National Indian Health Board

Regulation Review and Impact Analysis Report v. 6.05

as of May 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 reform[1] 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 a **recently 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 –

- 5.a. PACE Information Request (CMS-R-244; **comments due 6/1/2016**)
- 44.h. Comprehensive Primary Care Plus Model (CMS/no ref. #; **comments due 6/1/2016**)
- 80.b. Advanced Beneficiary Notice of Noncoverage (CMS-R-131; **comments due 6/1/2016**)
- 27.v. New System of Records (Risk Adjustment Data Validation) (CMS/no ref. #; **comments due approx. 6/2/2016**)
- 1.s. Assessing Interoperability for MACRA (HHS ONC/no ref. #; **comments due 6/3/2016**)
- 8.e. Healthy Indiana Program 2.0 Beneficiaries Survey (CMS-10615; **comments due 6/3/2016**)
- 71.d. ESRD Network Semi-Annual Cost Report Forms (CMS-685; **comments due 6/6/2016**)
- 136.f. CMS Innovation Partners Program Applications (CMS-10601; **comments due 6/6/2016**)
- 138.a. Organ Procurement Organization Health Insurance Agreement (CMS-576A; **comments due 6/6/2016**)
- 161.d. State Medicaid Eligibility Quality Control Sample Plans (CMS-317; **comments due 6/7/2016**)
- 161.e. State Medicaid Eligibility Quality Control Sample Selection Lists (CMS-319; **comments due 6/7/2016**)
- 161.f. Medicaid and CHIP Managed Care Claims (CMS-10178; **comments due 6/7/2016**)
- 3.c. Durable Medical Equipment Certificate of Medical Necessity (CMS-846-849, -10125, and -10126; **comments due 6/10/2016**)
- 3.d. Certification of Medical Necessity for Home Oxygen Therapy (CMS-484; **comments due 6/10/2016**)
- 112.m. Dear Tribal Leader Letter (Contract Support Costs Policy) (IHS/no ref. #; **comments due 6/10/2016**)
- 146.a. Data for Medicare Beneficiaries Receiving NaF-18 PET Scans (CMS-10152; **comments due 6/10/2016**)
- 135.a. LTCH Continuity Assessment Record and Evaluation (CMS-10409; **comments due 6/15/2016**)
- 25.jj. PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. (CMS-1655-P; **comments due 6/17/2016**)

[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.

- 25.kk. Exception for Severe Wound Discharges from LTCHs, et al. (CMS-1664-IFC; **comments due 6/17/2016**)
- 25.ll. Inpatient Rehabilitation Facility PPS for FY 2017 (CMS-1647-P; **comments due 6/20/2016**)
- 72.g. PPS and Consolidated Billing for SNFs for FY 2017, et al. (CMS-1645-P; **comments due 6/20/2016**)
- 78.l. Hospice Wage Index and Payment Rate Update for FY 2017 (CMS-1652-P; **comments due 6/20/2016**)
- 82.k. Health Insurance Reform Security Standards (HHS-OS-0945-0004-30D; **comments due 6/20/2016**)
- 82.l. HIPAA Privacy, Security, and Breach Notification Rules (HHS-OS-0945-0003-30D; **comments due 6/20/2016**)
- 194.f. 340B Drug Pricing Program Reporting Requirements (HRSA/OMB 0915-0176; **comments due 6/20/2016**)
- 60.n. Patient Request for Medicare Payment (CMS-1490S; **comments due 6/21/2016**)
- 67.b. Research on Outreach for Health Insurance Marketplace (CMS-10458; **comments due 6/21/2016**)
- 48.b. Medical Loss Ratio Rebate Calculation Report and Notices (CMS-10418; **comments due 6/24/2016**)
- 92.hhh. Updated Renewal and Product Discontinuation Notices (CCIIO/no ref. #; **comments due 6/27/2016**)
- 99.hh. Annual Eligibility Redetermination Notices, et al. (CMS-10527; **comments due 6/27/2016**)
- 136.h. MIPS and Alternative Payment Model Incentive Under PFS (CMS-5517-P; **comments due 6/27/2016**)
- 155.a. Research Exception Under GINA (CMS-10286; **comments due 6/28/2016**)
- 168. Enrollee Satisfaction Survey Data Collection (CMS-10488; **comments due 6/28/2016**)
- 121.p. Medicare Enrollment Application (CMS-855/A, B, and I; **comments due 6/30/2016**)
- 175.a. Medicaid Drug Program Monthly and Quarterly Drug Reporting (CMS-367; **comments due 7/1/2016**)
- 210. Functional Assessment Standardized Items (CARE Tool) (CMS-10243; **comments due 7/1/2016**)
- 7.www. Amendments to SEPs and the CO-OP Program (CMS-9933-IFC; **comments due 7/5/2016**)
- 11.j. Medicare Part D Reporting Requirements (CMS-10185; **comments due 7/5/2016**)
- 110.i. Self-Referral Disclosure Protocol (CMS-10328; **comments due 7/5/2016**)
- 7.q. Cooperative Agreement to Support Navigators in FFE (CMS-10463; **comments due 7/11/2016**)
- 11.g. Medicare Advantage Reporting Requirements (CMS-10261; **comments due 7/11/2016**)
- 36. Reporting Under Transitional Medical Assistance Provisions (CMS-10295; **comments due 7/11/2016**)
- 49.b. Medicare Credit Balance Reporting Requirements (CMS-838; **comments due 7/15/2016**)
- 82.h. HIPAA Eligibility Transaction System Partner Agreement (CMS-10157; **comments due 7/15/2016**)
- 89.d. Cost-Sharing Reductions Reconciliation Methodology (CMS-10469; **comments due 7/15/2016**)
- 143. Paid Feeding Assistants in Long-Term Care Facilities (CMS-10053; **comments due 7/25/2016**)
- 148.a. Acceptable Off-Label Uses of Certain Drugs and Biologicals (CMS-10302; **comments due 7/25/2016**)
- 112.g. Receipt of Non-VA Care Under Veterans Choice Program (VA/OMB 2900-0823; **comments due 7/26/2016**)
- 112.h. Health Care Plan Information for Veterans Choice Program (VA/OMB 2900-0823; **comments due 7/26/2016**)
- 112.i. Submission of Medical Records Under Veterans Choice Program (VA/OMB 2900-0823; **comments due 7/26/2016**)
- 112.j. Submission of Credentials by Eligible Entities or Providers (VA/OMB 2900-0823; **comments due 7/26/2016**)
- 112.r. Secondary Authorization Request for VA Community Care (VA/OMB 2900-0823; **comments due 7/26/2016**)

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

- 7.lll. 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)
- 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.q. 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)
- 112.n. Catastrophic Health Emergency Fund (CMS-359/360; comments submitted 5/10/2016 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)

