkg/FR-2013-03-05/pdf/2013-04945.pdf Under the 4/23/2013 revision, the current rate of 101/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 3/31/2013. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-04-23/pdf/2013-09578.pdf Under the 7/23/2013 revision, the current rate of 103/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2013. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-07-23/pdf/2013-17683.pdf Under the 11/12/2013 revision, the current rate of 101/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2013. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-11-12/pdf/2013-26994.pdf Under the 9/2/2014 revision, the current rate of 103/8%, as fixed by t | |
| | | | | | Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-11-12/pdf/2013-26994.pdf Under the 9/2/2014 revision, the current rate of 103/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2014. This rate is based on the Interest | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2014-09-02/pdf/2014-20773.pdf | |
| | | | | | Under the 10/27/2014 revision, the current rate of 10 3/4%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2014-10-27/pdf/2014-25443.pdf | |
| | | | | | Under the 1/27/2015 revision, the current rate of 10 1/2%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2015-01-27/pdf/2015-01429.pdf | |
| | | | | | Under the 8/17/2015 revision, the current rate of 9 3/4%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2015. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-20217.pdf | |
| | | | | | Under the 11/3/2015 revision, the current rate of 10.0%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2015. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-20217.pdf | |
| | | | | | Under the 1/27/2016 revision, the current rate of 9 3/4%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2015. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Agency | | File Date | | debt until HHS publishes a revision. https://www.gpo.gov/fdsys/pkg/FR-2016-01-27/pdf/2016-01649.pdf Under the 4/27/2016 revision, the current rate of 10.0%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 3/31/2016. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. https://www.gpo.gov/fdsys/pkg/FR-2016-04-27/pdf/2016-09758.pdf Under the 8/10/2016 revision, the current rate of 9 5/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2016. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. https://www.gpo.gov/fdsys/pkg/FR-2016-08-10/pdf/2016-18967.pdf Under the 10/21/2016 revision, the current rate of 9 5/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2016. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. https://www.gpo.gov/fdsys/pkg/FR-2016-08-10/pdf/2016-18967.pdf | |
| 126.a. | Medicare Rural Hospital Flexibility Grant Program ACTION: Request for Comment NOTICE: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination AGENCY: HRSA | HRSA (OMB 0915-0363) | Issue Date: 12/28/2012 Due Date: 60 days (approx. 3/1/2013) NIHB File Date: None Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination; <i>Use</i> : The Medicare Rural Hospital Flexibility Program (Flex), authorized by Section 4201 of the Balanced Budget Act of 1997 (BBA) and reauthorized by Section 121 of the Medicare Improvements for Patients and Providers Act of 2008, seeks to support improvements in the quality of health care provided in communities served by Critical Access Hospitals (CAHs); to support efforts to improve the financial and operational performance of the CAHs; and to support communities in developing collaborative regional and local delivery systems. This program also assists in the conversion of qualified small rural hospitals to CAH status. For this program, HRSA developed performance measures to provide data useful to the program and to allow the agency to provide aggregate program data required by Congress under the Government | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date Action, if any: Issued new request 4/26/2013; issued revision | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis Performance and Results Act (GPRA) of 1993. These measures cover principal areas of interest to the Office of Rural Health Policy (ORHP), including: (a) Quality reporting; (b) quality improvement interventions; (c) financial and operational improvement initiatives; and (d) multi-hospital patient safety initiatives. http://www.gpo.gov/fdsys/pkg/FR-2012-12-31/pdf/2012-31399.pdf | NIHB Recs. |
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| | | | 5/27/2015, 2/12/2016 <u>Due Date</u> : 30 days (approx. 5/28/2013); 7/27/2015; 3/17/2016 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: HRSA on 4/26/2013 issued a new version of this PRA request. In response to comments on the original request, ORHP adjusted the burden estimate based on new calculations. http://www.gpo.gov/fdsys/pkg/FR-2013-04-26/pdf/2013-09946.pdf HRSA on 5/27/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-27/pdf/2015-12700.pdf No comments recommended. HRSA on 2/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-16/pdf/2016-03014.pdf No comments recommended, but some tribal organizations might have an interest in the CAH-related proposed revised measures. | |
| 128.a. | ACA Internal Claims and Appeals and External Review Procedures ACTION: Request for Comment NOTICE: ACA Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and | CMS-10338 | Issue Date: 1/11/2013 Due Date: 2/11/2013 NIHB File Date: None Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; <i>Use</i> : As part of ACA, Congress added Public Health Service Act (PHS Act) section 2719, which provides rules relating to internal claims and appeals and external review processes. On 7/23/2010, interim final regulations (IFR) set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503-1 (the DOL claims procedure regulation) and update such | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| # | Agency Issuers and Individual Market Issuers AGENCY: CMS | | File Date Action, if any: Issued revision 6/17/2016 Due Date: 7/18/2016 | Response | processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations. The DOL claims procedure regulation requires an employee benefit plan to provide third-party notices and disclosures to participants and beneficiaries of the plan. In addition, paragraphs (b)(3)(ii)(C) and (b)(2)(ii)(C) of the IFR add an additional requirement that non-grandfathered group health plans and issuers of non-grandfathered health policies provide to the claimant, free of charge, any new or additional evidence considered, or generated by the plan or issuer in connection with the claim. Paragraph (b)(3)(i) of the IFR requires issuers offering coverage in the individual health insurance market to also generally comply with the DOL claims procedure regulation as updated by the Secretary of HHS in paragraph (b)(3)(ii) of the IFR for their internal claims and appeals processes. Furthermore, PHS Act section 2719 and the IFR provide that non-grandfathered group health plans, issuers offering group health insurance coverage, and self-insured nonfederal governmental plans (through the IFR amendment dated 6/24/2011) must comply either with a state external review process or a federal external review process. The IFR provides a basis for determining when such plans and issuers must comply with an applicable state external review process and when they must comply with the federal external review process. Plans and issuers must comply with the federal external review process must have electronically elected either the HHS-administered process or the private accredited IRO process as of 1/1/2012 or, in the future, at such time as the plans and issuers use the federal external review process. Plans and issuers must notify HHS as soon as possible if any of the above information changes at any time after it is first submitted. The election requirements associated with this ICR are articulated through guidance published 6/22/2011. The election requirements are necessary for the federal external revi | |
| | | | | | of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-17/pdf/2016-14405.pdf No comments recommended. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 129.b. | Awarding and Administration of MAC Contracts ACTION: Notice NOTICE: Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts AGENCY: CMS | CMS-1653- NC | Issue Date: 12/21/2015 Due Date: 2/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This request for information solicits public comment on the processes and procedures that CMS could use to leverage new legal authorities to incentivize and reward exceptional Medicare Administrative Contractor (MAC) contract performance; publish performance information on each MAC, to the extent permitted by law; and make MAC jurisdictional changes. https://www.gpo.gov/fdsys/pkg/FR-2015-12-21/pdf/2015-32027.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 131.a. | Medicare Parts C and D Audit Guide ACTION: Request for Comment NOTICE: Medicare Parts C and D Universal Audit Guide AGENCY: CMS | CMS-10191 | Issue Date: 1/22/2013 Due Date: 3/25/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/18/2013; issued revision | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Parts C and D Universal Audit Guide; Use: To ensure that Medicare Part D plan sponsors and Medicare Advantage organizations comply with all Medicare Parts C and D program requirements, CMS in 2010 moved to more targeted, data-driven and risk-based audit approach that focused on high-risk areas having the greatest potential for beneficiary harm. CMS combined all Part C and Part D audit elements into the Medicare Part C & D Universal Audit Guide, which also will promote consistency and effectiveness, as well as reduce financial and time burdens for CMS and Medicare-contracting entities. The universal audit guide received OMB approval in 2010. The Health Plan Management System (HPMS) serves as the current conduit by which organizations submit many sources of audit materials, such as bids and other ongoing updates to CMS. To maximize resources, CMS will develop an annual audit strategy that describes how the agency will select sponsors for audit and the areas that the agency will audit. CMS will share the audit strategy with the industry via the agency Web site, HPMS memo, the Part C & D user call, and other conferences. After CMS defines the audit areas, it will design audit protocols describing in detail the focus of the audit, the | |



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| | , igolioj | | 6/13/2016 <u>Due Date:</u> 8/19/2013; 8/12/2016 | | data required for the audit, etc. CMS will send the Engagement Letter and Protocols to all sponsors selected for audit 4 weeks prior to starting the audit. In addition, CMS will release the protocols to the industry at the beginning of each calendar year via the same manner as the audit strategy. To assist in improving the audit process, CMS sends the plan sponsors a survey at the end of each audit to obtain their feedback. Sponsors do not to have to complete the survey. http://www.gpo.gov/fdsys/pkg/FR-2013-01-22/pdf/2013-01167.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/18/2013 issued a reinstatement of this PRA request with changes. CMS has revised the supporting materials for this information collection request since the 60-day notice published in the 2/28/2013 FR (78 FR 4412). http://www.gpo.gov/fdsys/pkg/FR-2013-07-18/pdf/2013-17317.pdf CMS on 6/13/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13917.pdf | |
| | | | | | No comments recommended. | |
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| 131.b. | PACE Organization Monitoring and Audit Process ACTION: Request for Comment NOTICE: The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460 AGENCY: CMS | CMS-10630 | Issue Date: 8/5/2016 Due Date: 10/4/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460; Use: Historically, CMS has included the Programs of All-Inclusive Care for the Elderly (PACE) audit protocols in the Medicare Advantage (MA) and Medicare Part D audit protocol information collection request (CMS-10191). However, in examining previous submissions, CMS does not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the PACE burden. Due to PACE audits differing substantially from MA and Part D audits, CMS has separated the PACE audit protocols from the MA and Part D protocols and created this information collection request, which seeks OMB approval under a new control number. POs must comply with all PACE program requirements. The growth of these PACE organizations forced CMS to develop an audit strategy to ensure it continues to obtain meaningful audit results. As a result, the CMS audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. CMS focused on high-risk | |



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| | | | | | areas that have the greatest potential for participant harm. CMS has developed an audit protocol and will post it to the CMS Web site each year for use by POs to prepare for their audit. The data collected for audit appears in this protocol, with the exact fields located in the record layouts at the end of the protocol. In addition, CMS will distribute a questionnaire as part of its audit. CMS also has included the questionnaire in this package. https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18662.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 134.a. | Prepaid Health Plan Cost Report ACTION: Request for Comment NOTICE: Prepaid Health Plan Cost Report AGENCY: CMS | CMS-276 | Issue Date: 1/30/2013 Due Date: 4/1/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 5/3/2013; issued revision 2/10/2016, 4/15/2016 Due Date: 6/3/2013; 4/11/2016; 5/16/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Prepaid Health Plan Cost Report; Use: HMOs and Competitive Medical Plans contracting with the HHS Secretary under Section 1876 of the Social Security Act (the Act) must submit a budget and enrollment forecast, semi-annual interim report, interim final cost report, and a final certified cost report in accordance with 42 CFR 417.572-417.576. Health Care Prepayment Plans contracting with the HHS Secretary under Section 1833 of the Act must submit a budget and enrollment forecast, semi-annual interim report, and final cost report in accordance with 42 CFR 417.808 and 42 CFR 417.810. CMS seeks approval for the reinstatement with change of form CMS-276. The Cost Report outlines the provisions for implementing Section 1876(h) and Section 1833(a)(1)(A) of the Act. The revisions will implement some changes in response to ACA, clarify certain instructions, and update outdated issues within the Cost Report. http://www.gpo.gov/fdsys/pkg/FR-2013-01-30/pdf/2013-01849.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 5/3/2013 issued a reinstatement of this PRA request with changes. CMS has made revisions to implement certain changes associated with ACA, clarify instructions, and update outdated issues within the Cost Report and the Budget Report. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10530.pdf CMS on 2/10/2016 issued a revision of this PRA request. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02686.pdf No comments recommended. CMS on 4/15/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-15/pdf/2016-08784.pdf No comments recommended. | |
| 134.b. | Medicare Provider Cost Report Reimbursement Questionnaire ACTION: Request for Comment NOTICE: Medicare Provider Cost Report Reimbursement Questionnaire AGENCY: CMS | CMS-339 | Issue Date: 1/30/2013 Due Date: 4/1/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 5/3/2013; issued extension 7/15/2016, 10/31/2016 Due Date: 6/3/2013; 9/13/2016; 11/30/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Medicare Provider Cost Report Reimbursement Questionnaire; Use: Form CMS-339 assists the provider in preparing an acceptable cost report and to minimize subsequent contact between the provider and its Medicare Administrative Contractor (MAC). Form CMS-339 provides the basic data necessary to support the information in the cost report. Exhibit 1 of form CMS-339 contains a series of reimbursement-oriented questions that serve to update information on the operations of the provider. The MAC must settle the Medicare cost report and determine the reasonableness and accuracy of the reimbursement claimed. This process includes performing both a desk review of the cost report and an analysis leading to a decision to settle the cost report with or without further audit. The form provides essential information to enable the MAC to make the audit or no audit decision, determine scope of the audit if necessary, and update the provider documentation (i.e., documentation to support the financial profile of the provider). Exhibit 2 of form CMS-339 lists bad debts pertaining to uncollectible Medicare deductible and coinsurance amounts, offering a convenient way for providers to supply the MAC with information needed to determine the allowability of the bad debts for reimbursement. http://www.gpo.gov/fdsys/pkg/FR-2013-01-30/pdf/2013-01849.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 5/3/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10530.pdf | |



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| | | | | | These changes might have an impact on I/T/Us that file cost reports with Medicare. CMS on 7/15/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-15/pdf/2016-16797.pdf No comments recommended. CMS on 10/31/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | |
| 134.e. | Home Health Agency Cost Report ACTION: Request for Comment NOTICE: Home Health Agency Cost Report AGENCY: CMS | CMS-1728- 94 | Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 9/17/2013; issued revision 9/4/2015, 2/10/2016 Due Date: 10/17/2013; | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension without change of a currently approved collection; <i>Title</i> : Home Health Agency Cost Report; <i>Use</i> : In accordance with sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act, providers of service in the Medicare program must submit annual information to achieve reimbursement for health care services rendered to Medicare beneficiaries. In addition, they must submit cost reports to their Medicare contractor on an annual basis. The Medicare contractor uses the cost report to make settlement with the provider for the fiscal period covered by the cost report and to decide whether to audit the records of the provider. Section 413.24(a) requires providers receiving payment on the basis of reimbursable cost to provide adequate cost data based on their financial and statistical records that qualified auditors can verify. Besides determining program reimbursement, the data submitted on the cost reports supports the management of federal programs. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/17/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-09-17/pdf/2013-22515.pdf CMS on 9/4/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-04/pdf/2015-22033.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 11/3/2015; 3/11/2016 | | No comments recommended. CMS on 2/10/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02685.pdf No comments recommended. | |
| 135.a. | LTCH Continuity Assessment Record and Evaluation ACTION: Request for Comment NOTICE: Long Term Care Hospital Continuity Assessment Record and Evaluation Data Set AGENCY: CMS | CMS-10409 | Issue Date: 2/1/2013 Due Date: 4/2/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 4/12/2013; issued extension 3/11/2016, 5/16/2016 Due Date: 5/13/2013; 5/10/2016, 6/15/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection: Title: Long Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set; Use: Section 3004 of ACA authorizes the establishment of a new quality reporting program for LTCH. LTCHs that fail to submit quality measure data might face a 2 percentage point reduction in their annual update to the standard Federal rate for discharges occurring during a rate year. In the FY 2013 IPPS/LTCH PPS final rule (76 FR 51743-56), CMS retained three measures (NQF #0678, NQF #0138 and NQF #0139) and adopted two new measures (NQF #0680 and NQF#0431) for the FY 2016 payment determination. NQF #0680 is the percent of residents or patients assessed and appropriately given the seasonal influenza vaccine (short-stay). NQF #0431 is influenza vaccination coverage among healthcare personnel. The data collection for these two NQF endorsed measures will start 1/1/2014. LTCH CARE Data Set was developed specifically for use in LTCHs for data collection of NQF #0678 Pressure Ulcer measures beginning 10/1/2012, with the understanding that the data set would expand in future rulemaking years with the adoption of additional quality measures. Relevant data elements contained in other well-known and clinically established data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE, were incorporated into the LTCH CARE Data Set V1.01. http://www.gpo.gov/fdsys/pkg/FR-2013-02-01/pdf/2013-02155.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/12/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-04-12/pdf/2013-08677.pdf CMS on 3/11/2016 issued an extension of this PRA request. According to CMS, relevant data elements contained in other well-known and clinically established data sets, | |



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| | | | | | including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE, were incorporated into the LTCH CARE Data Set V1.01, V2.00, and V2.01. LTCH CARE Data Set V3.00 will take effect on 4/1/2016. https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05471.pdf No comments recommended. CMS on 5/16/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-16/pdf/2016-11500.pdf No comments recommended. | |
| 135.e. | Reform of Requirements for Long-Term Care Facilities ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities AGENCY: CMS | CMS-3260- PF | Issue Date: 7/16/2015 Due Date: 9/14/2015 10/15/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued notice of reopening of comment period 9/15/2015; issued Final Rule 10/4/2016 | | SUMMARY OF AGENCY ACTION: This proposed rule would revise the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs. These proposed changes are necessary to reflect the substantial advances made over the past several years in the theory and practice of service delivery and safety. These proposals also serve as an integral part of CMS efforts to achieve broadbased improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers. http://www.gpo.gov/fdsys/pkg/FR-2015-07-16/pdf/2015-17207.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/15/2015 issued a document (CMS-3260-N) that reopens the comment period for the 7/16/2015 proposed rule titled "Reform of Requirements for Long-Term Care Facilities." This document reopens the comment period for the proposed rule, which ended on 9/14/2015, for 30 days. http://www.gpo.gov/fdsys/pkg/FR-2015-09-15/pdf/2015-23110.pdf CMS on 10/4/2016 issued a final rule that will revise the requirements long-term care facilities must meet to participate in the Medicare and Medicaid programs. These changes reflect the substantial advances made over the past several years in the theory and practice of service delivery and safety. These revisions also serve as an integral part | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis of CMS efforts to achieve broad-based improvements, both in the quality of health care | NIHB Recs. |
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| | | | | | furnished through federal programs and in patient safety, while at the same time reducing procedural burdens on providers. https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf | |
| 136.c. | PQRS and the eRx Incentive Program Data Assessment ACTION: Request for Comment NOTICE: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support AGENCY: CMS | CMS-10519 | Issue Date: 3/17/2014 Due Date: 5/16/2014 TTAG File Date: 2/29/2016 Date of Subsequent Agency Action, if any: Issued new request 9/8/2014; issued revision 9/25/2015, 1/29/2016 Due Date: 10/6/2014; 11/24/2015; 2/29/2016 | TTAG response: | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support; Use: PQRS and the eRx Incentive Program have data integrity issues, such as rejected and improper payments. This four-year project will evaluate incentive payment information for accuracy and identify improper payments, with the goal of recovering these payments. Additionally, the results of the project will contribute to recommendations to avoid future data integrity issues. CMS will analyze data submission, processing, and reporting for potential errors, inconsistencies, and gaps related to data handling, program requirements, and clinical quality measure specifications of PQRS and the eRx Incentive Program. CMS will conduct surveys of Group Practices, Registries, and Data Submission Vendors (DSVs) to evaluate PQRS and the eRx Incentive Program. Follow-up interviews will occur with a small number of respondents. http://www.gpo.gov/fdsys/pkg/FR-2014-03-17/pdf/2014-05845.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended, given that this PRA request focuses on PQRS data integrity issues. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/8/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-05/pdf/2014-21179.pdf CMS on 9/25/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-24474.pdf No comments recommended. | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis CMS on 1/29/2016 issued a revision of this PRA request. | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-01-29/pdf/2016-01689.pdf This PRA request raises concerns that CMS might use its analysis to request repayment of funds paid as much as five years earlier. | |
| 136.e. | Requirements for Reporting Quality Measures ACTION: Request for Information NOTICE: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs AGENCY: CMS | CMS-3323- NC | Issue Date: 12/31/2016 Due Date: 2/1/2016 2/16/2016 NIHB File Date: 2/1/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/2/2016 | NIHB response: | SUMMARY OF AGENCY ACTION: This request for information seeks public comment regarding several items related to the certification of health information technology (IT), including electronic health records (EHR) products used for reporting to certain CMS quality reporting programs such as, but not limited to, the Hospital Inpatient Quality Reporting (IQR) Program and the Physician Quality Reporting System (PQRS). In addition, CMS seeks feedback on how often to require recertification, the number of clinical quality measures (CQMs) to which a certified Health IT Module should have to certify, and testing of certified Health IT Module(s). Specifically, CMS seeks public input on the following areas of certification and testing of health IT, particularly relating to how often to require recertification, the number of CQMs a certified Health IT Module should have to certify to, and the testing of certified Health IT Module(s) to reduce the burden and further streamline the process for providers and health IT developers while ensuring such products are certified and tested appropriately for effectiveness. The feedback will inform CMS and HHS ONC of elements that might need consideration for future rules relating to the reporting of quality measures under CMS programs. This request for information serves as part of the effort of CMS to streamline/reduce EP, eligible hospital, CAH, and health IT developer burden. https://www.gpo.gov/fdsys/pkg/FR-2015-12-31/pdf/2015-32931.pdf SUMMARY OF NIHB ANALYSIS: Tribal representatives might want to provide comments specific to EHR technologies used by I/Ts. | See Table C. |
| 136.f. | CMS Innovation Partners Program Applications ACTION: Request for Comment | CMS-10601 | <u>Issue Date:</u> 3/1/2016 <u>Due Date:</u> 5/2/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: CMS Innovation Partners Program Applications and Surveys; Use: CMS seeks to engage individuals from the front lines of health care who actively support delivery system transformation at local and regional levels to support and accelerate adoption of alternate payment models developed through the CMS Innovation Center. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | NOTICE: CMS Innovation Partners Program Applications and Surveys AGENCY: CMS | | NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 5/6/2016 Due Date: 6/6/2016 | | The Innovation Partners Program (IPP) will provide an opportunity for 100 selected individuals who currently lead and participate in delivery reform initiatives with local and regional networks to engage in a deeper way with CMS to enhance these efforts. During the course of one year, IPP will immerse individuals in the strategy and innovation work of CMS through intensive Webinars and small group discussions. Program participants will engage with CMS staff in the Innovation Center and Regional Offices to inform and support regional activities supporting innovation models. In collaboration with CMS and fellow program participants, they will create partnerships regionally and across the United States. An application process is necessary to select the individuals who will participate in IPP and serves as the first component of this data collection. Applicants likely will include physicians, nurses, and other clinical staff in leadership roles from various health care delivery, public health and community health organizations. The second data collection component is a set of surveys targeted at individuals participating in the program. CMS will use data from these surveys to design program activities and to identify opportunities for improvement to both activities and the program overall. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04463.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended, but tribal representatives might wish to participate in the CMS Innovation Partners Program. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/6/2016 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10704.pdf | |
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| 136.g. | CMS Quality Measure Development Plan ACTION: Guidance NOTICE: CMS Quality Measure Development Plan: Supporting the Transition to | CMS (no reference number) | Issue Date: 12/18/2016 Due Date: 3/1/2016 NIHB File Date: | NIHB response: | SUMMARY OF AGENCY ACTION: This document serves to meet the requirements of the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (MACRA) and serve as a strategic framework for the future of clinician quality measure development to support the new Medicare Merit-Based Incentive Payment System (MIPS) and Medicare alternative payment models (APMs). CMS welcomes comments on this draft plan from the public, including healthcare providers, payers, consumers, and other stakeholders, through 3/1/2016. The final plan, taking into account public comments on this draft plan, will appear on the CMS Web site by 5/1/2016, | See Table C. |



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| | the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) (DRAFT) AGENCY: CMS | | 3/18/2016 Date of Subsequent Agency Action, if any: Issued Final Guidance 5/2/2016 | | followed by updates annually or as otherwise appropriate. The plan highlights known measurement and performance gaps and recommends approaches to close those gaps through development, use, and refinement of quality measures. CMS draws from extensive experience in these processes and shares with its federal partners a commitment to promoting harmonization and alignment across programs, settings, and payers. We solicit comment on how CMS can further these objectives, CMS will solicit additional input from stakeholders through the annual Call for Measures and will begin to fill gaps by developing additional measures for MIPS with the funding provided in MACRA. CMS will use the rulemaking process to finalize an initial set of measures for the program. Updates to the MDP will prioritize the development of additional quality measures in identified gap areas and other priority areas using MACRA funding over the next five years Interested parties can submit comments online at https://www.surveymonkey.com/r/26NYQRB , via e-mail at | |



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| | Agency | | The Date | | This document highlights known measurement and performance gaps, such as those initially identified in Section V (Summary of Gaps and Priorities), and recommends prioritized approaches to close these gaps through the development, adoption, and refinement of quality measures. CMS draws from extensive experience in these processes in conjunction with cross-agency and private-sector expertise and shares with its federal partners a commitment to promoting harmonization and alignment across programs, settings, and payers. CMS will solicit input from stakeholders through the ongoing Call for Measures to fill gaps by developing additional measures for MIPS with the funding provided in MACRA. CMS will use the rulemaking process to finalize an initial set of measures for the program that it will make public by November 1 each year. Updates to the MDP, which CMS will release annually or otherwise as appropriate, will prioritize the development of additional quality measures to address identified gaps and other priority areas using MACRA funding. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf A CMS blog post on this document is available at https://blog.cms.gov/2016/05/02/cms-finalizes-its-quality-measure-development-plan/ . | |
| 136.h. | MIPS and Alternative Payment Model Incentive Under PFS ACTION: Proposed-Final Rule NOTICE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused | CMS-5517- PFC | Issue Date: 5/9/2016 Due Date: 6/27/2016 NIHB File Date: 6/27/2016; TTAG also filed comments 6/27/2016 | NIHB response: TTAG response: | SUMMARY OF AGENCY ACTION: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repeals the Medicare sustainable growth rate (SGR) methodology for updates to the physician fee schedule (PFS) and replaces it with a new Merit-Based Incentive Payment System (MIPS) for MIPS eligible clinicians or groups under the PFS. This proposed rule would establish the MIPS, a new program for certain Medicareenrolled practitioners. MIPS would consolidate components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-Based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals (EPs) and would continue the focus on quality, resource use, and use of certified EHR technology (CEHRT) in a cohesive program that avoids redundancies. This proposed rule also would establish incentives for participation in certain alternative payment models (APMs) and includes proposed criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations on physician-focused payment models. In this | See Table C. |



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| | Agency | | riie Date | | community, that provide added incentives to deliver high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. This final rule with comment period also establishes MIPS, a new program for certain Medicare-enrolled practitioners. MIPS will consolidate components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals (EPs) and will continue the focus on quality, cost, and use of certified EHR technology (CEHRT) in a cohesive program that avoids redundancies. In this final rule with comment period, CMS has rebranded key terminology based on feedback from stakeholders, with the goal of selecting terms more easily identified and understood by its stakeholders. https://qpp.cms.gov/docs/CMS-5517-FC.pdf A CMS executive summary of this final rule is available at https://qpp.cms.gov/docs/QPP_Executive_Summary_of_Final_Rule.pdf. A new Quality Payment Program Web site accompanying the announcement of this final rule is available at https://www.hhs.gov/about/news/2016/10/14/hhs-finalizes-streamlined-medicare-payment-system-rewards-clinicians-quality-patient-care.html. A Healthcare Dive article on this final rule is available at http://www.healthcaredive.com/news/here-are-the-macra-final-rule-changes-you-need-to-know/428341/. | |
| 136.i. | Advancing Care Coordination ACTION: Proposed Rule NOTICE: Medicare Program; Advancing Care Coordination Through Episode Payment Models; Cardiac Rehabilitation | CMS-5519-P | Issue Date: 8/2/2016 Due Date: 10/3/2016 NIHB File Date: None Date of | | SUMMARY OF AGENCY ACTION: This proposed rule would implement three new Medicare Parts A and B episode payment models under section 1115A of the Social Security Act. Acute care hospitals in certain selected geographic areas will participate in retrospective episode payment models targeting care for Medicare fee-for-service beneficiaries receiving services during acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes. The episode of care will include all related care within 90 days of hospital discharge. We believe this model will further CMS goals of improving the efficiency and quality of care for Medicare beneficiaries receiving care for these common clinical conditions and procedures. This proposed rule also includes several proposed modifications to the Comprehensive Care | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model AGENCY: CMS | | Subsequent Agency Action, if any: | | for Joint Replacement model. https://www.gpo.gov/fdsys/pkg/FR-2016-08-02/pdf/2016-17733.pdf SUMMARY OF NIHB ANALYSIS: A detailed summary of this proposed rule appears below. Indian-Specific Provisions This proposed rule does not include any Indian-specific provisions. Summary of Major Provisions 1. Model OverviewEPM Episodes of Care: Under the proposed episode payment models (EPMs), an acute myocardial infarction (AMI), coronary artery bypass graft (CABG), or surgical hip/femur fracture treatment (SHFFT) model episode would begin with an inpatient admission to an anchor hospital assigned to a medical severity diagnosis-related group (MS-DRG) upon beneficiary discharge. Episodes would end 90 days after the date of discharge from the anchor hospital. The proposed EPM episodes would include the inpatient stays and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services. 2. Model Scope: Under the proposed rule, acute care hospitals would serve as the episode initiators and bear financial risk under the proposed AMI, CABG and SHFFT models. All hospitals that are paid under the inpatient prospective payment system (IPPS), have a CMS certification number (CCN), and have an address located in selected geographic areas would have to participate in the EPMs, with limited exceptions. An eligible beneficiary who receives care at such a hospital would automatically get included in the applicable EPM. CMS proposes to select geographic areas through a random sampling methodology. Under the cardiac rehabilitation (CR) incentive payment model, CMS proposes to provide a CR incentive payment specifically to selected hospitals with financial responsibility for AMI or CABG model episodes (hereinafter EPM-CR participants) because they already engage in managling the overall care of the AMI or CABG model beneficiary for a period of time following hospital discharge. CMS also proposes to provide a CR incentive payment specifical | |
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| | | | | | 3. Payment: CMS proposes to test the AMI, CABG, and SHFFT EPMs for 5 performance years, with the first performance year to begin July 1, 2017. During these performance years, CMS would continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, would get combined to calculate an actual episode payment. The actual episode payment would then get reconciled against an established EPM quality-adjusted target price. If positive, the participant would receive the amount of this calculation (reconciliation payment). If negative, CMS would require repayment from the participant hospital beginning with episodes ending in the second quarter of performance year 2 of the EPMs. In addition, CMS would assess the quality performance of EPM participants at reconciliation; each participant would receive a composite quality score and a | |
| | | | | | corresponding quality category. EPM participants that achieve a quality category of "acceptable" or higher would qualify for a reconciliation payment. CMS also proposes to phase in the requirement that participants whose actual episode payments exceed the quality-adjusted target price pay the difference back to Medicare beginning for performance year 2. Further, CMS propose to limit how much a hospital can gain or lose based on its actual episode payments relative to quality-adjusted target prices. Finally, CMS proposes additional policies to further limit the risk of high payment cases for all participants and for special categories of participants. | |
| | | | | | In addition to the EPMs, CMS proposes to test a CR incentive payment model to encourage the utilization of CR/intensive cardiac rehabilitation (ICR) services for beneficiaries hospitalized for treatment of AMI or CABG. To determine the CR incentive payment, CMS would count the number of CR/ICR services for the relevant time periods under the outpatient prospective payment system (OPPS) and physician fee schedule (PFS) on the basis of the presence of paid claims of the Healthcare Common Procedure Coding System (HCPCS) codes that report CR/ICR services and the units of service billed. The initial level of the per-service CR incentive amount would total \$25 per CR/ICR service for each of the first 11 CR/ICR services paid for by Medicare during an AMI or CABG model episode or AMI or CABG care period. After 11 CR/ICR services are paid for by Medicare for a beneficiary, the level of the per-service CR incentive amount would increase to \$175 | |



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| | Agency | | The Date | | per CR/ICR service for each additional CR/ICR service paid for by Medicare during the AMI or CABG model episode or AMI care period or CABG care period. 4. Similar, Previous, and Concurrent Models: The proposed EPMs are informed by other models and demonstrations currently and previously conducted by CMS and would explore additional ways to use episode payment to enhance coordination of care and improve the quality of care. 5. Overlap with Ongoing CMS Efforts: The proposed rule would exclude from participation in the AMI, CABG, and SHFFT models certain acute care hospitals participating in Bundled Payments for Care Improvement (BPCI) Models 2 and 4 for the hip and femur procedures except major joint or for all three of the BPCI cardiac episodes (AMI, PCI, and CABG). The proposed rule also would exclude beneficiaries in the proposed EPM episodes from inclusion in certain Innovation Center accountable care organization (ACO) models, the Next Generation ACO Model and Comprehensive ESRD Care. Other CMS programs, such as the Medicare Shared Savings Program and other ACO or total cost of care initiatives will remain eligible for EPM episode initiation. CMS proposes to account for overlap (i.e., where EPM beneficiaries also are included in other models and programs) to ensure the financial policies of the models are maintained and results and spending reductions are attributed to one model or program. To allow the EPMs to meet the criteria for Advanced Alternative Payment Models (APMs) based on the requirements proposed in the Quality Payment Program proposed rule, CMS proposes to require EPM participants to use certified electronic health record technology (CEHRT) in Track 1 of each EPM. CMS proposes that EPM participants in these tracks must use certified health information technology (IT) functions, in accordance with the definition of CEHRT, to document and communicate clinical care with patients and other health care professionals as described in the Quality Payment Program proposed rule. CMS also makes similar | |
| | | | | | CMS proposes to implement two different tracks within the EPMs, whereby EPM participants that meet proposed requirements for use of CEHRT and financial risk would move into Track 1 (an Advanced APM track) and EPM participants that do not meet these requirements would move into Track 2 (a non-Advanced APM track). CMS also makes similar proposals with respect to the CJR model. In addition, CMS | |



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| | | | | | notes that it would consider modifying requirements proposed in this rule as necessary to reconcile them with policies adopted in the Quality Payment Program final rule. | |
| | | | | | 6. Quality Measures and Reporting Requirements: Similar to the quality measures selected for the CJR model, CMS proposes to use established measures utilized in other CMS quality-reporting programs for the proposed EPM episodes. CMS proposes to use these measures to test the success of an EPM in achieving its goals under section 1115A of the Social Security Act (Act) and to monitor for beneficiary safety. For the SHFFT model, this proposed rule would apply the same quality measures selected for the CJR model. | |
| | | | | | Additionally, similar to the CJR model, CMS proposes to adopt a pay-for-performance methodology for EPMs relying upon a composite quality score to assign respective EPM participants to four quality categories. These quality categories would determine the eligibility of an EPM participant for a reconciliation payment should such EPM participant achieve spending below the quality-adjusted target price, as well as the effective discount percentage at reconciliation. Points for quality performance and improvement (as applicable) would get awarded for each episode measure and then summed to develop a composite quality score that would determine the quality category of the EPM participant for the episode. Quality performance would comprise the majority of available points in the composite quality score, with improvement points available as "bonus" points for the measure. This approach resembles the CJR model methodology. | |
| | | | | | Beneficiary Protections: As with the CJR model, Medicare beneficiaries in the proposed models would retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Eligible beneficiaries who receive services from model participants would not have the option to opt out of inclusion in the applicable model. This proposed rule would require participants to supply beneficiaries with written information regarding the design and implications of these models, as well as the rights of the beneficiaries under Medicare, including their right to use their providers of choice. CMS would make a robust effort to reach out to beneficiaries and their advocates to help them understand the models. CMS also proposes to use its existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. Financial Arrangements: This proposed rule would use the same general | |



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| # | Agency | | File Date | Response | framework finalized in the CJR model to hold participants financially responsible for AMI, CABG and SHFFT model episodes. Specifically, only the EPM participants would fall directly subject to the requirements of this proposed rule for the proposed EPMs. EPM participants would have responsibility for ensuring that other providers and suppliers collaborating with the EPM participants on care redesign for the applicable EPM episodes are in compliance with the applicable EPM terms and conditions. CMS proposes adding hospitals to the list of providers and suppliers eligible for gainsharing as EPM collaborators due to the expected participation of multiple hospitals in the episode care for some beneficiaries in AMI and CABG episodes. Further, CMS proposes making ACOs eligible for gainsharing as EPM collaborators due to the interest of ACOs in gainsharing during the CJR model rulemaking and the ongoing challenges of addressing overlap between episode payment models and ACOs. CMS also propose provisions that allow for certain gainsharing within ACOs. 9. Data Sharing: CMS proposes to share data with participants upon request throughout the performance period of the models to the extent permitted by the HIPAA Privacy Rule and other applicable law. CMS proposes to share upon request both raw claims-level data and claims summary data with participants. CMS proposes to provide participants with up to 3 years of retrospective claims data upon request. In accordance with the HIPAA Privacy Rule, this proposed rule would limit the content of this data to the minimum data necessary for the participant to conduct quality assessment and improvement activities and effectively coordinate care. 10. Program Waivers: Section 1115A of the Act authorizes the HHS Secretary to waive Medicare program requirements as necessary to implement provisions for testing models. Under this proposed rule, CMS would: • Adopt waivers of the telehealth originating site and geographic site requirement and allow in-home telehealth visits for all three | |



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| 136.j. | Reducing Health Care- Acquired Conditions in Nursing Homes ACTION: Request for Comment NOTICE: Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes AGENCY: CMS | CMS-10622 | Issue Date: 6/30/2016 Due Date: 8/29/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/31/2016 Due Date: 11/30/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes; Use: This information collection will provide data to assess Quality Innovation Network-Quality Improvement Organization (QIN-QIO) efforts aimed at addressing health care-associated conditions (HACs) in nursing homes to participate in the program. CMS will conduct an annual survey of administrators of nursing homes participating in the QIN-QIO program (intervention group) and administrators at nursing homes not participating in the QIN-QIO program (comparison group). The proposed survey assesses progress toward the goals of the QIN-QIO program, including activities and strategies to increase mobility among residents, reduce infections, and reduce use of inappropriate antipsychotic medication among long-term stay residents. CMS plans to conduct qualitative interviews with nursing home administrators. This interview will supplement the Nursing Home Survey and provide more in-depth contextual information about the QIN-QIO program implementation at nursing homes, including: (i) Their experience with, and perceived success of, QIN-QIO collaboratives; (ii) their satisfaction with the QIN-QIO collaborative and QIO support; (iii) the perceived value and impact of the QIO program; and (iv) drivers and barriers to QIN-QIO involvement and success. CMS will collect information from QIO leadership and/or state/territory task leads by interviews and focus groups. CMS will conduct interviews with Nursing Home Task leaders at the QIN and QIO in person during site visits and/or over the phone. CMS will conduct focus groups with QIO-level Directors during the annual CMS Quality Conference. The interviews and focus groups will examine: (i) QIO processes for recruiting nursing homes, peer coaches, and beneficiaries to participate in the program; (ii) strengths and challenges of QIN-QIO activities re | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/31/2016 issued an | NIHB Recs. |
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| | | | | | extension of this PRA request. Subsequent to the 60-day notice in the 6/30/2016 FR, CMS has revised the survey by adding questions and rewording questions. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26242.pdf No comments recommended. | |
| | | | | | No comments recommended. | |
| 136.k. | State Innovation Model Concepts ACTION: Request for Information NOTICE: Request for Information on State Innovation Model Concepts AGENCY: CMS | CMS (no reference number) | Issue Date: 9/8/2016 Due Date: 10/28/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: Section 1115A of the Social Security Act, as enacted by section 3021 of ACA, authorizes the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative payment and service delivery models that have the potential to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and CHIP beneficiaries. This request for information (RFI) seeks input the following concepts related to state-based payment and delivery system reform initiatives: 1. Partnering with states to implement delivery and payment models across multiple payers in a state that could qualify as Advanced Alternative Payment Models (APMs) or Advanced Other Payer APMs under the proposed Quality Payment Program, to create additional opportunities for eligible clinicians in a state to become qualifying APM participants (QPs)and earn the APM incentive; 2. Implementing financial accountability for health outcomes for an entire state population; 3. Assessing the impact of specific care interventions across multiple states; and 4. Facilitating alignment of state and federal payment and service delivery reform efforts and streamlining interaction between the federal government and states. Although CMS seeks public input on the areas outlined above, it has made no decision to offer awards in these areas. Interested parties should submit comments electronically to SIM.RFI@cms.hhs.gov. https://innovation.cms.gov/Files/x/sim-rfi.pdf A CMS fact sheet on this RFI is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-09-08-2.html. | |



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| | | | | | A related CMS blog post is available at https://blog.cms.gov/2016/09/07/round-one-state-innovation-model/ . SUMMARY OF NIHB ANALYSIS: No comments recommended, but THOs should review this RFI to determine if any recommendations are warranted. | |
| 137.a. | Procedures for Making Medicare National Coverage Decisions ACTION: Request for Comment NOTICE: Procedures for Making National Coverage Decisions AGENCY: CMS | CMS-R-290 | Issue Date: 2/12/2013 Due Date: 4/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 5/31/2013; issued extension 6/24/2016, 8/24/2016 Due Date: 7/1/2013; 8/23/2016; 9/23/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a currently approved collection: Title: Medicare Program: Procedures for Making National Coverage Decisions; Use: CMS revised the notice published in the 4/27/1999 FR (64 FR 22619) and published a new notice in the 9/26/2003 FR (68 FR 55634) that describes the process used to make Medicare coverage decisions, including decisions regarding coverage of new technology and services. CMS has made changes to its internal procedures in response to comments received following publication of the 1999 notice and experience under the new process. Over the past several years, CMS has received numerous suggestions to revise the process further to continue to make it more open, responsive, and understandable to the public. CMS shares the goal of increasing public participation in the development of Medicare coverage issues. This will assist CMS in obtaining the information required to make a national coverage determinations in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. http://www.gpo.gov/fdsys/pkg/FR-2013-02-12/pdf/2013-03059.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/31/2013 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-31/pdf/2013-12934.pdf CMS on 6/24/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-24/pdf/2016-15029.pdf No comments recommended. CMS on 8/24/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-08-24/pdf/2016-20216.pdf | |



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| | | | | | No comments recommended. | | | | |
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| 137.d. | Data Collection for Beneficiaries Receiving Beta Amyloid PET ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease AGENCY: CMS | CMS-10583 | Issue Date: 9/25/2015 Due Date: 11/24/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/8/2015 Due Date: 1/7/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease; Use: In the Decision Memorandum #CAG-00431N issued on 9/27/2013, CMS determined sufficient evidence exists to support the use of beta amyloid PET in 2 scenarios: (1) to exclude Alzheimer's disease (AD) in narrowly defined and clinically difficult differential diagnoses; and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD. CMS will cover one beta amyloid PET scan per patient through Coverage with Evidence Development under section 1862(a)(1)(E) of the Social Security Act (Act) in clinical studies that meet specific criteria established by CMS. Clinical studies must have CMS approval, involve subjects from appropriate populations, and use comparative and longitudinal methods. Radiopharmaceuticals used in the scan must have FDA approval. Approved studies must address defined research questions established by CMS. Clinical studies in this National Coverage Determination (NCD) must adhere to the designated timeframe and meet standards established by CMS in the NCD. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines to meet specifically identified requirements and research questions. To qualify for payment, providers must prescribe beta amyloid PET for beneficiaries with a set of clinical criteria specific to each cancer. Providers must transmit data elements to CMS for evaluation of the short and long-term benefits of beta amyloid PET to beneficiaries and for use in future clinical decision making. http://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-24474.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/8/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-08/pdf/2015-30892.pdf | | | | |
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| 137.e. | Transcatheter Valve Therapy Registry and KCCQ-10 ACTION: Request for Comment NOTICE: Transcatheter Valve Therapy Registry and KCCQ-10 AGENCY: CMS | CMS-10443 | Issue Date: 3/18/2016 Due Date: 5/17/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/17/2016 Due Date: 7/18/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Transcatheter Valve Therapy Registry and KCCQ-10; <i>Use</i> : Under the CMS National Coverage Determination (NCD) titled, "Transcatheter Aortic Valve Replacement (TAVR)," Medicare covers the TAVR device only under specific conditions, including that the heart team and hospital submit data in a prospective, national, audited registry. The data includes patient, practitioner, and facility level variables that predict outcomes such as all cause mortality and quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis. The data also will include the variables on the eight-item Kansas City Cardiomyopathy Questionnaire (KCCQ-10) to assess health status, functioning and quality of life. The KCCQ allows the derivation of an overall summary score from the physical function, symptoms (frequency and severity), social function, and quality of life domains. CMS will use the data collected and analyzed in the TVT Registry to determine if the TAVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Social Security Act. Furthermore, data from the TVT Registry will assist the medical device industry and FDA in surveillance of the quality, safety, and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, the TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, CMS will make data available for research purposes under the terms of a data use agreement that provides only de-identified datasets. https://www.g | |



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| 138.a. | Organ Procurement Organization Health Insurance Agreement ACTION: Request for Comment NOTICE: Organ Procurement Organization's (OPOs) Health Insurance Benefits Agreement and Supporting Regulations AGENCY: CMS | CMS-576A | Issue Date: 2/14/2013 Due Date: 4/15/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 4/19/2013, 3/1/2016, 5/6/2016 Due Date: 6/20/2013; 5/2/2016; 6/6/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Organ Procurement Organization's (OPOs) HIBASRA at 42 CFR 486.301-486.348; <i>Use</i> : The Medicare and Medicaid Final Conditions for Coverage for Organ Procurement Organizations (OPOs) require OPOs to sign agreements with CMS to receive reimbursement and perform their services. The information provided on this form serves as a basis for continuing the agreements with CMS and the OPOs for participation in the Medicare and Medicaid for reimburse for service. http://www.gpo.gov/fdsys/pkg/FR-2013-02-14/pdf/2013-03452.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/19/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-04-19/pdf/2013-09256.pdf CMS on 3/1/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-01/pdf/2016-04463.pdf No comments recommended. CMS on 5/6/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10704.pdf No comments recommended. | |
| 139.a. | Examination and Treatment for Emergency Medical Conditions ACTION: Request for Comment NOTICE: Examination and | CMS-R-142 | Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Examination and Treatment for Emergency Medical Conditions and Women in Labor (EMTALA), 42 CFR 482.12, 488.18, 489.20, and 489.24; Use: Under 42 CFR 488.18, 489.20 and 489.24, during Medicare surveys of hospitals and state agencies, CMS will review hospital records for lists of on-call physicians and will review and obtain the information required on hospital medical records for individuals with emergency medical conditions and women in labor, as well as the emergency department reporting information Medicare participating | |



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| | Treatment for Emergency Medical Conditions and Women in Labor AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 6/13/2016 Due Date: 6/17/2013; 8/9/2016; 10/3/2016 | | hospitals and Medicare state survey agencies must submit to CMS. In addition, CMS will use the Quality Improvement Organizations Report assessing whether an individual had an emergency condition and whether the individual was stabilized to determine whether to impose a civil monetary penalty or physician exclusion sanctions. Without such information, CMS cannot make the hospital emergency services compliance determinations required by Congress under sections 1154, 1866, and 1867 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). http://www.gpo.gov/fdsys/pkg/FR-2013-02-28/pdf/2013-04673.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/17/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 6/13/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13800.pdf No comments recommended. CMS on 9/2/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-02/pdf/2016-21201.pdf No comments recommended. | |
| 139.d. | Ambulance Transports and Signature Requirements ACTION: Request for Comment NOTICE: Emergency and Non-Emergency Ambulance Transports and Beneficiary | CMS-10242 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Reinstatement with change of a previously approved collection; <i>Title</i> : Emergency and Non-Emergency Ambulance Transports and Beneficiary Signature Requirements in 42 CFR 424.36(b); <i>Use</i> : Ambulance providers and suppliers serve as the primary information users. Specifically, when ambulance providers and suppliers sign claims on behalf of beneficiaries, they must, under by § 424.36(b)(6), keep certain documentation in their files for at least four years from the date of service. This information collection seeks to document emergency and non-emergency ambulance transports where the beneficiary could not sign the claim and the ambulance provider or supplier signed the claim on behalf of the beneficiary. Others who might use the information include: (1) Part | |



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| | Signature Requirements AGENCY: CMS | | Subsequent Agency Action, if any: Issued reinstatement 8/16/2013; issued extension 7/29/2016, 10/7/2016 Due Date: 9/16/2013; 9/27/2016; 11/7/2016 | | A and Part B Medicare Administrative Contractors that process and pay ambulance claims; (2) CMS staff members who review and audit claims for medical necessity; (3) CMS staff members who review claims for overpayments; and (4) other individuals who investigate ambulance billing practices to ensure compliance under the False Claims Act and the anti-kickback statute. http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13578.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/16/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf CMS on 7/29/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17987.pdf CMS on 10/7/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17987.pdf | |
| | | | | | No comments recommended. | |
| 140. | Social Security Office Report of State Buy-in Problem ACTION: Request for Comment NOTICE: Social Security Office Report of State Buy-in Problem AGENCY: CMS | CMS-1957 | Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: Social Security Office (SSO) Report of State Buy-in Problem; Use: Under Section 1843 of the Social Security Act, states can enter into an agreement with HHS to enroll eligible individuals in Medicare and pay their premiums. The program seeks to ensure that Medicaid serves as the payer of last resort by permitting a state to provide Medicare protection to certain groups of needy individuals, as part of its total assistance plan. The program also transfers some medical costs for this population from Medicaid, a program partially funded by the state, to Medicare, a program funded by the federal government and individual premiums. Generally, states include in the program individuals who meet the eligibility requirements for Medicare and are cash recipients or are deemed cash recipients or categorically needy under Medicaid. In some cases, states might include individuals who are not cash assistance recipients under the Medical Assistance Only group. The day-to-day operations of the program are accomplished through an automated data exchange | |



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| | | | 5/10/2013, 2/10/2016, 4/15/2016 <u>Due Date:</u> 6/10/2013; 4/11/2016; 5/16/2016 | | process that exchanges Medicare and Buy-in entitlement information between the Social Security district offices, Medicaid state agencies, and CMS. When problems arise that the normal data exchange process cannot resolve, clerical actions are required. CMS-1957 is used to report Buy-in problems cases and serves as the only standardized form available for communications between the aforementioned agencies for the resolution of beneficiary complaints and inquiries regarding State Buy-in eligibility. http://www.gpo.gov/fdsys/pkg/FR-2013-02-28/pdf/2013-04551.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/10/2013 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11033.pdf CMS on 2/10/2016 issued a reinstatement of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02686.pdf No comments recommended. CMS on 4/15/2016 issued a reinstatement of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-15/pdf/2016-08784.pdf No comments recommended. | |
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| 142.a. | Detailed Notice of Discharge ACTION: Request for Comment NOTICE: Detailed Notice of Discharge (DND) | CMS-10066 | Issue Date: 3/6/2013 <u>Due Date:</u> 5/6/2013 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Detailed Notice of Discharge (DND); Use: When a Medicare beneficiary requests a Quality Improvement Organization review of his/her inpatient hospital discharge, hospitals and Medicare plans have used DND to provide the beneficiary with a detailed explanation regarding the reason for discharge. | |
| | AGENCY: CMS | | NIHB File Date: None | | http://www.gpo.gov/fdsys/pkg/FR-2013-03-06/pdf/2013-05176.pdf SUMMARY OF NIHB ANALYSIS: | |
| | | | <u>Date of</u> <u>Subsequent</u> | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/17/2013 issued an | |



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| | rigonoj | | Agency Action, if any: Issued extension 5/17/2013, 11/27/2015, 6/13/2016 Due Date: 6/17/2013; 1/26/2016; 7/13/2016 | | extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 11/27/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-30070.pdf No comments recommended. CMS on 6/13/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13916.pdf No comments recommended. | |
| 142.b. | Important Message from Medicare ACTION: Request for Comment NOTICE: Important Message from Medicare (IM) AGENCY: CMS | CMS-R-193 | Issue Date: 3/6/2013 Due Date: 5/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 12/8/2015, 6/13/2016 Due Date: 6/17/2013; 1/26/2016; 7/13/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Important Message from Medicare (IM); Use: Hospitals have used IM to inform original Medicare, Medicare Advantage, and other Medicare plan beneficiaries who are hospital inpatients about their hospital rights and discharge rights. In particular, IM provides information about when a beneficiary will and will not have liability for charges for a continued stay in a hospital and offers a detailed description of the Quality Improvement Organization review process. http://www.gpo.gov/fdsys/pkg/FR-2013-03-06/pdf/2013-05176.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/17/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 12/8/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-08/pdf/2015-30891.pdf No comments recommended. CMS on 6/13/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-06-13/pdf/2016-13916.pdf | |



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| | | | | | No comments recommended. | |
| 143. | Paid Feeding Assistants in Long-Term Care Facilities ACTION: Request for Comment NOTICE: Paid Feeding Assistants in Long-Term Care Facilities and Supporting Regulations AGENCY: CMS | CMS-10053 | Issue Date: 3/8/2013 Due Date: 5/7/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 5/26/2016, 7/29/2016 Due Date: 6/17/2013; 7/25/2016, 8/29/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Paid Feeding Assistants in Long-Term Care Facilities and Supporting Regulations at 42 CFR 483.160; <i>Use</i> : Under 42 CFR part 483, long-term care (LTC) facilities can use paid feeding assistants to supplement the services of certified nurse aides. If LTC facilities choose this option, feeding assistants must complete a training program. LTC facilities must maintain a record of all individuals they use as paid feeding assistants. http://www.gpo.gov/fdsys/pkg/FR-2013-03-08/pdf/2013-05389.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/17/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 5/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-26/pdf/2016-12476.pdf No comments recommended. CMS on 7/29/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17988.pdf | |
| 146.a. | Data for Medicare Beneficiaries Receiving NaF-18 PET Scans ACTION: Request for Comment NOTICE: Data Collection for | CMS-10152 | Issue Date: 3/14/2013 <u>Due Date:</u> 4/15/2013 <u>NIHB File</u> <u>Date:</u> None | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: Data Collection for Medicare Beneficiaries Receiving NaF-18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer; Use: In Decision Memorandum #CAG-00065R, issued on 2/26/2010, CMS determined that receiving a NaF-18 PET scan to identify bone metastasis in cancer is considered "reasonable and necessary" only as part of a clinical study designed to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location, and quantification of bone metastases in | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Medicare Beneficiaries Receiving NaF-18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued extension 3/4/2016, 5/11/2016 Due Date: 5/3/2016; 6/10/2016 | | Medicare beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must address specific hypotheses; collect appropriate data elements; ensure hospitals and providers are qualified to provide the PET scan and interpret the results; ensure participating hospitals and providers accurately report data on all enrolled Medicare patients; and follow all patient confidentiality, privacy, and other Federal laws. Consistent with section 1142 of the Social Security Act, the Agency for Healthcare Research and Quality supports clinical research studies that CMS determines meet specified standards and address the specified research questions. To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. http://www.gpo.gov/fdsys/pkg/FR-2013-03-14/pdf/2013-05802.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/4/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04861.pdf No comments recommended. CMS on 5/11/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11080.pdf No comments recommended. | |
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| 146.b. | Data for Medicare Beneficiaries Receiving ICDs ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries Receiving Implantable | CMS-10151 | Issue Date: 4/22/2013 Due Date: 6/21/2013 NIHB File Date: None Date of | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Reinstatement with change of a previously approved collection; <i>Title</i> : Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter Defibrillators for Primary Prevention of Sudden Cardiac Death; <i>Use</i> : CMS provides coverage for implantable cardioverter defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing the effectiveness of the use of ICDs among patients with a certain set of physiologic conditions. Accordingly, CMS considers coverage for ICDs reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death appears less compelling for certain patients. To encourage responsible and appropriate | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Cardioverter Defibrillators for Primary Prevention of Sudden Cardiac Death AGENCY: CMS | | Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016 Due Date: 8/23/2013; 9/20/2016 | | use of ICDs, CMS on 1/27/2005 issued a "Decision Memo for Implantable Defibrillators" indicating coverage for ICDs for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1), or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection). http://www.gpo.gov/fdsys/pkg/FR-2013-04-22/pdf/2013-09413.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/24/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-07-24/pdf/2013-17821.pdf CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17376.pdf No comments recommended. | |
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| 148.a. | Acceptable Off-Label Uses of Certain Drugs and Biologicals ACTION: Request for Comment NOTICE: Collection Requirements for Compendia for Determination of Medically Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen | CMS-10302 | Issue Date: 3/14/2013 Due Date: 5/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/31/2013, 5/26/2016, | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Collection Requirements for Compendia for Determination of Medically Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen; <i>Use</i> : Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended Section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: "On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest." CMS believes that the implementation of this statutory provision should occur by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interest. All currently listed compendia must to comply with these provisions, as of 1/1/2010 to remain on the list of recognized compendia. In addition, any compendium that seeks | |



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| | AGENCY: ČMS | | 7/29/2016 <u>Due Date:</u> 7/1/2013; 7/25/2016; 8/29/2016 | | future inclusion on the list must comply with these provisions. No compendium can remain on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of MIPPA. http://www.gpo.gov/fdsys/pkg/FR-2013-03-15/pdf/2013-06038.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/31/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-31/pdf/2013-12934.pdf CMS on 5/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-26/pdf/2016-12476.pdf No comments recommended. CMS on 7/29/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17988.pdf | |
| 148.b. | Data for Medicare Part B Drugs and Biologicals ACTION: Request for Comment NOTICE: Data for Medicare Part B Drugs and Biologicals AGENCY: CMS | CMS-10110 | Issue Date: 7/21/2015 Due Date: 9/21/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 10/2/2015, | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: Data for Medicare Part B Drugs and Biologicals; Use: In accordance with section 1847A of the Social Security Act (Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in calendar year (CY) 2005. The ASP data reporting requirements appear in section 1927 of the Act. CMS uses the reported ASP data to establish the Medicare payment amounts. CMS revised the reporting template in CY 2011 to facilitate accurate collection of ASP data. CMS also created an accompanying user guide with instructions on the template and an explanation of the data elements in the template. http://www.gpo.gov/fdsys/pkg/FR-2015-07-21/pdf/2015-17824.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/2/2015 issued a | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 3/4/2016 <u>Due Date</u> : 11/2/2015; 4/4/2016 | | reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-25109.pdf No comments recommended. CMS on 3/4/2016 issued a reinstatement of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04841.pdf No comments recommended. | |
| 149. | Evaluation of the Graduate Nurse Education Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Graduate Nurse Education Demonstration Program AGENCY: CMS | CMS-10467 | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/28/2013; issued revision 10/16/2015, 1/19/2016 Due Date: 7/29/2013; 12/15/2015; 2/28/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Evaluation of the Graduate Nurse Education Demonstration Program; Use: Section 5509 of ACA, under title XVIII of the Social Security Act, requires the Graduate Nurse Education (GNE) Demonstration Under section 5509, the five selected demonstration sites receive "payment for the hospital's reasonable costs for the provision of qualified clinical training to advance practice registered nurses." Section 5509 also requires completion of an evaluation of the GNE Demonstration by October 17, 2017. This evaluation includes analysis of the following: (1) growth in the number of advanced practice registered nurses (APRNs) with respect to a specific base year as a result of the demonstration; (2) growth for each of the following specialties: clinical nurse specialist, nurse practitioner, certified nurse anesthetist, and certified nurse midwife; and (3) costs to the Medicare program as result of the demonstration. For this evaluation, CMS will collect primary data through site visits, key stakeholder interviews, small discussion groups and focus groups, telephone interviews, electronic templates for quantitative data submission, and quarterly demonstration site reports. CMS will collect secondary data from mandatory hospital cost reports and several other existing data sources, such as the American Association of Colleges of Nursing (AACN). http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07798.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15539.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS on 10/16/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-26390.pdf | |
| | | | | | No comments recommended. | |
| | | | | | CMS on 1/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-19/pdf/2016-00844.pdf | |
| 151.a. | Request for Employment Information ACTION: Request for Comment NOTICE: Request for Employment Information | CMS-R-297 (CMS-L564) | Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension without change of a currently approved collection; <i>Title</i> : Request for Employment Information; <i>Use</i> : The Social Security Administration uses this form to obtain information from employers regarding whether Medicare beneficiary coverage under a group health plan is based on current employment status. http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07800.pdf SUMMARY OF NIHB ANALYSIS: | |
| | AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued extension 7/26/2013; issued revision 1/2/2014; issued extension 7/25/2016, 9/29/2016 Due Date: 8/26/2013; 2/3/2014; 9/23/2016; | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/26/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf No comments recommended as this PRA request pertains to an existing form used solely for Medicare purposes. CMS on 1/2/2014 issued a revision of this PRA request. <i>Use</i> : Section 1837(i) of the Social Security Act provides for a special enrollment period for individuals who delay enrolling in Medicare Part B because they receive coverage through a group health plan based on their own current employment status or that of their spouse. Disabled individuals with Medicare also might delay enrollment because they have large group health plan coverage based on their own current employment status or that of a family member. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. http://www.gpo.gov/fdsys/pkg/FR-2014-01-02/pdf/2013-31390.pdf CMS on 7/25/2016 issued an extension of this PRA request. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 10/31/2016 | | https://www.gpo.gov/fdsys/pkg/FR-2016-07-25/pdf/2016-17478.pdf No comments recommended. CMS on 9/29/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-29/pdf/2016-23537.pdf No comments recommended. | |
| 153.m. | CMS/SSA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974: CMS Computer Match No. 2016-12; HHS Computer Match No. 1604; SSA Computer Match No. 1097- 1899 AGENCY: CMS | CMS (no reference number) | Issue Date: 2/9/2016 Due Date: 30 days (approx. 3/10/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a computer matching program (CMP) that CMS plans to conduct with the Social Security Administration (SSA). Under this CMP, titled "Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services and the Social Security Administration for Determining Enrollment or Eligibility for Insurance Affordability Programs Under the Patient Protection and Affordable Care Act," SSA will disclose information to CMS in connection with the administration of state health subsidy programs under ACA and its implementing regulations. SSA will provide data to CMS, and CMS will use SSA data needed to make initial eligibility determinations, eligibility redeterminations and renewal decisions, including appeal determinations, for state health subsidy programs and certifications of exemption. https://www.gpo.gov/fdsys/pkg/FR-2016-02-09/pdf/2016-02527.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 153.n. | CMS/Homeland Security Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-10; HHS Computer | CMS (no reference number) | Issue Date: 2/17/2016 Due Date: 30 days (approx. 3/18/2016) NIHB File Date: None | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a computer matching program (CMP) that CMS plans to conduct with the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS). Under this CMP, titled "Computer Matching Agreement between the Centers for Medicare & Medicaid Services and the Department of Homeland Security, United States Citizenship and Immigration Services, for the Verification of United States Citizenship and Immigration Status Data for Eligibility Determinations," CMS will access USCIS data needed to make eligibility determinations in its capacity as a Federally-Facilitated Exchange, and state | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | Match No. 1607 AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued correction 9/20/2016 | | agencies that administer Medicaid, a Basic Health Program, CHIP, and State-Based Exchanges will receive the results of verifications using USCIS data accessed through the CMS Data Services Hub to make eligibility determinations. https://www.gpo.gov/fdsys/pkg/FR-2016-02-17/pdf/2016-03203.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice addresses ongoing actions by federal agencies to conduct automated matching of applicant information for verification and fraud detection. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/20/2016 issued a notice to correct the expiration date published in the heading of the notice of CMS Computer Match No. 2016-10; HHS Computer Match No. 1607, published in the 2/17/2016 FR (81 FR 8074). The expiration date should read 10/2/2017 instead of 10/2/2016. In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a CMP that CMS plans to conduct with the Department of Homeland Security (DHS), United States Citizenship and Immigration Services (USCIS). https://www.gpo.gov/fdsys/pkg/FR-2016-09-20/pdf/2016-22567.pdf | |
| 153.o. | CMS/IRS Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-08; HHS Computer Match No. 1606 AGENCY: CMS | CMS (no reference number) | Issue Date: 2/17/2016 Due Date: 30 days (approx. 3/18/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a computer matching program (CMP) that CMS plans to conduct with IRS, a bureau of the Department of the Treasury. Under this CMP, titled "Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services, and the Department of the Treasury, Internal Revenue Service, for the Verification of Household Income and Family Size for Insurance Affordability Programs and Exemptions," to support the verification of household income and family size for an applicant receiving an eligibility determination under the ACA, IRS will disclose tax return information to CMS, and CMS will disclose this information to entities administering Medicaid, CHIP, or Basic Health Programs (BHPs), as well as Exchanges (or Marketplaces) through the CMS Data Services Hub. CMS, in its capacity as the Federally-Facilitated Exchange (or Federally-Facilitated Marketplace), or an administering entity will match tax return information for the purpose of determining eligibility for state health subsidy programs (premium tax credits, cost-sharing reductions, | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | correction 9/20/2016 | | Medicaid, CHIP, or BHPs), as well as certain certificates of exemption. https://www.gpo.gov/fdsys/pkg/FR-2016-02-17/pdf/2016-03185.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice addresses ongoing actions by federal agencies to conduct automated matching of applicant information for verification and fraud detection. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/20/2016 issued a notice to correct the expiration date published in the heading of the notice of CMS Computer Match No. 2016-08; HHS Computer Match No. 1606, published in the 2/17/2016 FR (81 FR 8075). The expiration date should read 10/2/2017 instead of 10/2/2016. In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a CMP that CMS plans to conduct with IRS. https://www.gpo.gov/fdsys/pkg/FR-2016-09-20/pdf/2016-22568.pdf | |
| 153.p. | CMS/Administering Entities Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-11; HHS Computer Match No. 1601 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/3/2016 Due Date: 30 days (approx. 4/1/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the establishment of a computer matching program that CMS plans to conduct with state-based Administering Entities. Under this CMP, titled "Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services and the State-Based Administering Entities for Determining Eligibility for Enrollment in Applicable State Health Subsidy Programs under the Patient Protection and Affordable Care Act," the Administering Entities will use the data, accessed through the CMS Federal Data Services Hub, to make eligibility determinations for enrollment in an applicable state health subsidy program. This CMP also establishes the terms, conditions, safeguards, and procedures under which state Medicaid/CHIP agencies shall provide data to CMS (as the Federally-Facilitated Marketplace (FFM)), State-Based Marketplaces (SBMs), and Basic Health Programs to verify whether an applicant or enrollee who has submitted an application to an FFM or SBM has current eligibility or enrollment in a Medicaid/CHIP program. https://www.gpo.gov/fdsys/pkg/FR-2016-03-03/pdf/2016-04732.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice is part of a | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | sequence of notices on data matching undertaken by the federal government in implementing and administering ACA. | |
| 153.q. | CMS/VA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-07; HHS Computer Match No. 1605 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/3/2016 Due Date: 30 days (approx. 4/1/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the establishment of a computer matching program that CMS plans to conduct with VA, Veterans Health Administration (VHA). Under this CMP, titled "Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services and the Department of Veterans Affairs, Veterans Health Administration for the Verification of Eligibility for Minimum Essential Coverage under the Patient Protection and Affordable Care Act through a Veterans Health Administration Health Benefits Plan," CMS, in its capacity as a Federally-Facilitated Exchange and the federal eligibility and enrollment platform, as well as agencies administering applicable State health subsidy programs, will use the VHA data. These entities will receive the results of verifications using information received by CMS through the CMS Federal Data Services Hub from applicants and enrollees, with those results matched with the VHA data. https://www.gpo.gov/fdsys/pkg/FR-2016-03-03/pdf/2016-04735.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice is part of a sequence of notices on data matching undertaken by the federal government in implementing and administering ACA. | |
| 153.r. | CMS/DoD Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-07; HHS Computer Match No. 1602 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/3/2016 Due Date: 30 days (approx. 4/1/2016) NIHB File Date: None Date of Subsequent | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the establishment of a computer matching program that CMS plans to conduct with the Defense Enrollment Eligibility Reporting System (DEERS), Defense Manpower Data Center (DMDC), Department of Defense (DoD). Under this CMP, titled "Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services and the Department of Defense, Defense Manpower Data Center, for Verification of Eligibility For Minimum Essential Coverage Under The Patient Protection And Affordable Care Act Through a Department of Defense Health Benefits Plan," CMS, in its capacity as a Federally-Facilitated Exchange and the federal eligibility and enrollment platform, as well as agencies administering applicable State health subsidy programs, will use the DoD data. These entities will receive the results of verifications using information | |



| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date Agency Action, if any: | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis received by CMS through the CMS Federal Data Services Hub from applicants and enrollees, with those results matched with the DoD data. https://www.gpo.gov/fdsys/pkg/FR-2016-03-03/pdf/2016-04734.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice is part of a sequence of notices on data matching undertaken by the federal government in implementing and administering ACA. | NIHB Recs. |
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| 153.s. | CMS/DoD Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-02; HHS Computer Match No. 1603; DoD- DMDC Match No. 12 AGENCY: CMS | CMS (no reference number) | Issue Date: 3/18/2016 Due Date: 30 days (approx. 4/18/2016) NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a computer matching program (CMP) between CMS and the Department of Defense (DoD). Under this CMP, titled "Computer Matching Agreement between the Centers for Medicare & Medicaid Services and the Defense Manpower Data Center Department of Defense for Disclosure of Enrollment and Eligibility Information for Military Health System Beneficiaries who are Medicare Eligible," CMS will disclose Medicare enrollment information to DoD, the Defense Manpower Data Center, and the Health Affairs/Defense Health Agency. The disclosure by CMS will provide the Defense Health Agency with the information necessary to determine if Military Health System beneficiaries (other than dependents of active duty personnel) enrolled in Medicare Part B also qualify to receive continued military health care benefits. This disclosure will provide the Defense Health Agency with the information necessary to meet the congressional mandate outlined in legislative provisions in the National Defense Authorization Acts for FY 1992 and FY 1993. https://www.gpo.gov/fdsys/pkg/FR-2016-03-18/pdf/2016-06125.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice is part of a sequence of notices on data matching undertaken by the federal government in implementing and administering ACA. | |
| 153.t. | CMS/OPM Computer Matching Program ACTION: Notice | CMS (no reference number) | <u>Issue Date</u> : 10/11/2016 <u>Due Date</u> : 30 | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the establishment of a computer matching program (CMP) that CMS plans to conduct with OPM. The CMP, titled "Computer Matching Agreement between the Department of Health and Human | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-14, HHS Computer Match No. 1608 AGENCY: CMS | | days (approx. 11/10/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | | Services, Centers for Medicare & Medicaid Services and the Office of Personnel Management For The Verification of Eligibility For Minimum Essential Coverage Under the Patient Protection and Affordable Care Act Through an Office of Personnel Management Health Benefits Plan," establishes the terms, conditions, safeguards, and procedures under which OPM will provide records, information, or data to CMS for verifying eligibility for minimum essential coverage through the Federal Employees Health Benefits Program. CMS will use the data in its capacity as a Federally-Facilitated Exchange. Agencies administering applicable state health subsidy programs that will receive the results of verifications using OPM data obtained through the CMS Data Services Hub also will use the data. https://www.gpo.gov/fdsys/pkg/FR-2016-10-11/pdf/2016-24387.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 153.u. | CMS/Peace Corps Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-15, HHS Computer Match No. 1609 AGENCY: CMS | CMS (no reference number) | Issue Date: 10/11/2016 Due Date: 30 days (approx. 11/10/2016) NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the establishment of a computer matching program (CMP) that CMS plans to conduct with the Peace Corps (PC). The CMP, titled "Verification of Eligibility for Minimum Essential Coverage Under the Patient Protection and Affordable Care Act Through a Peace Corps Health Benefits Plan," establishes the terms, conditions, safeguards, and procedures under which PC will provide records, information, or data to CMS for verifying eligibility for minimum essential coverage through a Peace Corps Health Benefits Plan. CMS will use the data in its capacity as a Federally-Facilitated Exchange. Agencies administering applicable state health subsidy programs that will receive the results of verifications using OPM data obtained through the CMS Data Services Hub also will use the data. https://www.gpo.gov/fdsys/pkg/FR-2016-10-11/pdf/2016-24388.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 154.b. | Medicaid/CHIP Managed Care ACTION: Proposed Final Rule | CMS-2390- PF | Issue Date: 6/1/2015 Due Date: | NIHB response: TTAG | SUMMARY OF AGENCY ACTION: This proposed rule would modernize the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The proposed rule would align the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through qualified health | See Table C. |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | NOTICE: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability AGENCY: CMS | | 7/27/2015 NIHB File Date: 7/27/2015; TTAG also filed comments 7/27/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 5/6/2016; issued correction 7/20/2016 | response: | plans (QHPs) and Medicare Advantage (MA) plans; implement statutory provisions; strengthen actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; and promote the quality of care and strengthen efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries. It also would ensure appropriate beneficiary protections and enhance policies related to program integrity. This proposed rule would also require states to establish comprehensive quality strategies for their Medicaid and CHIP programs, regardless of how they provide services to beneficiaries. In addition, this proposed rule would implement provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) and addresses third party liability for trauma codes. http://www.gpo.gov/fdsys/pkg/FR-2015-06-01/pdf/2015-12965.pdf A CMS PowerPoint presentation on this proposed rule (screen shots) is embedded below. Medicaid Managed Care Proposed Rules. A KCMU issue brief on this proposed rule is available at http://files.kff.org/attachment/issue-brief-awaiting-new-medicaid-managed-care-rules-key- | |
| | | | | | issues-to-watch. A National Journal article on this proposed rule is available at http://www.nationaljournal.com/health-care/new-medicaid-rules-could-be-epic-20150514 . SUMMARY OF NIHB ANALYSIS: This proposed rule includes the following Indian-specific provisions: 1. Standards for Contracts Involving Indians, Indian Health Care Provider, and Indian Managed Care Entities (§438.14): This section would implement section 5006(d) of the American Reinvestment and Recovery Act of 2009 (ARRA), which created section 1932(h) of the Social Security Act (Act) governing the treatment of Indians, Indian health care providers, and Indian managed care entities participating in Medicaid managed care programs. This section would expand the standards that apply the provisions of section 1932(h) of the Act to | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) through the authority under section 1902(a)(4) of the Act. In this section and for this purpose, CMS proposes in paragraph (a) to define the following terms: "Indian," "Indian health care provider (IHCP)," and "Indian managed care entity (IMCE)" consistent with statutory and existing regulatory definitions. In paragraph (b), CMS proposes that: • Each managed care organization (MCO), PIHP, PAHP, and primary care case manager (PCCM) entity contract must demonstrate sufficient IHCPs in the managed care network and access to services for Indian enrollees; • IHCPs receive payment for covered services provided to Indian enrollees eligible to receive services from these providers, whether or not the IHCP participates in the managed care network; • Any Indian enrolled in a non-IMCE and eligible to receive services from a participating IHCP can choose the IHCP as his or her primary care provider, as long as that provider has capacity to furnish the services; • Indian enrollees can obtain covered services from out-of-network IHCPs; and • In any state where timely access to covered services cannot occur because of an inadequate number of IHCPs, CMS would consider an MCO, PIHP, or PAHP to have met the standard for adequacy of IHCP providers either if Indian enrollees can access out-of-state IHCPs or the state deems the lack of IHCP providers a justification of good cause for disenrollment of an Indian from both the MCO, PIHP, or PAHP and the state managed care program in accordance with §438.56(c). [CMS seeks comment on other ways to approach this issue]. | |
| | | | | | Proposed §438.14(c) outlines payment standards. Proposed paragraph (c)(1) specifies that when an IHCP participates in Medicaid as a FQHC but not as a participating provider with an MCO, PIHP, or PAHP, it must receive FQHC payment rates, including any supplemental payment due from the state. Where the IHCPs does not participate in Medicaid as a FQHC, proposed paragraph (c)(2) would have the MCO, PIHP, or PAHP payment equal the payment it would receive using a fee-for-service (FFS) payment methodology under the state plan or the applicable encounter rate, regardless of its contracting status with the MCO, PIHP, or PAHP. Proposed paragraph (d) would implement the statutory provision permitting an IMCE to restrict its enrollment to Indians in the same manner as Indian health programs can restrict the delivery of services to | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | , | | | | Indians without violating the standards in §438.3(d). | |
| | | | | | [CMS seeks comment on the overall approach to this section, including whether these proposals would ensure that Indian enrollees have timely and integrated access to covered services consistent with section 5006 of ARRA. In addition, CMS seeks comment on how to facilitate a coordinated approach for care for Indian enrollees who receive services from a non-participating IHCP and who need Medicaid covered services through a referral to a specialty provider. CMS also seeks comment on the potential barriers to contracting with managed care plans for IHCPs and what technical assistance and resources it should make available to states, managed care plans, and IHCPs to facilitate these relationships (such resources might include an I/T/U contract addendum, similar to the ones created for QHPs and organizations delivering the Medicare Part D benefit).] | |
| | | | | | 2. Requirement Related to Indians, Indian Health Care Providers, and Indian Managed Care Entities (§457.1208): | |
| | | | | | Section 2107(e)(1)(M) of the Act, as added by section 5006 of ARRA, specifies that the provisions related to managed care contracts that involve Indians, IHCPs, and IMCEs at sections 1932(a)(2)(C) and 1932(h) of the Act apply to CHIP. As such, CMS proposes to align CHIP with Medicaid when MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities enroll Indians at §438.14, which effectuates sections 1932(a)(2)(C) and 1932(h) of the Act. This would appear to extend the protection first enacted in the Balance Budget Act of 1997 to permit Al/ANs to decline to enroll in Medicaid managed care. | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule modernizes the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The final rule aligns, where feasible, many of the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through qualified health plans and Medicare Advantage plans; implements statutory provisions; strengthens actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; and promotes the quality of care and strengthens efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries. It also ensures appropriate beneficiary protections and enhances policies related to program integrity. In addition, this final rule implements provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) and addresses third party liability for trauma codes. | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB | Brief Summary of Proposed Agency Action | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf | |
| | | | | | More information on managed care is available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/managed-care-site.html . | |
| | | | | | A CMS blog post on this final rule is available at https://blog.cms.gov/2016/04/25/medicaid-moving-forward/ . | |
| | | | | | A 4/25/2016 <i>Modern Healthcare</i> article on this final rule is available at http://www.modernhealthcare.com/article/20160425/NEWS/160429951 . | |
| | | | | | A 2/19/2016 <i>Modern Healthcare</i> article on this final rule is available at http://www.modernhealthcare.com/article/20160219/NEWS/160219886 . | |
| | | | | | Analysis On the issue of CMS issuing additional subregulatory guidance (as suggested in the final rule) to address requests from a state to impose through a waiver mandatory managed care enrollment for Al/AN Medicaid enrollees, tribal organizations should engage in additional interaction with CMS. | |
| | | | | | CMS also has proposed finalizing the Indian Addendum "through subregulatory guidance to offer to managed care plans on a voluntary basis, to facilitate the network status of IHCPs." | |
| | | | | | Dear Tribal Leader Letter and All Tribes Call On 4/26/2016, CMS issued a Dear Tribal Leader Letter addressing the Indian-specific provisions of this final rule. The letter is embedded below. In the letter, CMS announced that it will host an All Tribes Call to provide an overview of this final rule and address any questions. During the call, CMS will walk through the Indian-specific provisions of this final rule in more detail. Details on the call appear below. | |
| | | | | | Date: Monday, 5/23/2016 Time: 12:30 p.m2 p.m. ET Conference call #: 1-866-901-6455 Participant code: 361-333-070 | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | Managed Care Call Series In May and early June 2016, CMS will hold a series of calls on this final rule each Thursday from 12 p.m1:30 p.m. ET. For all calls, participants should use the telephone number 1-844-396-8222 and participant code 646 062 309. Information on the topics of the calls by date appears below. May 5: Overview of the Final Rule May 12: Beneficiary Experience and Provisions Unique to Managed Long Term Services and Supports (MLTSS) May 19: Managed Care Quality May 26: Program Integrity June 2: Rate Setting, MLR, and Delivery System Reform June 9: CHIP Managed Care CMS on 7/20/2016 issued a document (CMS-2390-F2) to correct corrects a technical error that appeared in the final rule published in the 5/6/2016 FR (81 FR 27498) and titled "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability." On page 27896 of the final rule, in the regulation text of § 457.10, CMS inadvertently omitted an amendatory instruction to add the definition of "Federally Qualified HMO" in alphabetical order. Accordingly, this document revises the amendatory instruction for § 457.10 to add this definition as it appeared in the 5/6/2016 FR. https://www.gpo.gov/fdsys/pkg/FR-2016-07-20/pdf/2016-17157.pdf | |
| 154.c. | Use of Pass-Through Payments in Medicaid Managed Care ACTION: Proposed Rule NOTICE: The Use of New or | CMS-2402-P | Issue Date: [Pending at OMB as of 10/18/2016] Due Date: | | SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS: | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems AGENCY: CMS | | NIHB File Date: Date of Subsequent Agency Action, if any: | | | |
| 155.a. | Research Exception Under GINA ACTION: Request for Comment NOTICE: Notice of Research Exception Under the Genetic Information Nondiscrimination Act AGENCY: CMS | CMS-10286 | Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 4/29/2016, 7/12/2016 Due Date: 8/23/2013; 6/28/2016; 8/11/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved information collection; Title: Notice of Research Exception Under the Genetic Information Nondiscrimination Act; Use: Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer can request (but not require) a genetic test in connection with certain research activities, as long as such activities comply with specific requirements, including: (i) ensuring the research complies with 45 CFR part 46 or equivalent federal regulations and applicable state or local law or regulations for the protection of human subjects in research; (ii) making the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) in writing and clearly indicating that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) using no genetic information collected or acquired for underwriting purposes. The Secretary of Labor or HHS must receive notification if a group health plan or issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market must file with CMS. The Notice of Research Exception under GINA serves as a model notice that group health plans and issuers can complete and file with either DoL or CMS to comply with the notification requirement. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10522.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/24/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-07-24/pdf/2013-17821.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | CMS on 4/29/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-10083.pdf CMS on 7/12/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16445.pdf No comments recommended. | |
| 156. | Coverage for Diabetes Outpatient Self- Management Training ACTION: Request for Comment NOTICE: Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations AGENCY: CMS | CMS-R-247 | Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/24/2013; issued extension 7/22/2016, 9/26/2016 Due Date: 8/23/2013; 9/20/2016; 10/26/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with a change of a previously approved collection; Title: Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations Contained in 42 CFR 410.141, 410.142, 410.143, 410.144, 410.145, 410.146, 414.63; Use: HCFA-3002-F, titled "Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements," provided for uniform Medicare coverage of diabetes outpatient self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity approved to furnish the services. The physician or qualified non- physician practitioner treating the beneficiary would certify the need for these services as part of a comprehensive plan of care. This rule established the quality standards that an entity would have to meet to participate in furnishing diabetes outpatient self- management training services. It set forth payment amounts established in consultation with appropriate diabetes organizations. It also implements section 4105 of the Balanced Budget Act of 1997. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11035.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/24/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-07-24/pdf/2013-17821.pdf CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17376.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | No comments recommended. CMS on 9/26/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-09-26/pdf/2016-23157.pdf No comments recommended. | |
| 158. | Model Employer CHIP Notice ACTION: Request for Comment NOTICE: Model Employer CHIP Notice AGENCY: DoL | DoL (OMB 1210-0137) | Issue Date: 5/22/2013 Due Date: 7/22/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 10/2/2013, 5/26/2016, 9/20/2016 Due Date: 11/1/2013, 7/25/2016; 10/20/2016 | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Model Employer CHIP Notice; <i>Use</i> : Under the Employee Retirement Income Security Act of 1974 (ERISA) section 701(f)(3)(B)(i)(I), Public Health Service Act section 2701(f)(3)(B)(i)(I), and section 9801(f)(3)(B)(i)(I) of the Internal Revenue Code (Code), as added by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), an employer maintaining a group health plan in a State that provides medical assistance under a State Medicaid plan under title XIX of the Social Security Act (SSA)or child health assistance under a State child health plan under title XXI of the SSAin the form of premium assistance for the purchase of coverage under a group health plan must make certain disclosures. Specifically, the employer must notify each employee of potential opportunities currently available in the State in which the employee resides for premium assistance under Medicaid and CHIP for health coverage of the employee or his or her dependents. ERISA section 701(f)(3)(B)(i)(II) requires DoL to provide employers with model language for the Employer CHIP Notices to enable them to comply with this requirement in a timely manner. http://www.gpo.gov/fdsys/pkg/FR-2013-05-22/pdf/2013-12191.pdf The Model Employer CHIP Notice is available at http://www.dol.gov/ebsa/chipmodelnotice.doc. A Supporting Statement for this PRA request is available at http://www.reginfo.gov/public/do/DownloadDocument?documentID=186778&version=1. SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: DoL on 10/2/2013 issued an extension of this PRA request with no changes. http://www.qpo.gov/fdsys/pkg/FR-2013-10-02/pdf/2013-23945.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | DoL on 5/6/2016 issued an extension of this PRA request with no changes. https://www.gpo.gov/fdsys/pkg/FR-2016-05-26/pdf/2016-12363.pdf No comments recommended. DoL on 9/20/2016 issued an extension of this PRA request with no changes. https://www.gpo.gov/fdsys/pkg/FR-2016-09-20/pdf/2016-22559.pdf No comments recommended. | |
| 161.a. | Payment Error Rate in Medicaid and CHIP | CMS-10166 | <u>Issue Date:</u> 6/7/2013 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: Payment Error Rate | |
| | ACTION: Request for Comment | | Due Date: 8/6/2013 | | Measurement in Medicaid & Children's Health Insurance Program (CHIP); Use: The Improper Payments Information Act of 2002 (IPIA), as amended by the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA), requires CMS to produce national error rates for Medicaid and CHIP. To comply with IPIA, CMS will | |
| | NOTICE: Payment Error Rate Measurement in Medicaid & Children's Health Insurance Program (CHIP) | | NIHB File Date: None Date of | | engage a federal contractor to produce the error rates in Medicaid and CHIP based on the reviews of three components: fee-for-service claims medical reviews and data processing reviews, managed care claims data-processing reviews, and eligibility reviews. Each of the review components collects different types of information, and the | |
| | AGENCY: CMS | | Subsequent Agency Action, if any: Issued | | contractor will use state-specific error rates for each of the components to calculate an overall state-specific error rate and use individual state-specific error rates to produce a national error rate for Medicaid and CHIP. | |
| | | | reinstatement 8/30/2013; issued extension | | CMS will ask states to submit, at their option, test data that include full claims details to the contractor prior to the quarterly submissions to detect potential problems in the dataset and ensure the quality of the data. These states will have to submit quarterly claims data to the contractor, which will select a statistically valid random sample, each | |
| | | | 4/8/2016. 7/22/2016 | | quarter, by strata, to perform medical and data processing reviews, with state-specific error rates based on these review results. CMS needs to collect the fee-for-service claims data, medical policies, and other information from states, as well as medical | |
| | | | <u>Due Date:</u> 9/30/2013; 6/7/2016; 8/22/2016 | | records from providers, for the contractor to sample and review adjudicated claims in those states selected for medical reviews and data processing reviews. http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13578.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/30/2013 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-08-30/pdf/2013-21257.pdf No comments recommended. CMS on 4/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08106.pdf No comments recommended. CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17251.pdf No comments recommended. | |
| 161.b. | Eligibility Error Rate in Medicaid and CHIP ACTION: Request for Comment NOTICE: Eligibility Error Rate Measurement in Medicaid and the Children's Health Insurance Program AGENCY: CMS | CMS-10184 | Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/30/2013; issued extension | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Eligibility Error Rate Measurement in Medicaid and the Children's Health Insurance Program; Use: The Improper Payments Information Act of 2002 (IPIA) requires CMS to produce national error rates for Medicaid and CHIP. To comply with IPIA, CMS will use a national contracting strategy to produce error rates for Medicaid and CHIP fee-for-service and managed care improper payments. The federal contractor will review states on a rotational basis, with each state measured for improper payments, in each program, once every three years. Subsequent to the first publication, CMS has determined it will measure Medicaid and CHIP in the same state. As a result, states will measure Medicaid and CHIP eligibility in the same year measured for fee-for-service and managed care. CMS also has determined the need for interim case completion timeframes and reporting to ensure the integrity of the reviews and keep the reviews on schedule to produce a timely error rate. In addition, CMS has decided to increase sample sizes slightly to produce an equal sample size per strata each month. Each month, states submit a monthly sample selection list, eligibility review findings for active and negative cases, and claims review | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | 4/8/2016, 7/22/2016 <u>Due Date:</u> 9/30/2013; 6/7/2016; 8/22/2016 | | findings. At the end of the cycle, states would have submitted 48 forms. CMS has created a new form in which it compiled all of the information from the 48 forms into a format that will allow states to submit 12 forms for 12 months of eligibility data. This new form also will serve either of the data substitution options. Periodically, CMS will conduct federal re-reviews of states PERM files to ensure the accuracy of states review findings and the validity of the review process. CMS will select a random subsample of Medicaid/ CHIP cases from the sample selection lists provided by each state. States will submit all pertinent information related to the review of each sampled case that CMS selects. http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13578.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/30/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-08-30/pdf/2013-21257.pdf No comments recommended. CMS on 4/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08106.pdf No comments recommended. CMS on 7/22/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17251.pdf No comments recommended. | |
| 161.d. | State Medicaid Eligibility Quality Control Sample Plans ACTION: Request for Comment NOTICE: State Medicaid | CMS-317 | Issue Date: 8/16/2013 Due Date: 9/16/2013 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: State Medicaid Eligibility Quality Control (MEQC) Sample Plans; Use: The Medicaid Eligibility Quality Control (MEQC) system involves monthly state reviews of Medicaid and Medicaid expansion under Title XXI cases by states performing the traditional sampling process identified through statistically reliable statewide samples of cases selected from the eligibility files. These reviews determine whether the sampled cases meet applicable state Title XIX or XXI eligibility requirements when applicable. The reviews also assess beneficiary liability, if | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | Eligibility Quality Control Sample Plans AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued extension 4/8/2016, 7/22/2016 Due Date: 6/7/2016; 8/22/2016 | | any, and determine the amounts paid to provide Medicaid services for these cases. In the MEQC system, sampling serves as the only practical method of validating eligibility of the total caseload and determining the dollar value of eligibility liability errors. In 1993, CMS implemented MEQC pilots in which states could focus on special studies, targeted populations, geographic areas, or other forms of oversight with agency approval. States must submit a sampling plan, or pilot proposal, for approval by CMS before implementing their pilot program. Sections 203 and 601 of the Children's Health Insurance Program Reauthorization Act (CHIPRA) relate to MEQC. Section 203 of CHIPRA establishes an error rate measurement with respect to the enrollment of children under the express lane eligibility option. The law directs states not to include children enrolled using the express lane eligibility option in data or samples used for purposes of complying with the MEQC requirements. Section 601 of CHIPRA requires a new final rule for the Payment Error Rate Measurement (PERM) program and provides states with the option to apply PERM data resulting from its eligibility reviews for meeting MEQC requirements and vice versa, with certain conditions. CMS reviews, either directly or through its contractors, of the sampling plans help ensure states use valid statistical methods for sample selection. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08106.pdf No comments recommended. | |
| 161 .e. | State Medicaid Eligibility Quality Control Sample | CMS-319 | <u>Issue Date:</u> 8/16/2013 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: State Medicaid Eligibility Quality | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB | Brief Summary of Proposed Agency Action | NIHB Recs. |
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| # | Agency | The code | File Date | Response | and Summary of NIHB Analysis | MITID RCC3. |
| | Selection Lists ACTION: Request for Comment NOTICE: State Medicaid Eligibility Quality Control Sample Selection Lists AGENCY: CMS | | Due Date: 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/8/2016, 7/22/2016 Due Date: 6/7/2016; 8/22/2016 | | Control (MEQC) Sample Selection Lists; <i>Use</i> : The Medicaid Eligibility Quality Control MEQC system involves monthly state reviews of Medicaid and Medicaid expansion under Title XXI cases by states performing the traditional sampling process identified through statistically reliable statewide samples of cases selected from the eligibility files. These reviews determine whether the sampled cases meet applicable state Title XIX or XXI eligibility requirements when applicable. The reviews also assess beneficiary liability, if any, and determine the amounts paid to provide Medicaid services for these cases. In the MEQC system, sampling serves as the only practical method of validating eligibility of the total caseload and determining the dollar value of eligibility liability errors. At the beginning of each month, state agencies still performing the traditional sample must submit sample selection lists which identify all of the cases selected for review in their samples. The sample selection lists contain identifying information on Medicaid beneficiaries, such as: State agency review number, beneficiary name and address, the name of the county where the beneficiary resides, Medicaid case number, etc. The submittal of the sample selection lists allows Regional Office validation of state reviews. Section 1903(u) of the Social Security Act provides the authority for collecting this information. The specific requirement for submitting sample selection lists appears in regulations at 42 CFR 431.814(h). Regional Office staff review the sample selection lists to determine that states sample a sufficient number of cases for review. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-17251.pdf No comments recommended. | |
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| # Agency 161.f. Medicaid and CHIP Managed Care Claims Managed Care Claims File Date Response Agency Agency Agency | | T | | _ | | |
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| Managed Care Claims 8/16/2013 Reinstatement of a previously approved collection; Title: Medicaid and Children's Health Insurance (CHIP) Managed Care Claims and Related Information; Use: The Payment | | of Regulation/Title/ Agency | | Due Date & | | NIHB Recs. |
| Comment NOTICE: Medicaid and Children's Health Insurance Managed Care Claims and Related Information AGENCY: CMS Date of Subsequent Agency Action, if any: Issued extension 4/8/2016, 7/22/2016 Due Date: 6/7/2016; 8/22/2016 Subsequent agency Action if any: Issued extension 4/8/2016 and 1/22/2016 Subsequent agency Action if any: Issued extension 4/8/2016 and 1/22/2016 Subsequent agency Action if any: Issued extension 4/8/2016, 7/22/2016 Subsequent agency Action if any: Issued extension 4/8/2016, 7/22/2016 Subsequent agency Action if any: Issued extension 4/8/2016, 7/22/2016 Subsequent agency Action if any: Issued extension 4/8/2016, 7/22/2016 Subsequent agency Action if any: Issued extension 4/8/2016, 7/22/2016 Sections 1902(a)(6) and 2107(b)(1) of the Social Security Act grant CMS authority to collect information from the States. The Improper Payments Information Act of 2002 (IPIA) requires CMS to produce national error rates in Medicaid and CHIP and produce agency and produce and program and will use their and will use their analysed care carpitation prome the States. The Improper Payments In Medicaid and CHIP and produce and program and will use their bear agency acre capitation prome the States. The Improper Payments Information Act of 2002 (IPIA) requires CMS to produce national error rates in Medicaid and CHIP fee-for-service, including the managed care component. CMS will base the state-specific Medicaid managed care and CHIP managed care error rates in produce national Medicaid managed care and CHIP managed care error rates. https://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf SumMARY OF NIHB ANALYSIS: SumMARY OF Subsequent Agency Actions: CMS on 4/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-22/pdf/2016-17251.pdf | 161.f | Managed Care Claims ACTION: Request for Comment NOTICE: Medicaid and Children's Health Insurance Managed Care Claims and Related Information | CMS-10178 | 8/16/2013 Due Date: 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/8/2016, 7/22/2016 Due Date: 6/7/2016; | Reinstatement of a previously approved collection: <i>Title</i> : Medicaid and Children's Health Insurance (CHIP) Managed Care Claims and Related Information; <i>Use</i> : The Payment Error Rate Measurement (PERM) program has two phases: the measurement phase and the corrective action phase. PERM measures improper payments in Medicaid and CHIP and produces state and national-level error rates for each program. Reviews of Medicaid and CHIP fee-for-service (FFS) and managed care payments made in the federal fiscal year under review determine the error rates. States conduct eligibility reviews and report eligibility related payment error rates used in the national error rate calculation. CMS created a 17-state rotation cycle, ensuring that each state will participate in PERM once every three years. CMS needs to collect capitation payment information from the selected states to allow the federal contractor to draw a sample and review the managed care capitation payments. CMS also will collect state managed care contracts, rate schedules, and updates to the contracts and rate schedules. The federal contractor will use this information when conducting the managed care claims reviews. Sections 1902(a)(6) and 2107(b)(1) of the Social Security Act grant CMS authority to collect information from the States. The Improper Payments Information Act of 2002 (IPIA) requires CMS to produce national error rates in Medicaid and CHIP fee-for-service, including the managed care component. CMS will base the state-specific Medicaid managed care and CHIP managed care error rates on reviews of managed care capitation payments in each program and will use them to produce national Medicaid managed care and CHIP managed care error rates. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/8/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08106.pdf | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | No comments recommended. | |
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| 161.h. | Medicaid Eligibility Quality Control and PERM Programs ACTION: Proposed Rule NOTICE: Medicaid/CHIP Program; Medicaid Program and Children's Health Insurance Program (CHIP); Changes to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs in Response to the Affordable Care Act AGENCY: CMS | CMS-6068-P | Issue Date: 6/22/2016 Due Date: 8/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule would update the Medicaid Eligibility Quality Control (MEQC) and Payment Error Rate Measurement (PERM) programs based on the changes to Medicaid and the Children's Health Insurance Program (CHIP) eligibility under ACA. This proposed rule also would implement various other improvements to the PERM program. https://www.gpo.gov/fdsys/pkg/FR-2016-06-22/pdf/2016-14536.pdf A CMS fact sheet on this proposed rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-20.html. SUMMARY OF NIHB ANALYSIS: | |
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| 161.i. | Quality Measures for Medicaid Enrollees in MLTSS ACTION: Notice NOTICE: Quality Measure Development and Maintenance for CMS Programs Serving Medicare-Medicaid Enrollees and Medicaid-Only Enrollees: Measures for Medicaid Enrollees in Managed Long- | CMS (no reference number) | Issue Date: 9/15/2016 Due Date: 10/7/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: CMS has contracted with Mathematica Policy Research and its partners, the American Medical Association, Brandeis University, the National Committee for Quality Assurance, and Truven Health Analytics, to develop measures for several groups of Medicaid beneficiaries: (1) those eligible for both Medicare and Medicaid, or "dual enrollees"; (2) those receiving long-term services and supports (LTSS) through managed care organizations or through fee-for-service delivery arrangements; and (3) individuals with complex needs and high costs, substance use disorders, and physical and mental health integration needs. As part of its measure development process, CMS requests that interested parties submit comments on the candidate or concept measures potentially suitable for this project. This project seek to: (1) identify and prioritize candidate measures and measure concepts for development; (2) develop and refine measure specifications for priority measures; (3) conduct field testing to evaluate measure importance, | |



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 10/31/2016

| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Term Services and Supports AGENCY: CMS | | The Date | | feasibility, usability, and scientific validity and reliability; (4) submit validated, reliable measures to the National Quality Forum (NOF) for endorsement; and (5) assist CMS with an implementation strategy. This call for public comment concerns the measure specifications, and justification, for eight (8) measures for Medicaid beneficiaries enrolled in managed long-term services and supports (MLTSS) programs. The following documents are provided for review and comment: • A memo listing general and specific questions related to eight (8) measures for Medicaid enrollees in MLTSS programs; and • Measure Information Forms (MIFs) and Measure Justification Forms (MJFs) for the eight measures. The documents are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Quality-Measure-Development-MLTSS-MIFs-and-MJFs.zip. For parties interested in submitting comments, please follow the following instructions: • If providing comments on behalf of an organization, include the name of and contact information for the organization; • If commenting as an individual, submit identifying or contact information; • Do not include personal health information in comments; • Send comments to MedicaidQualMeasures@mathematica-mpr.com ; In the subject line of the message, put Public Comments MLTSS. Mttps://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#55 SUMMARY OF NIHB ANALYSIS: Tribal organizations might wish to comment on the 8 proposed measures pertaining to Medicaid beneficiaries enrolled in MLTSS. | |
| | | | | | proposed measures pertaining to inedically beneficialles enfolied in the 133. | |
| 164.b. | Medicare Secondary Payer and "Future Medicals" | CMS-6047 | Issue Date: [Approved by | | SUMMARY OF AGENCY ACTION: This proposed rule would announce the intention of CMS regarding means beneficiaries or their representatives can use to protect the | |



| Ref. | Short Title/Current Status | | Issue Date; | NIHB | Brief Summary of Proposed Agency Action | |
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| # | of Regulation/Title/ | File Code | Due Date & | Response | and Summary of NIHB Analysis | NIHB Recs. |
| | Agency ACTION: Proposed Rule NOTICE: Medicare Secondary Payer and "Future Medicals" AGENCY: CMS | | File Date OMB 10/9/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | | interest of Medicare with respect to Medicare Secondary Payer (MSP) claims involving automobile and liability insurance (including self-insurance), no-fault insurance, and workers' compensation where future medical care is claimed or the settlement, judgment, award, or other payment releases (or has the effect of releasing) claims for future medical care. SUMMARY OF NIHB ANALYSIS: | |
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| 164.c. | Medicare Secondary Payer Conditional Payment Amounts ACTION: Interim Final Rule NOTICE: Medicare Program; Obtaining Final Medicare Secondary Payer Conditional Payment Amounts via Web Portal AGENCY: CMS | CMS-6054- IFCF | Issue Date: 9/20/2013 Due Date: 11/19/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 5/17/2016 | | SUMMARY OF AGENCY ACTION: This interim final rule with comment period specifies the process and timeline for expanding the existing Medicare Secondary Payer (MSP) Web portal to conform to section 201 of the Medicare IVIG and Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act). This interim final rule specifies a timeline for developing a multifactor authentication solution to securely permit authorized users other than the beneficiary to access MSP conditional payment amounts and claims detail information via the MSP Web portal. It also requires that CMS add functionality to the existing MSP Web portal to allow users to: notify the agency that the specified case nears settlement; obtain time and date stamped final conditional payment summary forms and amounts before reaching settlement; and ensure the handling of relatedness disputes and any other discrepancies within 11 business days of receipt of dispute documentation. http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/pdf/2013-22934.pdf SUMMARY OF NIHB ANALYSIS: | |
| | | | | | SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule specifies the process and timeline for expanding the existing CMS Medicare Secondary Payer (MSP) Web portal to conform to section 201 of the Medicare IVIG and Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act). This final rule specifies a timeline for developing a multifactor authentication solution to securely permit authorized users other than the beneficiary to access CMS MSP conditional payment amounts and claims detail | |



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| | | | | | information via the MSP Web portal. It also requires that CMS add functionality to the existing MSP Web portal to permit users to: notify the agency that the specified case is approaching settlement; obtain time and date stamped final conditional payment summary statements and amounts before reaching settlement; and ensure that relatedness disputes and any other discrepancies are addressed within 11 business days of receipt of dispute documentation. https://www.gpo.gov/fdsys/pkg/FR-2016-05-17/pdf/2016-11270.pdf | |
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| AC Coi NO Sat Col | nrollee Satisfaction urvey Data Collection CTION: Request for omment DTICE: Enrollee atisfaction Survey Data ollection GENCY: CMS | CMS-10488 | Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 11/1/2013; issued revision 4/28/2015, 7/24/2015, 4/29/2016, 7/12/2016 Due Date: 12/2/2013; 6/29/2015; | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Enrollee Satisfaction Survey Data Collection; Use: Section 1311(c)(4) of the ACA requires HHS to develop an enrollee satisfaction survey system that assesses consumer experience with qualified health plans (QHPs) offered through an Exchange. It also requires public display of enrollee satisfaction information by the Exchange to allow individuals to compare enrollee satisfaction levels between comparable plans. HHS intends to establish an enrollee satisfaction survey system that assesses consumer experience with the Marketplaces and the qualified health plans (QHPs) offered through the Marketplaces. The surveys will include topics to assess consumer experience with the Marketplace, such as enrollment and customer service, as well as experience with the health care system, such as communication skills of providers and ease of access to health care services. CMS has considered using the Consumer Assessment of Health Providers and Systems (CAHPS) principles (http://www.cahps.ahrq.gov/about.htm) for developing the surveys. CMS also has considered an application and approval process for enrollee satisfaction survey vendors that want to participate in collecting ESS data. The application form for survey vendors includes information regarding organization name and contact(s) as well as minimum business requirements such as relevant survey experience, organizational survey capacity, and quality control procedures. CMS plans two rounds of developmental testing for the Marketplace and QHP surveys. The 2014 survey field tests will help determine psychometric properties and provide an initial measure of performance for Marketplaces and QHPs to use for quality improvement. Based on field test results, CMS will further refine the questionnaires and sampling designs to conduct the 2015 beta test of each survey. CMS plans to request clearance for two additional rounds of national implementation with public reporting of scores for each surv | |



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| Ref. # | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | Agency | | File Date 6/28/2016; 8/11/2016 NIHB File Date: 12/2/2013; TTAG also filed comments 12/2/2013 | Nosponso | implementation with public reporting, which will take place in 2016 and 2017. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf SUMMARY OF NIHB ANALYSIS: This PRA request might warrant comments similar those provided on the Medicaid enrollee survey (CMS-10493) to ensure adequate inclusion of Al/ANs and I/T/Us in surveys. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/1/2013 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26107.pdf Analysis from Sam Ennis: The surveys that CMS has proposed include no questions geared toward the Al/AN experience, other than one about Al/AN status as part of an examination of the background of respondents. These surveys should include Al/AN-specific elements to ensure that CMS and CCIIO receive feedback from Al/ANs about their questions, comments, and concerns related to their experiences with Marketplaces and QHPs. CMS on 4/28/2015 issued a revision of this PRA request. CMS requests clearance for the national implementation of the QHP survey, beginning in 2016. http://www.gpo.gov/fdsys/pkg/FR-2015-04-28/pdf/2015-09850.pdf CMS on 7/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-24/pdf/2015-18198.pdf No comments recommended. CMS on 4/29/2016 issued a revision of this PRA request. CMS has completed two rounds of developmental testing, including 2014 psychometric testing and 2015 beta testing of the QHP Enrollee Survey. The psychometric testing helped determine psychometric properties and provided an initial measure of performance for Marketplaces and QHPs to use for quality improvement. Based on psychometric test results, CMS further refined the questionnaire and sampling design to conduct the 2015 beta test of the QHP Enrollee Survey. CMS obtained clearance for the national implementation of the QHP Enrollee Survey, which has begun in 2016. At this time, CMS requests approval of adding six disability status items required by section 4302 of ACA and tested during the | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | 2014 psychometric testing of the QHP Enrollee Survey. https://www.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-10083.pdf CMS on 7/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-12/pdf/2016-16445.pdf No comments recommended. | |
| 172.a. | Medicare Current Beneficiary Survey ACTION: Request for Comment NOTICE: Medicare Current Beneficiary Survey AGENCY: CMS | CMS-P- 0015A | Issue Date: 7/26/2013 Due Date: 9/24/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 10/4/2013; issued revision 2/24/2016, 4/29/2016 Due Date: 11/4/2013; 4/25/2016; 5/31/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection: Title: Medicare Current Beneficiary Survey; Use: The Medicare Current Beneficiary Survey (MCBS), the most comprehensive and complete survey available on the Medicare population, captures data not otherwise collected through CMS operations. MCBSan in-person, nationally-representative, longitudinal survey of Medicare beneficiaries sponsored by CMS and directed by the Office of Information Products and Data Analytics (OIPDA) in partnership with the new Center for Medicare and Medicaid Innovation (CMMI)captures information on beneficiaries, whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. CMS enhances data produced as part of the MCBS with administrative data (e.g. fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. CMS has administered MCBS for more than 20 years (encompassing over 1 million interviews), with three annual interviews per survey participant. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-17985.pdf SUMMARY OF NIHB ANALYSIS: This PRA request might warrant comments similar those provided on the Medicaid enrollee survey (CMS-10493). SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/4/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 2/24/2016 issued a revision of this PRA request. According to CMS, the revisions to this information collection will streamline some questionnaire sections, add a few new measures, and update the wording of questions and response categories. Most of the revised questions reflect an effort to bring the MCBS questionnaire in line with | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | other national surveys that have more current wording of questions and response categories with well-established measures. As a whole, these revisions do not change the respondent burden, but they impose a small increase in overall burden reflecting a program change to oversample small population groups. https://www.gpo.gov/fdsys/pkg/FR-2016-02-24/pdf/2016-03908.pdf No comments recommended. CMS on 4/29/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-10084.pdf | |
| 174.g. | FEHBP: Access for Employees of Certain Indian Tribal Employers ACTION: Proposed Rule NOTICE: Access to Federal Employees Health Benefits (FEHB) for Employees of Certain Indian Tribal Employers AGENCY: OPM | OPM (RIN 3206-AM40) | Issue Date: 8/31/2016 Due Date: 10/31/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule addresses the implementation of certain provisions of ACA making federal employee health insurance accessible to employees of certain Indian tribal entities. ACA includes authorization for Indian Tribes, tribal organizations, and urban Indian organizations that carry out certain programs to purchase coverage, rights, and benefits under the Federal Employees Health Benefits Program (FEHBP) for their employees. Tribal employers and tribal employees will have responsibility for the full cost of benefits, plus an administrative fee. https://www.gpo.gov/fdsys/pkg/FR-2016-08-31/pdf/2016-20566.pdf SUMMARY OF NIHB ANALYSIS: OPM has drawn the provisions in this proposed rule from existing sub-regulatory guidance. However, this proposed rule might provide an opportunity to introduce new issues. A summary of this proposed rule appears below. Background This proposed rule would amend 5 CFR part 890 by creating a new subpart N to codify guidance previously issued by OPM to implement ACA provisions that authorized certain T/TO/U to purchase health insurance coverage under FEHBP for their employees. OPM performed tribal consultation and developed sub-regulatory guidance in 2011-2012 to administer the program. Tribal employers began purchasing FEHBP coverage for their employees on 3/22/2012, with a coverage effective date of 5/1/2012. As of the publication date of this proposed rule, 19,540 tribal employees and 90 Tribes participate in the program. | |



| # Agency File Date Response and Summary of NIHB Analysis 1. Definitions: This proposed rule defines several terms and includes a series of deemed references used in subpart N to clarify how OPM will modify and apply existing regulations to govern the purchase of FEHBP coverage for tribal employees. 2. Scope of Entitlement for Tribal Employers: This proposed rule indicates which | | | | | |
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| deemed references used in subpart N to clarify how OPM will modify and apply existing regulations to govern the purchase of FEHBP coverage for tribal employees. 2. Scope of Entitlement for Tribal Employers: This proposed rule indicates which | of Regulation/Title/ | File Code | Due Date & | and Summary of NIHB Analysis | NIHB Recs. |
| broadly as common law employees). To quality, TTO'US must carry out at least one of the programs under ISDEA or Title V of IHCIA as specified in section 409 of IHCIA. If a tribal employer ceases to carry out one of these programs, entitlement to purchase FEHBP coverage stops at the end of the calendar year in which the tribal employer care cligible to purchase FEHBP coverage, the tribal employer can appeal that decision to OPM. OPM maintains final authority to determine entitlement of a tribal employer can purchase FEHBP coverage. A tribal employer to purchase FEHBP coverage for tribal employees of one or more billing units carrying out programs or activities under ISDEAA or IHCIA. Ho can activities under ISDEAA or IHCIA. Ho tribal employer or more billing units carrying out programs or activities under ISDEAA or IHCIA. He tribal employer can enroll one or more billing units that are not carrying out programs or activities under ISDEAA or IHCIA. He Intibal employer must have the opportunity to enroll in FEHBP coverage. Intermittent, seasonal, and temporary tribal employees will receive treatment similar to intermittent, seasonal, and temporary tribal employees but a tribal employer can choose not to extend coverage to certain intermittent, seasonal, and temporary employees if the Iribal employer can condose not to extend coverage to certain intermittent, seasonal, and temporary employees if the Iribal employer of tribal employer can choose not to extend coverage to certain intermittent, seasonal, and temporary employees if the Iribal employer of tribal employees within a single billing unit (except if tribal employees will propose suppose of tribal employees within a single billing unit (except if tribal employees of edear employees within a billing unit are offered alternative coverage as part of a collective bargaining agreement). 3. Coverage of Family Members: Under this proposed rule, family members of tribal employees, who cannot enroll in FEHBP under the Civil Service Retirement Spouse Equily Act, and s | | | | deemed references used in subpart N to clarify how OPM will modify and apply existing regulations to govern the purchase of FEHBP coverage for tribal employees. 2. Scope of Entitlement for Tribal Employers: This proposed rule indicates which T/TO/Us are eligible to purchase FEHBP coverage for tribal employees (defined broadly as common law employees). To qualify, T/TO/Us must carry out at least one of the programs under ISDEAA or Title V of IHCIA as specified in section 409 of IHCIA. If a tribal employer ceases to carry out one of these programs, entitlement to purchase FEHBP coverage stops at the end of the calendar year in which the tribal employer ceased to carry out one of those programs. If OPM determines that a tribal employer is not eligible to purchase FEHBP coverage, the tribal employer can appeal that decision to OPM. OPM maintains final authority to determine entitlement of a tribal employer to purchase FEHBP coverage for tribal employees of one or more billing units carrying out programs or activities under ISDEAA or IHCIA. Once a tribal employer has enrolled at least one billing unit carrying out programs or activities under ISDEAA or IHCIA. All eligible full-time and part-time tribal employees of each participating billing unit of a tribal employer must have the opportunity to enroll in FEHBP coverage. Intermittent, seasonal, and temporary tribal employees will receive treatment similar to intermittent, seasonal, and temporary federal employees, but a tribal employer can choose not to extend coverage to certain intermittent, seasonal, and temporary employees if the tribal employees within a billing unit are offered alternative coverage as part of a collective bargaining agreement). 3. Coverage of Family Members: Under this proposed rule, family members of tribal employees, who cannot enroll in FEHBP under the Civil Service Retirement Spouse Equity Act, | |



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| | ngency | | | | Tribal Employer and Tribal Employee Contributions and Administrative Fee: This proposed rule indicates that a tribal employer can purchase FEHBP coverage if payment, defined as all premiums plus administrative fees, are currently deposited in the Employees Health Benefits Fund (meaning during, or within fourteen days after the end of, the calendar month covered by the payment). Under this proposed rule, a tribal employer will have responsibility for contributing a share of the premium for FEHBP coverage at least equivalent to the share that the federal government contribution amounts for each billing unit, provided each billing unit meets the requirements of this proposed rule. In addition, the tribal employer must pay an administrative fee, in an amount set by OPM each year, for the enrollment of each tribal employees on a monthly basis. The tribal employer cannot charge this fee to tribal employers' Entitlement and Election to Purchase FEHB: This proposed rule establishes a process by which a tribal employer can demonstrate entitlement and elect to purchase FEHBP coverage for tribal employees. The tribal employer must notify OPM by e-mail or telephone of the intention to purchase FEHBP coverage, and OPM will require the tribal employer to enter an agreement with the agency. A tribal employer can elect to purchase FEHBP coverage at least through the remainder of the calendar year. Elections will renew automatically year to year unless revoked by the tribal employer (with 60 days of notice to OPM) or terminated by OPM. OPM maintains final authority to determine entitlement of a tribal employer to purchase FEHBP coverage. A tribal employer electing to purchase FEHBP coverage for tribal employer-sponsored health insurance to any tribal employee eligible for FEHBP coverage. However, the tribal employer | |
| | | | | | 6. Interaction with Other FEHB Coverage: This proposed rule indicates that eligibility to enroll in FEHBP coverage does not make any tribal employee a federal employee, nor does it convey any additional rights or privileges of federal employment. A tribal employee who also is a federal employee can enroll in FEHBP | |



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| | | | | | coverage through either employer but not both employers. Initial Tribal Employee Enrollment Period, Open Season, and QLEs: Under this proposed rule, tribal employees can enroll in FEHBP coverage after the signing of an agreement between a tribal employer and OPM. The tribal employer and OPM will decide the effective date of FEHBP coverage. A third-party paymaster will handle payroll functions, including remitting tribal employer and tribal employee contributions to premiums for FEHBP coverage. | |
| | | | | | A tribal employer must establish an initial enrollment opportunity for tribal employees. After that initial enrollment opportunity, tribal employees will have the same FEHBP enrollment period as federal employees: up to 60 days after becoming a new tribal employee or changing to an eligible position, during the annual open season, or 31 days before to 60 days after experiencing a qualifying life event. Upon enrollment, tribal employees will choose among the same nationwide and local FEHBP plans available to Federal employees. A tribal employee can change enrollment type, plan, or option under the same circumstances as federal employees (restrictions might apply if a tribal employer has a premium conversion plan in effect (pre-tax treatment of premiums) and the tribal employee has elected premium conversion). | |
| | | | | | Cancellation of Coverage; Decreases in Enrollment: Under this proposed rule, a tribal employee can cancel his or her FEHBP coverage or decrease his or her enrollment only under the same circumstances as a federal employee (unless a tribal employer has a premium conversion plan in effect). Termination of Enrollment: This proposed rule indicates that FEHBP enrollment will terminate for a tribal employee when employment with a tribal employer ends due to resignation, dismissal, or retirement, or when the tribal employer discontinues its purchase of coverage. Upon termination of enrollment, the tribal employee will receive a 31-day temporary extension of FEHBP coverage without premium contribution and the opportunity to convert to an individual policy. Tribal employees whose FEHBP enrollment terminates due to separation from tribal employment (unless the separation results from gross misconduct) also qualify for temporary continuation of FEHBP coverage. If enrollment terminates due to the death of a tribal employee, his or her spouse and covered children qualify for a 31-day temporary extension of FEHBP coverage and the opportunity to convert to an individual policy. Termination Due to Non-Payment of Premiums: Under this proposed rule, | |



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| | | | | | insufficient payment from a tribal employer to the paymaster can result in termination of enrollment for all tribal employees affected by the failure of the paymaster to obtain current deposit, according to a process determined by OPM. FEHBP enrollment of all affected tribal employees will end as of midnight on the last day of the month in which premium payment was received. The affected tribal employees will qualify for a 31-day temporary extension of FEHBP coverage without premium contribution and the opportunity to convert to an individual policy. The tribal employer will have full responsibility for communicating notice of termination of enrollment, and accompanying rights and obligations, to affected tribal employees. OPM will treat any outstanding premium due for FEHBP coverage in arrears will as a debt owed solely by the tribal employer. 11. Non-Pay Status, Insufficient Pay, or Change to Ineligible Position: This proposed rule allows a tribal employee in non-pay status or with insufficient pay to cover the premium for FEHBP coverage to continue enrollment for up to 365 days. Tribal employees in non-pay status due to uniformed service can continue FEHBP enrollment for up to 24 months. After termination of enrollment, these tribal employees and covered family members qualify for a 31-day temporary extension of FEHBP coverage without premium contribution and the opportunity to convert to an individual policy. A temporary tribal employee who has insufficient pay to cover the premium for FEHBP coverage can choose a less expensive plan. If the tribal employee does not or cannot move to a less expensive plan, his or her enrollment will end, and the tribal employee will qualify for a 31-day temporary extension of FEHBP coverage without premium contribution and the opportunity to convert to an individual policy. If a tribal employee moves from an FEHBP-eligible to an FEHBP-ineligible position, FEHBP enrollment can continue if no break in service longer than three days has occurred. If a break in service of lon | |
| | | | | | disputes about eligibility of individuals for FEHBP enrollment. This panel must have | |



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| | | | | | the authority to adjudicate these disputes and enforce eligibility and enrollment determinations. The tribal employer must inform tribal employees of this avenue for dispute resolution. This panel must issue written decisions and keep a record of evidence available for OPM review. Any decisions made by this panel will remain subject to final OPM authority. | |
| 175.a. | Medicaid Drug Program Monthly and Quarterly Drug Reporting ACTION: Request for Comment NOTICE: Medicaid Drug Program Monthly and Quarterly Drug Reporting Format AGENCY: CMS | CMS-367 | Issue Date: 8/9/2013 Due Date: 9/9/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014, issued revision 5/2/2016, 7/11/2016 Due Date: 5/12/2014; 7/1/2016, 8/10/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Medicaid Drug Program Monthly and Quarterly Drug Reporting Format; Use: Labelers transmit drug data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) for each National Drug Code and distributes the URA to all state Medicaid agencies. States use the URA to invoice the labeler for rebates. CMS uses the monthly data to calculate Federal Upper Limit prices for applicable drugs, and states can use this data to establish their pharmacy reimbursement methodology. http://www.gpo.gov/fdsys/pkg/FR-2013-08-09/pdf/2013-19379.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/11/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf CMS on 5/2/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-02/pdf/2016-10232.pdf No comments recommended. CMS on 7/11/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-07-11/pdf/2016-16221.pdf No comments recommended. | |
| 175.b. | Medicaid Drug Use Review Program | CMS-R-153 | <u>Issue Date:</u> 11/29/2013 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicaid Drug Use Review (DUR) Program; Use: | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | ACTION: Request for Comment NOTICE: Medicaid Drug Use Review (DUR) Program AGENCY: CMS | | Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/17/2014, 1/29/2016, 4/12/206 Due Date: 4/16/2014; 3/29/2016; 5/12/2016 | | This information collection serves to: establish patient profiles in pharmacies, identify problems in prescribing, dispensing, or both prescribing and dispensing: determine the ability of each program to meet minimum standards required for federal financial participation; and ensure quality pharmaceutical care for Medicaid patients. State Medicaid agencies that have prescription drug programs must perform prospective and retrospective drug use review to identify aberrations in prescribing, dispensing, and patient behavior. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28537.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/17/2014 issued a revision of this PRA request. CMS has revised the information collection request subsequent to the publication of the 60-day notice in the 11/29/2013 FR. http://www.gpo.gov/fdsys/pkg/FR-2014-03-17/pdf/2014-05785.pdf Background Section 4401 of the Omnibus Budget Reconciliation Act of 1990 and section 1927(g) of the Social Security Act require states to operate a Drug Use Review (DUR) program for covered outpatient drugs under fee-for-service Medicaid. The DUR program must ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. The DUR program must consist of prospective drug use review (ProDUR), retrospective drug use review (RetroDUR), data assessment of drug use against predetermined standards, and ongoing educational outreach activities. In addition, states must submit an annual DUR program report that includes a description of the nature and scope of their DUR activities as outlined in the statute and regulations. Form CMS-R-153, a survey, serves as the collection instrument for state reporting of their DUR program. Over the years, technology has changed as has the practice of pharmacy. Therefore, CMS has revised the survey to address more fully the current practices and areas of concern within the Medicaid Pharmacy Programs. Analysis The survey included in this PRA request | |



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| | Agency | | The Date | | Generic Policy and Utilization Data section (VI) to clarify state authorization requirements for dispensation of brand-name drugs in lieu of generics. In the Fraud, Waste, and Abuse Detection section (VIII), CMS has added several new subsections that address state pain management program practices, screening and restrictions on opioid prescribing, monitoring of morphine-equivalent daily dose prescribing, and monitoring of buprenorphine prescribing. In addition to these revisions to the survey, this PRA request provides an opportunity to comment on any past problems that might have occurred regarding this information collection. According to the notice, this information collection is necessary to establish patient profiles in pharmacies, identify problems in prescribing and/or dispensing, determine the ability of each state DUR program to meet minimum standards required for federal financial participation, and ensure quality pharmaceutical care for Medicaid patients. CMS seeks to provide non-statistical information, comparisons, and trends back to states | |
| | | | | | based on their reported experiences with DUR. States might benefit from this information and might fine tune their programs each year based on state-reported innovative practices and CMS-identified best practices gathered from the DUR annual reports. CMS on 1/29/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-29/pdf/2016-01688.pdf | |
| | | | | | No comments recommended. | |
| | | | | | CMS on 4/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-12/pdf/2016-08116.pdf | |
| | | | | | No comments recommended. | |
| 176. | EPSDT Participation Report ACTION: Request for | CMS-416 | Issue Date: 8/9/2013 Due Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report; Use: CMS uses the baseline data collected to assess the effectiveness of state early and periodic screening, diagnostic, and | |
| | Comment | | 10/8/2013 | | treatment (EPSDT) programs in reaching eligible children, by age group and basis of Medicaid eligibility, who receive initial and periodic child health screening services, obtain | |