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)
- 188a. Emergency Preparedness Requirements (CMS-3178-F; sent to OMB 11/3/2015)
- 25.ii. Hospital Changes to Promote Innovation, etc. (CMS-3295-P; sent to OMB 1/4/2016)
- 5.d. PACE Update (CMS-4168-P; sent to OMB 1/25/2016)
- 179.d. Changes to Medicare Appeals Procedures (HHS/RIN 0991-AC02; sent to OMB 3/1/2016)
- 161.h. Medicaid Eligibility Quality Control and PERM Programs (CMS-6068-P; sent to OMB 4/13/2016)
- 184.j. Clinical Diagnostic Laboratory Tests Payment System (CMS-1621-F; sent to OMB 4/21/2015)
- 174.g. FEHBP: Tribes and Tribal Organizations (OPM/RIN 3206-AM40; sent to OMB 4/22/2016)
- 3.q. Requirements for Prosthetics Practitioners and Suppliers (CMS-6012-P; sent to OMB 4/27/2015)
- 10.g. Medicare Shared Savings Program: ACO Benchmarking (CMS-1644-F; sent to OMB 4/29/2016)
- 52.l. Home Health Agency Conditions of Participation (CMS-3819-F; sent to OMB 5/6/2016)

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.lll. 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)
- 92.ccc. Rate Filing Justifications for 2016 for Single Risk Pool Coverage (CCIIO/no ref. #; 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)
- 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)

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

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TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2016

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 80	
			SECTION II: MEDICARE	Beginning on page 13 of 80	
			SECTION III: HEALTH REFORM	Beginning on page 43 of 80	
			SECTION IV: OTHER	Beginning on page 71 of 80	
			SECTION I: MEDICAID (AND DUAL MEDICAID AND MEDICARE)		
1.l.	EHR Incentive Program--Stage 3 ACTION: ~~Proposed~~ Final Rule NOTICE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 3 and Modifications to Meaningful Use in 2015 through 2017 AGENCY: CMS	CMS-3310-~~P~~FC 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 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.

: regulation review complete : regulation currently under review : regulation release pending

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1.p.	Health IT Certification Program: Enhanced Oversight ACTION: Proposed 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:	• Summary of Agency action: √ • NIHB analysis of 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 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:
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: 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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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: 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:
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 Due Date: 6/3/2016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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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:
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-~~P~~FC	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: √
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 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:

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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: 12/21/2012 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:
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:

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43.	Medicaid Reimbursement for Outpatient Drugs ACTION: ~~Proposed~~ Final Rule NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS	CMS-2345-~~P~~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: 6/1/2016 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:
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 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.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 Due Date: 5/28/2013; 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:
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:

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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	• 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 Due Date: 9/30/2013; 6/7/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 9/30/2013; 6/7/2016	• 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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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 Due Date: 6/7/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 6/7/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 6/7/2016	• 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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161.h.	Medicaid Eligibility Quality Control and PERM Programs ACTION: Proposed Rule NOTICE: Revisions to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement (PERM) Programs AGENCY: CMS	CMS-6068-P	Issue Date: [Pending at OMB as of 4/13/2016 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:
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 Due Date: 5/12/2014; 7/1/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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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:
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; sent Final Rule to OMB 11/3/2015	• 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	• 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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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: 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:
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:
			SECTION II: MEDICARE		
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:

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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: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 7/8/2013; 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:
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:

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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:
5.a.	PACE Information Request ACTION: Request for Comment NOTICE: Medicare and Medicaid; Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS	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	• Summary of Agency action: √ • NIHB analysis of action: None. • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
5.d.	PACE Update ACTION: Proposed Rule NOTICE: Programs of All-Inclusive Care for the Elderly (PACE) Update AGENCY: CMS	CMS-4168-P	Issue Date: [Pending at OMB as of 1/25/2016] 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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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: √ • 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: Sent Final Rule to OMB 4/29/2016	• Summary of Agency action: √ • NIHB analysis of 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 Due Date: 2/19/2013; 12/3/2013; 1/21/2014; 11/25/2014; 1/23/2015; 11/23/2015; 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:
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 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 1/20/2015; 11/23/2015; 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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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 Due Date: 8/20/2013; 11/4/2013; 6/30/2015; 9/23/2015; 10/19/2015; 7/11/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 6/3/2013; 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:

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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 Due Date: 8/26/2013; 6/30/2015; 9/23/2015; 7/5/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 8/5/2013; 5/24/2016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 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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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:
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 Home Health Agencies 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:

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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 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:
25.gg.	Inpatient Prospective Payment Systems--0.2 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:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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25.ii.	Hospital Changes to Promote Innovation, etc. ACTION: Request for Comment NOTICE: Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care AGENCY: CMS	CMS-3295-P	Issue Date: [Pending at OMB as of 1/4/2016] 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:
25.jj.	PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. ACTION: Proposed 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 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 Cost Reports AGENCY: CMS	CMS-1655-P	Issue Date: 4/27/2016 Due Date: 6/17/2016 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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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: 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.ll.	Inpatient Rehabilitation Facility PPS for FY 2017 ACTION: Request for Comment NOTICE: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017 AGENCY: CMS	CMS-1647-P	Issue Date: 4/25/2016 Due Date: 6/20/2016 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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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 Due Date: 3/25/2013; 7/15/2016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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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	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
52.l.	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-C1/ICD-10 ACTION: Request for Comment NOTICE: Outcome and Assessment Information Set (OASIS) OASIS-C1/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 Due Date: 4/24/2015; 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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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:	• Summary of Agency action: √ • NIHB analysis of 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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60.c.	Health Insurance Common Claims Form ACTION: Request for Comment NOTICE: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR Part 424, Subpart C AGENCY: CMS	CMS-1500 (02/12) CMS-1500 (08/05) CMS-1490S	Issue Date: 9/21/2012 Due Date: 10/22/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/15/2015, 2/5/2016 Due Date: 12/16/2015; 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:
60.l.	Expanding Uses of Medicare Data by Qualified Entities ACTION: Proposed Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities AGENCY: CMS	CMS-5061-P	Issue Date: 2/2/2016 Due Date: 3/29/2016 NIHB File Date: 3/29/2016 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:
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: 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:
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-~~P~~FC	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 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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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	• 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:
71.o.	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:

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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:
72.g.	PPS and Consolidated Billing for SNFs for FY 2017, et al. ACTION: Proposed 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	Issue Date: 4/25/2016 Due Date: 6/20/2016 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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78.I.	Hospice Wage Index and Payment Rate Update for FY 2017 ACTION: Proposed Rule NOTICE: Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements AGENCY: CMS	CMS-1652-P	Issue Date: 4/28/2016 Due Date: 6/20/2016 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:
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, 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	• Summary of Agency action: √ • TTAG analysis of action: √ • Summary of subsequent Agency action: √	• 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: Date of Subsequent Agency Action, if any: Issued revision 7/18/2013, 3/11/2016 Due Date: 8/19/2013; 5/10/2016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 6/2/2014; 7/5/2016	• 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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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:
121.m.	Medicare Enrollment Application--DMEPOS 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 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:
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:

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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: 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:
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:

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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: √ • 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.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:

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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:
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	• 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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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:
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: √

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136.h.	MIPS and Alternative Payment Model Incentive Under PFS ACTION: Proposed 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 Payment Models AGENCY: CMS	CMS-5517-P	Issue Date: 5/9/2016 Due Date: 6/27/2016 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:
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:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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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 Due Date: 6/17/2013; 1/26/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 6/17/2013; 2/8/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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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 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 Due Date: 7/1/2013; 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:
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, 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:
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:
179.d.	Changes to Medicare Appeals Procedures ACTION: Proposed Rule NOTICE: Medicare Program: Changes to the Medicare Claim, Organization Determination, and Coverage Determination Appeals Procedures AGENCY: HHS	HHS RIN 0991-AC02	Issue Date: [Pending at OMB as of 3/1/2016] 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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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:
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 Due Date: 4/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 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:
			SECTION III: HEALTH REFORM		
6.i.	Pre-Existing Health Insurance Plan Program Updates ACTION: Interim Final Rule NOTICE: Pre-Existing Condition Insurance Plan Program Updates AGENCY: CMS	CMS-9995-IFC4	Issue Date: [Pending at OMB as of 2/3/2015] 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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7.l.	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:
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 Due Date: 8/26/2013; 6/10/2014; 8/25/2014; 5/29/2015; 7/27/2015; 7/11/2016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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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:
7.lll.	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:

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7.nnn.	Establishment of Exchanges and QHPs--Standards 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:
7.ooo.	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:	• Summary of Agency action: √ • NIHB analysis of 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 Appeals--Options 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 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.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: 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 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.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 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:

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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:	• Summary of Agency action: √ • NIHB analysis of action: √	• TSGAC recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 30 days (approx. 6/2/2016) 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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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:
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: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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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:	• Summary of Agency action: √ • NIHB analysis of 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:
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: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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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 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.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:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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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-~~P~~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:
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:
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: √

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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: √
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:

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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:
51.c.	Application of Market Reforms to Student Health Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin Series--INFORMATION: 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:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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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] 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:
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 Due date: 5/6/2013; 6/21/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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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 Due Date: 7/29/2013; 7/15/2016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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	• 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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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:
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 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.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:
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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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 Due Date: 2/23/2015; 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:

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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 Series--INFORMATION--Bulletin: 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: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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92.ddd.	Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data Bulletin--INFORMATION: 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 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: 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 Series--INFORMATION--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 Bulletin--INFORMATION: 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: 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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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:
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:
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 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: √

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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: √ • 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:
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:

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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.l.	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:
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: 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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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 TSGAC File Date: 5/10/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/25/2016, 3/11/3016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• TSGAC recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:
112.o.	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:
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: 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.q.	Recognition of Tribal Groups for Representation of VA Claimants ACTION: Request for Information NOTICE: Recognition of Tribal Organizations for Representation of VA Claimants AGENCY: VA	VA (no reference number)	Issue Date: 3/10/2016 Due Date: 4/11/2016 NIHB File Date: 4/11/2016 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:

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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: 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:
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:

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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 Due Date: 12/2/2013; 6/29/2015; 8/24/2015; 6/28/2016 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: √
174.g.	FEHBP: Tribes and Tribal Organizations ACTION: Proposed Rule NOTICE: Federal Employees Health Benefits Program; Tribes and Tribal Organizations AGENCY: OPM	OPM (RIN 3206-AM40)	Issue Date: [Pending at OMB as of 4/22/2016] 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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			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 Due Date: 6/24/2013; 7/11/2016	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 3/5/2014; 7/15/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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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.l.	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:
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:

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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: 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	• 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 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: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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 Due Date: 6/17/2013; 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:

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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:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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: 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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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:
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:

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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: √ • 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 Due Date: 8/23/2013; 6/28/2016	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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	• 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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TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2016

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?
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-~~P~~F	Issue Date: 10/1/2015 Due Date: 11/24/2015 NIHB File Date: 11/24/2015 Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 4/21/2016	• 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:
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:

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TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2016

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194.d.	340B Ceiling Price and CMPs Regulation ACTION: Proposed 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 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.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:
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 Works--BPPPLE Form ACTION: Request for Comment NOTICE: IHS Sharing What Works --Best 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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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:

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TABLE B: SUMMARY OF NOTICES & REGULATIONS
UPDATED THROUGH 5/31/2016

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.
1.l.	EHR Incentive Program--Stage 3 ACTION: ~~Proposed~~ Final Rule NOTICE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 3 and Modifications to Meaningful Use in 2015 through 2017 AGENCY: CMS	CMS-3310-~~P~~FC 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 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 the Medicare and Medicaid EHR Incentive Programs reporting period in 2015 to a 90-day period aligned with the calendar year. This final rule with comment period also removes reporting requirements on measures that have become redundant, duplicative, or topped out from the Medicare and Medicaid EHR Incentive Programs. In addition, this final rule with comment period establishes the requirements for Stage 3 of the program as optional in 2017 and required for all participants beginning in 2018. This final rule with comment period continues to encourage the electronic submission of clinical quality measure	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.
					(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.  HC Client Memo - EHR Stage 3 Final Rul 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 Program--Stage 3 and Modifications to Meaningful Use in 2015 through 2017." https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04785.pdf	
1.p.	Health IT Certification Program: Enhanced Oversight ACTION: Proposed 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:		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 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.	

National Indian Health Board

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
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. 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	
1.r.	Voluntary Personal Health Record Model Privacy Notice ACTION: Request for Information NOTICE: Request for Information on Updates to	HHS ONC (no reference number)	Issue Date: 3/1/2016 Due Date: 4/15/2016 NIHB File Date:		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	

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.
	the ONC Voluntary Personal Health Record Model Privacy Notice AGENCY: HHS ONC		Date of Subsequent Agency Action, if any:		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 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: Date of Subsequent Agency Action, if any: Issued correction 4/27/2016		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 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	

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.
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-2016-02-19/pdf/2016-03474.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/2016-11080.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.
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: *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Documentation Requirements; *Use*: 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 NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 2/19/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03474.pdf No comments recommended. CMS on 5/11/2016 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.
					https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11080.pdf No comments recommended.	
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 Due Date: 7/8/2013; 5/31/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Reinstatement with change of a previously approved collection; *Title*: Grandfathering Provisions of the Medicare DMEPOS Competitive Bidding Program; *Use*: Section 1847(a)(4) of the Social Security Act (the Act) requires--in the case of covered durable medical equipment (DME) items for which payment occurs on a rental basis under section 1834(a) of the Act and in the case of oxygen for which payment occurs under section 1834(a)(5) of the Act--the HHS Secretary to establish a grandfathering process by which covered items and supplies rented by suppliers before the implementation of a competitive bidding program can continue. CMS established the grandfathering process in the 4/10/2007 final rule for competitive bidding for rented DME and oxygen and oxygen equipment when these items are included under the Medicare DMEPOS Competitive Bidding Program. This process only applies to suppliers that rented DME and oxygen and oxygen equipment to beneficiaries who maintain a permanent residence in a competitive bidding area (CBA) before the implementation of the competitive bidding program. 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.	

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.
					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.	
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: This proposed rule would specify the qualifications 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 Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations	CMS-359/360	Issue Date: 1/4/2016 Due Date: 3/4/2016 NIHB File Date: None Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations; *Use*: 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 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	

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: CMS		Action, if any: Issued extension 3/11/2016 Due Date: 4/11/2016		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.	
5.a.	PACE Information Request ACTION: Request for Comment NOTICE: Medicare and Medicaid; Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS	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:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of 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.	