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| | NOTICE: Annual Early and Periodic Screening, Diagnostic, and Treatment Participation Report AGENCY: CMS | | NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/6/2013, 10/31/2016 Due Date: 1/6/2014; 12/30/2016 | | referral for corrective treatment, and receiving dental, hearing, and vision services. CMS couples this assessment with state results in attaining the set participation goals. The information gathered from this report permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. http://www.gpo.gov/fdsys/pkg/FR-2013-08-09/pdf/2013-19321.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/6/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-06/pdf/2013-29143.pdf CMS on 10/31/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26246.pdf No comments recommended. | | | |
| 179.d. | | HHS-2015- | Issue Date: | | SUMMARY OF AGENCY ACTION: This proposed rule would revise the procedures that | | | |
| | Appeals Procedures ACTION: Proposed Rule NOTICE: Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures AGENCY: HHS | 49 | 7/5/2016 Due Date: 8/29/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | HHS would follow at the Administrative Law Judge (ALJ) level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in Medicare Advantage and other Medicare competitive health plans, and enrollees in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations and certain Medicare premium appeals. In addition, this proposed rule would revise procedures that HHS would follow at the CMS and the Medicare Appeals Council (Council) levels of appeal for certain matters affecting ALJ level. https://www.gpo.gov/fdsys/pkg/FR-2016-07-05/pdf/2016-15192.pdf SUMMARY OF NIHB ANALYSIS: Tribal representatives might have an interest in a review of this proposed rule. | | | |
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| 179.e. | CY 2017 Amount in Controversy Thresholds for Medicare Appeals ACTION: Notice NOTICE: Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2017 AGENCY: CMS | CMS-4179-N | Issue Date: 9/23/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This notice announces the annual adjustment in the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will apply to requests for ALJ hearings and judicial review filed on or after January 1, 2017. The calendar year 2017 AIC threshold amounts are \$160 for ALJ hearings and \$1,560 for judicial review. https://www.gpo.gov/fdsys/pkg/FR-2016-09-23/pdf/2016-23002.pdf SUMMARY OF NIHB ANALYSIS: | |
| 180. | Flu Vaccination Standard for Certain Providers and Suppliers ACTION: Request for Comment NOTICE: Influenza Vaccination Standard for Certain Participating Providers and Suppliers AGENCY: CMS | CMS-3213-F | Issue Date: [Approved by OMB on 4/18/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This final rule requires certain Medicare and Medicaid providers and suppliers to offer all patients an annual influenza vaccination, unless medically contraindicated or unless the patient or his or her representative or surrogate declined vaccination. This final rule seeks to increase the number of patients receiving annual vaccination against seasonal influenza and decrease the morbidity and mortality rate from influenza. This final rule also requires certain providers and suppliers to develop policies and procedures that will allow them to offer vaccinations for pandemic influenza in case of a future pandemic influenza event. SUMMARY OF NIHB ANALYSIS: | |
| 181.b. | Nondiscrimination Under ACA ACTION: Proposed Final Rule | HHS OCR RIN 0945- AA02 | <u>Issue Date</u> : 9/8/2015 <u>Due Date</u> : 11/9/2015 | TSGAC response: | SUMMARY OF AGENCY ACTION: Section 1557 of ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557(c) of ACA authorizes the HHS Secretary to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the HHS Secretary can prescribe regulations for department governance, conduct, and | See Table C. |



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| NOTICE: Nondiscrimination in Health Programs and Activities AGENCY: HHS OCR Date of Subsequent Agency Action, if any: Issued Final Rule 5/18/2016; issued correction 7/18/2016 SUMMARY OF NIHB ANALYSI how Indian-specific provisions at Standards of Section 1557 issue Summary. SUMMARY OF SUBSEQUENT 1557 of ACA (Section 1557). Secolor, national origin, sex, age, of final rule clarifies and codifices educational institutions and the programs administered by HHS the HHS Secretary can prescrib department business, including, Section 1557 to HHS-administer https://www.gpo.gov/fdsys/pkg/FF HHS OCR on 7/18/2016 issued appeared in the final rule publish Health Programs and Activities. This document make includes an incorrect telephone complaint. This document make | ' |



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| | <u> </u> | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-07-18/pdf/2016-16680.pdf | |
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| 184.j. | Clinical Diagnostic Laboratory Tests Payment System ACTION: Proposed Final Rule NOTICE: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System AGENCY: CMS | CMS-1621- PF | Issue Date: 10/1/2015 Due Date: 11/24/2015 NIHB File Date: 11/24/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 6/23/2016 | NIHB response: | SUMMARY OF AGENCY ACTION: This proposed rule would significantly revise the Medicare payment system for clinical diagnostic laboratory tests and would implement other changes required by section 216 of the Protecting Access to Medicare Act of 2014. http://www.gpo.gov/fdsys/pkg/FR-2015-10-01/pdf/2015-24770.pdf SUMMARY OF NIHB ANALYSIS: A thorough review of the proposed payment changes is recommended to determine the potential impact on tribal health programs. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule implements requirements of section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which significantly revises the Medicare payment system for clinical diagnostic laboratory tests. This final rule also announces an implementation date of January 1, 2018, for the private payor rate-based fee schedule required by PAMA. https://www.gpo.gov/fdsys/pkg/FR-2016-06-23/pdf/2016-14531.pdf A CMS press release on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-06-17.html. A CMS fact sheet on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-17.html. | See Table C. |
| 187.b. | Program for Parallel Review of Medical Products ACTION: Notice NOTICE: Program for Parallel Review of Medical | CMS-3180-N FDA-2010-N- 0308 | Issue Date: 10/21/2016 Due Date: None NIHB File Date: | | SUMMARY OF AGENCY ACTION: This notice serves to inform the public that CMS and FDA (Agencies) will fully implement and extend indefinitely the Parallel Review of medical devices pilot program. The Agencies seek nominations from manufacturers of innovative medical devices to participate in the program, a collaborative effort intended to reduce the time between FDA grants marketing approval or a de novo request and Medicare coverage decisions through the CMS national coverage determination (NCD) process. This program seeks to ensure prompt and efficient patient access to safe and effective and appropriate medical devices for the Medicare population. | |



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| | Devices AGENCY: CMS/FDA | | Date of Subsequent Agency Action, if any: | | https://www.gpo.gov/fdsys/pkg/FR-2016-10-24/pdf/2016-25659.pdf SUMMARY OF NIHB ANALYSIS: | |
| 188.a. | Emergency Preparedness Requirements ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS | CMS-3178- PF | Issue Date: 12/27/2013 Due Date: 2/25/2014 3/31/2014 TTAG File Date: 3/31/2014 Date of Subsequent Agency Action, if any: Issued due date extension 2/21/2014; Issued Final Rule 9/16/2016 | TTAG response: | SUMMARY OF AGENCY ACTION: This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and manmade disasters and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It also would ensure that these providers and suppliers adequately prepare to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. CMS proposes emergency preparedness requirements that 17 provider and supplier types must meet to participate in the Medicare and Medicaid programs. Since existing Medicare and Medicaid requirements vary across the types of providers and suppliers, CMS also proposes variations in these requirements. CMS has based these variations on existing statutory and regulatory policies and differing needs of each provider or supplier type and the individuals to whom they provide health care services. Despite these variations, this proposed rule would provide generally consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30724.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule, which seeks to ensure the availability of health care during emergencies, would impose substantial new emergency and disaster preparedness requirements on various Medicare and Medicaid providers and suppliers in an effort to safeguard human resources, ensure business continuity, and protect physical resources. Of note, this proposed rule directs providers to "comply with all applicable Federal and State emergency preparedness requirements" and requires a communications plan that complies with federal and state law, provisions potentially imposing additional emergency preparedness requir | See Table C. |



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| | of Regulation/Title/ | File Code | Due Date & | | with tribal law. A Health Policy Alternatives summary report on this proposed rule is available at http://www.chausa.org/docs/default-source/advocacy/010814-cha-summary-of-emergency-preparedness-rule.pdf . SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/21/2014 issued document (CMS-3178-N) that extends the comment period for this proposed rule from 2/25/2014 to 3/31/2014. CMS have received inquiries from industry organizations regarding the short time to canvass their membership for input on this proposed rule. One organization stated that it needed additional time to respond because of current regional emergencies requiring the attention of emergency management personnel who likely would have an interest in commenting on this proposed rule. Because of its scope, and because CMS specifically seeks comments to benefit from the vast experiences of emergency management and provider/supplier communities, the agency wants to allow ample time for all sections of the public to comment on this proposed rule. http://www.gpo.gov/fdsys/pkg/FR-2014-02-21/pdf/2014-03710.pdf CMS on 9/16/2016 issued a final rule that establishes national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to plan adequately for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It also will assist providers and suppliers to adequately prepare to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. Despite some variations, this final rule will provide consistent emergency preparedness requirements, enhance patient safety during emergencies for individuals served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and manmade disasters. https://www.federalregister.gov/documents/ | NIHB Recs. |
| | | | | | A CMS press release on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-09-08.html . | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 188.b. | Fire Safety Requirements for Certain Health Care Facilities ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Fire Safet Requirements for Certain Health Care Facilities AGENCY: CMS | CMS-3277- PF | Issue Date: 4/16/2014 Due Date: 6/16/2014 TTAG File Date: 6/16/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 5/4/2016; issued correction 6/30/2016 | TTAG response: | SUMMARY OF AGENCY ACTION: This proposed rule would amend the fire safety standards for Medicare and Medicaid participating hospitals, critical access hospitals (CAHs), long-term care facilities, intermediate care facilities for individuals with intellectual disabilities (ICF-IID), ambulatory surgery centers (ASCs), hospices that provide inpatient services, religious non-medical health care institutions (RNHCIs), and programs of all-inclusive care for the elderly (PACE) facilities. Further, this proposed rule would adopt the 2012 edition of the Life Safety Code (LSC) and eliminate references in CMS regulations to all earlier editions. It also would adopt the 2012 edition of the Health Care Facilities Code, with some exceptions. This proposed rule provides the LSC citation, a description of the 2012 requirement, and an explanation of its benefits for health care facilities, patients, staff, and visitors over the 2000 version in each occupancy section. http://www.gpo.gov/fidsys/pkg/FR-2014-04-16/pdf/2014-08602.pdf SUMMARY OF NIHB ANALYSIS: These proposed regulations might exceed building code requirements in some jurisdictions, as well as the current or planned fire safety standards for some THO facilities. This proposed rule does not specifically discuss applicability to Indian/tribal health care facilities. The document below includes a summary of the proposed regulations applicable to various provider types. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule will amend the fire safety standards for Medicare and Medicaid participating hospitals, critical access hospitals (CAHs), long-term care facilities, intermediate care facilities for individuals with intellectual disabilities (ICFIID), ambulatory surgery centers (ASCs), hospices that provide inpatient services, religious non-medical health care institutions (RNHCIs), and Programs Of All-Inclusive Care for the Elderly (PACE) facilities. Further, this final rule will adopt the 2012 edition of the Life Safety Code (LSC) and eliminate references or provid | See Table C. |



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| | | | | | regulations to all earlier editions of the Life Safety Code. It also will adopt the 2012 edition of the Health Care Facilities Code, with some exceptions. https://www.gpo.gov/fdsys/pkg/FR-2016-05-04/pdf/2016-10043.pdf A CMS press release on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-05-03.html. A summary of this final rule prepared by Hobbs Strauss is embedded below. HC Memo_16.05.11_CM! CMS on 6/30/2016 issued a document (CMS-3277-CN) to correct technical errors that appeared in the final rule published in the 5/4/2016 FR and titled "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities." https://www.gpo.gov/fdsys/pkg/FR-2016-06-30/pdf/2016-15460.pdf | |
| 188.c. | Fire Safety Requirements for Certain Dialysis Facilities ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Fire Safety Requirements for Certain Dialysis Facilities AGENCY: CMS | CMS-3334-P | Issue Date: [Approved by OMB 10/20/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS: | |
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| 189.c. | Annual Update of the HHS Poverty Guidelines ACTION: Notice NOTICE: Annual Update of the HHS Poverty Guidelines AGENCY: HHS | HHS (no reference number) | Issue Date: 1/25/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This notice provides an update of the HHS poverty guidelines to account for the increase in prices as measured by the Consumer Price Index for the last calendar year. https://www.gpo.gov/fdsys/pkg/FR-2016-01-25/pdf/2016-01450.pdf SUMMARY OF NIHB ANALYSIS: A TSGAC memo on applicable federal poverty level (FPL) thresholds for Medicaid and Marketplace coverage is embedded below. TSGAC - 2016 and 2017 FPL Handout - | |
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| 194.c. | Enrollment and Re-Certification of Entities in the 340B Program ACTION: Request for Comment NOTICE: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations AGENCY: HRSA | HRSA (OMB 0915-0327) | Issue Date: 9/30/2014 Due Date: 12/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 4/21/2015, 4/8/2016 Due Date: 5/21/2015; 5/9/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations; Use: Section 602 of 102, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act), provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign with the HHS Secretary a Pharmaceutical Pricing Agreement (PPA) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula ("ceiling price"). Section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the HHS Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities. The system must include the following: • Developing and publishing, through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection; • Comparing regularly the ceiling prices calculated by the HHS Secretary with the quarterly pricing data reported by manufacturers to the HHS Secretary; • Performing spot checks of sales transactions by covered entities; and • Inquiring into the cause of any pricing discrepancies identified and either taking, | |



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| | | | | | or requiring manufacturers to take, appropriate corrective action in response to such price discrepancies. The HRSA Office of Pharmacy Affairs (OPA) has previously obtained approval for information collections in support of 340B covered entity recertification and registration, as well as registration of contract pharmacy arrangements and the PPA itself. OPA seeks comments on an additional information collection in response to the above pricing verification requirements. http://www.gpo.gov/fdsys/pkg/FR-2014-09-30/pdf/2014-23183.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: HRSA on 4/21/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-21/pdf/2015-09079.pdf No comments recommended. HRSA on 4/8/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-08/pdf/2016-08110.pdf No comments recommended. | |
| 194.d. | 340B Ceiling Price and CMPs Regulation ACTION: Proposed Final Rule NOTICE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation AGENCY: HRSA | HRSA RIN 0906- AA89 | Issue Date: 6/17/2015 Due Date: 8/17/2015 NIHB File Date: None Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: This proposed rule would apply to all drug manufacturers required to make their drugs available to covered entities under the 340B Drug Pricing Program. This proposed rule sets forth the calculation of the ceiling price and application of civil monetary penalties. http://www.gpo.gov/fdsys/pkg/FR-2015-06-17/pdf/2015-14648.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule represents one proposal in a string of possible 340B Drug Pricing Program-related modifications. SUMMARY OF SUBSEQUENT AGENCY ACTION: HRSA on 4/19/2016 issued a document that reopens for 30 days the comment period for the 6/17/2015 proposed rule | |



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| | go.ioj | | Action, if any: Issued notice of 30-day comment period 4/19/2016; sent Final Rule to OMB 10/21/2016 Due Date: 5/19/2016 | | titled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation." The comment period previously ended on 8/17/2015. The proposed rule, which would apply to all drug manufacturers required to make their drugs available to covered entities under the 340B Drug Pricing Program, sets forth the calculation of the ceiling price and application of civil monetary penalties. In light of the comments received, HRSA is reopening the comment period for 30 days for the purpose of inviting public comments on several specific areas. Interested parties can submit comments on any aspect of the proposed rule, not only these specific areas. Commenters do not need to resubmit comments previously submitted, as HRSA will consider all previous comments prior to the finalization of the proposed rule. https://www.gpo.gov/fdsys/pkg/FR-2016-04-19/pdf/2016-09017.pdf No comments recommended. | |
| 194.e. | 340B Drug Pricing Program Omnibus Guidance ACTION: Notice NOTICE: 340B Drug Pricing Program Omnibus Guidance AGENCY: HRSA | HRSA RIN 0906- AB08 | Issue Date: 8/28/2015 Due Date: 10/27/2015 NIHB File Date: 10/27/2015 Date of Subsequent Agency Action, if any: | NIHB response: | SUMMARY OF AGENCY ACTION: HRSA administers section 340B of the Public Health Service Act (PHS Act), referred to as the "340B Drug Pricing Program" or the "340B Program." This notice proposes guidance for covered entities enrolled in the 340B Program and drug manufacturers required by section 340B to make their drugs available to covered entities under the 340B Program. When finalized after consideration of public comments solicited by this notice, the guidance will assist 340B covered entities and drug manufacturers in complying with the statute. http://www.gpo.gov/fdsys/pkg/FR-2015-08-28/pdf/2015-21246.pdf A Modern Healthcare article on this notice is available at http://www.modernhealthcare.com/article/20150827/NEWS/150829882. A Politico Pro article on this notice is available at https://www.politicopro.com/health- | |
| | | | Sent Final Notice to OMB 9/1/2016 | | care/story/2015/08/hhs-clamping-down-on-huge-drug-discount-program-051827 (subscription required). SUMMARY OF NIHB ANALYSIS: This notice includes one Indian-specific provision regarding individuals eligible to receive 340B drugs (Part C). Under this notice, for "Indian Tribes or Tribal Organizations whose 340B Program eligibility arises solely from the | |



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| use of 340B drugs is limited to those individuals that the tribe or tribal organizated to serve under its ISDEAA contract, in accordance with the requirements in Section 813 of the Indian Health Care Improvement Act." This notice does not otherwise specifically mention Indian health care providers. One mention of the encounter rate appears in the discussion of a provision that defines drugs eligible for purchase under 3408 (Part B). According to this notice, a "covered outpatient drug, as defined in 1927(k)(3) and (3) of the Social Security Act, is eligible for purchase under the 340B Program. For purposes of the 340B Program, only drugs bundled for and receiving such bundled reimbursement under Title XIX of the Social Security Act described in section 1927(k)(3) will be considered excluded from the definition of covered outpatient drug. Section 1927(k)(3) of the Act (limiting definition) reads: "The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug; (A) Inpatient hospital services (B) Hospice services; (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement for the dispensing dentist are covered outpatient drugs; (D) Physicians' services; (E) Outsign Services; (F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded; (G) Other laboratory and x-ray services; and (H) Renal dialysis. Such term also does not include any such drug for which a National Drug Ode number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication." According to HRSA, on 5/13/1994, HHS published guidance clarifying that, in the settings identified in the limiting definition, if a covered drug is | of Regulation/Title/ | File Code | Due Date & | and Summary of NIHB Analysis | NIHB Recs. |
| billed and paid for instead as a separate line item as an outpatient drug in a cost | _ | File Code | | Indian Self-Determination and Education Assistance Act, Public Law 93-638 (ISDEAA), use of 340B drugs is limited to those individuals that the tribe or tribal organization is authorized to serve under its ISDEAA contract, in accordance with the requirements in Section 813 of the Indian Health Care Improvement Act." This notice does not otherwise specifically mention Indian health care providers. One mention of the encounter rate appears in the discussion of a provision that defines drugs eligible for purchase under 340B (Part B). According to this notice, a "covered outpatient drug, as defined in section 1927(k)(2) and (3) of the Social Security Act, is eligible for purchase under the 340B Program. For purposes of the 340B Program, only drugs bundled for and receiving such bundled reimbursement under Title XIX of the Social Security Act described in section 1927(k)(3) will be considered excluded from the definition of covered outpatient drug." Section 1927(k)(3) of the Act (limiting definition) reads: "The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug): (A) Inpatient hospital services; (B) Hospice services; (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs; (D) Physicians' services; (E) Outpatient hospital services; (F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded; (G) Other laboratory and x-ray services; and (H) Renal dialysis. Such term also does not include any such drug for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication." According to HRSA, on 5/13/ | NIHB Recs. |
| This notice proposes that a drug satisfying both conditions of the limiting definition will not qualify as a covered outpatient drug in the 340B Program. Under this notice, the | | | | billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program." This notice proposes that a drug satisfying both conditions of the limiting definition will | |



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| | V 1 | | | | limiting definition applies only when the drug is bundled for payment under Medicaid as part of a service in the settings described in the limiting definition. In contrast, a drug provided as part of a hospital outpatient service and billed to any other third party or directly billed to Medicaid still would qualify as a covered outpatient drug. | |
| 194.f. | 340B Drug Pricing Program Reporting Requirements ACTION: Request for Comment NOTICE: 340B Drug Pricing Program Reporting Requirements AGENCY: HRSA | HRSA (OMB 0915-0176) | Issue Date: 12/23/2015 Due Date: 2/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/20/2016 Due Date: 6/20/2016 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision a currently approved collection; Title: 340B Drug Pricing Program Reporting Requirements; Use: Section 602 of the Veterans Health Care Act of 1992 enacted section 340B of the Public Health Service Act (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Under section 340B, a manufacturer that participates in Medicaid must sign a Pharmaceutical Pricing Agreement with the HHS Secretary in which the manufacturer agrees to charge enrolled covered entities a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities that choose to participate in the section 340B Drug Pricing Program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from requesting Medicaid reimbursement from a drug discounted under the 340B Program. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to an individual who is not a patient of the entity. Section 340B(a)(5)(C) of the PHS Act permits the HHS Secretary and manufacturers of a covered outpatient drug to conduct audits of covered entities in accordance with procedures established by the HHS Secretary related to the number, duration, and scope of the audits. In response to the statutory mandate of section 340B(a)(5)(C) and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) developed an informal voluntary dispute resolution process for manufacturers and covered entities, which, prior to filing a request for resolution of a dispute with OPA, should attempt in good faith to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written re | |



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| | | | | | guidelines and the informal dispute resolution process. The expected revision to this package includes additional background information on the dispute resolution process and clarifies the need and proposed use of information regarding the manufacturer audit guidelines and the informal dispute resolution process. https://www.gpo.gov/fdsys/pkg/FR-2015-12-23/pdf/2015-32171.pdf SUMMARY OF NIHB ANALYSIS: Although this is only a PRA notice, tribal organizations might have concerns with the implementation of this policy. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/20/2016 issued a revision of this PRA request. HRSA has reviewed all comments submitted in response to the publication of the 60-day notice published in the 12/23/2015 FR requesting comments on this information collection request (ICR). Comments submitted included requests for standardized reporting forms. Commenters also expressed concerns that the 60-day notice significantly understated burden hours. HRSA agrees and has included adjusted burden estimates in this 30-day notice. Finally, HRSA appreciates the comments received regarding the development of a formal dispute resolution process. HRSA has begun developing a regulation to establish and implement a binding administrative dispute resolution process pursuant to section 340(d)(3) of the PHS Act. HRSA also has received some comments regarding the audit process that exceeded the scope of this ICR. https://www.gpo.gov/fdsys/pkg/FR-2016-05-20/pdf/2016-11869.pdf | |
| 194.g. | 340B Administrative Dispute Resolution Process ACTION: Proposed Rule NOTICE: 340B Drug Pricing Program; Administrative Dispute Resolution AGENCY: HRSA | HRSA RIN 0906- AA90 | Issue Date: 8/12/2016 Due Date: 10/11/2016 NIHB File Date: None Date of Subsequent Agency | | SUMMARY OF AGENCY ACTION: HRSA implements section 340B of the Public Health Service Act (PHSA), referred to as the "340B Drug Pricing Program" or the "340B Program." This proposed rule would apply to all drug manufacturers and covered entities that participate in the 340B Program. This proposed rule sets forth the requirements and procedures for the 340B Program administrative dispute resolution process. https://www.gpo.gov/fdsys/pkg/FR-2016-08-12/pdf/2016-18969.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |



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| | | | Action, if any: | | | |
| 195.c. | Collection of Customer Satisfaction Surveys ACTION: Request for Comment NOTICE: Generic Clearance for the Collection of Customer Satisfaction Surveys AGENCY: CMS | CMS-10415 | Issue Date: 10/30/2015 Due Date: 12/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/30/2015 Due Date: 1/29/2015 | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection: Title: Generic Clearance for the Collection Customer Satisfaction Surveys; Use: This information collection allows CMS to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with its commitment to improving service delivery. The information collected from customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with CMS programs. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations; serve as an early warning of issues with service; and focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. This collection will allow for ongoing, collaborative, and actionable communications between CMS and its customers and stakeholders. It also will allow feedback to contribute directly to the improvement of program management. Collecting voluntary customer feedback serves as the least burdensome, most effective way for CMS to determine whether its public Web sites are useful to and used by its customers. CMS needs generic clearance to ensure that it can continuously improve its Web sites though regular surveys developed from these pre-defined questions. Surveying the CMS Web sites on a regular, ongoing basis will help ensure that users have an effective, efficient, and satisfying experience, maximizing the impact of the information and resulting in optimum benefit for the public. The surveys will ensure that this communication channel meets customer and partner priorities, builds CMS brands, and contributes to the health and human services impact goals of the agency. http://www.gpo.gov/fdsys/pkg/FR-2015-10-30/pdf/2015-27619.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/30/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-30/pdf/2015-32633.pdf | |
| 199.b. | CLAS County Data | CCIIO (no | <u>Issue Date</u> : | | SUMMARY OF AGENCY ACTION: Public Health Service Act (PHS Act) section 2719 | |



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| | ACTION: Guidance NOTICE: CLAS County Data AGENCY: CCIIO | reference number) | 12/12/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 1/7/2015, 2/9/2015, 1/27/2016 | | requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered health insurance coverage to provide relevant notices in a culturally and linguistically appropriate manner. The regulations implementing section 2719 require these plans and issuers to make certain accommodations for notices sent to an address in a county meeting a threshold percentage of people literate only in the same non-English language (10 percent or more of the population residing, as determined based on American Community Survey (ACS)). Section 2715 of the PHS Act requires group health plans and health insurance issuers offering group and individual coverage to provide the summary of benefits and coverage (SBC) and uniform glossary in a culturally and linguistically appropriate manner. The regulations implementing section 2715 adopt the ten percent threshold set forth in the section 2719 implementing regulations. This guidance includes all counties that meet or exceed the 10 percent threshold (rounded to the nearest percent) for the 2009-2013 ACS data and applies until the next edition. CMS will update this list annually following the release of the applicable ACS data. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data 12-05-14 clean 508.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CCIIO on 1/7/2015 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data-01-07-15-508.pdf CCIIO on 2/9/2015 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data-pdf CCIIO on 1/27/2016 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CO-OP-Questions-Final-1-27-16.pdf | |
| 200. | Mental Health Parity Rules for Medicaid and CHIP | CMS-2333- PF | <u>Issue Date:</u> 4/10/2015 | | SUMMARY OF AGENCY ACTION: This proposed rule would address application of certain requirements set forth in the Public Health Service Act (PHS Act), as amended by | |



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| | ACTION: Proposed Final Rule NOTICE: Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and ABPs AGENCY: CMS | | Due Date: 6/9/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/30/2016 | | the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), to coverage offered by Medicaid managed care organizations (MCOs), Medicaid Alternative Benefit Plans (ABPs), and CHIP. HHS and the Departments of Labor and the Treasury (collectively, the Departments) published interim final regulations implementing MHPAEA on 2/2/2010 (75 FR 5410), and final regulations applicable to group health plans and health insurance issuers on 11/13/2013 (78 FR 68240) (MHPAEA final regulations). The MHPAEA final regulations did not apply to Medicaid MCOs, ABPs, or CHIP state plans. This rule proposes regulations to address how the MHPAEA requirements in section 2726 of the PHS Act, as implemented in the MHPAEA final regulations, will apply to MCOs, ABPs and CHIP. This proposed rule would not apply mental health parity requirements to state plan services provided to beneficiaries covered only through a fee-for-service (FFS) delivery system, even if care for other beneficiaries is delivered through a managed care delivery system. However, CMS strongly encourages states to consider changes to the state plan benefit package to comport with the mental health parity requirements of section 2726 of the PHS Act. http://www.gpo.gov/fdsys/pkg/FR-2015-04-10/pdf/2015-08135.pdf An article that provides a "checklist for states" regarding this proposed rule is available at http://www.nashp.org/the-mental-health-parity-and-equity-addictions-act-proposed-rules-a-checklist-for-states/. SUMMARY OF NIHB ANALYSIS: This proposed rule generally mirrors the policies set forth in the MHPAEA final regulations to implement the statutory provisions that require MCOs, ABPs, and CHIP to comply with certain requirements of section 2726 of the PHS Act (mental health parity requirements). This proposed rule would incorporate these requirements into CMS regulations, requiring compliance within 18 months of the publication of the final rule. Under section 1932(b)(8) of the Social Security Act (Act), Medicaid MCOs mus | |



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| | | | | | Under section 1937(b)(6) of the Act, Medicaid ABPs (see note 1 below) that are not offered by an MCO (see note 2 below) and that provide both medical and surgical benefits and mental health (MH) or substance use disorder (SUD) benefits must ensure that financial requirements and treatment limitations for such benefits comply with the mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, now renumbered 2726(a) of the PHS Act), in the same manner as such requirements apply to a group health plan. The section 1937 provision applies only to ABPs that are not offered by MCOs; ABPs offered by MCOs currently must comply with these requirements under section 1932(b)(8) of the Act. | |
| | | | | | [Note 1. States have the option to provide alternative benefit plans/packages specifically tailored to meet the needs of certain Medicaid population groups, target residents in certain areas of the state, or provide services through specific delivery systems instead of following the traditional Medicaid benefit plan. ABPs mirror the more narrow benefit packages common in the (non-Medicaid) private health insurance market. | |
| | | | | | [Note 2. States have the option to provide services through a managed care delivery mechanism using entities other than MCOs, such as prepaid inpatient health plans (PIHPs) or prepaid ambulatory health plans (PAHPs). In many instances, states will provide the medical/surgical services through an MCO but will not include in the MCO benefit package some or all of their MH/SUD state plan services, delivering them instead through a PIHP or a PAHP or a nonmanaged care delivery system, typically FFS. The statutory provisions making mental health parity requirements applicable to MCOs do not explicitly address the situation in which medical/surgical benefits and MH/SUD benefits included in coverage are furnished through separate but interrelated and interdependent service delivery systems, requiring additional guidance. This proposed rule generally would require that each MCO enrollee in a state must have access to a set of benefits meeting the requirements of this rule regardless of whether the MH/SUD services are provided by the MCO or through another service delivery system.] | |
| | | | | | Section 2103(c)(6) of the Act requires state CHIP plans that provide both medical and surgical benefits and mental health or substance use disorder benefits to ensure financial requirements and treatment limitations for such benefits comply with mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, now renumbered as section 2726(a) of the PHS Act) to the same extent as such requirements apply to a group health plan. In addition, section 2103(f)(2) of the Act requires that CHIP benchmark or benchmark equivalent plans comply with all of the requirements of subpart | |



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| | | | | | 2 of part A of the title XXVII of the PHS Act, which includes the mental health parity requirements of the PHS Act, insofar as such requirements apply to health insurance issuers that offer group health insurance coverage. | |
| | | | | | CMS estimates that this proposed rule would benefit approximately 21.6 million Medicaid beneficiaries and 850,000 CHIP beneficiaries in 2015, based on service utilization estimates from 2012 Medicaid and CHIP enrollment. In addition, according to CMS, by increasing access to and utilization of MH/SUD benefits, this proposed rule could result in a reduction of medical and surgical costs. CMS also predicts that the proposed rule could result in small increases in costs and capitated rates. | |
| | | | | | Main Provisions of Proposed Rule A brief summary of the provisions of this proposed rule appears below. | |
| | | | | | A. Meaning of Terms (§438.900, §440.395, §457.496) The definitions of terms in this proposed rule include most terms included in the MHPAEA final regulation at 45 CFR 146.136(a), but this proposed rule would modify or add several terms to reflect the terminology used in the Medicaid program and CHIP statutes, regulations, or policies and exclude some terms not relevant to the Medicaid program or CHIP. | |
| | | | | | B. Parity Requirements for Aggregate Lifetime and Annual Dollar Limits Sections 438.905 and 457.496(c) of this proposed rule address the parity requirements for aggregate lifetime and annual dollar limits and would apply these requirements generally the same as under the MHPAEA final regulations (45 CFR 146.136(b)). | |
| | | | | | C. Parity Requirements for Financial Requirements and Treatment Limitations Sections 438.910, 440.395(b), and 457.496(d) of this proposed rule would set forth parity requirements for financial requirements and treatment limitations. | |
| | | | | | D. Cumulative Financial Requirements (§438.910(c)(3), §440.395(b)(3)(iii), §457.496(d)(3)(iii)) As in the MHPAEA final regulation at 45 CFR 146.136(c)(2)(v), this proposed rule would not allow any separate cumulative financial requirement (separate for mental health/substance use disorder (MH/SUD) or medical/surgical) for affected entities but would permit quantitative treatment limitations to accumulate separately for medical/surgical and MH/SUD services as long as they comply with the general parity | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| | of Regulation/Title/ | File Code | Due Date & | | | NIHB Recs. |
| | | | | | [These requirements do not directly apply to the benefit design for Medicaid non-ABP state plan services. States that have individuals enrolled in MCOs and have MH/SUD services offered through FFS will have the option of amending their non- | |



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| | | | | | ABP state plan to make it consistent with the provisions in this proposed rule or offering MH/SUD services through a managed care delivery system (MCOs, PIHPs, and/or PAHPs) to comply.] | |
| | | | | | K. Scope and Applicability of the Proposed Rule (§438.920(a) and (b), §440.395(d), and §457.496(f)(1)) Sections 438.920, 440.395(d), and 457.496(f) of this proposed rule address its applicability and scope. | |
| | | | | | L. Scope of Services (§438.920(c), §457.496(f)(2)) This proposed rule would not require an MCO, PIHP, or PAHP to provide any MH/SUD benefits for conditions or disorders beyond the conditions or disorders covered as required by their contract with the state, and for MCOs, PIHPs, or PAHPs that provide benefits for one or more specific MH conditions or SUDs under their contracts, this rule would not require them to provide benefits for additional MH conditions or SUDs. | |
| | | | | | M. ABP State Plan Requirements (§440.395(d)) This proposed rule would add a section in part 440, subpart C requiring states using ABPs to provide sufficient information in ABP state plan amendment requests to assure compliance with MHPAEA. | |
| | | | | | N. Increased Cost Exemption This proposed rule would change payment provisions in part 438 to allow states to include the cost of providing additional services or removing or aligning treatment limitations in their actuarially sound rate methodology where such costs are necessary to comply with the MHPAEA parity provisions. | |
| | | | | | O. Enforcement, Managed Care Rate Setting (§438.6(e)), and Contract Review and Approval (§ 438.6(n)) This proposed rule would require the state Medicaid agency to include contract provisions requiring compliance with parity requirements in all applicable MCO, PIHP, and PAHP contracts. | |
| | | | | | P. Applicability and Compliance (§438.930, §440.395(d), §457.496(f)) This proposed rule would take effect on the date of the publication of the final rule but would allow MCOs, PIHPs, PAHPs, and states to have 18 months to comply with its provisions. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | Medicaid MCOs, PIHPs, or PAHPs would have to comply with the specific provisions in this proposed rule in contract years starting 18 months after the publication of the final rule (new managed care contracts, or amendments, would have to comply in most cases). States would have 18 months after the publication of the final rule to make ABPs compliant with the provisions in this proposed rule. States would have 18 months after the publication of the final rule to make CHIP plans compliant with the provisions in this proposed rule. Q. Utilization Management This proposed rule would eliminate current language from existing regulations that require Medicaid agencies to evaluate the need for admissions to mental hospitals. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule will address the application of certain requirements set forth in the Public Health Service Act, as amended by the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, to coverage offered by Medicaid managed care organizations, Medicaid Alternative Benefit Plans, and CHIP. https://www.gpo.gov/fdsys/pkg/FR-2016-03-30/pdf/2016-06876.pdf A CMS press release on this final rule is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-03-29.html. | |
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| 202. | Health Needs of the Al/AN LGBT Community ACTION: Request for Information NOTICE: Notice of Request for Information | IHS (no reference number) | Issue Date: 6/5/2015 Due Date: 7/6/2015 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: IHS seeks broad public input as it begins efforts to advance and promote the health needs of the Al/AN Lesbian, Gay, Bisexual, and Transgender (LGBT) community. In summer 2015, IHS will hold a public meeting to garner information from individuals on Al/AN LGBT health issues. Through this meeting, IHS seeks to gain a better understanding of the health care needs of Al/AN LGBT individuals so that it can implement health policy and health care delivery changes to advance the health care needs of the Al/AN LGBT community. IHS aims to increase community access to and | |
| | AGENCY: IHS | | Date of | | engagement with agency leadership and secure a legacy of transparent, accountable, | |



| Subsequent Agency Action, if any: Issued meeting notice 7/22/2015, 8/26/2015, 4/7/2016 Subsequent Agency Action, if any: Issued meeting notice 7/22/2015, 8/26/2015, 4/7/2016 Summary of Subsequent on the dimensions of the health needs of the Al/AN LGBT community. Issued Mttp://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13774.pdf Summary of Subsequent on the dimensions of the health needs of the Al/AN LGBT community. Summary of Nihb Analysis: Summary of Subsequent Agency Action: IHS on 7/22/2015 issued a notice to announce a public meeting on efforts to advance and promote the health needs of the | Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| a.m. to 4:30 p.m. ET at 801 Thompson Avenue, Rockville, MD 20852. Interested parties can submit written statements to Lisa Neel, MPH, Program Coordinator, Office of Clinical and Preventibes, Sorvices, IH-S, 801 Thompson Avenue, Suite 300, Rockville, MD 20852. Individuals who plan to attend the meeting should RSVP to Lisa Neel at lisa.neel@his.gov or by telephone at 301-443-4305. http://www.gpo.gov/fdsys/pkg/FR-2015-07-23/pdf/2015-18002.pdf IHS on 8/26/2015 issued a notice to announce a public meeting on efforts to advance and promote the health needs of the Al/AN Lesbian, Gay, Bisexual, and Transgender (LGBT) community on 9/11/2015 from 12 p.m. to 2 p.m. ET at the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Interested parties can submit written statements to Lisa Neel, MPH, Program Coordinator, Office of Clinical and Preventitve Services, Indian Health Service, 801 Thompson Avenue, Suite 300, Rockville, MD 20852. To facilitate the building security process, those who plan to attend should RSVP to Lisa Neel at lisa.neel@his.gov or by telephone at 301-443-4305 no later than 5 p.m. ET on 8/31/2015. Members of the public can make statements during the meeting to the extent time permits. http://www.gpo.gov/fdsys/pkg/FR-2015-08-26/pdf/2015-21068.pdf IHS on 4/7/2016 issued a notice to announce a series of public teleconferences on best practices to advance and promote the health needs of the Al/AN lesbian, gay, bisexual, transgender and love-spirit (LGBT2S) community, in these teleconferences, participants will have the opportunity comment on several key dimensions of the health needs of the Al/AN LGBT2S community, including but not limited to the following questions: • Are effective models and best practices surrounding the health care of the | | Agency | | Agency Action, if any: Issued meeting notice 7/22/2015, 8/26/2015, | | fair, and inclusive decision-making specific to Al/AN LGBT individuals. This request for information seeks public comment on the dimensions of the health needs of the Al/AN LGBT community. http://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13774.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: IHS on 7/22/2015 issued a notice to announce a public meeting on efforts to advance and promote the health needs of the Al/AN Lesbian, Gay, Bisexual, and Transgender (LGBT) community on 7/27/2015 from 9 a.m. to 4:30 p.m. ET at 801 Thompson Avenue, Rockville, MD 20852. Interested parties can submit written statements to Lisa Neel, MPH, Program Coordinator, Office of Clinical and Preventive Services, IHS, 801 Thompson Avenue, Suite 300, Rockville, MD 20852. Individuals who plan to attend the meeting should RSVP to Lisa Neel at lisa.neel@ihs.gov or by telephone at 301-443-4305. http://www.gpo.gov/fdsys/pkg/FR-2015-07-23/pdf/2015-18002.pdf IHS on 8/26/2015 issued a notice to announce a public meeting on efforts to advance and promote the health needs of the Al/AN Lesbian, Gay, Bisexual, and Transgender (LGBT) community on 9/11/2015 from 12 p.m. to 2 p.m. ET at the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Interested parties can submit written statements to Lisa Neel, MPH, Program Coordinator, Office of Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 300, Rockville, MD 20852. To facilitate the building security process, those who plan to attend should RSVP to Lisa Neel at lisa.neel@ihs.gov or by telephone at 301-443-4305 no later than 5 p.m. ET on 8/31/2015. Members of the public can make statements during the meeting to the extent time permits. http://www.gpo.gov/fdsys/pkg/FR-2015-08-26/pdf/2015-21068.pdf IHS on 4/7/2016 issued a notice to announce a series of public teleconferences on best practices to advance and promote the health needs of the Al/AN lesbian, gay, bisexual, transgender and two-spirit (LGBT2S) community. In thes | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | LGBT2S community available for replication? What specific measures are available to track progress in improving the health of LGBT2S individuals? How can IHS better engage with stakeholders around the implementation of improvements? Do gaps or disparities exist in current IHS services offered to LGBT2S persons? What additional information should IHS consider while developing plans to improve health care for the LGBT2S community? The first public teleconference will occur on 5/5/2016 from 3 p.m. to 5 p.m. ET. This public virtual meeting is available via teleconference line and will accommodate 200 participants. Join the meeting by calling the toll free phone number at 800-857-9744 and providing the public participant passcode number: 3618057. Participants should call and connect 15 minutes prior to the meeting. Call 301-443-4305 or send an e-mail to lisa.neel@ihs.gov with questions. Members of the public can make statements during the teleconference to the extent time permits and file written statements with the agency for its consideration. In general, individuals or groups requesting to present an oral statement at a public teleconference will have three minutes per speaker. Individuals or groups should submit written statements to Lisa Neel, MPH, Program Coordinator, Office of Clinical and Preventive Services, IHS, 5600 Fishers Lane, Mailstop 08N34A, Rockville, MD 20857. http://www.gpo.gov/fdsys/pkg/FR-2015-08-26/pdf/2015-21068.pdf | |
| 204. | Medicaid Services "Received Through" an IHS/Tribal Facility ACTION: Request for Information Final Policy NOTICE: Medicaid Services "Received Through" an Indian Health Service/Tribal Facility: A Request for Comment | CMS (no reference number) SHO #16- 002 | Issue Date: 10/27/2015 Due Date: 11/17/2015 TTAG File Date: 11/17/2015; TSGAC also filed comments | TTAG response: TSGAC response: | SUMMARY OF AGENCY ACTION: CMS proposes to update its policy regarding the circumstances for the availability of 100 percent federal funding for services furnished to Medicaid-eligible Al/ANs through facilities of IHS or Tribes. Through this policy change, which would affect all states, CMS seeks to improve access to care for Al/AN Medicaid beneficiaries. This Request for Comment paper describes the policy options under consideration and seeks feedback from states, Tribes, and other stakeholders. http://www.medicaid.gov/medicaid-chip-program-information/by-topics/indian-health-and-medicaid/downloads/tribal-white-paper.pdf SUMMARY OF NIHB ANALYSIS: A background paper on this issue is embedded below. | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | AGENCY: CMS | | 11/17/2015 Date of Subsequent Agency Action, if any: Issued Final Policy 2/26/2016 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/26/2016 issued a final policy via a State Health Official Letter. This letter informs state Medicaid agencies and other state health officials about an update in payment policy affecting federal funding for services received by Medicaid-eligible individuals who are Al/ANs through facilities of IHS, whether operated by IHS or by Tribes. As described in this letter, IHS/tribal facilities can enter into care coordination agreements with non-IHS/tribal providers to furnish certain services for their patients who are Al/AN Medicaid beneficiaries, and the amounts paid by the state for services requested by facility practitioners in accordance with those agreements would qualify for the enhanced federal matching authorized under section 1905(b) of the Social Security Act at a rate of 100 percent. Upon execution of a written care coordination agreement, this will take effect immediately for states for the expenditures for services furnished by non-IHS/tribal providers to Al/AN Medicaid beneficiaries who are patients of an IHS/tribal facility acting under such agreement, as described in this letter. This update in payment policy serves to help states, IHS, and Tribes to improve delivery systems for Al/ANs by increasing access to care, strengthening continuity of care, and improving population health. https://www.medicaid.gov/federal-policy-quidance/downloads/sho022616.pdf | |
| 205. | Sharing What WorksBPPPLE Form ACTION: Request for Comment NOTICE: IHS Sharing What WorksBest Practice, Promising Practice, and Local Effort (BPPPLE) Form AGENCY: IHS | IHS (OMB 0917-0034) | Issue Date: 10/9/2015 Due Date: 12/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension without change of a currently approved collection; <i>Title</i> : IHS Sharing What WorksBest Practice, Promising Practice, and Local Effort (BPPPLE) Form; <i>Use</i> : IHS seeks to raise the health status of the Al/AN population to the highest possible level by providing comprehensive health care and preventive health services. To support the IHS mission and encourage the creation and utilization of performance driven products/services by IHS, tribal, and urban Indian health (I/T/U) programs, Office of Preventive and Clinical Services program divisions (i.e., behavioral health, health promotion/disease prevention, nursing, and dental) have developed a centralized program database of best practices, promising practices, and local efforts (BPPPLE) and resources. This collection serves to further the development of a database of BPPPLE, resources, and policies available to the public on the IHS Web site. This database will serve as a resource for program evaluation and for modeling examples of various health care projects occurring in Al/AN | |



| Ref. | Short Title/Current Status of Regulation/Title/ | File Code | Issue Date; Due Date & | NIHB | Brief Summary of Proposed Agency Action | NIHB Recs. |
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| # | Agency | | File Date | Response | and Summary of NIHB Analysis | |
| | | | Issued extension 11/17/2015, issued due date extension 12/15/2015 Due Date: 12/17/2015 1/9/2016 | | http://www.gpo.gov/fdsys/pkg/FR-2015-10-09/pdf/2015-25733.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: IHS on 11/17/2015 issued an extension of this PRA request. IHS received no comments in response to the 60-day notice on this information collection published in the 10/9/2015 FR (80 FR 61215). http://www.gpo.gov/fdsys/pkg/FR-2015-11-17/pdf/2015-29251.pdf No comments recommended. IHS on 12/15/2015 issued a document that extends the due date to submit comments regarding the 30-day notice on this information collection to 1/9/2016, as the agency issued the 30-day notice before the comment period for the 60-day notice ended on 12/8/2015. https://www.gpo.gov/fdsys/pkg/FR-2015-12-15/pdf/2015-31534.pdf | |
| 206. | Measures of Quality Improvement Activities ACTION: Request for Information NOTICE: Request for Measures Assessing Health Care Organization Quality Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self- Management AGENCY: AHRQ | AHRQ (no reference number) | Issue Date: 2/10/2016 Due Date: 3/4/2016 NIHB File Date: 3/4/2016 Date of Subsequent Agency Action, if any: | NIHB response: | SUMMARY OF AGENCY ACTION: AHRQ requests information from the public (including health care delivery organizations, health information developers, payers, quality measure developers, clinicians, and health care consumers) about quality improvement measures designed to help health care organizations monitor initiatives aimed at: improving patient understanding of health information, simplifying navigation of health care systems and facilities, and enhancing the ability of patients to manage their health. Specifically, AHRQ seeks quality improvement measures in four domains: 1. Communication; 2. Ease of Navigation; 3. Patient Engagement and Self-Management; and 4. Organizational Structure, Policy, and Leadership. AHRQ seeks measures that do not require patient survey data and that health care organizations currently use, or have used in the past, to guide quality improvement activities designed to address these domains. AHRQ also seeks information about relevant measures under development or suggested for future development. | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02679.pdf SUMMARY OF NIHB ANALYSIS: Tribal organizations might wish to communicate I/T/U-specific approaches to quality improvement activities. | |
| 207. | Confidentiality of Substance Use Disorder Patient Records ACTION: Proposed Rule NOTICE: Confidentiality of Substance Use Disorder Patient Records AGENCY: SAMHSA | SAMHSA- 4162-20 | Issue Date: 2/9/2016 Due Date: 4/11/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule addresses changes to the Confidentiality of Alcohol and Drug Abuse Patient Records regulations. SAMHSA has issued this proposed rule out of a need to update and modernize the regulations, which sought to address the potential use of substance abuse information against an individual, preventing those individuals with substance use disorders from seeking needed treatment. The last substantive update to these regulations happened in 1987. Within the U.S. health care system over the last 25 years, significant changes have occurred that the current regulations did not envision, including new models of integrated care built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient information, and a new focus on performance measurement within the health care system. SAMHSA wants to ensure that patients with substance use disorders have the ability to participate in, and benefit from, new integrated health care models without fear of putting themselves at risk of adverse consequences. These new integrated models serves the triple aim of HHS: improving health care quality improving population health, and reducing unnecessary health care costs. SAMHSA strives to facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. These concerns include: the potential for loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration. This proposed rule also seeks to make the regulations more understandable and less burdensome. https://www.gpo.gov/fdsys/pkg/FR-2016-02-09/pdf/2016-01841.pdf | |
| 208. | Medicare Probable Fraud | CMS-10406 | Issue Date: | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of | |



| | Short Title/Current Status | | Iccus Data: | | | |
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| # | of Regulation/Title/ | File Code | Due Date & | Response | and Summary of NIHB Analysis | NIHB Recs. |
| " | Agency | | File Date | Response | j j | |
| | Measurement Pilot | | 2/5/2016 | | <u>a currently approved collection</u> ; <i>Title</i> : Medicare Probable Fraud Measurement Pilot; <i>Use</i> : | |
| | | | | | CMS seeks OMB approval of the collections required for a probable fraud measurement | |
| | ACTION: Request for | | Due Date: | | pilot. The probable fraud measurement pilot will establish a baseline estimate of probable | |
| | Comment | | 4/5/2016 | | fraud in payments for home health care services in the fee-for-service Medicare program. | |
| | Comment | | 1/3/2010 | | CMS and its agents will collect information from home health agencies (HHAs), the | |
| | NOTICE: Medicare Probable | | NIHB File | | referring physicians, and Medicare beneficiaries selected in a national random sample of | |
| | Fraud Measurement Pilot | | Date: None | | home health claims. The pilot will rely on the information collected along with a summary | |
| | Fraud Measurement Phot | | <u>Date</u> : None | | | |
| | 1051014 0140 | | 5 | | of the service history of the HHA, the referring provider, and the beneficiary to estimate | |
| | AGENCY: CMS | | Date of | | the percentage of total payments associated with probable fraud and the percentage of | |
| | | | <u>Subsequent</u> | | all claims associated with probable fraud for Medicare fee-for-service home health. | |
| | | | <u>Agency</u> | | | |
| | | | Action, if any: | | https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02277.pdf | |
| | | | Issued | | | |
| | | | extension | | SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| | | | 4/29/2016 | | | |
| | | | 1/2//2010 | | SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/29/2016 issued an | |
| | | | <u>Due Date:</u> | | extension of this PRA request. | |
| | | | 5/31/2016 | | https://www.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-10084.pdf | |
| | | | 3/31/2010 | | <u>ппфз.//www.gpo.gov/rusys/prkg/1 1x-2010-04-2 //pul/2010-10004.pul</u> | |
| | | | | | | |
| 209. | Reassignment of | HHS (no | Issue Date: | | SUMMARY OF AGENCY ACTION: This notice announces the availability of final | |
| 207. | Personnel in a Public | reference | 4/1/2016 | | guidance titled "Guidance for Temporary Reassignment of State, Tribal, and Local | |
| | Health Emergency | number) | 4/1/2010 | | Personnel during a Public Health Emergency." Section 201 of the Pandemic and All- | |
| | nealth Emergency | number) | Dua Data | | | |
| | A OTION AL II | | <u>Due Date</u> : | | Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) amends section 319 | |
| | ACTION: Notice | | None | | of the Public Health Service (PHS) Act to allow the HHS Secretary, when she | |
| | | | | | declares a public health emergency under section 319 of the PHS Act, to authorize, | |
| | NOTICE: Temporary | | NIHB File | | upon request by a state or tribal organization or their designee, the temporary | |
| | Reassignment of State, | | <u>Date</u> : | | reassignment of state, tribal, and local personnel funded through programs | |
| | Tribal, and Local Personnel | | | | authorized under the PHS Act to address immediately a public health emergency in the | |
| | During a Public Health | | Date of | | state or Indian Tribe. This final guidance addresses that provision. | |
| | Emergency | | Subsequent | | y | |
| | | | Agency | | Discussion: "The PHS Act requires HHS issue proposed guidance on this provision, to be | |
| | AGENCY: HHS | | Action, if any: | | followed by a 60-day public comment period. Consistent with this requirement, a notice | |
| | AGENOT. TITIS | | Issued | | appeared in the Federal Register on October 1, 2013 (78 FR 60283) notifying the public | |
| | | | correction | | that HHS was accepting comments on such proposed guidance. This 60-day public | |
| | | | | | | |
| | | | 4/12/2016 | | comment period concluded in December 2013. There were nine submissions received in | |
| | | | | | the public comment period. Five of the submissions were local governments, one state | |



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| | | | | | government, and three associations. Revisions made based on feedback received included setting timelines for HHS to review; standardizing the request template for states and Indian tribes, expanding the post event reporting requirements from 90 to 120 days, and clarifications on which Public Health Service programs were potentially affected. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs. This authority terminates on September 30, 2018. This new provision provides an important flexibility to state and local health departments and tribal organizations during an event requiring all the resources at their disposal. The temporary reassignment provision permits state, tribal, and local personnel to be voluntarily reassigned so they can immediately respond to the public health emergency in the affected jurisdiction." https://www.gpo.gov/fdsys/pkg/FR-2016-04-01/pdf/2016-07404.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: HHS on 4/12/2016 issued a document to correct one technical error that appeared in the notice titled "Temporary Reassignment of State, Tribal, and Local Personnel During a Public Health Emergency" and published in the 4/1/2016 FR (81 FR 18865). On page 18865, in the second column, this document corrects the Web site address to read www.PHE.gov/TemporaryReassignment. https://www.gpo.gov/fdsys/pkg/FR-2016-04-12/pdf/2016-08289.pdf | |
| 210. | Functional Assessment Standardized Items (CARE Tool) ACTION: Request for Comment NOTICE: Testing Experience and Functional | CMS-10243 | Issue Date: 5/2/2016 Due Date: 7/1/2016 NIHB File Date: None | | SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a currently approved collection; Title: In 2012, CMS funded a project titled Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration involves amending and testing the reliability of a setting-agnostic, interoperable set of data elements, called "items," that can support standardized assessment of individuals across the continuum of care. Community-based long-term services and supports (CB-LTSS) programs have adopted, modified, or supplemented items created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool. This project will | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool AGENCY: CMS | | Date of Subsequent Agency Action, if any: Issued reinstatement 8/5/2016 Due Date: 9/6/2016 | | test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings and in various populations: older adults (65 years and older): younger adults (18-64 years) with physical disabilities; and adults of any age with intellectual or developmental disabilities, severe mental illness, or traumatic brain injury. Collection of individual-level data will occur two times using the TEFT FASI Item Set. The first data collection effort will gather data for analysis to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Assessors might recommend changes to individual TEFT FASI items prior to releasing the TEFT FASI items for use by the states. The public will have access to the FASI Field Test Report. States will conduct the second data collection to demonstrate their use of the FASI data elements. States could use the assessment data for multiple purposes. They could use the standardized items to determine individual eligibility for state programs, to help determine levels of care within which people can receive services, or for other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have received funding under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. CMS could use the reports in its evaluation of the TEFT grants. https://www.gpo.gov/fdsys/pkg/FR-2016-05-02/pdf/2016-10232.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. No comme | |



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| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
| 211. | Non-Enforcement of Overtime Rule for Certain Providers ACTION: Guidance NOTICE: Time Limited Non- Enforcement Policy for a Subset of Medicaid-Funded Providers AGENCY: DoL | DoL (no reference number) | Issue Date: 5/19/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: DoL on 5/18/2016 released a final rule (RIN 1235-AA11, scheduled for publication in the 5/23/2016 FR) that revises final regulations under the Fair Labor Standards Act (FLSA) implementing the exemption from minimum wage and overtime pay for executive, administrative, professional, outside sales, and computer employees. The final rule updates the salary threshold under which most white collar workers are entitled to overtime compensation to equal the 40th percentile of weekly earnings of full-time salaried workers in the lowest wage Census region, currently the South. The final rule will raise the salary threshold from \$455 per week (\$23,660 for a full-year worker) to \$913 per week (\$47,476 for a full-year worker) on 12/1/2016. However, DoL has announced a time-limited non-enforcement policy for providers of Medicaid-funded services for individuals with intellectual or developmental disabilities in residential homes and facilities with 15 or fewer beds, lasting from 12/1/2016 to 3/17/2019. This guidance provides more information on the time-limited non-enforcement policy for these providers of Medicaid-funded services. https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf The final rule is available at https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf Additional information on the final rule is available at https://www.dol.gov/whd/overtime/final2016/ . A Native American Finance Officers Association policy alert on the final rule is available at https://www.nafoa.org/broadcasts/department-of-labor-releases-overtime-rule-tribal-employers-have-six-months-to-prepare . SUMMARY OF NIHB ANALYSIS: | |
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| 212. | Enhancing Retailer Standards in SNAP ACTION: Proposed Rule NOTICE: Enhancing Retailer | USDA FNS RIN 0584- AE27 | <u>Issue Date</u> : 2/17/2016 <u>Due Date</u> : 4/18/2016 5/19/2016 | NIHB response: | SUMMARY OF AGENCY ACTION: The USDA Food and Nutrition Service (FNS) proposes to make changes to Supplemental Nutrition Assistance Program (SNAP) regulations pertaining to the eligibility of SNAP retail food stores. The Agricultural Act of 2014 (2014 Farm Bill) amended the Food and Nutrition Act of 2008 (Act) to increase the requirement that certain SNAP authorized retail food stores have available on a continual basis at least three varieties of items in each of four staple food categories, to a | See Table C. |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
|------|---|-----------|--|------------------|---|------------|
| | Standards in the Supplemental Nutrition Assistance Program (SNAP) AGENCY: USDA FNS | | NIHB File Date: 5/16/2016 Date of Subsequent Agency Action, if any: Issued due date extension/ clarification 4/5/2016 | Response | mandatory minimum of seven varieties. The 2014 Farm Bill also amended the Act to increase, for certain SNAP authorized retail food stores, the minimum number of categories in which perishable foods are required from two to three. This proposed rule would codify these mandatory requirements. Further, using existing authority in the Act and feedback from a Request for Information that included five listening sessions in urban and rural locations across the nation and generated 233 public comments, FNS proposes several additional changes. Among other items, these proposed changes address depth of stock, amend the definition of staple foods, and amend the definition of "retail food store" to clarify when a retailer is a restaurant rather than a retail food store. The rulemaking also proposes that FNS begin disclosing to the public specific information about retailers that have violated SNAP rules. https://www.gpo.gov/fdsys/pkg/FR-2016-02-17/pdf/2016-03006.pdf SUMMARY OF NIHB ANALYSIS: The new provisions in this proposed rule would require certain SNAP authorized retail food stores to abide by the "four staple food categories." Essentially, this means that these stores will have to increase their stock of fresh fruits and vegetables, otherwise they will lose their SNAP eligibility. Although laudable to try and incentivize an increase in fresh produce options, realities in Indian Country regarding access to such fresh foods will make it nearly impossible for stores to comply. This could turn into a significant crisis in Indian Country if tribal members cannot use their SNAP benefits at local stores. A Center on Budget and Policy Priorities report detailing how the FY 2017 House appropriations bill seeks to downsize SNAP by \$125 billion over the next 10 years and turn it into a block grant program by 2021 (the federal government currently administers SNAP, and it is uniform across the nation, although states have some say in determining eligibility) is available at | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| 213.a. | Civil Monetary Penalties Inflation ACTION: Interim Final Rule NOTICE: Civil Monetary Penalties Inflation Adjustment AGENCY: DoJ | AG Order No. 3690- 2016 | Issue Date: 6/30/2016 Due Date: 8/29/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: In accordance with the provisions of the Bipartisan Budget Act of 2015, this interim final rule with comment period adjust for inflation civil monetary penalties (CMPs) assessed or enforced by components of DoJ. SUMMARY OF NIHB ANALYSIS: This rule makes adjustments to CMPs using calculations based on the Consumer Price Index (CPI) for October 2015 (see Table A at 81 FR 42494-7 for a complete listing of these adjustments). The key factors for these calculations include (1) the year in which each CMP amount was established or adjusted under a provision of law other than the Inflation Adjustment Act; (2) the amount of each CMP as so established or adjusted; (3) the inflationary adjustment factor (as determined according to a chart prepared by OMB) for the year of the most recent establishment or adjustment of the amount of the CMP; and (4) the resulting amount of the new adjusted CMP. The only departures from these calculations involve CMPs whose amount was set decades ago and not previously adjusted; in those few cases, this rule caps the CMP amount at 2.5 times the amount currently in effect. EXAMPLE: For a CMP established by law at the amount of \$1,000 in 1996, applying the inflationary adjustment factor of 1.50245 for that year, the adjusted amount as determined under this rule equals \$1,502, as rounded to the nearest \$1. Under this rule, the adjusted CMP amounts apply to only penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015. Violations occurring on or before 11/2/2015 and assessments made prior to 8/1/2016 whose associated violations occurred after 11/2/2015 will remain subject to the CMP amounts set forth in existing regulations in 28 CFR parts 20, 22, 36, 68, 71, 76 and 85 (or as set forth by statute if the amount remains unadjusted by regulations). | |
| 213.b. | Adjustment of Civil Monetary Penalties for Inflation ACTION: Interim Final Rule NOTICE: Adjustment of Civil Monetary Penalties for | HHS RIN 0991- AC0 | Issue Date: 9/6/2016 Due Date: None NIHB File Date: | | SUMMARY OF AGENCY ACTION: This interim final rule adjusts for inflation the maximum civil monetary penalty amounts for the various civil monetary penalty authorities for all agencies within HHS. HHS has taken this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. In addition, this interim final rule includes updates to certain agency-specific regulations to identify their updated information and note the location of HHS-wide regulations. | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | Inflation AGENCY: HHS | | Date of Subsequent Agency Action, if any: | | https://www.gpo.gov/fdsys/pkg/FR-2016-09-06/pdf/2016-18680.pdf SUMMARY OF NIHB ANALYSIS: | |
| 214. | Medicaid Supplemental Payment and Accountability ACTION: Proposed Rule NOTICE: Medicaid Supplemental Payment and Accountability AGENCY: CMS | CMS-2393-P | Issue Date: [Pending at OMB as of 7/19/2016] Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: This proposed rule would promote transparency by establishing new reporting requirements for states to provide to CMS certain information on supplemental payments to Medicaid providers, including supplemental payments approved under either Medicaid state plan or demonstration authority. The reporting requirements would not apply to supplemental payments to federally qualified health centers, rural health clinics, and Indian providers or "pass through" or wraparound payments. The reporting requirements also would not apply to disproportionate share hospital payments. SUMMARY OF NIHB ANALYSIS: | |
| 215. | Initial Request for State Implemented Moratorium Form ACTION: Request for Comment NOTICE: Initial Request for State Implemented Moratorium Form AGENCY: CMS | CMS-10628 | Issue Date: 8/18/2016 Due Date: 10/17/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: | | SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Initial Request for State Implemented Moratorium Form; <i>Use</i> : Under 42 CFR 424.570, prior to implementing a state Medicaid moratorium, the state Medicaid agency must notify the HHS Secretary in writing, including all of the details of the moratorium, and obtain the concurrence of the HHS secretary with its imposition. Section 1866 (j)(7) of the Social Security Act allows for the imposition of temporary moratoria. CMS created the Initial Request for State Medicaid Implemented Moratorium form to collect, in a uniform manner, the data that states report to the agency when they request a moratorium. Currently, CMS collects this data on an ad-hoc basis, but this process requires standardization so that the agency makes moratoria decisions based on the same criteria each time. The Initial Request for State Medicaid Implemented Moratorium form provides a uniform application process that all of the states can follow and allows CMS to administer the Medicaid or CHIP moratorium process in a standardized and | |



| Ref. | Short Title/Current Status of Regulation/Title/ Agency | File Code | Issue Date; Due Date & File Date | NIHB Response | Brief Summary of Proposed Agency Action and Summary of NIHB Analysis | NIHB Recs. |
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| | | | | | repeatable manner. https://www.gpo.gov/fdsys/pkg/FR-2016-08-18/pdf/2016-19656.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. | |
| 216. | HHS Grants Regulation ACTION: Proposed Rule NOTICE: Health and Human Services Grants Regulation AGENCY: HHS | HHS (RIN 0991-AC06) | Issue Date: 7/13/2016 Due Date: 8/12/2016 NIHB File Date: 8/11/2016 Date of Subsequent Agency Action, if any: | NIHB response: | SUMMARY OF AGENCY ACTION: This notice of proposed rulemaking (NPRM) proposes changes to HHS adoption of OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("Uniform Administrative Requirements") published in the 12/19/2014 FR (79 FR 75871) and the technical amendments published by HHS in the 1/20/2016 FR (81 FR 3004). HHS codified the OMB language, with noted modifications as explained in the preamble to the December promulgation, in 45 CFR part 75. The HHS-specific modifications to the Uniform Administrative Requirements adopted prior regulatory language that did not conflict with the OMB language and provided additional guidance to the regulated community. Unlike all of the other modifications to the Uniform Administrative Requirements, these proposed changes, although based on existing law or HHS policy, were not previously codified in regulation. This NPRM seeks comments on these important proposed regulatory changes. https://www.gpo.gov/fdsys/pkg/FR-2016-07-13/pdf/2016-15014.pdf SUMMARY OF NIHB ANALYSIS: A Hobbs-Straus memo on this NPRM is available at http://hobbsstraus.com/general-memorandum-16-50. | See Table C. |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| 4.0. | Hospital OPPS and ASC Payment System for CY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain | CMS-1656-PFC Issue Date: 7/24/2016 Due Date: 9/6/2016 NIHB File Date: 9/6/2016; TTAG also filed comments 9/6/2016 Date of Subsequent Agency Action, if any: Final Rule approved by OMB 10/28/2016 | "Grandfather" Provision Under 42 CFR 413.65(m): In the proposed rule, CMS appears to have taken a very narrow interpretation of 42 CFR 413.65(m)a special "grandfather" provision under which for certain IHS and tribal clinics and other facilities that do not meet provider-based criteria but had billed as components of IHS or tribal hospitals at the time of the first publication of the final regulations (on April 7, 2000) can retain their status as provider-based—meaning that the rule might apply to the Indian health care system; CMS should provide clarification in the final rule to ensure that the grandfather provision remains intact for IHS and tribal facilities. | No subsequent formal Agency action taken (as of 10/31/2016). |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| | Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program AGENCY: CMS | | | |
| 7.111. | 2017 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft 2017 Letter to Issuers in the Federally- Facilitated Marketplaces AGENCY: CCIIO | CCIIO (no reference number) Issue Date: 12/23/2015 Due Date: 1/17/2016 TSGAC File Date: 1/17/2016 Date of Subsequent Agency Action, if any: Issued Final Letter 2/29/2016 | Chapter 1, Section 4Standardized Options: Under the 2017 Issuer Letter, qualified health plan (QHP) issuers would have to offer "standardized options," with each option standardized in terms of in-network cost-sharingdeductible, annual limitation on cost-sharing, and copayment or coinsurance for a key set of essential health benefits (EHBs) that comprise a large percentage of total spending for the average enrollee; CCIIO should include balance billing charges and policies as an element of the standardized options to enable better plan comparisons and to facilitate selection of plans with the greatest value for QHP enrollees. Chapter 3, Section 3Out-of-Pocket Cost Comparison Tool: CCIIO has created an out-of-pocket (OOP) cost comparison tool to help improve the ability of consumers to make comparisons between QHP offerings and determine the QHP that offers the greatest value depending on a variety of factors; in designing the OOP cost comparison tool, CCIIO should incorporate the impact of the Indian-specific | In the 2/29/2016 Final Letter 1. Chapter 1, Section 4Standardized Options: Not accepted. CCIIO did not address this issue. 2. Chapter 3, Section 3Out-of-Pocket Cost Comparison Tool: Not accepted. CCIIO did not address this issue. |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| | | | cost-sharing protections or, if not feasible for the 2017 coverage year, at least provide information indicating to potential AI/AN enrollees that the calculations do not include the impact of the Indian-specific cost-sharing protections. | |
| 8.d. | Oklahoma 1115 Waiver Amendment ACTION: Request for Comment NOTICE: §1115(a) SoonerCare Research and Demonstration Waiver Amendment Request AGENCY: N/A | 11-W-00048/6 Issue Date: 3/4/2016 Due Date: 4/14/2016 TSGAC File Date: 4/5/2016 Date of Subsequent Agency Action, if any: | TSGAC recommendations CMS should approve the request by the Oklahoma Health Care Authority to amend its section 1115 waiver to incorporate the Insure Oklahoma Sponsor's Choice Option, which would allow I/T/Us to sponsor eligible individuals by paying their premiums for health insurance coverage through Insure Oklahoma, as this amendment would: • Permit IHS and tribal health care facilities to bill managed care entities for the health care services they provide to the newly-eligible enrollees in the Sponsor's Choice Option; • At low cost to the Medicaid program, provide significant opportunities for reimbursement by IHS and tribal health care facilities in Oklahoma; • Result in health insurance coverage for about 80,000 Al/ANs who currently lack sufficient access to needed care; • Help the federal government meet its federal trust responsibility for Al/ANs in Oklahoma, where I/T/Us in fiscal year 2014 had more than 56,000 unmet Purchased and Referred Care claims that accounted for tens of millions of dollars in necessarybut not providedspecialty care. | No subsequent Agency action taken (as of 10/31/2016). |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| 14.c. | Waivers for State Innovation ACTION: Notice NOTICE: Waivers for State Innovation AGENCY: CMS/Treasury | CMS-9936-N Issue Date: 12/16/2015 Due Date: Open TSGAC File Date: 2/23/2016 Date of Subsequent Agency Action, if any: | Indian-Specific Protections Under ACA: ACA contains a number of Indian-specific protections—some within the section 1332 waiver authority of CMS and Treasury (Agencies) and some outside this authority—and a State Innovation Waiver could have a direct negative impact on Al/ANs because of changes in Indian-specific and non-Indian specific provisions of the law; to ensure that a State Innovation Waiver does not adversely affect Al/ANs, the Agencies should clarify that representations made by a state pertaining to the state satisfying the requirements for granting such a waiver must consider the specific impact on each individual Al/AN and not remain limited to the overall, or average, impact on the population as a whole. Indian-Specific Protections Under the Balanced Budget Act of 1997 (BBA): BBA established section 1932(a)(2)(C) of the Social Security Act, which provides that no state can require Al/ANs to enroll in a Medicaid managed care system, except in cases in which an I/T/U operates the system; to ensure that a State Innovation Waiver does not adversely affect Al/ANs, the Agencies should emphasize the importance of maintaining the Indian-specific protections contained in section 1932 under such a waiver. Indian-Specific Protections Under the American Recovery and Reinvestment Act of 2009 (ARRA): As a supplement to section 1932(a)(2)(C), ARRA section 5006 provides a number of protections for Al/ANs who elect to enroll in Medicaid managed care; to ensure that a State | No subsequent Agency action taken (as of 10/31/2016). |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| | | | Innovation Waiver does not adversely affect Al/ANs, the Agencies should emphasize the importance of maintaining the Indian-specific protections contained in section 5006 under such a waiver. | |
| 25.jj. | PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and FY 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification | CMS-1655-PF CMS-1664-F CMS-1632-F2 Issue Date: 4/27/2016 Due Date: 6/17/2016; TTAG and TSGAC also filed comments 6/17/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 8/22/2016 | Change in Factor 3 Methodology: In addressing the Medicare disproportionate share hospital (DSH) program, the proposed rule would redefine uncompensated care costs for Factor 3 payments as the costs of charity care and non-Medicare bad debt, as well as incorporate, over a three-year period, Worksheet S-10 data, with insured low-income day data averaged with uncompensated care cost datachanges under which IHS and tribal hospitals could ultimately lose all payments under Factor 3 of the uncompensated care pool of funds; CMS should address this issue to prevent the devastating financial impact it would have on IHS and tribal hospitals. Tribal Consultation: Although CMS has had a conversation with IHS about finding a solution to the issue with Factor 3 payments posed by the proposed rule, further analysis and meaningful tribal consultation must take place before the agency finalizes the rule; CMS should engage in additional consultation with IHS and Tribes to ensure that IHS and tribal hospitals continue to access third-party revenues for tribal health programs. | In the 8/22/2016 Final Rule 1. Change in Factor 3 Methodology: Accepted in part. CMS stated, "We appreciate these comments and acknowledge that the use of data from Worksheet S-10 to calculate uncompensated care costs does not take into account the unique funding structure of IHS hospitals and therefore using these data to determine Factor 3 may have an unintended impact on the uncompensated care payments to these hospitals. We intend to continue working with IHS and Tribal stakeholders to devise an appropriate solution for estimating uncompensated care for these facilities and will undertake further rulemaking as appropriate to address this issue." [81 FR 56972-3] 2. Tribal Consultation: Accepted in part. See response to recommendation #1 above. |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| | Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports AGENCY: CMS | | | |
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| 31.iii. | Tribal Consultation | IRS (no | TSGAC recommendations | No subsequent formal Agency action taken (as of 10/31/2016). |
| | on ACA Employer Shared | reference number) | Administrative ReliefEmployer Shared Responsibility | |
| | Responsibility | Hambery | Payments: For tribal government employers, IRS should | |
| | | Issue Date: | issue sub-regulatory guidance providing that tribal member | |
| | ACTION: Notice | 4/20/2016 | employees would not count with regard to calculations of the employer shared responsibility payment under Internal | |
| | NOTICE: Tribal | Due Date: | Revenue Code (IRC) § 4980H. | |
| | Consultation on the | None | 2. Administrative ReliefContinued Access to Marketplace | |
| | ACA Employer Shared | TSGAC File | Benefits : For tribal member employees of a tribal government employer (and including a spouse and | |
| | Responsibility | Date: | dependents of such employees), IRS should issue sub- | |
| | Provisions | 5/13/2016 | regulatory guidance establishing that an offer of health | |
| | ACENCY, IDC | Data of | insurance coverage from the employer would not constitute | |
| | AGENCY: IRS | <u>Date of</u> Subsequent | an offer of minimum essential coverage (MEC) under IRC § 36B(c)(2)(B)(i) for purposes of qualifying for premium tax | |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| | | Agency Action, if any: | credits (PTCs) and cost-sharing reductions (CSRs) unless the employee enrolls in the coverage offered by the tribal government employer. 3. Extension of Transition Relief: IRS should extend transition relief in the application of the following requirements under the ACA employer shared responsibility mandate (employer mandate) on Tribes, tribal organizations as defined by Section 4(L) of the Indian Self-Determination and Education Assistance Act, and tribally owned entities (collectively referred to as Tribes) from January 1, 2015, until at least January 1, 2016, and preferably to January 1, 2017: • Employer coverage requirements, including any associated mandate to make shared responsibility payments under Internal Revenue Code (Code) § 4980H; • Employer reporting requirements under Code §§ 6055 and 6056; and • Application of the extension of transition relief to all employees of Tribes. | |
| 31.III. | Indian-Specific | CCIIO (no | TTAG recommendations (3/18/2016, additional subsequent | In the 4/28/2016 draft Indian-specific templates |
| | CSV Sample SBC Templates | reference number) | recommendations appear below) | |
| | ACTION: Guidance | Issue Date: | The approach taken by CCIIO in creating these sample SBC templates largely incorporates the prior recommendations made | Not accepted. |
| | NOTICE: Sample | 3/16/2016 | by TTAG and will help in communicating the proper application of the Indian-specific cost-sharing protections; among other | CCIIO did not include "\$0 with IHCP referral or" in each cell in the cost columns for services provided at non-Indian health |
| | Summary of Benefits and | <u>Due Date:</u> 3/18/2016 | recommended changes (see attachments below for specific line edits), the agency should include "\$0 with IHCP referral or" in | care providers (IHCPs). See attachments below for responses to specific line edits. |



| Coverage (SBC) Templates: Zero Cost-Sharing Variation (Z-CsV) and Limited Cost- Sharing Variation (L-CsV) AGENCY: CCIIO Date of Subsequent Agency Action, if any; Issued template 4/6/2016 (general), 4/28/2016 (draft Indian-specific); issued final Indian-specific templates 7/13/2016 Death cost columns for services provided at non-Indian health care providers (IHCPs), as placing this language in each cell has proven to eliminate a great deal of confusion for enrollees and providers when seeking to interpret the coverage documents. Batch cell in the cost columns for services provided at non-Indian health care providers (IHCPs), as placing this language in each cell has proven to eliminate a great deal of confusion for enrollees and providers when seeking to interpret the coverage documents. Batch cell in the cost columns for services provided at non-Indian health care providers (IHCPs), as placing this language in each cell has proven to eliminate a great deal of confusion for enrollees and providers when seeking to interpret the coverage documents. Batch cell in the cost columns for services provided at non-Indian health care providers (IHCPs), as placing this language in each cell has proven to eliminate a great deal of confusion for enrollees and providers when seeking to interpret the coverage documents. Batch cell in the cost columns for services provided at non-Indian health care providers (IHCPs), as placing this language in each cell has proven to eliminate a great deal of confusion for enrollees and providers when seeking to interpret the coverage documents. Batch cell in the cost columns for services provided at non-Indian health care providers (IHCPs), as placing this language in each cell has providers (PICPS). Batch cell in the cost columns for services provided at non-Indian health care providers (IHCPs). Batch cell in the cost columns for services provides deal of confusion for enrollees and providers when seeking to interpret the coverage of sech cell has providers (PICPS). Batch cell in | ile Issued/ icy |
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| (general), 4/28/2016 (draft Indian-specific); issued final Indian-specific templates TTAG recommendations (5/4/2016) 1. Definition of ICHP: CMS should initially spell out "Indian health care provider" or add the term "IHCP" in the Glossary and link to it; if CMS opts to add IHCP to the Glossary, it should use one of the following definitions: In the 7/13/2016 final Indian-specific templates CMS spelled out "Indian health care provider" or add the term "IHCP" in the Glossary, it should use one of the following definitions: | |
| tribal organization, or an urban Indian organization." Long definition: "The Indian Health Service; An Indian health program operated by an Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the Indian Health Service pursuant to the Indian Self—Determination Act (25 U.S.C. 450 et seq.); and An urban Indian health program operated by an urban | |



| RRIAR Ref. # | Short Title/Current Status of Regulation/ Title/Agency | File Code & Dates | Summary of NIHB and/or TTAG Recommendations | Evaluation of Subsequent Rule Issued/ Action Taken by Agency |
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| | | | the Indian Health Service pursuant to title V of the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.)." 2. Reference to "Balance Billing": CMS should add a reference to "balance billing" to the entries in the "Limitations, Exceptions, & Other Important Information" column. 3. Statement on Costs at Non-ICHP Without Referral (L-CSV SBC only): CMS should place in bold the following statement: "Note: These numbers assume the patient received care from an IHCP provider or with IHCP referral at a non-IHCP. If you receive care from a non-IHCP provider without a referral from an IHCP, your costs may be higher." See attachments below for specific line edits. SBC 2017 Template SBC 2017 Template AI AN zero 041516 d AI AN limited 041516 | Reference to "Balance Billing": Accepted. CMS adopted this change as recommended. Statement on Costs at Non-ICHP Without Referral (L-CSV SBC only): Not accepted. CMS did not adopt this change. |
| 43. | Medicaid Reimbursement for Outpatient Drugs ACTION: Proposed Final Rule | CMS-2345- PFC <u>Issue Date:</u> 2/2/2012 <u>Due Date:</u> 4/2/2012 | NIHB recommendations (4/2/2012, additional subsequent recommendations appear below) 1. Tribal Consultation : CMS should consider in its decisions regarding the final rule all comments received during tribal consultation, although the agency would not have received these comments until after the 4/2/2012 deadline. | In the 2/1/2016 Final Rule Tribal Consultation: Rejected in part. CMS did not commit to considering comments provided through the tribal consultation process, if provided after the 4/2/2012 deadline for comments. |



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| | NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS | NIHB File Date: 4/2/2012 Date of Subsequent Agency Action, if any: Issued Final Rule 2/1/2016 Due Date: 4/1/2016 NIHB File Date: 4/21/2016 | 2. Payment Methodologies: Proposed § 447.518 requires the State plan to describe the payment methodology for prescription drugs, including those dispensed by I/T/U pharmacies, provided that the allowable methodologies include reimbursement on the same basis as retail pharmacies and the OMB encounter rate already approved by CMS in a number of State plans; CMS should retain this provision in the final rule but provide clarification regarding allowable methodologies to ensure that states do not mistakenly believe that current reimbursement models, such as encounter rates, are not permitted. | CMS stated, "We agree that the Tribal consultation process is valuable in helping us to finalize policies and support Indian health programs. We obtained the advice and input of Tribal officials during the Tribal Technical Advisory Group (TTAG) face-to-face meeting in Washington, DC on February 23, 2012; and under Executive Order 13175 and the CMS HHS Tribal Consultation Policy (November 2011), we consulted with Tribal officials during an All Tribes' Call on March 16, 2012, and through the regulatory review process. In determining our final policies and regulations, we considered all comments received before the close of the comment period (including comments received through Tribal consultations)." [81 FR 5316-7] 2. Payment Methodologies: Accepted. CMS stated, "We recognize there are unique aspects of dispensing CODs to Al/ANs by I/T/U pharmacies and understand the various concerns expressed through the regulatory comment process Unlike AAC [actual acquisition cost], which is defined in § 447.502, the encounter rate is more reflective of services provided and is not granular to the extent of identifying the ingredient cost of a drug. Therefore, if a state pays I/T/Us at the encounter rate, it will satisfy the requirements in § 447.518(a)(2), which specifies that the state's payments must be in accordance with the definition of AAC. We have determined that the encounter rate is one model that states may use to reimburse I/T/U pharmacies, given that the |