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.
			11/8/2010; 12/3/2013; 1/21/2014; 2/8/2016; 6/1/2016		CMS on 10/4/2013 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.	
5.d.	PACE Update ACTION: Proposed Rule NOTICE: Programs of All-Inclusive Care for the Elderly (PACE) Update AGENCY: CMS	CMS-4168-P	Issue Date: [Pending at OMB as of 1/25/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would update the PACE regulations published on 12/8/2006. This proposed rule would improve the quality of the existing regulations, provide operational flexibility and modifications, and remove redundancies and outdated information. These updates seek to ensure the health and safety of PACE participants. SUMMARY OF NIHB ANALYSIS:	
6.i.	Pre-Existing Health Insurance Plan Program Updates	CMS-9995-IFC4	Issue Date: [Pending at OMB as of 2/3/2015]		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.
	ACTION: Interim Final Rule NOTICE: Pre-Existing Condition Insurance Plan Program Updates AGENCY: CMS		Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:			
7.I.	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	

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.
					2/10/2015, applies to the 2016 plan year. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Voluntary-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;		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Cooperative Agreement to Support Navigators in Federally-Facilitated and State Partnership Exchanges; *Use*: 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	

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.
			issued extension 6/26/2015, issued revision 5/11/2016 Due Date: 8/26/2013; 6/10/2014; 8/25/2014; 5/29/2015; 7/27/2015; 7/11/2016		appropriate. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf 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.	
7.jjj.	Establishment of QHPs and Exchanges ACTION: Request for Comment NOTICE: Establishment of Qualified Health Plans and	CMS-10400	Issue Date: 11/23/2015 Due Date: 1/22/2015 NIHB File Date:		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). As directed by the rule titled "Establishment of Exchanges and 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.
	American Health Benefit Exchanges AGENCY: CCIIO		Date of Subsequent Agency Action, if any: Issued revision 3/4/2016 Due Date: 4/4/2016		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 QHP must meet certain minimum 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.	
7.kkk.	ECP Petition for 2017 ACTION: Notice NOTICE: Essential Community Provider Petition for the 2017 Benefit Year	CCIIO (no reference number)	Due Date: ~~1/8/2016~~ 1/15/2016 NIHB File Date: None Date of		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. 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	

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: CCIIO		Subsequent Agency Action, if any: Issued due date extension		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 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 non-exhaustive list of available ECPs, based on data it and other federal agencies maintain, that has served as an initial source of ECP information. The non-exhaustive HHS ECP list for the 2016 benefit year is available at https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html. HHS updates this ECP list annually to assist issuers with identifying providers that qualify for inclusion in issuer networks toward satisfaction of the ECP standard under 45 CFR 156.235. That regulation defines ECPs as health care providers serving predominantly low-income, medically-underserved individuals. They include health care providers defined in section 340B(a)(4) of the Public Health Service Act (PHS Act) and described in section 1927(c)(1)(D)(IV) of the Social Security Act (Act). Interested parties should submit their petition by no later than 11:59 p.m. ET on 1/8/2016 in order for HHS to consider their provider data for the 2017 ECP List. HHS will allow petitions submitted after 1/8/2016 but no later than 8/22/2016 as a write-in for a respective issuer that has listed the provider on its ECP template for the 2017 QHP certification cycle. https://data.healthcare.gov/cciio/ecp_petition More information on QHPs is available on the CCIIO Web site at https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html. SUMMARY OF TSGAC ANALYSIS: A TSGAC briefing memo on the petition is embedded below.  TSGAC-Memo-Action -Needed-to-Retain-St	

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.
					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.III.	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 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.	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.
					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 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	

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.
					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 up-to-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	

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.
					specific to SBE-FPs.	
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: *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 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 comment. 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 comments impacted the burden, CMS made no changes. https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04841.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.nnn.	Establishment of Exchanges and QHPs--Standards 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: *Type of Information Collection Request*: New collection; *Title*: Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; *Use*: Section 1321(a) requires HHS to issue regulations setting standards for meeting the requirements under Title I of ACA, including the offering of qualified health plans (QHPs) through the Marketplaces. On 3/27/2012, HHS published the rule CMS-9989-F, Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (Exchange rule). The Exchange rule contains provisions that mandate reporting and data collections necessary to ensure that health insurance issuers meet the requirements of ACA. These information collection requirements appear in 45 CFR part 156. The data collection and reporting requirements will assist HHS in creating a seamless and coordinated system of eligibility and enrollment. The data collected by health insurance issuers will help to inform HHS, Marketplaces, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf 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). 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-	

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.
					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.ooo.	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:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: CMS Healthcare.gov Site Wide Online Survey; *Use*: 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.	
7.rrr.	Key Dates for CY 2016: QHP Certification in the FFM, et al. ACTION: Guidance NOTICE: ~~Proposed~~ Key Dates for Calendar Year	CCIIO (no reference number)	Issue Date: 12/23/2015 Due Date: None NIHB File Date:		SUMMARY OF AGENCY ACTION: This guidance provides proposed key dates in 2016 related to qualified health plan (QHP) 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	

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.
	2016: QHP Certification in the Federally-Facilitated Marketplaces; Rate Review; Risk Adjustment and Reinsurance AGENCY: CCIIO		Date of Subsequent Agency Action, if any: Issued Final Guidance 2/29/2016		SUMMARY OF NIHB ANALYSIS: Some key dates regarding QHP certification appear below. QHP Agreement/Final Certification --Certification Notices Sent to Issuers: 9/15/2016-9/16/2016 --Agreements Signed by Issuers and Returned to CMS with Final Plan List: 9/19/2016-9/23/2016 --Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers: 10/3/2016-10/4/2016 --Open 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 (QHP) 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 Certification --Certification Notices Sent to Issuers: 9/15/2016-9/16/2016 --Agreements Signed by Issuers and Returned to CMS with Final Plan List: 9/19/2016-9/23/2016 --Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers: 10/3/2016-10/4/2016 --Open Enrollment: 11/1/2016-1/31/2017	
7.sss.	April 2016 Transition of Issuers to Policy-Based Payments ACTION: Guidance NOTICE: Policy-Based	CCIIO (no reference number)	Issue Date: 3/22/2016 Due Date: None NIHB File		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	

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.
	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		Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 5/2/2016		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 Appeals--Paper-Based Processes ACTION: Guidance NOTICE: Marketplace Eligibility Appeals--Options 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: 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 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	

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					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 §155.205(c) and §156.250 AGENCY: CCIIO	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 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 Taglines--Languages Are Listed in Alphabetical	

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					Order: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-B-Sample-Translated-Taglines.pdf 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 AI/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 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	CMS-9933-IFC	Issue Date: 5/11/2016 Due Date: 7/5/2016 NIHB File Date: Date of		SUMMARY OF AGENCY ACTION: This interim final rule with comment period (IFC) establishes provisions that alter the parameters of select special enrollment periods and that revise certain rules governing consumer operated and oriented plans (CO-OPs). Section 1311(c)(6) of ACA establishes enrollment periods, including special enrollment periods for qualified individuals, for enrollment into qualified health plans (QHPs) through an Exchange. This IFC amends the eligibility requirements of the special enrollment period for individuals who gain access to new QHPs as a result of a permanent move so that this special enrollment period is generally available only to those individuals who had minimum essential coverage prior to their permanent move. This change aligns the	

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	Oriented Plan Program AGENCY: CMS		Subsequent Agency Action, if any:		eligibility requirements with the intent of this special enrollment period (i.e., to afford individuals the full range of plan options when they relocate) and promotes stability in the health insurance market. This IFC does not alter the eligibility for special enrollment 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). 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 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. 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.	