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| | | | 3. Dispensing Fee Calculations : CMS should retain in the final rule the proposed requirement that dispensing fee calculations take into account special circumstances of I/T/U pharmacies. | rates are designed to address provider costs. It was not our intent in the proposed rule to change the state's authority to reimburse I/T/U pharmacies using the encounter rate, and we believe that nothing in this final rule prevents states from using the encounter rate as a model to reimburse I/T/U pharmacies. We believe that as designed, the current CMS SPA review and approval process which requires states to obtain the advice and input from I/T/Us before making changes to Medicaid reimbursements to I/T/U pharmacies, before CMS approval of the SPA, provides sufficient oversight and input regarding states establishing such pharmacy rates." [81 FR 5316] 3. Dispensing Fee Calculations: Accepted in part. CMS stated, "We agree that there may be unique circumstances for 340B covered entities that states should consider when establishing their professional dispensing fees for these providers and that states must express the rationale for the reimbursement methodologies being proposed in their state plans. We also believe that it is important the providers are reimbursed adequately for the provision of care to beneficiaries. Therefore, we will require states to substantiate how their dispensing fee reimbursement to pharmacy providers, including 340B providers, is consistent with section 1902(a)(30)(A) of the Act. We note that states may decide to use different professional dispensing fee rates for different entities and providers. While we do not mandate any specific professional dispensing fee methodologies that states must use, states are required to provide data which indicates |



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| | | | | that the methodology is consistent with the regulation and ensures access." [81 FR 5317] |
| | | | NIHB recommendations (4/21/2016) A State Health Official Letter (SHO #16-001) issued subsequent to the final rule briefly addressed reimbursement of I/T/U pharmacies for covered outpatient drugs, but states could misinterpret some statements in the letter, as well as some provisions of the rule, as a constraint on their rate-setting flexibility, to the detriment of affected I/T/Us; to address these concerns, CMS should prepare a supplemental SHO or other guidance clarifying that: | No subsequent Agency action taken (as of 10/31/2016). |
| | | | Any state can elect to reimburse I/T/U pharmacies through the OMB encounter rate, not only states currently using that methodology; Because "actual acquisition cost" (AAC) represents an aggregate payment limit and because the final rule does not mandate any specific reimbursement methodology, states have the same flexibility to establish AAC for I/T/Us as for other pharmacies, meaning they can base AAC on various benchmarks and surveys and do not have to adopt published Federal Supply Schedule (FSS) prices for I/T/U pharmacies that procure some covered drugs through FSS; and The requirement that states establish "professional" dispensing fees does not preclude appropriate dispensing fees for prescriptions dispensed by qualified community health aides or other qualified | |



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| | | | paraprofessionals in compliance with applicable state and federal laws. | |
| 46.f. | Treatment of Third Party Payers in Calculating DSH Uncompensated Care Costs ACTION: Proposed Rule NOTICE: Medicaid Program; Disproportionate Share Hospital Payments Treatment of Third Party Payers in Calculating Uncompensated Care Costs AGENCY: CMS | CMS-2399-P Issue Date: 8/15/2016 Due Date: 9/14/2016 NIHB File Date: 9/14/2016 Date of Subsequent Agency Action, if any: | NIHB recommendations Payments Under Factor 3: CMS proposes to re-define uncompensated care costs for Factor 3 payments as the costs of charity care and non-Medicare bad debt and to incorporate Worksheet S-10 data over a three-year period, with insured low income day data averaged with uncompensated care cost data, and for FY 2018, the agency proposes to use Worksheet S-10 data from FY 2014 cost reports in combination with insured low income days from the two preceding periods for determining the distribution of uncompensated care payments; CMS should make changes to the allocation of Factor 3 funds, as these policies could cause IHS and tribal hospitals to lose all payments under Factor 3 of the uncompensated care pool of funds. Tribal Consultation: Although the proposed rule offers Tribes and tribal organizations the opportunity to comment, it does not serve as a substitute for tribal consultation pursuant to the CMS Tribal Consultation Policy and Executive Order 13175; CMS should engage in meaningful tribal consultation on the rule. | No subsequent Agency action taken (as of 10/31/2016). |
| 60.1. | Expanding Uses of Medicare Data by Qualified Entities | CMS-5061-PF <u>Issue Date:</u> 2/2/2016 | NIHB recommendations 1. Definition of "Authorized User" : The Medicare Access and Children's Health Insurance Program Reauthorization Act | In the 7/7/2016 Final Rule 1. Definition of "Authorized User" : Accepted in part. |



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| | ACTION: Proposed Final Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities AGENCY: CMS | Due Date: 3/29/2016 NIHB File Date: 3/29/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 7/7/2016 | (MACRA) permits qualified entities to access Medicare claims data to evaluate the performance of providers and suppliers, as well as create non-public analyses and provide or sell these analyses to authorized users, and the proposed rule defines "authorized user" as a provider, a supplier, an employer, a health insurance issuer, a medical society, a hospital association, a health care professional association, or a state agency but excludes from this definition IHS and Indian health programs operated under the Indian Self-Determination and Education Assistance Act (ISDEAA); CMS should include IHS and Indian health programs in this definition as a separate distinct categoryincorporating as well Tribal Epidemiology Centers and Tribal Advisory Committees, such as TTAGas access to the data and its associated analyses would help IHS and tribal health programs improve the quality of health care services and reduce costs. 2. Expansion of Data Available to Qualified Entities: In the proposed rule, CMS states that given certain limitations associated with its Medicaid/CHIP data, qualified entities would have to seek this data through state Medicaid agencies; CMS should not impose this restriction, as states do not have the same obligations to Tribes that the federal government does, and should direct state Medicaid agencies to work with Tribes and provide them with the data they request. | CMS stated, "We recognize that many organizations are interested in accessing analyses provided by the qualified entity. However, CMS believes we must maintain a carefully curated list of authorized users to prevent the monitoring of the qualified entity program from becoming too cumbersome. As a result, we are only adding federal agencies, including, but not limited to the Indian Health Service (and Indian Health programs), to the definition of authorized users." [81 FR 44466] However, CMS did not identify IHS and Indian health programs as a separate distinct category. CMS did not adopt this recommendation. However, CMS stated, "We believe that T-MSIS can create a framework for CMS collection of Medicaid and CHIP data that addresses many of the concerns about the timeliness and quality of the MSIS data that we raised in the proposed rule. As a result, we anticipate future rulemaking to make Medicaid and CHIP data available to qualified entities when the T-MSIS data becomes available and is determined to be of sufficient quality for use in public provider performance reporting." [81 FR 44470] |



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| 70.g. | Revisions to PFS and Other Changes to Part B for CY 2017 ACTION: Proposed Final Rule NOTICE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program | CMS-1654-PF Issue Date: 7/14/2016 Due Date: 9/6/2016 NIHB File Date: 9/6/2016; TTAG also filed comments 9/6/2016 Date of Subsequent Agency Action, if any: Issued correction 8/10/2016; sent Final Rule to OMB 10/18/2016 | No subsequent Agency action taken (as of 10/31/2016). 1. Medicare Diabetes Prevention Program (MDPP) Expansion: As part of its proposal to expand MDPP, CMS has asked for comments on whether the agency should expand the program nationally in the first year or phase in the expansion with populations in specific regions or by a subpopulation of MDPP suppliers; CMS should expand MDPP nationally in the first year, but if it decides to phase in the expansion, the agency should include current Special Diabetes Program for Indians (SDPI) participants in the first phase. 2. CDC Recognition Requirement: The proposed rule would require a DPP to obtain CDC recognition to qualify to apply for enrollment as a Medicare supplier, a provision that would impose an unnecessary burden on existing SDPI Diabetes Prevention (SDPI DP) programs; CMS should grant existing SDPI DP programs automatic CDC recognition and, for future programs, authorize an a SDPI DP recognition status program developed by IHS (alternatively, if CMS cannot provide SDPI programs with automatic CDC recognition, it should conduct an outreach and education initiative for SDPI and Tribal health care programs to obtain CDC recognition). 3. Eligible Beneficiaries: The proposed rule would define an eligible pre-diabetic patient as a Medicare beneficiary having a body mass index (BMI) of 25 or greater (23 or greater for Asian beneficiaries) in addition to a hemoglobin A1c test with a value of 5.7-6.4 percent, or a fasting plasma glucose of 110-125mg/dL within the last 12 months, or 2-hour plasma |



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| | Model AGENCY: CMS | | glucose of 140-199 mg/dL after the 75 gram oral glucose tolerance test, and no previous diagnosis of diabetes or lifethreatening conditions, mobility issues, etc. that would prohibit them from participating in the program; CMS should collaborate with SDPI to ensure alignment, collaboration, and consistency with program eligibility. 4. Payment Structure and Quality Measure Reporting: CMS proposes a payment structure that links payment for MDPP services to the number of MDPP sessions attended and the achievement and maintenance of minimum weight loss; with regard to payment structure and quality measure reporting: • CMS should set Medicare reimbursement through the encounter rate for all outpatient services in MDPP as the established reimbursement rate for Indian health care providers (ICHPs); • In terms of which quality measures MDPP entities must report to guide beneficiary choice of entities, CMS should use existing Government Performance Results Act (GPRA) measures, which IHCPs already utilize; • CMS should not rely on change in weight as the only measure of success for MDPP programs and should allow tribal health programs, especially SDPI, the flexibility to determine their own measures of success. 5. IT Considerations and Capabilities: The proposed rule would require MDPP entities to submit claims to Medicare | |
| | | | using standard claims forms and procedures, submitted electronically in batches, as well as maintain and handle any beneficiary Protected Health Information or Personally | |



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| | | | Identifiable Information in compliance with HIPAA and CMS standards; CMS should take into consideration the lack of availability of internet access and barriers for rural tribal health programs to obtain an up-to-date IT infrastructure and make efforts to accommodate non-electronic claims submission. 6. Program Integrity Initiatives: As part of its proposal to expand MDPP, CMS has asked for comments on the best approaches to mitigate program integrity risks, with the intent to develop policies to monitor and audit MDPP entities; CMS should collaborate with SDPI to determine best practices and learning opportunities from which MDPP could benefit. 7. Site of Service Requirements: As part of its proposal to expand MDPP, CMS has asked for comments on a provision that would allow diabetes prevention service delivery virtually; CMS should adopt this provision, as tribal health programs that serve patients in rural geographic regions could increase patient access to MDPP. 8. Tribal Consultation: Although the proposed rule offers Tribes and tribal organizations the opportunity to comment, it does not serve as a substitute for tribal consultation pursuant to the CMS Tribal Consultation Policy and Executive Order 13175; CMS should engage in meaningful tribal consultation on the rule. | |
| 83.a. | Medicaid/ Transformed- Medicaid Statistical Information | CMS-R-284 <u>Issue Date:</u> 8/15/2012 | TTAG recommendations 1. Inclusion of Indian Status: CMS should include Indian status in the information collected by states on Medicaid beneficiaries and providers, including Indian health care | No subsequent Agency action taken (as of 10/31/2016). |



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| | ACTION: Request for Comment NOTICE: Medicaid Statistical Information System (MSIS) and Transformed-Medicaid Statistical Information System (T-MSIS) AGENCY: CMS | Due Date: 10/15/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/19/2012; issued revision 12/3/2012, 12/31/2015, 4/12/2016 Due Date: 11/19/2012; 1/2/2013; 2/29/2016; 5/12/2016 TTAG File Date: 2/29/2016 | providers (ICHPs). 2. Quarterly Reports to TTAG: CMS should provide TTAG with regular quarterly reports to monitor the use of measures, Al/AN protections, and I/T payments from T-MSIS to ensure the quality, utility, and clarity of the information collected. | |
| 89.m. | Notice of Benefit and Payment Parameters for | CMS-9937-PF Issue Date: | TTAG recommendations 1. Hardship Exemptions: The proposed rule would permit | In the 3/8/2016 Final Rule 1. Hardship Exemptions: Accepted. |



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| | ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 AGENCY: CMS | 12/2/2015 Due Date: 12/21/2015 TTAG File Date: 12/21/2015; TSGAC also filed comments 12/21/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 3/8/2016; issued correction 8/11/2016 | the intent of the entity to make payments of premiums and burden Indian tribes, Ryan W | miums: Accepted. |
| | | | Tribes. GAC recommendations Application of Federal Requirements on Network Adequacy and ECPs to SBE-FP [45 CFR §155.200(f)]: The proposed rule would establish a federal platform agreement 1. Application of Federal Req Adequacy and ECPs to SB | |



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| | | | through which a State-Based Exchange (SBE) can rely on the Federally-Facilitated Exchange (FFE) for certain functions (SBE-FP), with SBE-FPs required to promulgate regulations at least as stringent as a number of FFE regulations, including current and proposed regulations on network adequacy standards and essential community provider (ECP) standards, to maintain consistency of the HealthCare.gov experience; CMS should retain this provision and explicitly state in the Preamble of the final rule that the requirements in the annual CCIIO Letter to Issuers in the Federally Facilitated Marketplaces apply to issuers in SBE-FPs. 2. Standardized Options for Cost-Sharing Protections: The rule discusses the possibility of establishing standardized cost-sharing packages for at least a portion of the plan offerings through the Marketplace, and current federal | CMS stated, "Moving forward, the annual Letter to Issuers will include implementing guidance that is specific to SBE-FPs." [81 FR 12246] Standardized Options for Cost-Sharing Protections: Accepted in part. CMS retained this provision, although on a voluntary basis |
| | | | regulations stipulate that QHP issuers must prepare and circulate a summary of benefits and coverage (SBC) for each plan variation; CMS should move forward with the proposal to standardize cost-sharing packages, but more importantly at this point, it should ensure that each QHP issuer prepares and makes available an SBC for the zero cost-sharing variation (Z-CSV) and the limited cost-sharing variation (L-CSV) to potential and actual enrollees. 3. Adjustments Required for Cost-Sharing Payments Advanced to Issuers: The proposed rule would make adjustments to amounts paid to QHP issuers to account for overestimates made by QHP issuers and overpayments made by CMS pertaining to cost-sharing protections extended on behalf of Marketplace enrollees; CMS should retain this provision, as QHP issuers must not have an | for plans, but did not address the issue of SBC for Z-CSV and L-CSV plans. 3. Adjustments Required for Cost-Sharing Payments Advanced to Issuers: Accepted. CMS retained this provision. |



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| | | | incentive to overestimate the value of cost-sharing protections paid out to enrollees and to under-provide the cost-sharing protections actually made on behalf of enrollees. 4. Modification of Provisions on Acceptance of Third-Party Payments by QHP Issuers: The proposed rule would require I/T/Us and other entities that make third-party payments of premiums to notify HHS, in a format and timeline specified in guidance, with the notification reflecting the intent of the entity to make payments of premiums and the number of individuals for whom it intends to make payments; CMS should clarify that this provision does not apply to I/T/Us. 5. Size of Rating Areas: CMS should consider the establishment of an additional criterion in the design of rating areas, applying a minimum threshold for the number of residents in a rating area and/or a minimum population threshold for a rating area no less than a specified percentage of residents in the nonmetropolitan statistical areas (MSAs) of a state. | 4. Modification of Provisions on Acceptance of Third-Party Payments by QHP Issuers: Accepted. See response to TTAG recommendation #3 above. 5. Size of Rating Areas: Not accepted. CMS declined to make changes to the regulations on the size of rating areas, stating, "We are not making changes to these regulations in this final rule and will consider these comments as we continue to study these issues." [81 FR 12212] |
| | | | 6. Induced Utilization Factors: "Induced utilization factors" provide adjustments to payments to QHP issuers for the provision of cost-sharing reductions due to increased utilization of health care services by enrollees who receive these reductions, and the proposed rule includes equivalent induced utilization factors/adjustments under the Z-CSV and L-CSV; CMS should retain this provision, as well as review the data pertaining to Al/AN enrollees under the Z-CSV and L-CSV to determine if the induced utilization factors fully compensate QHP issuers for the actual utilization of | Induced Utilization Factors: Accepted. CMS retained this provision and noted, "We will continue to evaluate this adjustment in future years as more data becomes available." [81 FR 12228] |



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| | | | medically necessary health care services under these plan variations. Informing Employers of Employee Financial Assistance Eligibility Determinations: The proposed rule would clarify when an employer receives notification of an employee obtaining financial assistance through a Marketplace, with this clarification predicated on CMS refining the definition of "financial assistance" for purposes of determining when an employer might have to make a shared responsibility payment; CMS should retain the clarification of the definition of financial assistance and work with tribal organizations to | Informing Employers of Employee Financial Assistance Eligibility Determinations: Not accepted. CMS did not address this issue. |
| | | | secure a comparable clarification from IRS. Special Enrollment Periods: At the request of Tribal organizations, CCIIO issued guidance to enrollment assisters on 10/15/2014, indicating that family members of individuals eligible for the monthly special enrollment period (M-SEP) for Indians can enroll in Marketplace coverage with the eligible individuals, but CMS has not codified this provision in regulations; CMS should continue to facilitate enrollment (and disenrollment) of individuals who meet the definition of Indian under ACA, as well as their family members, during the M-SEP provided for under §155.420(d)(8), as well as incorporate the phrase ", or his or her dependent," into §155.420(d)(8). Termination of Coverage: CMS should retain the proposed addition to the regulations at §155.430(b)(1)(iv) but also should focus on the disenrollment-enrollment administrative process to ensure a smooth transition between the Marketplace and Medicaid (and vice-versa). Eligibility Standards and Process for Exemptions: The proposed rule would permit certain individuals, including | Special Enrollment Periods: Not Accepted. Accepted. In the final rule, CMS did not revise this provision, stating, "We are not finalizing new qualifying events, eliminating current qualifying events, or changing the scope of current qualifying events for special enrollment periods at this time, but are continuing to study this issue." [81 FR 12274] |



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| | | | members of federally recognized Tribes, to claim exemptions from the tax penalty for not securing health insurance coverage during the federal tax-filing process without obtaining an exemption certification number (ECN); CMS should retain this provision. 11. Network Adequacy Standards: CMS should provide more information on the options under consideration in developing network adequacy standards prior to tribal representatives providing comments on the proposed standards. | See response to TTAG recommendation #1 above. 11. Network Adequacy Standards: Accepted in part. CMS stated that "we are not finalizing the default time and distance standard at this time," adding that "our intention is to give States time to adopt the NAIC Network Adequacy Model Act provisions and implement associated standards." [81 FR 12302] |
| | | | 12. Additional Network Adequacy Standards: The proposed rule includes a variety of approaches to ensuring adequate provider networks under QHPs offered through a Marketplace; CMS should continue to pursue options to improve the breadth of provider networks, both in QHPs offered in FFEs and in SBEs, as well as present information on plan networks in the form of a matrix that indicates which plans on and across metal levels are in the same "set" (meaning the plans have the same benefit package and provider networks and differ only on cost-sharing structure). | Additional Network Adequacy Standards: Not accepted. CMS did not address this issue. |
| 89.t. | Notice of Benefit and Payment Parameters for 2018 ACTION: Proposed | CMS-9934-P <u>Issue Date:</u> 9/6/2016 <u>Due Date:</u> | Special Enrollment Periods (§ 155.420): The proposed rule would codify at § 155.420(d)(8)(ii) the special enrollment period for dependents of Al/ANs who enroll in a QHP at the same time as the Al/AN individual; in the final rule, CMS | No subsequent Agency action taken (as of 10/31/2016). |



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| | Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 AGENCY: CMS | TSGAC File Date: 10/5/2016 Date of Subsequent Agency Action, if any: | should retain this proposal. FFE User Fee for the 2018 Benefit Year (§ 156.50): a. Outreach and Education Funding: At § 156.50(c), CMS specifies that a participating issuer offering a plan through a Federally-Facilitated Marketplace (FFM) must remit to HHS each month a user fee, which CMS proposed to set at 3.5% for all participating FFM issuers in 2018; in the final rule, CMS should expressly designate a greater amount of premiums collected by the FFM for outreach and education, plan management, and oversight activities, either funded through an increase in user fees or a reallocation of resources from other funding sources, as well as earmark a portion of this funding specifically for outreach and education activities targeted at Al/ANs and other special populations. b. Transition Year for User Fee for State-Based Marketplaces on the Federal Platform (SBM-FPs): At § 156.50(c)(2), CMS specifies that SBM-FPs must remit a user fee to HHS, and although the agency proposes to charge issuers offering QHPs through an SBM-FP a user fee rate of 3.0% of the monthly premium charged by the issuer for each policy under a plan offered through an SBM-FP in 2018, it also seeks comments on whether to extend a 2017 transition policy that lowered the rate at 1.5%; in the final rule, CMS should not extend the transition policy and should set the user fee rate at the full 3.0% of premiums charged. | |



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| | | | Levels of Coverage: Bronze Plans (§ 156.140): CMS proposes to permit bronze plans that cover and pay for at least one major service before the deductible, other than preventive services, to have an allowable variance in AV of -2 percentage points and +5 percentage points; in the final rule, CMS should retain its current policy of restricting bronze plans to an allowable variance in AV of -2 percentage points and +2 percentage points or, at minimum, should ensure that an issuer offering a bronze plan with an AV greater than 62% also offers a bronze plan with an AV that does not exceed 62%. Network Adequacy Standards (§ 156.230): In the proposed rule, CMS proposes to incorporate more specificity into the network breadth indicator—in particular, identifying for consumers whether a QHP is offered as part of an integrated delivery system—for the 2018 benefit year, noting that, for QHPs with an integrated delivery system, network breadth as calculated through the network breadth indicator methodology might not accurately describe the ability of consumers enrolled in these plans to access providers relative to consumers enrolled in plans without an integrated delivery system in the same county; in the final rule, CMS should: | |
| | | | Create a definition for QHPs that utilize an integrated delivery system separate from the definition used for determining whether plans can use the alternate ECP standard; Clarify, in any related communication to consumers, that plans utilizing an integrated delivery system do not have | |



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| | | | to meet certain requirements with regard to essential community providers (ECPs), specifically the requirement to offer contracts to all Indian health care providers (IHCPs) in their service area; and Reconsider which plans are designated as integrated delivery systems and permitted to utilize the alternate ECP standard, which permits exclusion of IHCPs. | |
| 112.d. | I/T/U Payment for Physician and Non-Hospital- Based Services ACTION: Proposed Final Rule NOTICE: Payment for Physician and Other Health Care Professional Services Purchased | IHS RIN 0917-AA12 Issue Date: 12/5/2014 Due Date: 1/20/2015 2/4/2015 NIHB File Date: 2/4/2015 | NIHB recommendations (2/4/2015, additional subsequent TSGAC recommendations appear below) 1. Treatment of Professional Services Under Existing Medicare-Like Rate Regulations: The titles for Subpart I and Section 136.201 erroneously suggest that current Medicare-Like Rate regulations do not apply to care provided by physicians and other health care professionals; IHS should clarify that the rule applies to all non-hospital providers (including non-hospital based physicians and other health care professionals). | 1. Treatment of Professional Services Under Existing Medicare-Like Rate Regulations: Accepted. IHS has added at § 136.201 an applicability provision to specify that the rule applies to IHS-operated PRC programs, urban Indian health programs, and tribally operated programs. In addition, IHS has added at § 136.202 a definition section to define important terms used in the rule, including notification of a claim, provider, supplier, referral, and repricing agent. |
| | by Indian Health Programs and Medical Charges Associated with Non-Hospital-Based Care AGENCY: IHS | Date of Subsequent Agency Action, if any: Issued due date extension 1/14/2015; issued Final Rule 3/21/2016 | 2. Section 136.201(a)(1)(3): Section 136.201 states that I/T/Us can pay only the lowest of either (1) the Medicare-Like Rate; (2) a rate negotiated by the I/T/U or its repricing agent; or (3) the amount the provider "bills the general public for the same service," but (3) seems vague and might result in misinterpretation; IHS should change this provision to the amount the provider "accepts as payment for the same service from nongovernmental entities, including insurance | 2. Section 136.201(a)(1)(3): Accepted in part. IHS stated, "IHS agrees with the commenter that the proposed language may be open to more than one interpretation. To avoid multiple interpretations and to align this subsection with others changes made to § 136.203, the reference to "bills the general public" has been deleted and provisions have been inserted providing for payment |



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| | | <u>Due Date:</u> 5/20/2016 TSGAC File Date: 5/20/2016 | providers." 3. Need for Exceptions in New Section 136.201(b): Section | not to exceed the provider or supplier's MFC rate, as evidenced by commercial price lists or paid invoices and other related pricing and discount data to ensure that the I/T/U is receiving a fair and reasonable pricing arrangement. Additionally, in the event that a Medicare rate does not exist for an authorized item or service, and no other payment methodology provided by the rule is applicable, IHS has included a provision in 136.203(a)(3) that authorizes payment at 65% of authorized charges." [81 FR 14979] |
| | | | 136.201(a) cites Medicare-Like Rates as the highest rates IHS could pay, and this lack of discretion renders this provision unworkable in many areas in Indian country; IHS should allow I/T/Us the discretion and flexibility to deal with unique circumstances that might necessitate negotiating a rate different from, or even higher than, the Medicare-Like Rate by adding the following sections to the rule: | |
| | | | a. Section 136.201(b)(1): This section, which would apply to Tribes and tribal organizations that have negotiated agreements with IHS under the Indian Self-Determination and Education Act and urban Indian organizations, would make clear that they have the right to choose not to apply the rule; and | a. Accepted in part. IHS noted, "IHS agrees with Tribal stakeholders that Tribal health programs should have the option to administer PRC programs outside of the rule. Rather than memorialize this option as an opt-out clause, IHS is finalizing the recommendation as an opt-in provision in section 136.201. The opt-in provision is intended to be consistent with 25 U.S.C. 458aaa-16(e), which |



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| | | | b. Section 136.201(b) (2): This section would allow I/T/Us, when necessary, to negotiate a rate with providers higher than the rate provided for in Section 136.201(a), capping the rate at no more than what the provider charges non-governmental entities, including insurance providers, for the same service. | provides, with certain exceptions, that Tribes are not subject to rules adopted by the IHS unless they are expressly agreed to by the Tribe in their compact, contract, or funding agreement with IHS. Although 25 U.S.C. 458aaa-16(e) only expressly applies to Tribes compacted under Title V of the ISDEAA, IHS is extending opt-in flexibility to Tribes contracted under Title I of the ISDEAA too. IHS is not incorporating a comparable provision allowing urban Indian health programs to opt-in or opt-out of the requirements of the rule. Urban Indian health programs are funded through procurement contracts or grants with IHS, not ISDEAA contracts, and the principles underlying self-determination and the opt-in flexibility do not extend to such agreements" (emphasis added). [81 FR 14979] • b. Accepted in part. IHS stated, "IHS agrees with commenters that more flexibility must be built into the rule. IHS also agrees with Tribal stakeholders that Tribes should be provided more flexibility to negotiate rates that exceed Medicare rates and agrees that controls should be put into place to ensure that negotiated rates remain fair and reasonable. Section 136.203 provides that, if a specific amount has been negotiated with a specific provider or supplier or its agent by the I/T/U, the I/T/U |



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| | | | 4. Tribal Consultation : The proposed rule would have significant tribal implications and substantial direct effects on one or more Tribes; IHS should engage in tribal consultation before finalizing the rule. | will pay that amount, provided such amount is equal to or better than the provider or supplier's MFC rate, as evidenced by commercial price lists or paid invoices and other related pricing and discount data, to ensure the I/T/U is receiving a fair and reasonable pricing arrangement. Further, the MFC rate does not apply if the I/T/U determines the prices offered to the I/T/U are fair and reasonable and the purchase of the service is otherwise in the best interest of the I/T/U. It will be incumbent on the provider of services to provide the necessary documentation to ensure the rates charged are fair and reasonable." [81 FR 14978-9] 4. Tribal Consultation: Accepted in part. According to IHS, "IHS consulted with Tribes, during listening sessions and other meetings, on whether Tribes thought IHS should pursue applying PRC rates for nonhospital-based services. It has been noted that, while these interactions indicated that regulations may have been a good idea, the level of discussion did not get into the complexities of developing a regulation and how such regulations would impact Tribes given the variation in access to specialty care and the number of hospitals across the Indian health system. IHS recognizes that specific provisions of the rule were not developed in consultation with Tribes. In the development of this final rule, however, IHS has collaborated significantly with the Director's PRC Workgroup. The PRC workgroup is composed of technical experts who have a deep |



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| | | | Definition of Referral: In the final rule, IHS at § 136.202 defined a "referral" as "an authorization for medical care by the appropriate ordering official in accordance with 42 CFR part 136 subpart C," but this subpart makes reference to a purchase order, which constitutes an "authorization for payment," not a "referral for services"; the agency should define both the terms "referral for services" and "authorization for payment," clarifying that a referral for services occurs without regard to whether IHS makes a commitment for payment. Opt-In Method: IHS at §136.201 added an applicability provision to specify that the final rule applies to IHS-operated CHS/PRC programs, urban Indian health programs, and tribally operated programs opt-in to the requirements of the rule, with this decision expected to occur through a | understanding of the complexities of administering PRC programs. The rule has been revised to provide the flexibility many Tribal stakeholders have requested, and as finalized, will not apply to any Tribally-operated PRC program until it elects to opt-in in accordance with § 136.201. IHS recognizes that these steps may not relieve all concerns regarding Tribal consultation. Accordingly, IHS is also publishing this final rule with a comment period in which to receive additional feedback from stakeholders, to determine whether any revisions should be made to the rule" (emphasis added). [81 FR 14980] No subsequent Agency action taken (as of 10/31/2016). |



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| | | | modification to the existing annual funding agreement of a Tribea complicated process that requires agency approval; to address these issues, IHS should make the opt-in method as simple as a Tribe sending a letter to notify the agency of its decision to opt-in to the requirements of the final rule and should include a notification process to opt-out of the rule if a CHS/PRC program has included an opt-in proviso in its annual funding agreement. | |
| 112.m. | Dear Tribal Leader Letter (Contract Support Costs Policy) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) Issue Date: 1/7/2016 Due Date: Open NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revised policy 4/11/2016 Due Date: 60 | Duplication Issue: Much of the new content in the Contract Support Costs (CSC) policy concerns the controversial "duplication" issuei.e., how to account for costs requested as CSC that might duplicate amounts already transferred by IHSwith footnote 1 on page 9 and footnote 10 on page 41 summarizing the competing agency and tribal views on this issue; the final CSC policy should either adopt the tribal position on this issue (i.e., nothing in the ISDEAA disqualifies any category of costs for consideration as CSC, as long as a given type of cost meets the definitional provisions set forth in 25 U.S.C. § 450j-1(a)(3), where the duplication provision appears) or retain these footnotes unchanged. Duplication in Recurring Service Unit Tribal Shares: The CSC policy provides an optional (and prospective) provision under which 3% of Recurring Service Unit Tribal Shares would constitute a duplication of CSC amounts otherwise due (page 18); IHS should adopt this provision, with the following caveats: | No subsequent Agency action taken (as of 10/31/2016). |



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| | | days (approx. 6/10/2016) NIHB File Date: 6/10/2016 | a. Grandfathering in Existing Agreements: This provision should grandfather in existing and longstanding agreements over contracted amounts (including existing agreements about duplicated amounts or the lack thereof) and apply only (1) to new or expanded programs; (2) where new costs are placed into the indirect cost pool of a Tribe, causing the pool to grow by more than 2% for that reason; or (3) to past ongoing contracted operations where the Tribe chooses to negotiate a new amount with IHS. b. Clarification of "2% in the Value of the IDC pool": IHS should explain the term "2% in the value of the IDC pool" at the top of page 18, since this provision as written could indicate a change in the pool leading to an increase in an indirect cost rate exceeding 2 percentage points (i.e., from a 30% rate to a rate in excess of 32%), rather than an increase in the size of the pool exceeding 2% of the value of the pool. c. Interpretation of "New Type" of Cost: In deciding whether a cost constitutes a "new type" so as to trigger a detailed duplication analysis (or the 3% offset), IHS should interpret this phrase liberally in favor of the awardee, in accordance with the letter and spirit of ISDEAA. d. Avoiding Disproportionate Impact on Tribes with Low Rates: Tribes with low indirect cost rates necessarily have few costs in their pools and therefore less duplication, but this provision makes no accommodation to such Tribes | |



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| | | | Startup and Pre-Award Costs (page 12): If IHS retains compromise provisions calling for a post year-end tribal self-certification that Tribes have spent startup costs on negotiated startup activities and provisions stating that Tribes can either repay excess startup costs or apply them to the CSC requirement for the subsequent year, the agency should revise these provisions to allow Tribes to apply any excess funds to health care. Direct Contract Support Costs (DCSC) (pages 12-14; and pages 58 and 59): | |
| | | | a. Renegotiation of DCSC: IHS should retain provisions retaining DCSC costs as recurring costs, subject to an inflationary adjustment, and calling for renegotiation only in limited circumstances. b. Inflation adjustment: IHS should switch the inflationary adjustment to a medical inflation rate (as discussed in footnote 2, page 13) and make this change in 2016. c. Identification of Additional Permissible DCSC Item: Examples of DCSCs appear in the standards for the review and approval of CSC in Manual Exhibit 6-3-G, and in the tables on pages 58 and 59, items permissible for inclusion in the DCSC calculations as fringe costs are shown; IHS should add payments made to satisfy federal employer shared responsibility requirements under section 4980H of the Internal Revenue Code (Code) for applicable employees (added to the Code by ACA) as an example of allowable fringe costs under DCSCs. | |



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| | | | a. Negotiating Estimated Indirect CSC Requirement at Front End: Given IHS insistence upon an "incurred cost" approach to estimating and paying CSC requirements, the agency assumption of the calculation of CSC based on the entire contracted amount if at least that much in total tribal health care funding (from whatever source) was spent in the preceding year would limit the adverse impact on Tribes; IHS should retain this assumption if it does not return to its past practice of simply calculating CSC on the contracted amount for the current year. b. Negotiating Final Indirect CSC Requirement After Year End: Because IHS has seized upon the "incurred cost" approach, the agency has discussed in recent years waiting as long as 5 years to reconcile final CSC requirements against not only full audits, but subsequent indirect cost rate carryover schedules issued two and even four years out; IHS should return to a policy of negotiating final amounts for each year within 90 days of the end of that contract year based on the best available data at the time. c. Aged IDC Rates: The compromise approach that IHS developed to permit close-out of the CSC negotiation process within a few months after the close of the contract year poses some concerns; IHS should carefully monitor the impact of this policy. d. Bilateral amendments: The new practice of doing | |



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| | | | post-year bilateral amendments to reflect finally- negotiated CSC amounts (pages 16-17) would impose a substantial additional burden upon IHS, as well as tribal, personnel; IHS should take this increased burden into account. • e. Overpayments: When the parties agree that the awardee has received an overpayment, the policy provides that the awardee must either pay back IHS or IHS will apply the overpayment to the CSC need of the awardee in the subsequent year; IHS should recognize the right of the Tribe to apply the "overpayment" to direct services, such as health care, and failing that, to ensure right of the Tribe to decide on the handling of the overpayment, should revise the last sentence of section 6-3.2E.1.b.6 (page 17) to read as follows (new language underlined; removed language in strikethrough): "If the awardee was overpaid, the awardee will have the option to either (a) it will reimburse IHS for the overpayment; or, (b) agree that IHS will apply the overpayment to the awardee's CSC need in the subsequent year." | |
| | | | 6. Negotiating Indirect-like Costs (pages 17, 57): IHS should retain language on page 17 and in Exhibit H (page 57 and footnote 14) recognizing the right of a Tribe to negotiate indirect-like costs even if the Tribe also receives indirect CSC amounts as a result of having an indirect cost rate. 7. Annual Funding Report to Tribes (pages 23-24): IHS should retain its clarification that it will produce a funding report independent of any reports due to Congress and that it will provide its funding report to Tribes annually regardless of | |



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| | Title/Agency | | any delays associated with issuance of any congressional report. 8. CSC on Federal Programs, Services, Functions or Activities Supported with Third- Party Revenues: The CSC policy remains neutral on the disputed issue of whether IHS by law must add CSC funding to support the delivery of federal programs, services, functions, or activities financed with third-party revenues (page 55, note 12), as well as on MSPI/SASP, DVPI, and CHEF funds; IHS should retain this position. 9. Impact on Ratemaking Process: The CSC policy affects not only awardee relationships with IHS, but also with the cognizant agencies charged with negotiating indirect cost rates, in turn affecting relationships with every other federal agency with which awardees interact; IHS should consider how these agencies would deal with the CSC policy treatment of overpayments during the year-end reconciliation process. 10. Training: The CSC policy is so long, complex, and daunting that non-expert tribal leaders and staff—not to mention IHS negotiators—likely would have difficulty understanding and applying it; IHS should develop a thorough and thoughtful training curriculum for both tribal and IHS personnel, with input from the CSC Workgroup on the best ways to make the necessary training available. | |
| | | | 11. Calculation Template: IHS and tribal representatives have reached agreement on a summary worksheet showing the basic math behind the CSC calculation process (Exhibit F, page 37), but the various tabs that feed into the summary sheet (part of an Excel workbook) are not included because of a lack of agreement of them; IHS should make the | |



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| | | | negotiation of these tabs its highest priority. | |
| 112.n. | Catastrophic Health Emergency Fund ACTION: Proposed Rule NOTICE: Catastrophic Health Emergency Fund AGENCY: IHS | IHS RIN 0905- AC97 Issue Date: 1/26/2016 Due Date: 3/11/2016 4/11/2016 5/10/2016 Open (until at least 10/24/2016) TSGAC File Date: 5/10/2016, 10/28/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/25/2016, 3/11/3016; | TSGAC recommendations (5/10/2016, additional subsequent recommendations appear below) Tribal Sources of Payment as "Alternative Resources": In the proposed rule, sections 136.501 and 136.506 would include tribal sources of payment as "alternate resources" to CHEF, exceeding the rulemaking authority of the HHS Secretary to adopt regulations governing the CHEF program and marking a major, unacceptable departure from longstanding IHS policy; the agency should revise these sections to address these issues. Definition of "Purchased/Referred Care (PRC)": The proposed definition of the term "PRC" includes the word "referral" and, by doing so, confuses the distinction between a referral for services and an authorization for payment; to address this issue, for purposes of the operation of the CHEF program, the agency should modify the definition of PRC in this proposed rule as follows: "6. Purchased/Referred Care (PRC)any health service that is(a) delivered based on an authorization for payment of an Indian health care program delivered based on a referral by, or at the expense of, an Indian health program; and (b) provided by a public or private medical provider or hospital which is not a provider or hospital of the IHS health program." Lack of Procedure Governing the Awarding of CHEF | No subsequent Agency action taken (as of 10/31/2016). Although IHS has not taken subsequent action on these recommendations, on 6/1/2016, the agency issued a Dear Tribal Leader Letter announcing tribal consultation on this proposed rule. IHS will not move forward with this proposed rule until tribal consultation has occurred, including an inperson consultation session at NCAI on 10/9-14/2016 in Phoenix, AZ. This letter comes in response to numerous requests from Tribes and tribal organizations to conduct tribal consultation before finalizing the rule (see #4 in the column to the left). |



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| | | issued tribal consultation notice 6/1/2016, 7/29/2016 (comment period reopened) | Funds: The proposed rule does not establish a procedure for making a determination to award CHEF funds, leaving the decision to award or not award CHEF funds in a particular case entirely at the discretion of IHS; the agency should create procedures to guide both the CHEF award-making and submission processes. Tribal Consultation: IHS developed and published the proposed rule without first consulting with Tribes as required by Executive Order (E.O.) 13175 and HHS policies, including those of IHS; HHS should suspend any further action on the proposed rule until it and IHS have carried out meaningful consultation with Tribes and tribal organizations as required by E.O. 13175 and departmental policies. TSGAC recommendations (10/28/2016) Definition of Alternate Resources: IHS should remove "Tribal" from the list of primary payers in the "alternate resource" definition, as the inclusion of tribal self-insurance (or other resources) as an alternate resource prior to CHEF reimbursement is not appropriate. Reimbursement Procedure: The procedure for reimbursement set out in the proposed rule does not provide any criteria or procedure for how Purchased and Referred Care (PRC) directors will review CHEF claims or how IHS headquarters will determine whether alternate resources exist, leaving determinations entirely to the discretion of Area Office PRC programs and IHS headquarters; to address this lack of transparency, IHS should ensure that the procedures for governing the reimbursement of CHEF funds include procedures guiding the award process, as well as the | |



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| | | | submission process. 3. Distinction Between Referral vs. Authorization for Payment: The proposed definition of PRC includes the word "referral" and, by doing so, confuses the distinction between a referral for services and an authorization for payment; to facilitate the effective implementation of the ACA cost-sharing protections, IHS should make a clear distinction between a referral for services and an authorization for payment. | |
| 112.p. | FDA Tribal Consultation Policy ACTION: Notice NOTICE: U.S. Department Of Health And Human Services Food And Drug Administration Tribal Consultation Policy (Draft) AGENCY: FDA | FDA (no reference number) Issue Date: 2/29/2016 Due Date: 5/31/2016 NIHB File Date: 5/31/2016 Date of Subsequent Agency Action, if any: | Definition of "Critical Event": The FDA tribal consultation process revolves around the identification and communication of "critical events" that have tribal implications, followed by open interactions between affected Tribes and the agency, eventually leading to a joint resolution; FDA, in conjunction with Tribes, should clearly define the parameters of what constitutes a "critical event," as in many cases what the agency might consider insignificant might prove imperative to Tribes. Separate Office for Tribal Consultation: FDA currently houses tribal, state, and territorial relations within its Office of Intergovernmental Affairs, an arrangement not always inclusive of Tribes, especially given the often turbulent relationship between Tribes and states; FDA should establish a separate office specifically demarcated for consultation with tribal governments, inter-tribal organizations, or other representative bodies authorized to speak on behalf of their tribal constituents. | No subsequent Agency action taken (as of 10/31/2016). |



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| | | | 3. Barriers to Adequate Tribal Consultation: Given the significant controversies that arose around the perceived lack of tribal consultation before the passage of the Food Safety Modernization Act (FSMA), a need exists for proactive measures to ensure that timely, appropriate, and comprehensive consultation occurs prior to enacting new legislation; in its tribal consultation process, FDA should take into account the barriers within Indian Country, including limited access to electronic forms of communication due to lack of IT infrastructure, lack of awareness or education around how the consultation process works, or inability to prepare comments by a fixed deadline. | |
| 112.q. | Recognition of Tribal Groups for Representation of VA Claimants ACTION: Request for Information Proposed Rule NOTICE: Recognition of Tribal Organizations for Representation of VA Claimants AGENCY: VA | VA RIN 2900-AP51 Issue Date: 3/10/2016 Due Date: 4/11/2016 NIHB File Date: 4/11/2016 Date of Subsequent Agency Action, if any: Issued Proposed Rule | NIHB recommendations Eligibility of Tribal Governments for Recognition as a Veterans Service Organization (VSO): If VA seeks to "address the needs of Native American populations who are geographically isolated from existing recognized" VSOs, it should clarify that tribal governments, including veterans departments within these governments, qualify for recognition as a VSO. Requirements for Tribal Organizations Becoming | In the 7/15/2016 Proposed Rule Eligibility of Tribal Governments for Recognition as a Veterans Service Organization (VSO): Accepted in part. VA stated, "A Department of Veterans Affairs or a Veterans Affairs office that is established and funded by a tribal government would be included in the definition of tribal organization. Therefore, no change to this rulemaking is warranted based on these comments." [81 FR 47092] However, VA did not offer a clarification for tribal governments generally and did not adopt related requests to include "tribal government" in the definition of "tribal organization." Requirements for Tribal Organizations Becoming |



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| | | 7/15/2016 <u>Due Date:</u> 9/13/2016 | Recognized as a VSO: A significant number of tribal organizations will not have the ability meet the requirements outlined in 38 CFR 14.628(d) for becoming recognized as a VSO, as these requirements do not align with the inherent responsibilities of tribal nations; VA should amend these requirements to address gaps for Al/AN veterans and to better fit the unique circumstances of how tribal nations serve their veterans. | Recognized as a VSO: Not accepted. VA stated, "Exempting tribal organizations from meeting the § 14.628(d) requirements would not be consistent with the purpose of VA recognition to ensure that veterans are receiving qualified, competent representation on their VA benefit claims. As previously discussed, VA has provided additional means to achieve VA recognition or accreditation for those tribal governments that may have difficulty establishing a tribal organization capable of meeting the § 14.628(d) requirements, to include the ability for one or more tribal governments to establish and fund a tribal organization and the ability of an employee of a tribal government to become accredited as a tribal veterans' service officer through a recognized State organization. Therefore, VA makes no changes based on these comments." [81 FR 47092] |
| | | | Requirement on "Sizable" Number of Veterans: VA should clarify what measurement would constitute a "sizable" number of veterans or eliminate this requirement for recognizing tribal nations and tribal organizations as a VSO, as some Tribes have smaller governments and fewer resources than others. Requirement on Commitment of "Significant Portion" of Assets: Tribal governments, which have inherent authority to delegate funding based on the needs of their citizens, cannot comply with the requirement that tribal nations "commit a significant portion of its assets to veterans' services" to become recognized as a VSO, as they provide many types of different services to their citizens; VA should waive this | Requirement on "Sizable" Number of Veterans: Not accepted. VA did not address this issue. Requirement on Commitment of "Significant Portion" of Assets: Not accepted. VA did not address this issue. |



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| | | | requirement or clarify a narrow application of this language, in consultation with tribal nations. 5. Tribal Consultation: Prior to the rulemaking process, VA should engage in additional tribal consultation with Tribes that have an interest in becoming recognized as a VSO but cannot meet the requirements, as well as hold an All Tribes Call to inform fully, update, and gather input from Tribes on its proposal to update its regulations to recognize tribal organizations for representation of VA claimants. | 5. Tribal Consultation : Not accepted. VA stated, "VA extended the comment period for an additional 15 days to ensure that all interested parties had an appropriate time to provide input. Therefore, VA finds that it has complied with the requirements of Executive Order 13175. VA notes that an additional 60-day comment period is provided for this proposed rule and invites any additional comment to this rulemaking to be provided during that time." [81 FR 47093] |
| 112.s. | Dear Tribal Leader Letter (Community Health Aides) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) Issue Date: 6/1/2016 Due Date: 7/29/2016 10/27/2016 NIHB File Date: 10/27/2016 Date of Subsequent | NIHB recommendations TBE | No subsequent Agency action taken (as of 10/31/2016). |



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| | | Agency Action, if any: Issued due date extension 7/29/2016 | | |
| 112.u. | Dear Tribal Leader Letter (Tribal Premium Sponsorship) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) Issue Date: 7/18/2016 Due Date: 8/17/2016 10/31/2016 TSGAC File Date: 10/28/2016 Date of Subsequent Agency Action, if any: Issued due date extension 7/29/2016 | TSGAG recommendations The draft Circular seeks to provide further detailed guidance to IHS Area Offices regarding the current IHS policy if IHS, Tribes or tribal organizations, or an urban Indian organization (I/T/U) wishes to purchase coverage for IHS beneficiaries with funding provided under the Indian Self-Determination and Education Assistance Act (ISDEAA) or the Indian Health Care Improvement Act (IHCIA), but as drafted, the proposal might unreasonably prevent IHS and participating Tribes from exercising full authorities available in ISDEAA and IHCIA; to address these concerns, IHS should: • Withdraw the draft Circular; • Rescind the October 24, 2013, Dear Tribal Leader Letter, which incorrectly interpreted section 402(b) of IHCIA (as added by section 152 of the Indian Health Care Reauthorization and Extension Act of 2009); and • Coordinate through a workgroup comprised of I/T/U representatives (appointed by TSGAC, the Direct Service Tribes Advisory Committee, and IHS) to make recommendations to IHS to address the issues raised in the Draft Circular and other Sponsorship-related issues, including determining the preferred mechanism(s) for | No subsequent Agency action taken (as of 10/31/2016). |



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| | | | providing guidance to the I/T/U programs on Sponsorship. | |
| 112.v. | Dear Tribal Leader Letter (Consultation on Tribal Priorities) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: VA | VA (no reference number) Issue Date: 5/19/2016 Due Date: 10/7/2016 NIHB File Date: 10/7/2016 Date of Subsequent Agency Action, if any: | NIHB recommendations 1. Tribal Priorities: VA seeks information on the top 3 to 5 priorities that Tribes have for serving veterans in Indian Country and plans to use this information to assist with the collaborative development of an Indian Country Veterans Affairs policy agenda; VA should consider the following priorities: a. Priority 1Creation of a VA Tribal Technical Advisory Health Care Committee: VA should create this committee to properly ensure that the department fulfills its trust responsibility to Al/ANs in a culturally competent manner and continues to meet the requirements of meaningful tribal consultation. b. Priority 2Improve Access to Medical Care: VA should provide additional outreach and advocacy resources to ensure that Al/AN veterans are aware of various health care benefits available in their community c. Priority 3VA and Tribal/IHS Facilities Working Together: VA should fully implement the 2010 national VA, IHS, and Tribal Health Programs (THPs) memorandum of understanding (MOU). d. Priority 4VA Support of Traditional Healing Providers and Treatments: VA should include traditional treatment approachessuch as herbal remedies, purification ceremonies, empowering rituals, sweat lodges, and dream interpretationsin | No subsequent Agency action taken (as of 10/31/2016). |



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| | | | consideration of how the culture of trauma patients might impact what and how they experience their trauma. e. Priority 5Suicide Prevention: VA should expand its use of telemental health care to reach Al/AN veterans with post-traumatic stress disorder (PTSD) and other mental health care needs. f. Priority 6Treatment for PTSD and Mental Health: VA should utilize innovative culturally-based approaches to treatment, such as acculturation assessments to allow for culturally competent providers to assess the cultural identity of a patient. | |
| 112.x. | Dear Tribal Leader Letter (IHS Draft Quality Framework) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS | IHS (no reference number) Issue Date: 7/20/2016 Due Date: 9/19/2016 NIHB File Date: 10/3/2016 Date of Subsequent Agency Action, | NIHB recommendations Tribal Priorities: The IHS Quality Framework outlines two goals: (1) improve health outcomes for patients receiving care and (2) provide a care delivery service all patients trust; to help meet these goals, IHS should address the following priorities: Priority 1Strengthen Organizational Capacity to Improve Quality of Care and Systems: IHS should strengthen recruitment and retention of highly qualified clinicians, providers, and administrators, as effective communication between IHS Headquarters and the Service Units will serve as an important part of successful implementation of the Draft Quality Framework; the agency also should provide better provider network coordination and processes for | No subsequent Agency action taken (as of 10/31/2016). |



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| | | if any: Issued due date extension 9/15/2016 | repayment and include access to necessary medical equipment and supplies for Service Units to fulfill greater patient safety and quality of care. • b. Priority 2Meet and Maintain Accreditation for IHS Direct Service Facilities: IHS should adequately communicate the reports and quality of care incidents, sharing the information with Tribes, and take actions to alter procedures and behaviors with input and reporting to Tribes; the agency also should build a continuous survey readiness process and create a learning environment to highlight the best practices to ensure accreditation standards get met throughout the year. • c. Priority 3Align Service Delivery Processes to Improve Patient Experience: IHS should create an incentivized program for providers to strive for cultural competency, as well as utilize the Indian Preference Policy to ensure that applicants possess cultural competency; the agency also should make available online a system-wide repository of policies and procedures for all facilities, reviewing this repository on an annual basis and permitting feedback from Tribes. • d. Priority 4Ensure Patient Safety: IHS should have an effective safety event reporting and identification system to reduce adverse events and risks to patient safety and utilize best practices and approaches currently operating in other health care systems to reduce health care associated infections. • e. Priority 5Improve Processes and Strengthen Communications for Early Identification of Risks: IHS should identify and standardize quality | |



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| | | | management measures publicly on a quarterly basis and implement a review process for accountability similar to the VA Strategic Analytics for Improvement and Learning (SAIL) Program, aligning quality measures with established data measures already required of all health care facilities; the agency also should strive for transparency in partnership with Tribes and tribal organizations to improve access and quality of care throughout the Indian Health System. | |
| 136.c. | PQRS and the eRx Incentive Program Data Assessment ACTION: Request for Comment NOTICE: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support | CMS-10519 Issue Date: 3/17/2014 Due Date: 5/16/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/8/2014; issued revision 9/25/2015, 1/29/2016 | Treatment of I/T/Us: In this PRA notice, CMS indicated that it plans to use this information collection to "evaluate incentive payment information for accuracy and identify improper payments, with the goal of recovering these payments" to avoid future data integrity issues, but recovering past payments would pose an undue burden on I/T/Us, which already are chronically underfunded; as such, CMS should insulate I/T/Us from attempts to recover past payments that the agency made in error. Tribal Consultation: CMS should consult with Tribes regarding this information collection and the uses to which it intends to put the data gathered. | No subsequent Agency action taken (as of 10/31/2016). |



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| | AGENCY: CMS | <u>Due Date</u> : 10/6/2014; 11/24/2015; 2/29/2016 <u>TTAG File</u> <u>Date</u> : 2/29/2016 | | |
| 136.e. | Requirements for Reporting Quality Measures ACTION: Request for Information NOTICE: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs AGENCY: CMS | CMS-3323-NC Issue Date: 12/31/2016 Due Date: 2/1/2016 2/16/2016 NIHB File Date: 2/1/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/2/2016 | Policy Option 3/Option A: Option 3 would require eligible professional (EP) health IT developers to certify health IT products to more than the current minimum number of clinical quality measures (CQMs) required for reporting, but not to all available CQMs, and within Option 3, Option A would set a minimum number of measures to which health IT developers must certify for the EP settings or eligible hospital/critical access hospital (CAH) settings, with this minimum number greater than the minimum number required for provider reporting; CMS should adopt Option 3/Option A, which provides a benefit to both providers and health IT vendors by meeting the needs of consumers and allowing vendors flexibility to provide a product to meet their targeted consumer population, and should set the minimum number of EP measures at 15 and the minimum number of eligible hospital/CAH measures at 20. Policy Option 1: Option 1 would require EP health IT developers to certify Health IT Modules to all CQMs in the | No subsequent Agency action taken (as of 10/31/2016). |



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| | | | EP selection list and would require eligible hospital/CAH health IT developers to certify to all CQMs in the selection list for eligible hospitals and CAHs; CMS should not adopt Option 1, which would prove impractical because not all measures apply to EPs and eligible hospitals in Indian Country and would lead to an increase in development, testing, and certification time. 3. Policy Option 2: Option 2 would incrementally increase the number of CQMs required to have certification each year until Health IT Modules have certification for all CQMs available for reporting by EPs, eligible hospitals, and CAHs to meet their CQM reporting requirements; although Option 2 provides more time to develop all the measures in which the requirements would become effective beyond the first year, CMS should not adopt this option, as CQM measures that do not apply to the provider population would require maintenance by health IT developers. | |
| 136.g. | CMS Quality Measure Development Plan ACTION: Guidance NOTICE: CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based | CMS (no reference number) Issue Date: 12/18/2016 Due Date: 3/1/2016 NIHB File Date: 3/18/2016 | 1. Quality Measure Development: CMS should • a. Apply the National Quality Forum (NQF) Rural Health Committee report on Performance Measurement for Rural Low Volume Providers to quality measure development for Indian Country, make participation by rural providers in agency quality measurement and quality improvement programs flexible, and reconsider exclusions for existing quality measures for rural providers; | In the 5/2/2016 Final Guidance 1. Quality Measure Development: • a. Accepted in part. CMS noted that it would seek to develop quality measures "appropriate for low-volume clinicians (e.g., rural providers, small and independently owned physician practices)." [page 10]. In addition, CMS indicated that it would consider recommendations in the report on <i>Performance Measurement for Rural</i> |



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| | Incentive Payment System (MIPS) and Alternative Payment Models (APMs) (DRAFT) AGENCY: CMS | Date of Subsequent Agency Action, if any: Issued Final Guidance 5/2/2016 | b. Develop new patient experience surveys for implementation across multiple programs and settings of care to understand and measure the patient and caregiver experience, with a focus on minimizing the patient and provider burden in implementing and responding to the surveys; | Low Volume Providers in the development of quality measures and "consider the inclusion of rural and low-volume clinicians on measure development technical expert panels, when appropriate." [page 21]. CMS did not specifically discuss the development of quality measures for Indian Country. b. Accepted. CMS stated, "CMS will continue to develop new patient experience surveys to ensure that these important measures of quality encompass all care settings and providers (e.g., specialists). CMS will also refine existing patient experience surveys based on stakeholder feedback to incorporate additional topics that are important to patients and families/caregivers (e.g., knowledge, skill, and confidence for self-management and whether the provider acted in accordance with the person's preferences; participation of family members in care discussions or electronic communications; accurate documentation of family members who are authorized decision-makers). CMS will explore incorporating an assessment of cultural competency and perspectives of minority and vulnerable populations (e.g., individuals with limited English proficiency, low health literacy, mobility impairments, or other disabilities). CMS will balance the effort to obtain important information with the need to minimize burden to patients and clinicians in implementing and |



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| | | | c. Collaborate with Al/AN groups and associations to develop quantifiable measures important to both patients and providers within Indian Country to reflect the health of the Al/AN population; and d. For Electronic Health Record (EHR) Incentive Program quality measures within the domain of efficiency and cost reduction, consider the differences of reporting clinical quality measures through the Government Performance and Results Act (GPRA) and the Common Reporting Standard (CRS) reporting, as these differences have a large impact on the I/T/U health care delivery system. Tribal Consultation: CMS should seek early and frequent input from Tribes in the development process of quality measures to fulfill its tribal consultation policy, as well as its mission to improve access and quality of health care delivery for Al/ANs. | responding to the surveys." [page 39] c. Not accepted. CMS did not address this issue. d. Not accepted. CMS did not address this issue. 2. Tribal Consultation: Not accepted. CMS did not address this issue. |
| 136.h. | MIPS and Alternative Payment Model Incentive Under PFS ACTION: Proposed Final Rule | CMS-5517- PFC <u>Issue Date:</u> 5/9/2016 <u>Due Date:</u> 6/27/2016 | 1. Cost of Compliance and Need for Federal Support: The cost of compliance with the reporting, technology, and care coordination requirements in the proposed rule might prove prohibitive for many I/T/Us; either through funding, assistance, and/or exemptions, CMS should address this issue to ensure that I/T/Us do not have to divert funding that would otherwise go toward health care programs and | In the 11/4/2017 Final Rule 1. Cost of Compliance and Need for Federal Support: Accepted in part. CMS stated, "In keeping with the objectives of providing education about the program and maximizing participation, and as mandated by the MACRA, \$100 million in technical assistance will be available to MIPS eligible clinicians in |



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| | NOTICE: Medicare Program; Merit- Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models AGENCY: CMS | NIHB File Date: 6/27/2016; TTAG also filed comments 6/27/2016 Date of Subsequent Agency Action, if any: Issued Final Rule 11/4/2016 Due Date: 12/19/2016 | 2. Low-Volume Threshold Exclusion: The proposed low-volume threshold exclusion raises concerns, as many eligible clinicians (ECs) might bill less than \$10,000 in Medicare allowable charges, if the allowable charges are specific to the Part B physician fee schedule (PFS); CMS should For providers not participating in an ACO, clarify whether the low-volume threshold includes the rural health clinic (RHC) all-inclusive rates (AIR) or FQHC PPS (preferred) or whether it excludes these other payment methodologies; For providers that change positions frequently or work as locums tenans, clarify whether the low-volume threshold will be cumulative throughout the year as they bill under different TINs or will be specific to an NPI/TIN combination (preferred). | small practices, rural areas, and practices located in geographic health professional shortage areas (HPSAs), including IHS, tribal, and urban Indian clinics, through contracts with quality improvement organizations, regional health collaboratives, and others to offer guidance and assistance to MIPS eligible clinicians in practices of 15 or fewer MIPS eligible clinicians." [page 21] 2. Low-Volume Threshold Exclusion: Accepted. CMS noted that "we are modifying our proposed low-volume threshold to be based on a dollar value of \$30,000 of billed Medicare Part B allowed charges during a performance period or 100 Part B-enrolled beneficiary count, which would apply to clinicians in RHCs and FQHCs with billed Medicare Part B allowed charges." [page 243] In addition, CMS stated, "In sections II.E.2.a. and II.E.2.b. of this final rule with comment period, we describe the identifiers for MIPS eligible clinicians participating in MIPS at the individual or group level. For MIPS eligible clinicians reporting as individuals, we use a combination of billing TIN/NPI as the identifier to assess performance. In order to determine the low-volume status of eligible clinicians reporting individually, we will calculate the low-volume threshold for each TIN/NPI combination. For individual MIPS eligible clinicians billing under multiple TINs, the low-volume threshold is calculated for each TIN/NPI combination. In the case of an individual eligible clinician exceeding the low-volume threshold under any TIN/NPI combination, the eligible clinician would be considered a MIPS eligible clinician and required to meet the MIPS |



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| | | | 3. Need for IHS/Tribal-Specific Data: The regulatory impact analysis of the proposed rule indicates that CMS has estimated the number of physicians and other professionals that will receive a CPS score in MIPS Year 1, and the number that will get excluded as QPs, but whether this estimate included a category for clinicians who serve Al/AN Medicare beneficiaries remains uncertain; if yes, CMS should share this information with the TTAG, IHS, Tribes, and urban Indian programs, and if no, the agency should add this category in future studies (as well as provide a category or function for comparing IHS, tribal, and urban Indian providers only on the Physician Compare Web site). 4. Scoring and Payment Adjustments: The scoring formula and payment adjustment process must account for the unique position of tribal and urban Indian health programs; to that end, CMS should address the following concerns: a. Fairness: Ensure that the scoring system and weighting of performance categories remains fair, particularly in the absence of available data for one or more category; b. Special Rules for Indian Health Programs: Potentially establish special rules for IHS, tribal, and urban Indian health programs to avoid adverse results; c. Emergency Preparedness and Response Sub-Category: Clarify this sub-category, possibly adding | requirements for those TIN/NPI combinations." [page 243-4] 3. Need for IHS/Tribal-Specific Data: Not accepted. However, CMS indicated that, "if feasible and appropriate under the statute, we may possibly consider these issues in future rulemaking and will conduct tribal consultation with tribes and tribal officials, as feasible and appropriate." [page 1514] 4. Scoring and Payment Adjustments: Not accepted. CMS stated, "We appreciate the unique challenges that face MIPS eligible clinicians that are part of IHS, Tribal, and Urban Indian health programs. We considered creating different performance criteria for certain types of clinicians; however, we believe that approach would create more confusion and burden than a cohesive set of criteria. Rather, to ease the participation burden, we have reduced the performance threshold to 3 points for the transition year only, which provides a pathway for MIPS eligible clinicians to engage in MIPS. We are also committed to continuing to work with IHS and its partners to streamline and coordinate programs where possible." [page 1271] |



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| | | | language including the Commissioned Corps of the United States Public Health Service (USPHS) officers, who Indian health programs often employ, in the definition of active duty military MIPS eligible clinicians; • d. Advancing Care Information Category: With regard to this category, take into consideration how the high level of staff turnover experienced in Indian Country might impact its ability to meet group reporting requirements, as well as how to accommodate frequent changes in the group of MIPS Eligible Clinicians; implement the proposed method of estimating the proportion of physicians as defined in section 1861(r) who are meaningful EHR users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of at least 75 percent under the proposed scoring methodology for a performance period; avoid removing the Broadband Access Exclusion as written in the "Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017" final rule for the two measures that require providers to have broadband access. | |
| | | | 5. Utilize Existing Reporting Measures/Systems: The proposed rule provides for the annual selection of quality measures through a call for quality measures process, with the selection of measures based on certain criteria that align with CMS priorities; CMS should accept the Government Performance Results Act (GPRA) measures that Tribes and urban Indian health program already must report to avoid | 5. Utilize Existing Reporting Measures/Systems: Accepted in part. CMS stated, "There are many GPRA measures that are similar to measures that already exist within the program. In addition, some GPRA measures are similar to measures that are part of a CQMC core measure set. We strive to lessen duplication of measures and to align with measures |



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| | | | duplication of effort and to lessen the burden on I/T/Us, as well as accept the IHS RPMS as a qualified entity when compiling the list of entities qualified to submit data as a QCDR. | used by private payers to the extent practicable. If there are measures reportable within GPRA that are not duplicative of measures within MIPS, we recommend the commenters work with measure owners to submit these measures during our annual Call for Measures." [page 544] In regard to accepting the IHS RPMS, CMS stated, "We would like to explain that while we will consider all entities that seek to qualify as a QCDR, we cannot conclude that a particular entity is capable of meeting our criteria in advance of the qualification process. It is important to note that an entity must meet the criteria in §414.1400(c) and be approved by CMS to qualify as a QCDR. We will develop further subregulatory guidance, including through tribal consultation to address issues raised by entities that want to be QCDRs." [page 1378-9] |
| | | | 6. IHS/Tribal/Urban Indian Health Programs as Alternative Payment Models: The proposed rule rewards participation in APMs; CMS should explore population/provider based APMs or consider other options for categorizing I/T/U health programs as APMs. | 6. IHS/Tribal/Urban Indian Health Programs as Alternative Payment Models: Accepted in part. CMS stated, "We support the pursuit of developing Other Payer Advanced APMs under a variety of health care payment programs. Payment arrangements not included under Medicare Part B could potentially qualify as Other Payer Advanced APMs for QP Performance Periods in 2019 and later." [page 1753] |
| | | | 7. Need for Tribal Consultation : CMS should engage in meaningful face-to-face tribal consultation to provide a better understanding of how the proposed rule will impact I/T/Us and allow the opportunity for meaningful feedback before adopting the final rule. | 7. Need for Tribal Consultation : Not accepted. CMS did not specifically address this issue but did indicate the potential for future tribal consultation related to this rule (see #3 and #5 above). |



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| 154.b. | Medicaid/CHIP Managed Care ACTION: Proposed Rule NOTICE: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability AGENCY: CMS | CMS-2390-P Issue Date: 6/1/2015 Due Date: 7/27/2015 NIHB File Date: 7/27/2015; TTAG also filed comments 7/27/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 5/6/2016 | NIHB/TTAG recommendations 1. Clarification States Cannot Obtain a Waiver of § 1932(a)(2)(C): Although CMS has consistently rejected attempts by states to force Al/ANs into managed care through section 1115 waivers, the agency should codify this policy in the final rule, as Medicaid managed care entities (MCEs) lack experience or incentive to work with Indian health systems. | In the 5/6/2016 Final Rule 1. Clarification States Cannot Obtain a Waiver of § 1932(a)(2)(C): Not accepted. CMS stated, "We appreciate the opportunity to clarify the scope of section 1932(a)(2)(C) of the Act pertaining to enrollment of Indians into Medicaid managed care programs and the relation of that provision to other authorities for Medicaid managed care programs. Section 1932(a)(1) of the Act provides the ability for states to operate a mandatory Medicaid managed care program under the state plan subject to special rules at section 1932(a)(2) of the Act, and the Indian enrollment provisions are found at section 1932(a)(2)(C) of the Act Because section 1932(a)(2)(C) of the Act refers to the state option to authorize a Medicaid managed care program under section 1932(a) authority, the prohibition on mandatory enrollment of Indians into a Medicaid managed care program can only be read as limited to that authority. Many states use section 1115(a) demonstration authority to operate Medicaid managed care programs We take this opportunity to address the statement by commenters that past practice under section 1115(a) demonstrations was a decision not to waive section 1932(a)(2)(C) of the Act. That is not correct. Section 1115(a) of the Act authorizes the Secretary to waive provisions of section 1902 of the Act and grant expenditures of FFP under |



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| | Hille/Agency | | 2. Section 483.14(b)(1)Network Adequacy: Proposed § 438.14(b)(1) would require MCEs to have "sufficient" IHCPs in their networks; in the final rule, CMS should amend this section to require that MCEs demonstrate sufficiency by 1) | section 1903 of the Act. As discussed above, section 1932(a)(2)(C) of the Act applies only to managed care programs operated under section 1932(a) of the Act. Any past decisions not to permit mandatory enrollment of Indians into managed care under section 1115(a) demonstration authority was the result of negotiations with those specific states and tribes. We decline to formalize any past practice related to Indian enrollment into managed care under section 1115(a) demonstrations in this regulation. However, in light of the significant comments received on the differences across managed care authorities and the parameters for mandatory enrollment of Indians, we intend to develop subregulatory guidance on mandatory enrollment of Indians under section 1932(a), 1915(b), and 1115(a) authorities through the tribal consultation process." [pages 918-20] Section 483.14(b)(1)Network Adequacy: Not accepted. CMS stated, "We decline to require managed care plans to offer a network provider agreement to all IHCPs as we |
| | | | offering network provider agreements using an Indian Managed Care Addendum at the request of IHCPs in their service area (see the model Addendum embedded below); 2) allowing into their networks any IHCP that seeks to participate; and 3) waiving for IHCPs any limitation placed on the number of providers in their networks. | believe we lack clear and specific statutory authority to mandate such a requirement at the federal level We decline to set specific standards for sufficiency of IHCPs in managed care plan networks since §438.14(b)(4) provides that Indian enrollees have the ability to receive care from out-of-network IHCPs Notwithstanding out-of-network access, §438.14(b) does |



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| | | | 3. Oversight of Managed Care Plans: To promote strong oversight of states and their managed care plans to ensure their compliance with the Indian-specific requirements in proposed § 438.14, CMS in the final rule should: Cross-reference the quality assessment requirements in proposed section 438, Subpart E with § 438.14; Require that managed care plans actively and regularly provide verification of compliance with the Indian-specific requirements; | require that managed care plans and PCCM entities, as appropriate, demonstrate that there are a sufficient number of IHCPs in the network unless there are no or too few IHCPs to ensure timely access to services for Indian enrollees. We appreciate the engagement and the work of the TTAG to date to develop a draft Indian Managed Care Addendum and we are committed to finalizing that addendum through subregulatory guidance to offer to managed care plans on a voluntary basis, to facilitate the network status of IHCPs. Because we do not have explicit statutory authority to require the use of an addendum by managed care plans for the provider agreements with IHCPs, we will follow an approach similar to QHPs operating under the FFM We recognize that some states have required the use of an addendum through Medicaid managed care contracts and we encourage states to do so to facilitate provider agreements with IHCPs and to ensure that managed care programs meet the needs of Indian enrollees." [pages 923-4] 3. Oversight of Managed Care Plans: Accepted in part. CMS stated, "We agree that a state's oversight practices should address all populations within its Medicaid managed care program, including Indians; however we disagree that part 438 subpart E broadly applies to §438.14. Section 438.14 addresses network and payment requirements for managed care plans that serve Indians and contract with Indian health care providers; compliance with these provisions generally is outside of the scope of 438 subpart E. The one exception is §438.358(b)(1)(iv), |



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| | | | Require states to hold their managed care plans accountable, with consequences for failing to meet the IHCP network adequacy and other Indian-specific requirements; and Offer technical assistance by maintaining a current list of the IHCPs in managed care plan service areas to allow the plans to know who to contact about participating in their networks. | which requires network adequacy validation as part of the EQR process. We therefore are adding a cross reference to §438.14(b)(1) (relating to network adequacy for managed care plans serving Indians) in §438.358(b)(1)(iv)." [page 656] CMS added, "Regarding comments about managed care plans failure to adhere to the cost sharing protections for Indians at §447.56, we note that §438.108 incorporates the cost sharing provisions in §§447.50 through 448.82 of this chapter as a contractual requirement. In the event managed care plans are inappropriately assessing cost sharing on Indian enrollees, such non-compliance must be brought to the attention of the states as a contract compliance issue to be remedied." [page 921] |
| | | | 4. Section 483.14(b)(5)Access to Services in States with Few or No IHCPs: Proposed § 483.14(b)(5) provides that, in states where a guarantee of timely access to covered services cannot occur because of the presence of "few or no" IHCPs, CMS would consider MCEs in compliance with the network adequacy standards of § 483.14(b)(1) if Indian enrollees can access out-of-state IHCPs or the "circumstance is deemed to be good cause for disenrollment from both the [MCE] and the State's managed care program in accordance with section 438.56(c)"; in the final rule, CMS should remove the phrase "few or" from this section and, regarding good cause for disenrollment, add the stipulation that "there is a fee-for-service alternative." | 4. Section 483.14(b)(5)Access to Services in States with Few or No IHCPs: Not accepted. CMS stated, "Section 438.14(b)(4) sets forth the procedures for demonstrating adequate access and permits Indian enrollees to obtain covered services from an out-of-network IHCP from whom the enrollee is otherwise eligible to receive services. Due to this flexibility for enrollees to see out-of-network IHCPs, we decline to apply the operation of the disenrollment right in paragraph (b)(5)(ii) only to instances where no IHCPs are in the managed care plan's service area. In cases where the state deems the presence of few or no IHCPs as a for cause disenrollment reason for Indian enrollees from the managed care program, a FFS delivery system would have |



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| | | | 5. Sections 483.14(b) and 438.9(b)Non-Emergency Transportation: States can contract with entities that provide only non-emergency medical transportation (NEMT), and although these prepaid ambulatory health plans (PAHPs)referred to as NEMT-PAHPsmust meet the requirements identified in proposed § 438.9(b), the special provisions applicable to other MCE contracts involving Al/ANs, IHCPs, and Indian managed care entities (IMCEs) appear in § 438.14; CMS should amend the final rule to ensure that these provisions also apply to NEMT-PAHPs, as many IHCPs provide their patients with various | to be maintained by the state to provide Medicaid covered services. Because Indian enrollees may see out-of-network IHCPs under §438.14(b)(4) and out-of-state IHCPs under paragraph (b)(5)(i), we do not anticipate that states will choose to utilize the provision for disenrollment specified in paragraph (b)(5)(ii) with significant frequency; regardless, we believe it is important to include it as an option in the final rule. However, we anticipate that the use of the Indian Managed Care Addendum will facilitate the inclusion of IHCPs in managed care networks and reduce the instances of reliance on paragraph (b)(5)." [pages 924-5]. 5. Sections 483.14(b) and 438.9(b)Non-Emergency Transportation: Accepted. CMS noted, "We appreciate the commenters observation and have added the provisions of §438.14 to §438.9(b) in a new paragraph (b)(10)." [page 886] |
| | | | nonemergency transportation services. 6. Sections 483.14(b)(2) and (c)(2)Payment to IHCPs: Proposed §§ 483.14(b)(2) and (c)(2) would implement the payment requirement provisions of ARRA; to address some uncertainty about which payment rates apply, CMS in the final rule should amend these sections to clarify that IHCPs | Sections 483.14(b)(2) and (c)(2)Payment to IHCPs: Accepted in part. According to CMS, "We agree §438.14(c)(2) is not clear as proposed; therefore, we will amend §438.14(c)(2) to specify that the IHCP is entitled to receive the encounter |



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| | | | State plan or the encounter rate, whichever is higher. | Indian Health Service, or in the absence of a published encounter rate, the amount the IHCP would receive if the services were provided under the State plan's FFS payment methodology Additionally paragraph (c)(3) provides for the state to pay the difference should the managed care plan pay less than the required amount. As these payments from the state to a provider are required by the statute, they fall under the exception to the general rule in §438.60 (otherwise prohibiting state payments directly or indirectly to health care providers for services covered by a managed care contract)." [page 926] |
| | | | 7. Waiver of Referral and Prior Authorization Requirements: Managed care plans routinely impose referral and prior authorization requirements that do not comport with how IHCPs coordinate care, both within their own health systems and with outside providers through purchase/referred care; to address this issue, CMS should include in the final rule a provision under which MCEs must waive referral and prior authorization requirements for a network primary care provider if the patient receives his or her primary care through an IHCP that applies the same standards. | 7. Waiver of Referral and Prior Authorization Requirements: Accepted. CMS stated, "We understand the commenters' concern and agree that duplicative services and payments should be avoided if possible. Thus, under our authority in section 1902(a)(4) of the Act, we have added a new requirement at §438.14(b)(6) to clarify that MCO, PIHPs, and PAHPs must permit an out-of-network IHCP to refer an Indian to a network provider. This provision prohibits the managed care plan from requiring the Indian to receive the referral from an in-network primary care provider under those circumstances." [page 928]. |
| | | | 8. Enrollment Protections: a. Monthly Special Enrollment Periods: The proposed | 8. Enrollment Protections: a. Monthly Special Enrollment Periods: Not accepted. |



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| | | | rule would allow individuals required to enroll in a managed care program to change plans without cause within 90 days of enrollment in a plan and once every 12 months; to better align Medicaid with enrollment in a QHPa goal indicated in the preambleCMS in the final rule should provide monthly special enrollment periods during which Al/ANs required to enroll in a managed care program can opt into a plan or change plans without cause. • b. Initial Selection Period: The proposed rule would allow individuals required to enroll in a managed care program a minimum period of 14 days between the date they are notified that they must enroll in the program and the date on which the they become covered by the default MCE; in the final rule, CMS should extend this period to 30 days for Al/ANs, many of whom live in remote areas with no Internet access and slow mail delivery. | CMS did not address this issue. b. Initial Selection Period: Not accepted. CMS did not address this issue. |
| | | | 9. Section 438.71Beneficiary Support System: Proposed § 438.71 appears to prohibit a Medicaid provider from assisting patients with enrollment in managed care plans; to better align the Medicaid managed care regulations with ACA regulations for Navigators and certified application counselors, CMS in the final rule should clarify that IHCP participation in a network, or network service area, does not constitute a conflict of interest in assisting patients with enrollment in plans. | 9. Section 438.71Beneficiary Support System: Not accepted. CMS stated, "We reiterate our position that any individual or entity providing choice counseling services is considered an enrollment broker under our regulations that implement section 1903(b)(4) of the Act, and therefore, must meet the independence and conflict of interest standards at §438.810 to provide such services We also clarify that entities, including Indian Health providers and the Indian Health System, receiving non-Medicaid federal grant funding (distinct from Medicaid funding) may continue to |



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| | | | 10. Suspension of Payments to a Network Provider: The proposed rule would allow certain MCEs to retain recoveries of overpayments made to providers excluded from Medicaid participation or made as a result of fraud, waste or abuse; to avoid conflicts of interest and foster partnership among CMS, states, MCEs, and providers, in ensuring proper use of the complex Medicaid billing process, CMS in the final rule should revise this provision by requiring affected MCEs to "return to the state any collection of overpayments made to a network provider who was barred from the Medicaid program or the result of fraud, waste, or abuse." 11. Section 438.10-Information Standards: Proposed § 438.10 would require standardized managed care definitions and terminology and model enrollee handbooks and notices for use by managed care plans, but Al/ANs also need information that clearly states they can continue to access their IHCP whether they innetwork or out-of-network and that explains other | perform such activities as long as such entities are not performing these activities under a memorandum of agreement or contract with the state to provide Medicaid choice counseling on the state's behalf. While we understand that Marketplace Navigators have different conflict of interest standards, it is not our intention to adopt the Marketplace Navigator program's conflict of interest standards for the beneficiary support system; the statutory basis and the specific standards for these programs are different." [page 485] 10. Suspension of Payments to a Network Provider: Not accepted. CMS did not make this change. |



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| | | | special protections for Indians; CMS should address this issue in the final rule. 12. Medicaid Estate Recovery: The proposed rule does not include Medicaid estate recoveryan issue that has meaning for Al/ANs tied to historical trauma and federal Indian lawas one of the topics listed for standardized consumer information for potential enrollees; at a minimum, CMS in the final rule should ensure that potential enrollees undergo a determination process and receive either an exemption from estate recovery or a definitive statement informing them they do not qualify for an exemption. 13. Section 438.4Capitation Rates: Proposed § 438.4 would require states to develop capitation rates for MCEs serving Medicaid enrollees in accordance with generally accepted actuarial principles and practices, with the qualifier that any "proposed differences among capitation rates according to covered populations must not be based on the Federal financial participation [FFP] percentage associated with the covered populations"a provision that might cause uncertainty among states as they attempt to comply and potential confusion among CMS staff as they conduct related enforcement activities, particularly as applied to Indian health care programs; in the final rule, CMS should indicate that a state can develop capitation rates higher than they would set them otherwise as a result of the anticipated enrollment of IHS beneficiaries in the Medicaid managed care plan, including an Indian Medicaid managed care plan. 14. Tribal Consultation: The proposed rule has the | 12. Medicaid Estate Recovery: Not accepted. CMS noted, "This comment is outside the scope of this rule. We note that the statutory authority for Medicaid estate recovery is separate and distinct from the authority for Medicaid managed care, and that estate recovery applies to Medicaid beneficiaries age 55 and over, or permanently institutionalized, whether they are enrolled in a Medicaid MCO or not." [page 929]. 13. Section 438.4Capitation Rates: Accepted in part. CMS stated, "We agree that additional guidance and clarification is appropriate for §438.4(b)(1). The practice intended to be prohibited in paragraph (b)(1) was variance in capitation rates per rate cell that was due to the different rates of FFP associated with the covered populations The provision would not prohibit the state from having different capitation rates per rate cell based on the projected risk of populations under the contract or based on different payment rates to providers that are required by federal law (for example, section 1932(h) of the Act). We will finalize §438.4(b)(1) to provide that any differences among capitation rates according to covered populations must be based on valid rate development standards and not be based on the FFP associated with the covered populations." [page 259] 14. Tribal Consultation: Accepted. |



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| | | | potential to significantly impact both Al/AN access to Medicaid and tribal health care program reimbursement, indicating a need for CMS to work directly with the TTAG and other tribal entities to ensure that the final rule reflects suggestions from Indian Country about minimizing any disruption for individual Al/ANs or Tribes as a whole, but to date no meaningful tribal consultation has occurred; CMS should address this issue prior to the finalization of the rule. | CMS stated, "This proposed rule has tribal implications and is therefore, subject to the CMS Tribal Consultation Policy Consistent with this policy, after the proposed rule was published on June 1, 2015, CMS issued a Dear Tribal Leader Letter soliciting advice and input from tribes and held a second All Tribes Call on June 25 to present an overview of the rule and the tribal specific provisions. On July 15, 2015, CMS attended the Tribal Technical Advisory Group meeting to discuss the proposed rule provisions and solicit tribal advice and input." [page 916] |
| 168. | Enrollee Satisfaction | CMS-10488 | NIHB/TTAG recommendations | In the 4/28/2015 and 7/24/2015 revisions (review of 4/29/2016 revisions TBE): |
| | Survey Data Collection | <u>Issue Date:</u> 6/28/2013 | Questions Specific to Al/ANsMarketplace Survey: To address questions specific to the experiences of Al/ANs, ONE about disclude a caption titled "American Indiana and Indiana | Questions Specific to Al/ANsMarketplace Survey: N/A. |
| | ACTION: Request for Comment NOTICE: Enrollee | <u>Due Date:</u> 8/27/2013 <u>NIHB File Date:</u> | CMS should include a section titled "American Indians and Alaska Natives and Other Individuals Eligible to Receive Services from an Indian Health Care Provider," which should solicit responses to the below questions. | CMS did not include a revised version of the Marketplace Survey in this PRA request. |
| | Satisfaction Survey Data Collection | None <u>Date of</u> | a. Whether the Marketplace provides specific information on how it determines "Indian" status for both Marketplace of OUDs. And Status for both | |
| | AGENCY: CMS | Subsequent Agency Action, if any: Issued new request 11/1/2013: | Medicaid and QHPs, as well as the process by which an individual can challenge an unfavorable determination; b. What types of documents that the Marketplace accepts as proof of Al/AN status, as well as the ease of | |
| | | issued revision 4/28/2015, | uploading or otherwise providing these documents; c. Whether the Marketplace informs Al/ANs of their eligibility for a special monthly enrollment period; | |