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					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:		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 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:	
7.yyy.	FAQs on Incarceration and	CCIIO (no	Issue Date:		SUMMARY OF AGENCY ACTION: Section 1312(f)(1)(B) of ACA and 45 CFR	

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.
	the Marketplace ACTION: Guidance NOTICE: Incarceration and the Marketplace Frequently Asked Questions AGENCY: CCIIO	reference number)	5/3/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		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 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:	
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.	See Table C.

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					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://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ok/ok-soonercare-pa.pdf 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 Due Date: 6/3/2016		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	

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.
					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.	

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.
					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-~~P~~F	Issue Date: 2/3/2016 Due Date: 3/28/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 4/29/2016		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-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 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:	
11.d.	Bid Pricing Tool ACTION: Request for Comment	CMS-10142	Issue Date: 10/5/2012 Due Date:		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	

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: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs) AGENCY: CMS		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 Due Date: 2/19/2013; 12/3/2013; 1/21/2014; 11/25/2014; 1/23/2015; 11/23/2015; 1/19/2016		"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. 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	

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.
					No comments recommended.	
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 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 1/20/2015; 11/23/2015; 1/19/2016		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) 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 11/1/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26107.pdf CMS on 1/17/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00915.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.
					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 12/19/2014 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-2014-12-19/pdf/2014-29739.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.	
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		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.	

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.
			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 Due Date: 8/20/2013; 11/4/2013; 6/30/2015; 9/23/2015; 10/19/2015; 7/11/2016		SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/21/2013 issued a revision 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 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 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	

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.
					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. https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11078.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 Due Date: 6/3/2013; 2/12/2016		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). CMS on 12/14/2015 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.
					https://www.gpo.gov/fdsys/pkg/FR-2015-12-14/pdf/2015-31399.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 Due Date: 8/26/2013; 6/30/2015; 9/23/2015; 7/5/2016		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. 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 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.	

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.
					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.	
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 Due Date: 8/5/2013; 5/24/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use*: 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). 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	

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.
					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	
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 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. • 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.	

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					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. 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:	
14.c.	Waivers for State Innovation ACTION: Notice NOTICE: Waivers for State Innovation	CMS-9936-N	Issue Date: 12/16/2015 Due Date: Open TSGAC File Date:	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	See Table C.

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	AGENCY: CMS/Treasury		2/23/2016 Date of Subsequent Agency Action, if any:		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 AI/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 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." No explicit mention of AI/AN has a distinct group of residents, whereby the state's proposal would be evaluated to ensure no reduction in coverage. 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	

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					explicit mention of AI/ANs is included in the guidance. Coverage: "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 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	

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.
					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 require states to provide a public notice and comment period for a waiver application sufficient to ensure a meaningful level of public input prior to submitting an application. As part of the public notice and comment period, a state with one or more Federally-recognized tribes must conduct a separate process for meaningful consultation with such tribes … Section 1332 and its implementing regulations also require the Federal Government to provide a public notice and comment period, once the Secretaries receive an application."	
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	CMS-2249-~~P2~~F2	Issue Date: 5/3/2012 Due Date: ~~6/4/2012~~ 7/2/2012 NIHB File Date: None		SUMMARY OF AGENCY ACTION: This proposed rule would revise Medicaid 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	

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	AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued due date extension 5/3/2012; Final Rule approved by OMB 1/13/2014		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:	
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-~~P~~FC	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		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	

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			Due Date: 1/4/2016		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 proposed rule suggests mechanisms for ongoing beneficiary input; the most effective way of reaching AI/ANs is through Indian health care providers and Tribes 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-2015-11-02/pdf/2015-27697.pdf CMS on 4/12/2016 issued a document (CMS-2328-F2) that extends the deadline for submitting an access monitoring review plan, as required by the final rule with comment period, until 10/1/2016. The final rule with comment period had established that states must develop and submit to CMS an access monitoring review plan by 7/1/2016.	

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.
					https://www.gpo.gov/fdsys/pkg/FR-2016-04-12/pdf/2016-08368.pdf	
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 Due Date: 1/4/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In this request for information (RFI), CMS seeks 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 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: 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	

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.
					at http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27696.pdf. SUMMARY OF NIHB ANALYSIS:	
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: 12/21/2012 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	TSGAC resposne:	SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Medicaid and CHIP Program (MACPro); Use: Medicaid, authorized by Title XIX of the Social Security Act and, CHIP, reauthorized by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), play an important role in financing health care for approximately 48 million people throughout the country. By 2014, it is expected that an additional 16 million people will become eligible for Medicaid and CHIP as a result of the Affordable Care Act (Pub. L. 111–148). In order to implement the statute, CMS must provide a mechanism to ensure timely approval of Medicaid and CHIP state plans, waivers and demonstrations, and provide a repository for all Medicaid and CHIP program data that supplies data to populate Healthcare.gov and other required reports. Additionally, 42 CFR 430.12 sets forth the authority for the submittal and collection of state plans and plan amendment information. Pursuant to this requirement, CMS has created the MACPro system. Generally, MACPro will be used by both state and CMS officials to: Improve the state application and federal review processes, improve federal program management of Medicaid programs and CHIP, and standardize Medicaid program data. More specifically, it will be used by state agencies to (among other things): (1) Submit and amend Medicaid state plans, CHIP state plans, and Information System Advanced Planning Documents, and (2) submit applications and amendments for state waivers, demonstration, and benchmark and grant programs. It will be used by CMS to (among other things): (1) Provide for the review and disposition of applications, and (2) monitor and track application activity. A paper-based version of the MACPro instrument would be sizable and time consuming for interested parties to follow as a paper-based instrument. In our effort to provide the public with the most efficient means to make sense of the MACPro system, we held four webinars in lieu of including a paper-based version of MACPro. SUMMARY OF TSCAG ANALYSIS: MACPro requires the State to submit information on both general and Tribal consultation processes in the "initial application," which the State completes at the outset of any submission. With regard to Tribal consultation, the application first asks whether "one or more Indian Health Programs or Urban Indian	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.
					Organizations furnish health care services in this State." If the State answers "yes," the application asks whether "this state plan amendment is likely to have a direct effect on Indians, Indian health care programs, or urban Indian organizations." If the State answers "yes," the application asks whether "the State has solicited advice from Tribal governments prior to submission of this SPA application." If the State answers "yes," the 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.bb.	Comprehensive Care for Joint Replacement Payment Model	CMS-5516-~~P~~F	Issue Date: 7/14/2015 Due Date:		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	

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: ~~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		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		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. 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	

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.
					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 and typographical errors identified in the final rule. https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04786.pdf	
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 Home Health Agencies 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: 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 participate in the Medicare and Medicaid programs. This proposed rule also would implement the discharge planning requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014. SUMMARY OF NIHB ANALYSIS:	
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		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Reinstatement without change of a previously approved collection; *Title*: Emergency and Foreign Hospital Services; *Use*: Section 1866 of the Social Security Act (Act) states that any provider of services must qualify to participate in the Medicare program and qualify for payments under Medicare if it files an agreement with the HHS Secretary to meet the conditions outlined in this section of the Act. Section 1814(d)(1) of the Act and 42 CFR 424.100 allow payment of Medicare benefits for a Medicare beneficiary to a nonparticipating hospital that does not have an agreement in effect with CMS. These payments can occur if such services were emergency services and if CMS would have to make the payment if the hospital had an agreement in effect and met the conditions of payment. This form is used in connection with claims for emergency hospital services	

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: Issued reinstatement 11/9/2015, 2/5/2016 Due Date: 12/9/2015, 4/5/2016		provided by hospitals that do not have an agreement in effect under Section 1866 of the Act. As specified in 42 CFR 424.103(b), before a non-participating hospital can receive payment for emergency services rendered to a Medicare beneficiary, it must submit a statement sufficiently comprehensive to support that an emergency existed. Form CMS-1771 contains a series of questions relating to the medical necessity of the emergency. The attending physician must attest to the need for the hospitalization under the regulatory emergency definition and give clinical documentation to support the claim. http://www.gpo.gov/fdsys/pkg/FR-2015-09-21/pdf/2015-23528.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. 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	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:	

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.
	Experiences with Care Received in Long-Term Care Hospitals AGENCY: CMS					
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 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 inpatient rehabilitation facilities (IRFs). http://www.gpo.gov/fdsys/pkg/FR-2015-11-20/pdf/2015-29623.pdf SUMMARY OF NIHB ANALYSIS:	
25.gg.	Inpatient Prospective Payment Systems--0.2 Percent Reduction ACTION: Notice NOTICE: Medicare Program; Inpatient Prospective Payment Systems; 0.2 Percent	CMS-1658-NC	Issue Date: 12/1/2015 Due Date: 2/2/2016 NIHB File Date: None Date of		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.	

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.
	Reduction AGENCY: CMS		Subsequent Agency Action, if any: Issued update 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	
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:		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:	
25.ii.	Hospital Changes to Promote Innovation, etc. ACTION: Proposed Rule NOTICE: Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and	CMS-3295-P	Issue Date: [Pending at OMB as of 1/4/2016] Due Date: NIHB File Date:		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. This proposed rule would change the requirements to meet current standards of practice, as well as support improvements in quality of care, reduce barriers to care, and reduce some issues that might exacerbate workforce shortage concerns. 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.
	Improvement in Patient Care AGENCY: CMS		Date of Subsequent Agency Action, if any:			
25.jj.	PPS for Acute and Long-Term Care Hospitals for FY 2017, et al. ACTION: Request for Comment 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 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 Cost Reports AGENCY: CMS	CMS-1655-P	Issue Date: 4/27/2016 Due Date: 6/17/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		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 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	

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.
					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 • Inpatient Psychiatric Facility Quality Reporting Quality Reporting (IPFQR) Program • Long-Term Care Hospital Prospective Payment System Changes • Long Term 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 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.	

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.
					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.  MMPC Memo - Medicare Hosp Payn	
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: 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 *Geisinger Community Medical Center v. Secretary, United States Department of Health and Human Services*, 794 F.3d 383 (3d Cir. 2015) and *Lawrence + Memorial Hospital v. Burwell*, 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.	
25.ll.	Inpatient Rehabilitation Facility PPS for FY 2017	CMS-1647-P	Issue Date: 4/25/2016		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	

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: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2017 AGENCY: CMS		Due Date: 6/20/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		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.	
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 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	

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.
					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 $33.00 per covered life, and the second payment due by 11/15/2016, 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. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RIC_2015ContributionsGuidance.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.
					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: 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.	
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		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. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10463.pdf 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	

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.
			Rule 9/1/2015; issued Final Rule 12/18/2015; issued correction 1/15/2016 Due Date: 11/2/2015		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 (QHPs) through Affordable Insurance Exchanges (Exchanges, or Marketplaces) and claim the health insurance premium tax credit and Exchanges that make QHPs available to individuals and employers. https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31866.pdf 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.	

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.
					https://www.gpo.gov/fdsys/pkg/FR-2016-01-15/pdf/2016-00701.pdf	
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 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	CCIIO (no reference number)	Issue Date: 11/20/2015		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 non-	

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: Guidance NOTICE: ~~Draft~~ 2017 Actuarial Value Calculator AGENCY: CCIIO		Due Date: 12/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 1/21/2016		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 *de minimis* 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/Resources/Regulations-and-Guidance/Downloads/Draft-2017-AV-Calculator-111615xlsm.xlsm. 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	

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.
					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 *de minimis* 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 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	CMS-10465	Issue Date: 3/11/2016 Due Date:		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	

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: Minimum Essential Coverage AGENCY: CMS		5/10/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		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.	
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?	

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.
					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 expeditiously. The Departments intend that health plans and issuers that maintain an annual open enrollment period will be required to use the new 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, 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 year) that begins on or after April 1, 2017. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQS-30_final-3-11-16.pdf SUMMARY OF NIHB ANALYSIS: Issuers must use of the new/reformatted SBC template for plan years that start on or after 1/1/2017.	
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 cost-	

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.
					sharing 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 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 NIHB File Date: Date of Subsequent Agency Action, if any:		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 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	CMS-10468	Issue Date: 4/1/2016 Due Date:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; *Use*: ACA expands access to health	

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.
	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		5/31/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		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 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.	
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	

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.
					to provide EHB. ... https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Waiting-period-FAQ-05262016-Final-.pdf SUMMARY OF NIHB ANALYSIS:	
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 Due Date: 6/24/2013; 7/11/2016		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 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.	
39.f.	Basic Health Program: Federal Funding	CMS-2396-~~P~~FN	Issue Date: 10/22/2015		SUMMARY OF AGENCY ACTION: This document provides the methodology and data sources necessary to determine federal payment amounts made in program years 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.
	Methodology for 2017 ACTION: ~~Proposed~~ Final Methodology NOTICE: Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018 AGENCY: CMS		Due Date: 11/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Methodology 2/29/2016		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 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: 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 SUMMARY OF NIHB ANALYSIS:	
43.	Medicaid Reimbursement for Outpatient Drugs ACTION: ~~Proposed~~ Final Rule	CMS-2345-~~P~~FC	Issue Date: 2/2/2012 Due Date: 4/2/2012	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.	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.
	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		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 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.	

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 memo -Covered Outpatien A CMS presentation on this final rule is embedded below.  CMS - PP Presentation to TTAC Tribal representatives should considering two actions: • 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: 6/1/2016 NIHB File Date: 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	

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.
					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. 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 4/15/2016 through 6/1/2016. CMS will accept practice applications in the determined regions from 7/15/2016 through 9/1/2016. 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. A document that answers frequently asked questions on CPC+ is available at https://innovation.cms.gov/Files/x/cpcplus-faqs.pdf. A CMS press release on CPC+ 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.
					https://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Plus. 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.	
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 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 2013 and the preliminary federal share DSH allotments for FY 2015. This notice also announces the final FY 2013 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 includes background information describing the methodology for determining the amounts of state FY DSH allotments. https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01836.pdf SUMMARY OF NIHB ANALYSIS:	
48.b.	Medical Loss Ratio Rebate Calculation Report and Notices	CMS-10418	Issue Date: 12/4/2012 Due Date:		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 implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering	

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		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		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/fdsys/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 student health plans on a nationwide basis, similar to expatriate plans. In addition, the instructions address recent applicability guidance issued by the Departments of Labor and Treasury and HHS concerning expatriate plan reporting prior to plan years ending before or on 12/31/2015. In 2014, issuers likely will send fewer notices and rebate checks to policyholders and subscribers, resulting in a reduction in burden. However, the requirement to report data on student health plans will increase burden for some issuers. CMS estimates a net reduction in total information collection burden. http://www.gpo.gov/fdsys/pkg/FR-2013-11-22/pdf/2013-28049.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.
					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 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. CMS on 2/19/2016 issued an extension of this PRA request. According to CMS, the 2015	