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| | | 7/24/2015, 4/29/2016 <u>Due Date:</u> 12/2/2013; 6/29/2015; 8/24/2015; 6/28/2016 <u>NIHB File Date:</u> 12/2/2013; TTAG also filed comments 12/2/2013 | d. Whether the Marketplace explains (1) the existence of Al/AN-specific cost-sharing protections under both QHPs and Medicaid; (2) the differences in eligibility for cost-sharing protections in QHPs compared with Medicaid; and (3) the manner in which an Al/AN can establish eligibility for any relevant cost-sharing protection; e. Whether the Marketplace specifically explains (1) how Al/ANs and IHS-eligibles can apply for exemptions from the shared responsibility payment; the differences in the exemption process for members of federally recognized Indian tribes and shareholders in Alaska Native Regional or Village Corporations as compared to IHS-eligibles; and (3) the actual process for obtaining the exemptions; and f. What interaction the Al/AN individual has experienced with any enrollment assisters or similar Marketplace personnel concerning Al/AN-specific enrollment issues. Questions Specific to Al/ANsQHP Survey: To address questions specific to the experiences of Al/ANs, CMS should include a section titled "American Indians and Alaska Natives and Other Individuals Eligible to Receive Services from an | 2. Questions Specific to Al/ANsQHP Survey: |
| | | | Indian Health Care Provider," which should solicit responses to the below questions. a. How the QHP interacts with both the individual Al/AN and health care providers to ensure that Al/ANs do not have cost-sharing for which ACA exempts them; b. Whether the individual Al/AN has ever had cost- | a. Not accepted. |



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| | | | sharing (as defined) in any circumstances in which ACA exempts then and, if so, how the individual resolved the dispute with the QHP, as well as the availability of resources in the event of an unresolved dispute; • c. Whether the QHP includes the I/T/U of the individual AI/AN within its network; • d. Whether and why the QHP ever refused to pay a bill, in full or in part, for services provided at an I/T/U; and • e. What interaction the AI/AN individual has experienced with QHP personnel concerning AI/AN-specific issues. 3. AI/AN Survey Responses: To address concerns about an inadequate survey response rate from AI/ANs, CMS should designate a portion of the annual funding for the Marketplace and QHP surveys for grants or contracts to tribes, tribal organizations, and/or I/T/Us to conduct the data collection in person in AI/AN communities. 4. Question Wording and Answers: To ensure accuracy and cultural propriety in the AI/AN context, CMS should change slightly the wording and answers on the below questions. • a. Race Questions: Question 77 in the Marketplace survey and Question 94 in the QHP survey ask respondents about their "race," with "American Indian or Alaska Native" included as one option, but Indian status does not constitute a "race" under the law; CMS should use the following set of questions to address this issue: "Question 1: Please indicate all of the following that | b. Not accepted. c. Not accepted. d. Not accepted. e. Not accepted. 3. Al/AN Survey Responses: N/A. Unable to determine whether CMS addressed this issue. 4. Question Wording and Answers: a. Not accepted. |



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| | | | apply to you: | |
| | | | a. American Indian or Alaskan Native. I am a person having origins in any of the original peoples of North, Central, or South America. b. Asian. I am a person having origins in any of the countries of Asia. c. Black. I am a person having origins in any of the black racial groups of Africa. d. Pacific Islander or Native Hawaiian. I am a person having origins in Hawaii, the Philippines, or other Pacific Island. e. White. I am a person having origins in any of the original peoples of Europe, North Africa, or the Middle East. [For those who check 'a. Al/AN,' regardless of any | |
| | | | other race or ethnicity they check, CMS should ask:] | |
| | | | Question 2a: Are you a member of a federally recognized Indian tribe or a shareholder in an Alaska Native Regional or Village Corporation? | |
| | | | a. Yes b. No c. Don't Know | |
| | | | Question 2b: Have you ever obtained health services from an Indian Health Service, tribal, or urban Indian health program, or are you eligible to do so? | |



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| | | | a. Yes b. No c. Don't Know" b. Recent Provider Visit Questions: In the section of questions (3-9) in the QHP survey about whether an individual went to a "clinic, emergency room, or doctor's office" in the past several months, add "Indian health facility" as a possible response. c. "Personal Doctor" Questions: In the section of questions in the QHP survey (21-38) about having a "personal doctor," change this term to "regular source of health care," as in most I/T/U facilities, individuals might see various providers, including doctors, nurse practitioners, physician assistants, and community health aides. | b. Recent Provider Visit Questions: Not accepted. c. "Personal Doctor" Questions: Not accepted. |
| 181.b. | Nondiscrimination Under ACA ACTION: Proposed Final Rule NOTICE: Nondiscrimination in Health Programs and Activities AGENCY: HHS OCR | HHS OCR RIN 0945-AA02 Issue Date: 9/8/2015 Due Date: 11/9/2015 TSGAC File Date: 11/9/2015 | Indian Health Program Protections: In the Preamble of the final rule, CMS should explicitly refer to the unique political status of Tribes, the federal trust responsibility for Indian health, and the Indian health program exemption to non-discrimination claims under Title VI and otherwise. Applicability Provisions: CMS should revise the proposed applicability provisions in part 92.2 to include Indian health programs. Exceptions to Nondiscrimination Provisions: CMS should explicitly refer to Indian health programs in the text of the | In the 5/18/2016 Final Rule Indian Health Program Protections: Not accepted. See HHS OCR response below. Applicability Provisions: Not accepted. See HHS OCR response below. Exceptions to Nondiscrimination Provisions: Not accepted. |



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| | | Date of Subsequent Agency Action, if any: Issued Final Rule 5/18/2016 | final regulations regarding exceptions to the nondiscrimination provisions. 4. Exemption for Tribal Governments and Health Programs: In the provisions in the final rule regarding the application of section 1557 to entities that provide or administer health insurance or coverage and employers that administer employee health benefit programs, CMS should state that tribal governments and health programs are exempt from claims of discrimination for limiting services to Indians. | See HHS OCR response below. 4. Exemption for Tribal Governments and Health Programs: Not accepted. HHS OCR generally responded to these four recommendations, stating, "45 CFR 80.3(d) is not an exemption from coverage; it provides an exception to application of the prohibitions on race, color, and national origin discrimination when programs are authorized by Federal law to be restricted to a particular race, color, or national origin. The final rule incorporates that exception, and OCR will fully apply it, as well as other exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of the law to tribes in the context of individual complaints." [81 FR 31381] |
| 184.j. | Clinical Diagnostic Laboratory Tests Payment System ACTION: Proposed Final Rule NOTICE: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System | CMS-1621-PF Issue Date: 10/1/2015 Due Date: 11/24/2015 NIHB File Date: 11/24/2015 Date of | 1. Definition of "Applicable Laboratory": CMS should make the definition "applicable laboratory" in the final rule broad enough to encompass many types of laboratories that perform various testing services paid for by Medicare, including those within an IHS clinic, tribal health clinic, or urban Indian organization clinic (I/T/U clinics). | In the 6/23/2016 Final Rule 1. Definition of "Applicable Laboratory" : Accepted in part. CMS revised the definition of "applicable laboratory" at § 414.502, in part to account for hospital outreach laboratories. CMS stated, "Specifically, we are removing the first two requirements from the proposed definition that pertained to the TIN-level entity. Because all NPI-level entities that qualify as applicable laboratories will be laboratories, we are specifying that an applicable laboratory is a laboratory as defined in § 493.2 that bills |



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| | AGENCY: CMS | Subsequent Agency Action, if any: Issued Final Rule 6/23/2016 | 2. | Definition of "Payment Rate": In most cases, the payment rate that a private payor sets for a laboratory test accounts for both the amount the private payor will pay and any copayment from a patient, but in I/T/U system, patients do not have cost-sharing or make copayments; as such, CMS should make clear to applicable laboratories the definition of "payment rate," taking the special AI/AN protections into account when issuing the final rule. | 2. | Medicare part B under its own NPI. Because we are defining applicable laboratory in terms of the NPI rather than the TIN, we are specifying in the definition of applicable laboratory that the majority of Medicare revenues threshold is to be applied by the NPI-level entity, that is, the applicable laboratory, rather than by the TIN-level entity collectively with all its associated NPIs In addition, we are revising the dollar amount for the low expenditure threshold from \$50,000 to \$12,500, which is also reflected in the revised definition of applicable laboratory." [81 FR 41047] However, CMS did not address this issue specifically as it pertains to I/T/U clinics. Definition of "Payment Rate": Accepted in part. CMS clarified that "private payor rate includes any patient cost sharing amounts required by private payors, including patient deductible amounts, coinsurance amounts (that is, the percentage of the fee schedule amount a private payor requires the patient to pay for a given laboratory test), and copayment amounts (that is, the specific dollar amount a private payor requires the patient to pay for a given laboratory test)." [81 FR 41055] However, CMS did not address this issue specifically as it pertains to I/T/Us. |
| | | | 3. | Paper Reporting Exception: The American Clinical Laboratory Association suggests that CMS establish an electronic reporting mechanism, such as an Internet-based portal, for laboratories to use to report their payor rates; if CMS adopts such a system in the final rule, it should take into account the lack of access to technology (Wi-Fi, | 3. | Paper Reporting Exception: Accepted. CMS did not address this issue (and did not establish an electronic reporting mechanism in the final rule). |



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| | | | Internet, hardware, etc.) in Indian Country and create a paper reporting exception for I/T/Us. 4. Tribal Consultation: CMS should engage in tribal consultation prior to issuing the final rule, as it is of the utmost importance that the IHS and Medicare units within CMS conduct consultation to coordinate their efforts. | Tribal Consultation: Not accepted. CMS did not address this issue. |
| 188.a. | Emergency Preparedness Requirements ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS | CMS-3178-PF Issue Date: 12/27/2013 Due Date: 2/25/2014 3/31/2014 TTAG File Date: 3/31/2014 Date of Subsequent Agency Action, if any: Issued due date extension 2/21/2014; Issued Final Rule 9/16/2016 | Impact on Tribes and Indian Health Programs: To acknowledge the challenges that this proposed rule will pose for Tribes and Indian health programs, CMS should: a. Perhaps collaboratively with other federal agencies, provide training for Tribes and Indian health programs regarding current emergency preparedness laws and directives and their roles in satisfying these laws and directives; b. Perhaps collaboratively with other federal agencies, offer on- site technical assistance and other support to Indian health programs that need help obtaining the necessary collaboration of non-Indian health providers and state and local of governments; and c. Schedule consultation with Indian health programs, in conjunction with TTAG, about how the new requirements will affect various provider types and adopt provisions for delayed implementation of the requirements in Indian health care facilities until adequate consultation and training occur. | In the 9/16/2016 Final Rule 1. Impact on Tribes and Indian Health Programs: Not accepted. CMS did not address any issues specifically related to Tribes and Indian health programs. |



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| | _ | | 2. Alternative Approaches to Implementation: CMS should: | 2. Alternative Approaches to Implementation: |
| | | | a. Allow providers to obtain waivers of the deadlines and of specific requirements, if the provider has a minimal plan for compliance within its proposed timeline, because one year might not provide adequate time for some providers to become familiar with all of the new requirements and to implement them. | a. Not accepted. CMS stated, "We do not agree with including a provision that will allow for facilities to apply for extensions or waivers to the emergency preparedness requirements. We believe that an implementation date that is beyond 1 year after the effective date of this final rule for these requirements is inappropriate and leaves the most vulnerable facilities and patient populations without life-saving emergency preparedness plans," adding, "However, we do understand that some facilities, especially smaller and more rural facilities, may experience difficulties developing their emergency preparedness plans. Therefore, we believe that setting an implementation date of 1 year after the effective date of this final rule for these requirements will give these and other facilities sufficient time for compliance." [81 FR 63872-3] |
| | | | b. Allow providers to establish their own training exercise schedule based on local conditions, because with the large variation in the types of facilities and the conditions under which they operate, "one-size-fits-all" training will not necessarily achieve the best outcome. | b. Accepted in part. CMS did not adopt the recommendation to allow providers to establish their own training exercise schedule based on local conditions. However, CMS revised proposed §482.15(d)(2) to require facilities to conduct one full-scale exercise and an additional exercise of their choice, rather than one full-scale |



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| | | | c. When the same owner administers multiple facility types (a common practice among Indian health programs), allow the facilities to obtain waivers of specific requirements or have a single, multi-facility plan approved, if they can collectively adopt a functionally equivalent strategy based on the requirements that might apply to one of their other facility typesas proposed, this rule would require each of these facility types to meet certain specific requirements, a policy that might lead to duplicative, and ultimately confusing, emergency protocols; and | exercise and one tabletop exercise as the proposed rule would have required. c. Not accepted. CMS stated, "Although we disagree with the commenter's recommendation that we allow multiple facility types that are administered by the same owner to obtain implementation waivers of specific requirements, we agree that multiple facilities that are administered by the same owner, that effectively operate as an integrated health system, can have a unified emergency preparedness program. We previously discussed this final policy in the Integrated Health System section of this final rule." [81 FR 63873] |
| | | | d. Offer facilities an opportunity to review their existing policies and procedures and seek approval for continuing to rely on them instead of implementing the new requirements, if the facility can demonstrate that this would achieve a substantially similar outcome, with deadlines for compliance with any new requirements applied only after a review of the continuation plan. | d. Not accepted. CMS stated, "We appreciate that some facilities have existing emergency preparedness plans. However, all facilities will be required to develop and maintain an emergency preparedness plan based on an all-hazards approach and address the four major elements of emergency preparedness in their plan that we have identified in this final rule. Each facility will be required to evaluate its current emergency preparedness plan and activities to ensure that it complies with the new requirements." [81 FR 63873] |



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| 188.b. | Fire Safety Requirements for Certain Health Care Facilities ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities AGENCY: CMS | CMS-3277-PF Issue Date: 4/16/2014 Due Date: 6/16/2014 TTAG File Date: 6/16/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 5/4/2016; issued correction 6/30/2016 | Occupancy Standards: CMS should clarify the scope of occupancy standards in the proposed rule, and in the case of hospitals, apply these requirements to the hospital itself, not off-site facilities billing under the hospital provider number; if the agency does intend to apply these standards to all facilities billing under a hospital provider number, it should extend the comment period to allow hospitals and other facilities more time to properly respond. Timeframe for Implementing Evacuation/Fire Watch Procedures: The proposed rule would require evacuation or a fire watch when a sprinkler system remains out of service for more than 4 hours, rather than 10 hours as recommended by the National Fire Protection Association (NFPA) Life Safety Code (LSC) 2012 edition; CMS should extend the timeframe to 10 hours, a standard that would ensure proper monitoring of facilities but would not implement expensive and burdensome evacuation/fire watch procedures without good cause. Smoke Exhaust Systems in Operating Rooms: The proposed rule would mandate that facility operating rooms (ORs) contain smoke exhaust systems, a requirement eliminated in the 2012 edition of the LSC after NFPA determined that hospitals no longer use flammable anesthetics and have limited the presence of any combustibles in ORs; CMS should remove this requirement. | Occupancy Standards: Not accepted. CMS did not address this issue. Timeframe for Implementing Evacuation/Fire Watch Procedures: Accepted. CMS stated, "We agree that most sprinkler system outages occur during a regular work day with sufficient staff levels to provide appropriate monitoring and assure patient safety from fire. Therefore, we are withdrawing the proposal that all system shutdowns of more than 4 hours would require a fire watch." [page 64] Smoke Exhaust Systems in Operating Rooms: Accepted. CMS stated, "In light of the concerns raised by commenters, we agree that requiring the installation of smoke ventilation systems would not be an effective use of hospital and ASC resources Therefore, we have removed this requirement from the regulations text for hospitals, CAHs, and ASCs." [page 66] |
| | | | 4. Window Requirements: The proposed rule would require | 4. Window Requirements: Accepted. |



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| | | | that every health care occupancy patient sleeping room have an outside window or outside door with a sill height not to exceed thirty-six inches above the floor, although NFPA eliminated this standard in the 2012 edition of the LSC; CMS should remove this requirement or at least clarify that it applies only to new construction and not existing facilities, as requiring existing facilities to retrofit their occupancy rooms could result in a significant expense for comparatively little reward in terms of increased safety. | CMS stated, "We agree with commenters that requiring existing facilities to change their existing window structures to meet this requirement would be an undue burden. We have revised the regulation to assure that any facilities built after the effective date of this final rule will have to meet the 36 inch window sill height requirement, in accordance with the 2000 edition of the LSC. Existing facilities that were not required to meet this specification at the time of construction would not be required to change window sill heights at this time." [page 68] |
| | | | | |
| 204. | Medicaid Services "Received Through" an IHS/Tribal Facility | CMS (no reference number) SHO #16-002 | TTAG/TSGAC recommendations 1. Paragraph 1Modifying the Second Condition: CMS should | In the 2/26/2016 Final Policy 1. Paragraph 1Modifying the Second Condition: CMS should |
| | ACTION: Request for Information Final Policy NOTICE: Medicaid Services "Received Through" an Indian Health Service/Tribal Facility: A Request for Comment AGENCY: CMS | Issue Date: 10/27/2015 Due Date: 11/17/2015 TTAG File Date: 11/17/2015; TSGAC also filed comments 11/17/2015 | a. Retain this proposal (with clarifications). b. Clarify that a service the IHS/Tribal facility can provide includes any service authorized under the Snyder Act, the Transfer Act, the Indian Health Care Improvement Act, the Indian Self-Determination and Education Assistance Act, or other applicable federal law. c. Clarify that services provided pursuant to section 1915 waivers and 1115 demonstrations would qualify under this proposal. | a. Accepted in part. CMS retained this proposal with some clarifications. b. Not accepted. CMS did not address this issue. c. Accepted in part. CMS stated that state expenditures for services |



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| | | Date of Subsequent Agency Action, if any: Issued Final Policy 2/26/2016 | | "covered under section 1115 demonstration authority are eligible for 100 percent FMAP as long as all of the elements of being 'received through' an IHS or Tribal facility that are described in this SHO are present." [page 7] However, CMS did not address the issue of section 1915 waivers. |
| | | | d. Implement this proposal in a manner that protects the general 100 percent FMAP rule for Indians in the | d. Not accepted. |
| | | | general 100 percent FMAP rule for Indians in the Medicaid Expansion population. | CMS did not address this issue. |
| | | | e. Retain and highlight that services covered include "transportation services, as well as emergency Output Description: | e. Accepted. |
| | | | transportation (EMT) services and non-emergency transportation (NEMT), including related travel expenses (such as meals, lodgings, and cost of an attendant pursuant to federal and state requirements)." | CMS addressed this issue as recommended. |
| | | | Comments in Response to Paragraph 2Modifying the Third Condition: CMS should | Comments in Response to Paragraph 2Modifying the Third Condition: CMS should |
| | | | a. Retain this proposal (with clarifications). | a. Accepted in part. |
| | | | | CMS retained this proposal with some clarifications. |
| | | | b. Revise the phrase "who provides items or services not within the scope of a Medicaid "facilities services" | b. Accepted. |
| | | | benefit but within the IHS/tribal facility authority" to ensure that it is not susceptible to an interpretation intended to disqualify Medicaid facilities services | CMS removed this language. |



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| | | | benefits and that it expresses clearly the intention for consistency with the policy change proposed in Paragraph 1. • c. Rather than requiring a written contract in all cases, allow a written referral providing that, as a condition of accepting the referral, the provider would have to furnish materials and records back to the referring IHS/tribal facility; exclude the phrase "[t]he IHS/Tribal facility would need to retain responsibility for the provision of services, meaning that the IHS/Tribal facility must retain control of the medical records, including updating medical records with information from care provided by contractual agents and providing care coordination for the Al/AN individual" or similar such conditions; and not require that an Al/AN is a "patient" of the IHS/tribal facility. | • c. Not accepted. CMS stated, "A covered service will be considered to be 'received through' an IHS/Tribal facility not only when the service is furnished directly by the facility to a Medicaid-eligible AI/AN patient, but also when the service is furnished by a non-IHS/Tribal provider at the request of an IHS/Tribal facility practitioner on behalf of his or her patient and the patient remains in the Tribal facility practitioner's care in accordance with a written care coordination agreement Under this policy, there must be an established relationship between the patient and a qualified practitioner at an IHS/Tribal facility [C]are must be provided pursuant to a written care coordination agreement between the IHS/Tribal facility and the non-IHS/Tribal provider, under which the IHS/Tribal facility practitioner remains responsible for overseeing his or her patient's care and the IHS/Tribal facility retains control of the patient's medical record." [page 4] |
| | | | d. Not suggest that the IHS/tribal facility must "arrange" for the provision of services and clarify that a referral can qualify as "received through" an IHS/tribal facility even if the patient did not first obtain primary care or physical treatment within the four walls of an IHS/tribal facility for a specific referral or episode of care. | d. Not accepted. CMS did not address this issue. |



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| | | | e. Clarify that a referral to a contractual agent can occur for a specific treatment, for an episode or care, or as a standing referral. f. Adopt an approach that gives Tribes in each state the opportunity to work with their states to develop the type of referral arrangement and requirements that best suit the relationship between the IHS/tribal facilities in the state and outside providers. | e. Not accepted. CMS did not address this issue. f. Accepted in part. According to CMS, "Written care coordination agreements under this policy could take various forms, including but not limited to a formal contract, a provider agreement, or a memorandum of understanding and, to the extent it is consistent with IHS authority, would not be governed by federal procurement rules. The IHS/Tribal facility may decide the form of the written agreement that is executed with the non-IHS/Tribal provider." [page 5] |
| | | | 3. Paragraph 3Modifying the Fourth Condition: CMS should retain this proposal. | Paragraph 3Modifying the Fourth Condition: Accepted. CMS retained this proposal. |
| | | | 4. Paragraph 4Application to Fee-for-Service: CMS should | 4. Paragraph 4Application to Fee-for-Service: |
| | | | a. Retain this proposal. | a. Accepted. CMS addressed this issue as recommended. |
| | | | b. Retain and highlight the language it used in its proposal to indicate that "states retain flexibility in establishing economic and efficient payment rates to sufficiently reimburse for the provision of services." | b. Accepted. CMS addressed this issue as recommended. |



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| | | | 5. Paragraph 5Application to Managed Care: CMS should | 5. Paragraph 5Application to Managed Care: |
| | | | a. Retain this proposal (with clarifications). | a. Accepted in part. CMS retained this proposal with some clarifications. |
| | | | b. Clarify that the 100 percent FMAP reimbursement applies to capitation payments made for services "received through" IHS/tribal facilities in managed care systems established by state plan amendment or waiver authority. c. Allow states flexibility in ensuring that managed care plans actually pay for services by allowing them continued flexibility to give managed care plans the incentives they need to provide information back to the state to assist them in claiming 100 percent FMAP and flexibility in determining the total estimate of payments made for services "received through" IHS/tribal facilities based on aggregated data, rather than per referral or per encounter data. | b. Accepted. CMS addressed this issue as recommended. c. Not accepted. CMS did not address this issue. |
| | | | | |
| 206. | Measures of Quality Improvement Activities ACTION: Request for Information NOTICE: Request for | AHRQ (no reference number) Issue Date: 2/10/2016 Due Date: 3/4/2016 | Improving Patient Care (IPC) Program Model: In its development of health care organization quality improvement measures, AHRQ should consider the use of the Indian health medical home system within the IHS IPC Program to enhance access to care and improve the quality of care for Al/ANs, as this population faces a variety of health disparities when compared with the general U.S. population. | No subsequent Agency action taken (as of 10/31/2016). |



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| | Measures Assessing Health Care Organization Quality Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self-Management AGENCY: AHRQ | NIHB File Date: 3/4/2016 Date of Subsequent Agency Action, if any: | | |
| | AGLINCT. ATTRO | | | |
| 212. | Enhancing Retailer Standards in SNAP ACTION: Proposed Rule NOTICE: Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP) AGENCY: USDA FNS | USDA FNS RIN 0584-AE27 Issue Date: 2/17/2016 Due Date: 4/18/2016 5/19/2016 NIHB File Date: 5/16/2016 Date of Subsequent Agency Action, if any: Issued | Technical Assistance and Grants: USDA currently has only one rural development grant exclusively available to Al/AN communities, and without access to adequate funds, Tribes will not have the ability to meet the new requirements in the proposed rule or harness the full potential of the roughly 42 million acres of agricultural land in Indian Country; to help address this issue, USDA should provide technical assistance, capacity building and agricultural development grants to tribal communities. Federally Recognized Tribes Extension Program (FRTEP) Funding: USDA has not adjusted for inflation the FRTEP funding level, currently \$3 million annually, in nearly 25 years, despite a tripling in size of program budgetary requirements; to assist tribal communities in developing their agricultural resources, bolstering their economies, and | No subsequent Agency action taken (as of 10/31/2016). |



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| | | due date extension/ clarification 4/5/2016 | increasing their access to fresh foods, the department should fund FRTEP at \$10 million annually. Flexible Compliance Timelines and Requirements: If the provisions in the proposed rule take effect without the necessary exemptions or adjusted requirements that correspond to the issues facing Indian Country, the results could prove disastrous; USDA should work with tribal communities and assign timelines sensitive to current standards, as well as implement a graduated system of compliance that works with retailers to impose incremental improvements representative of geographic and environmental barriers. Nutrition Education Program Funding: Currently, USDA funds nutrition education programs at less than \$1 million annually in Indian Country and does not allocate a specific portion of this funding to Tribes, meaning that Tribes must compete with states and counties for funding; the department should increase funding for these programs to \$3 million annually and create programs tailored specifically for Tribes. | |
| 216. | HHS Grants Regulation ACTION: Proposed Rule NOTICE: Health and Human Services Grants Regulation | HHS (RIN 0991-AC06) Issue Date: 7/13/2016 Due Date: 8/12/2016 NIHB File Date: | NIHB recommendations Tribal Consultation: The proposed rule would make Indian Self-Determination and Education Assistance Act (ISDEAA) contracts, compacts, and funding agreements subject to HHS grant regulationsan overreach of the authority of the HHS Secretary under ISDEAAand the department has not engaged in meaningful tribal consultation on this and other provisions in the rule; HHS should not move forward with the proposed rule until meaningful tribal consultation can occur. | No subsequent Agency action taken (as of 10/31/2016). |



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| | AGENCY: HHS | | | |
| | | Date of | | |
| | | <u>Subsequent</u> | | |
| | | Agency Action, | | |
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From left-to-right in the table, the term is listed (*e.g.*, "Indian-specific ACA provisions"); the subtopic is listed (*e.g.*, "Cost-sharing reductions"); the RRIAR entry number is shown (*e.g.*, "7.a"); in parenthesis, the page number in Table B is shown first in red (*e.g.*, "(18)") and the page number in Table C is shown second in blue, underlined (*e.g.*, "(16)"). The RRIAR entry numbers and page numbers are listed in the column associated with the most recent edition of the RRIAR in which they appear.

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| Indian-specific ACA provisions | | | | | | |
| Cost-sharing reductions | | | | | | |
| Eligibility | | | | 7.ccc. (29/ <u>10</u>), 89.a. (/ <u>34</u>), 89.k. (<u>210/42</u>) | | |
| General | 7.a. (18/ <u>16</u>), 7.c. (24/ <u>67</u>), 7.g. (29/ <u>76</u>), 29.a. (70/112) | 7.u. (32/12), 50.d. (136/61), 50.h. (68), 89.a. (194/79), 89.b. (195/87), 111.b. (238/96), | 31.w. (133/ <u>14</u>), 31.x. (135/ <u>16</u>) | 7.ww. (26), 7.xx. (27), 27.n. (97), 89.h. (203/ <u>35</u>) | 50.h. (152) | |

¹ "Health reform" is inclusive of (1) the Patient Protection and Affordable Care Act (Pub. L. 111-148), incorporating by reference S. 1790 as reported by the Committee on Indian Affairs of the Senate in December 2009 (containing amendments to the Indian Health Care Improvement Act, IHCIA), and as amended by the Health Care and Education Reconciliation Act (HCERA; Public Law 111–152) (collectively referred to as "ACA") and (2) the American Recovery and Reinvestment Act of 2009 (ARRA, Pub. L. 111-5).

This Index lists key terms found in regulations implementing "health reform," which is inclusive of (1) the Patient Protection and Affordable Care Act (Pub. L. 111-148), incorporating by reference S. 1790 as reported by the Committee on Indian Affairs of the Senate in December 2009 (containing amendments to the Indian Health Care Improvement Act, IHCIA), and as amended by the Health Care and Education Reconciliation Act (HCERA; Public Law 111–152) (collectively referred to as "ACA") and (2) the American Recovery and Reinvestment Act of 2009 (ARRA, Pub. L. 111-5). The terms, when applicable, are further sorted by subtopic, with the corresponding RRIAR entry numbers and page numbers shown.

See the accompanying "RRIAR Number Reference Guide: Health Reform" for a listing, by RRIAR entry number, of the notice type, short title, and issuing agency or agencies for each entry.

² The purpose of the Regulation Review and Impact Analysis Report (RRIAR) is to identify and summarize key regulations issued by the Centers for Medicare and Medicaid Services (CMS) pertaining to Medicare, Medicaid, CHIP, and health reform that affect (a) American Indians and Alaska Natives and/or (b) Indian Health Service, Indian Tribe and tribal organization, and urban Indian organization providers. Further, the RRIAR includes summaries of the regulatory analyses prepared by NIHB and the recommendations to CMS (and other agencies) made by the Tribal Technical Advisory Group, NIHB, and/or other tribal organizations (if any). The RRIAR also indicates the extent to which these recommendations were incorporated into any subsequent CMS actions.



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| Referrals | | 111.c. (240/ <u>102</u>) | | 89.l. (211 / <u>48</u>) | | |
| Definition of Indian | 7.a. (18/16), 7.b. (21/22), 7.c. (24/67), 7.d. (26/75) | 7.u. (32/12), 31.e. (94/40), 50.d. (136/61), 50.f. (64), 50.h. (68), 89.a. (194/79), 111.b. (238/96) | | | 50.f. (149), 50.h. (152) | |
| Employer mandate | | | | 31.ccc. (136/ <u>26</u>) | 31.iii. (<mark>124/<u>6</u>)</mark> | |
| Essential community providers | 7.a. (18/ <u>16</u>), 7.b. (21/ <u>22</u>) | 7.i. (19), 7.n. (23/1), 50.c. (135/54), 111.b. (238/96) | 7.ee. (29/4), 92.cc. (255) | 7.vv. (24/9), 7.ddd. (33), 50.e. (147), 89.h. (203/35), 92.ll. (218/54) | 7.kkk. (32), 7.III. (34/7), 7.iiii. (55) | |
| Exemption from tax penalty | | 31.e. (94/ <u>40</u>), 31.g. (103/ <u>44</u>), 31.q. (<u>47</u>) | 7.mm. (42), 31.v. (133/ <u>13</u>) | 7.ww. (26), 89.h. (203/ <u>35</u>) | 31.q. (117) | |
| Fees | 116. (154) | 89.a. (194/ <u>79</u>) | | 145.c. (279) | | |
| Implementation of section 402 of IHCIA | | | 50.q. (173), 50.r. (175), 50.x. (179/ <u>30</u>) | | | |
| Indian addendum | 7.b. (21/ <u>22</u>) | 50.c. (135/ <u>54</u>), 111.a. (237/ <u>94</u>), 111.b. (238/ <u>96</u>) | 7.ee. (29/ <u>4</u>) | 7.vv. (24/ <u>9</u>), 89.h. (203/ <u>35</u>) | 7.III. (<mark>34/<u>2</u>)</mark> | |
| Issuer regulations (Indian-specific concerns) | 7.a. (18/ <u>16</u>), 7.b. (21/ <u>22</u>), 7.g. (29/ <u>76</u>) | 7.n. (23/ <u>1</u>), 89.a. (<u>194/<u>79</u>), 89.b. (<u>195/<u>87</u>),</u></u> | 7.ee. (29/ <u>4</u>), 50.t. (176/ <u>29</u>), 65. (199/ <u>36</u>), | 7.vv. (24/ <u>9</u>), 31.pp. (11 <u>9</u> / <u>21</u>), 89.h. (203/ <u>35</u>), | 7.III. (34/ <u>2</u>), 31.III. (126/ <u>7</u>), 168. (344/ <u>65</u>) | |



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| Premium sponsorship | 7.a. (18/ <u>16</u>), 7.b. (<u>21/22</u>), 7.g. (<u>29/76</u>), 29.a. (<u>70/112</u>) | 50.d. (136/ <u>61</u>), 111.a. (237/ <u>94</u>), 111.b. (238/ <u>96</u>) | 7.b. (3), 7.ee. (29/4), 50.q. (173), 50.r. (175), 50.x. (179/30), 65. (199/36) | 7.vv. (24/ <u>9</u>) | 7.III. (34/ <u>2</u>) | |
| Tribal consultation | | | 64.a. (196/ <u>31</u>), 64.b (198/ <u>33</u>) | 64.c. (173/ <u>30</u>) | | |
| Tribal employer/organization participation in FEHBP | | | 174.c. (<mark>315/63</mark>), 174.d. (<mark>317</mark>) | | 174.g. (347) | |
| Tobacco use (ceremonial) | | 50.d. (136/ <u>61</u>), 50.f. (<u>64</u>), 50.h. (<u>68</u>), 92.a. (<u>202/91</u>) | | | 50.f. (149), 50.h. (152) | |
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| Cost-sharing reductions | 7.a. (18/ <u>16</u>), 45. (87) | 29.f. (89), 50.d. (136/ <u>61</u>), 50.h. (<u>68</u>), | 29.g. (107/ <u>12</u>), 29.h. (108), 31.w. (133/ <u>14</u>), | 27.n. (97), 89.k. (210/ <u>42</u>), 89.l. (211/ <u>48</u>), | 50.h. (152), 89.d. (203), 89.g. (205), | |



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| 92.00. | Guidance | Eligibility Redeterminations for Marketplace Coverage | CCIIO |
| 92.pp. | Guidance | ACA Reporting Requirements for Health Coverage Providers | IRS |
| 92.qq. | Guidance | Evaluation of EDGE Data Submissions | CCIIO |
| 92.rr. | Guidance | EDGE Data Submission Grace Period | CCIIO |
| 92.ss. | Guidance | Rate Review Requirements in States with SBMs | CCIIO |
| 92.tt. | Request for Comment | QIS Implementation Plan and Progress Report | CMS |
| 92.uu. | Guidance | Information Distribution on PTCs and CSRs for FFM Coverage | CCIIO |
| 92.vv. | Guidance | FAQs on Uniform Modification and Plan/Product Withdrawal | CCIIO |
| 92.ww. | Guidance | Standard Notices of Product Discontinuation and Renewal | CCIIO |
| 92.xx. | Guidance | FAQ on Transparency Reporting for Non-QHP Coverage | CCIIO |
| 92.yy. | Request for Comment | Transparency in Coverage Reporting by QHP Issuers | CMS |

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| Number | Action | Short Title | Agency |
| 92.zz. | Guidance | FAQs on the Impact of PACE Act on State Small Group Expansion | CCIIO |
| 92.aaa. | Guidance | FAQs on ACA and Mental Health Parity Implementation | CCIIO |
| 92.bbb. | Final Rule | Final Rules for Grandfathered Plans, Preexisting Condition Exclusions, et al. | IRS/DoL/CMS |
| 92.ccc. | Guidance | Rate Filing Justifications for 2016 for Single Risk Pool Coverage | CCIIO |
| 92.ddd. | Guidance | Evaluation of EDGE Data Submissions for 2015 | CCIIO |
| 92.eee. | Guidance | Extension of Transitional Policy Through CY 2017 | CCIIO |
| 92.fff. | Guidance | FAQs on the 2017 Moratorium on Health Insurance Provider Fee | CCIIO |
| 92.ggg. | Guidance | Evaluation of EDGE Data Submissions for 2015 | CCIIO |
| 92.hhh. | Guidance | Updated Renewal and Product Discontinuation Notices | CCIIO |
| 92.iii. | Guidance | FAQs on ACA Implementation (Parity and Women's Health) | CCIIO |
| 92.jjj. | Guidance | Marketplace Eligibility Redetermination for 2017 | CCIIO |
| 92.kkk. | Proposed Rule | Rules for Expatriate Health Plans, et al. | IRS/DoL/CMS |
| 92.III. | Request for Comment | Health Insurance Enforcement and Consumer Protections Grants | CMS |
| 92.mmm. | Guidance | NQTLs Requiring Analysis to Determine Parity Compliance | CCIIO |
| 92.nnn. | Guidance | FAQs on ACA Implementation (COBRA Model Election Notice) | CCIIO |
| 92.000. | Guidance | Netting of Payments and Charges | CCIIO |
| 92.ppp. | Guidance | Issuer Posting of Rate Filing Information | CCIIO |
| 92.qqq. | Guidance | FAQs on ACA Implementation (Market Reforms and Parity) | CCIIO |
| 99.a. | Final Rule | Wellness Programs | IRS/DoL/CMS |
| 99.b. | Request for Information | Nondiscrimination in Certain Health Programs or Activities | HHS OCR |
| 99.c. | Request for Comment | Evaluation of Wellness and Prevention Programs | CMS |
| 99.d. | Guidance | FAQs About ACA Implementation (Wellness Programs) | CCIIO |
| 99.e. | Guidance | FAQs on Market Reforms and Wellness Programs | CCIIO |
| 100.a. | Request for Information | Health Care Quality for Exchanges | CMS |
| 100.b. | Request for Comment | Marketplace Quality Standards | CMS |
| 111.a. | Request for Comment | Multi-State Plan Application | OPM |
| 111.b. | Final Rule | Multi-State Plan Program for Exchanges | OPM |
| 111.c. | Request for Comment | Request for External Review | OPM |
| 111.d. | Notice | New System of Records (MSP Program) | OPM |
| 111.e. | Final Rule | Establishment of Multi-State Plan Program for Exchanges | OPM |
| 111.f. | Request for Comment | Mental Health Parity Rules: External Review for MSPP | IRS |
| 116. | Final Rule | Fees for the Patient-Centered Outcomes Research Trust Fund | Treasury |
| 122.a. | Request for Comment | Special Enrollment Rights Under Group Health Plans | DoL |
| 122.b. | Request for Comment | Pre-Existing Condition Exclusion Under Group Health Plans | DoL |

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| Number | Action | Short Title | Agency |
| 122.c. | Request for Comment | Creditable Coverage Under Group Health Plans | DoL |
| 128.a. | Request for Comment | ACA Internal Claims and Appeals and External Review Procedures | CMS |
| 128.b. | Guidance | State External Review Process for Health Plans | CCIIO |
| 128.c. | Guidance | County Level Estimates Related to CLAS Standards Under ACA | CCIIO |
| 128.d. | Request for Comment | ACA Internal Claims and Appeals and External Review Disclosures | IRS |
| 128.e. | Guidance | Electing a Federal External Review Process | CCIIO |
| 128.f. | Request for Comment | ACA Internal Claims and Appeals and External Review Procedures | DoL |
| 145.a. | Final Rule | Health Insurance Providers Fee | IRS |
| 145.b. | Request for Comment | Report of Health Insurance Provider Information | IRS |
| 145.c. | Proposed Rule | Health Insurance Providers Fee | IRS |
| 145.d. | Final/Temporary Rule | Health Insurance Providers Fee | IRS |
| 159.b. | Final Rule | Medicare PPS for Federally Qualified Health Centers, et al. | CMS |
| 168. | Request for Comment | Enrollee Satisfaction Survey Data Collection | CMS |
| 169. | Request for Comment | Health Care Sharing Ministries | CMS |
| 174.a. | Final Rule | FEHBP: Members of Congress and Congressional Staff | OPM |
| 174.b. | Final Rule | FEHBP: Coverage of Children | OPM |
| 174.c. | Final Rule | FEHBP: Eligibility for Temporary and Seasonal Employees | OPM |
| 174.d. | Guidance | New Flexibility for Tribal Employer Participation in FEHBP | OPM |
| 174.e. | Final Rule | FEHBP Miscellaneous Changes: Medically Underserved Areas | OPM |
| 174.f. | Final Rule | FEHBP: Rate Setting for Community-Rated Plans | OPM |
| 174.g. | Proposed Rule | FEHBP: Access for Employees of Certain Indian Tribal Employers | OPM |
| 181.b. | Final Rule | Nondiscrimination Under ACA | HHS OCR |
| 198.a. | Final/Temporary Rule | Branded Prescription Drug Fee | IRS |
| 198.b. | Proposed Rule | Branded Prescription Drug Fee | IRS |
| 198.c. | Request for Comment | Branded Prescription Drug Fee | IRS |