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.
					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.	
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		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	

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.
			2/17/2015; issued Final Rule 2/12/2016		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. A summary of this final rule is embedded below. Repayment of Overpayments - CMS	
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;		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. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/22/2013 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.
			issued extension 5/16/2016 Due Date: 3/25/2013; 7/15/2016		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.	
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 (QHPs) 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 response to the notice published in the 7/6/2012 FR (77 FR 40061), CMS received public comments from more than 20 entities. Some of commenters raised concerns	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.
					about duplicate or overly burdensome data collection as related to the employee 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 the availability of other coverage, pre-populating certain applicant information, and indicating whether the employee has waived SHOP coverage. 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	CMS-10439 See also 50.m.	Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses 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 (QHPs) offered in the small group market. Section 1311(c)(1)(F) of ACA mandates that HHS establish criteria for certification of health plans	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.
	NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in SHOP AGENCY: CMS		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		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. 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:	

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 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.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 extension 12/2/2015; issued revision 12/2/2015, 3/25/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Affordable Insurance Exchanges, Medicaid and Children's Health Insurance Program Agencies; *Use*: 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,	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.
			Due Date: 2/1/2016; 4/25/2016		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. In response to the notice published in the July 6, 2012, FR (77 FR 40061), CMS received approximately 65 public comments. In response, CMS has made significant changes to 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 AI/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 AI/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.	

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.
					http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf No comments recommended. 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.	
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 Enrollment Transition	CCIIO (no reference	Issue Date: 4/18/2016		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	

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: Guidance NOTICE: Extension of State-Based SHOP Direct Enrollment Transition AGENCY: CCIIO	number)	Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		two years--for 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 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:	
51.c.	Application of Market Reforms to Student Health Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin Series--INFORMATION: 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: 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 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).	

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.
					https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/student-health-bulletin.pdf SUMMARY OF NIHB ANALYSIS:	
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:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Student Health Insurance Coverage; *Use*: 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 the AV of the coverage and the metal level (or the next lowest metal level) the coverage otherwise would satisfy under § 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.	

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.
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: *Type of Information Collection Request*: New collection; *Title*: Home Health Change of Care Notice (HHCCN); *Use*: 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 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	

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.
					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.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		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 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-2015-02-02/pdf/2015-01696.pdf CMS on 7/27/2015 issued a document (CMS-6059-N3) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies, subunits, and branch locations 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-2015-07-28/pdf/2015-18327.pdf CMS on 2/2/2016 issued a document (CMS-6059-N4) to announce the extension of temporary moratoria on the enrollment of new Medicare Part B ground ambulance	

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.
					suppliers and Medicare home health agencies, subunits, and branch locations in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. These moratoria also apply to the enrollment of home health agencies and ground ambulance suppliers in Medicaid and CHIP. https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01835.pdf	
52.l.	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-C1/ICD-10 ACTION: Request for Comment NOTICE: Outcome and	CMS-10545	Issue Date: 1/9/2015 Due Date: 3/10/2015		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-	

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.
	Assessment Information Set (OASIS) OASIS-C1/ICD-10 AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/25/2015; issued revision 4/1/2016 Due Date: 4/24/2015; 5/31/2016		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 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.	
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:		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.	

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.
			1/27/2016		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 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:		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	

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.
					program in advance to determine appropriate payment. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02277.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
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 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.
					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.	
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.I.	Expanding Uses of Medicare Data by Qualified Entities ACTION: Proposed Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities	CMS-5061-P	Issue Date: 2/2/2016 Due Date: 3/29/2016 NIHB File Date: 3/29/2016 Date of	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.	See Table C.

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	AGENCY: CMS		Subsequent Agency Action, if any:		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. Impact on Medicaid According to CMCS, this proposed rule has relevance to Medicaid in two areas: • State Medicaid Agencies as Qualifies Entities: This proposed rule includes a policy to include state Medicaid agencies under the definition of a qualified entity, a change that would allow state Medicaid agencies to access Medicare data from CMS for research purposes (CMCS encourages states to submit comments as to whether or not they agree with this policy). • Access to Medicaid/CHIP Data: This proposed rule also includes a policy under which qualified entities (possibly including states) could not access Medicaid/CHIP data via CMS and would have to turn directly to state agencies for this data (CMCS encourages states to submit comments as to whether or not they agree with this policy). SUMMARY OF NIHB ANALYSIS: Tribal representatives might want to submit comments on the proposed requirement to secure Medicaid data through each state and not through CMS.	
60.m.	Reapplication Submission for Qualified Entities	CMS-10596	Issue Date: 2/5/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Reapplication Submission Requirement for Qualified Entities Under ACA	

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: Reapplication Submission Requirement for Qualified Entities Under ACA Section 10332 AGENCY: CMS		Due Date: 4/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		Section 10332; *Use*: 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.	
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: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: 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 0938-1197. https://www.gpo.gov/fdsys/pkg/FR-2016-04-22/pdf/2016-09425.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
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 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.	

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.
					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 4/4/2013; issued extension 4/22/2016 Due date: 5/6/2013; 6/21/2016		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 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	

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.
					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	
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-~~P~~FC	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 Due Date: 12/29/2015	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 resources--work, 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: • 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;	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.
					• 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 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 *Modern Healthcare* article reported on several key provisions in this proposed	

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.
					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 in-person 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, tele-rehabilitation 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 modifier--all 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 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 forms--one 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.	

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 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." https://www.gpo.gov/fdsys/pkg/FR-2016-03-08/pdf/2016-05054.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	

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.
					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/ap-us-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-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:	
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: None Date of Subsequent Agency Action, if any: Issued revision 4/26/2013,		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a previously approved collection; *Title*: 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; *Use*: 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 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	

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.
			3/1/2016, 5/6/2016 Due Date: 5/28/2013; 5/2/2016; 6/6/2016		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.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: 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”.	

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.
					http://www.gpo.gov/fdsys/pkg/FR-2015-09-02/pdf/2015-21783.pdf 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.o.	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		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.	

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.
			Due Date: 3/31/2016			
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: *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing; *Use*: CMS seeks approval of a reinstatement of a Change of Therapy OMRA for Skilled Nursing Facilities (SNFs). As described in CMS-1351-F, CMS finalized the assessment effective 10/1/2011. SNFs must submit this assessment. The COT OMRA includes a subset of resident assessment information developed for use by SNFs to satisfy a Medicare payment requirement. The burden associated with this involves the SNF staff time required to complete the COT OMRA, SNF staff time to encode the data, and SNF staff time spent in transmitting the data. SNFs must complete a COT OMRA when a resident receives a sufficient level of rehabilitation therapy to qualify for an Ultra High, Very High, High, Medium, or Low 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.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
72.g.	PPS and Consolidated Billing for SNFs for FY 2017, et al. ACTION: Proposed 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	Issue Date: 4/25/2016 Due Date: 6/20/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		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 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. SUMMARY OF NIHB ANALYSIS: No comments recommended.	
78.l.	Hospice Wage Index and Payment Rate Update for FY 2017 ACTION: Proposed Rule NOTICE: Medicare Program; FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements AGENCY: CMS	CMS-1652-P	Issue Date: 4/28/2016 Due Date: 6/20/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		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:	

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.
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, 4/5/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Fiscal Soundness Reporting Requirements; *Use*: 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 revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf 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 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 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.
					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 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		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Notice of Denial of Medical Coverage (or Payment); *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 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 processes. Section 1932 of SSA sets forth requirements for Medicaid managed care 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 the Notice of Denial of Payment and includes optional language for use in cases where a Medicare health plan enrollee also receives full Medicaid benefits managed by the Medicare health plan. SUMMARY OF TTAG ANALYSIS: The majority of claims filed by Indian health care providers under Medicare and Medicaid involve direct fee-for-service reimbursement from the Federal program and not private managed care plans. However, private plan participation by enrollees, as well as by Indian health care providers, has increased under Medicare and Medicaid, and the proposed Notice of Denial of Medical Coverage (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 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.	

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.
					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 for Medicaid managed care enrollees. Since a state can offer additional 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). 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	CMS-R-131	Issue Date: 12/12/2012 Due Date: 2/11/2013		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	

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: Advance Beneficiary Notice of Noncoverage AGENCY: CMS		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		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/fdsys/pkg/FR-2012-12-12/pdf/2012-29951.pdf SUMMARY OF NIHB ANALYSIS: 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/fdsys/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. Additionally, CMS has made minor language and grammatical changes to the instructions to improve 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.	

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.
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: Date of Subsequent Agency Action, if any: Issued revision 7/18/2013, 3/11/2016 Due Date: 8/19/2013; 5/10/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Notice of Denial of Medicare Prescription Drug Coverage; *Use*: 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. 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.	

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.
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 Due Date: 3/5/2014; 7/15/2016		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 No comments recommended.	
82.j.	Complaint Forms for Health Information Privacy Issues ACTION: Request for Comment NOTICE: Complaint Forms for Discrimination; Health Information Privacy	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		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.	

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.
	Complaints AGENCY: HHS OCR		Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016		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 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: *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 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.l.	HIPAA Privacy, Security, and Breach Notification Rules	HHS-OS-0945-0003-60D	Issue Date: 3/17/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR parts 160 and 164; *Use*: 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.
	ACTION: Request for Comment NOTICE: HIPAA Privacy, Security, and Breach Notification Rules AGENCY: HHS	HHS-OS-0945-0003-30D	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		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. 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.	
83.a.	Medicaid/Transformed-Medicaid Statistical Information System ACTION: Request for Comment	CMS-R-284	Issue Date: 8/15/2012 Due Date: 10/15/2012 NIHB File	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-	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.
	NOTICE: Medicaid Statistical Information System (MSIS) and Transformed-Medicaid Statistical Information System (T-MSIS) AGENCY: CMS		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		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 AI/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 AI/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. She told me she would try to obtain information for me on the "changes in collection of information," other than changing state reporting data to CMS monthly with T-MSIS instead of quarterly, and on AI/AN and 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 Register--even 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	

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.
					report data more frequently to CMS, I think a response to this notice could: 1. Support state Medicaid programs' monthly submissions of data to CMS in order to have timely data on Medicaid enrollees and providers; 2. Describe AI/AN disparities and key Medicaid AI/AN and I/T provider provision; 3. State the importance of having T-MSIS data for AI/AN and I/T/Us to monitor implementation of AI/AN protections and I/T payments to ensure "the proper performance of CMS functions"; 4. T-MSIS is a national database and source for information from all states; 5. Note since its implementation we have not seen reports for AI/AN enrollees or I/T providers; and 6. Request that regular reports be available on a quarterly basis to monitor use of measures, AI/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 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;		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Issuer Reporting Requirements for Selecting a Cost-Sharing Reductions Reconciliation Methodology; *Use*: 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 request establishes the data collection requirements for a QHP issuer to report to HHS which reconciliation reporting option the issuer will undergo for a given benefit year. Sections 1402 and 1412 of ACA provide for reductions in cost sharing on essential health benefits for low- and moderate-income enrollees in silver level QHPs on individual market Exchanges. ACA also provides for reductions in cost sharing for Indians enrolled 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 HHS Secretary to make periodic and timely payments to the QHP issuer equal to 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.
			issued extension 5/16/2016 Due Date: 7/29/2013; 7/15/2016		value of those reductions. Further, the law permits advance payment of the cost-sharing reduction amounts to QHP issuers based upon amounts specified by the HHS Secretary. 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 which CMS would make monthly advance payments to issuers to cover projected cost-sharing reduction amounts and then reconcile those advance payments after the end of the benefit year to the actual cost-sharing reduction amounts. The reconciliation process 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. 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	

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.
					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.	
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		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New 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 QHP 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 (QHP) through an Exchange. On 3/11/2013,	

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.
			9/26/2014; issued revision 9/14/2015, 1/20/2016 Due Date: 10/27/2014; 11/13/2015; 2/19/2016		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 re-estimated) by the issuer on behalf of an enrollee and recoup or remit the balance. In prior recommendations, TTAG suggested that CMS "should continue to use as the primary payment methodology a mechanism based on actual (and not estimated) payments made by issuers for the cost-sharing protections provided to AI/ANs under the limited and zero cost-sharing variations and propose to transition to an alternative payment mechanism only after demonstrating such an alternative would not create counter-productive financial incentives." This recommendation sought to diminish opportunities for health plans to receive payments from CMS for cost-sharing reductions and not actually provide the cost-sharing reductions due to enrollees. In response, CMS 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 AI/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 AI/ANs and not inadvertently create incentives for health plans to deny the cost-sharing protections due	

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.
					to AI/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 (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	CMS-9937-~~P~~F	Issue Date: 12/2/2015	TTAG 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-	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.
	ACTION: ~~Proposed~~ Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 AGENCY: CMS		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	TSGAC response:	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 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	

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.
					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 up-to-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. A *Modern Healthcare* article about this final rule is available at http://www.modernhealthcare.com/article/20160229/NEWS/160229878.	
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	CCIIO (no reference number)	Issue Date: 1/15/2016 Due Date: 2/15/2016 NIHB File Date: None Date of		SUMMARY OF AGENCY ACTION: This draft 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 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.	

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.
	2014 and 2015 AGENCY: CCIIO		Subsequent Agency Action, if any: Issued Final Guidance 3/16/2016		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-Attestation-Inbound-Specification-DRAFT.pdf. The document titled "CSR Reconciliation: Issuer to MIDAS Inbound Specification" is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CSR-Recon-Issuer-to-MIDAS-Inbound-Specification_DRAFT.pdf. 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.	

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.
					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 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	

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.
					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.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: 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 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	CCIIO (no reference number)	Issue Date: 3/9/2016 Due Date: None NIHB File Date:		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.	

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.
	Specification AGENCY: CCIIO		Date of Subsequent Agency Action, if any:		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_Q-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 Agency Action, if any:		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 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:	
92.b.	Compliance with Individual and Group Market Reforms ACTION: Request for Comment	CMS-10430	Issue Date: 11/21/2012 Due Date: 1/22/2013		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	

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: Information Collection Requirements for Compliance with Individual and Group Market Reforms AGENCY: CMS		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		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 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;	

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 of intent to discontinue a product or abandon the market; • 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 opt-out; 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 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	CMS-10330	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date:		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.	

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.
	to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection Under the Affordable Care Act AGENCY: CMS		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		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. 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	CMS-10325	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: Date of		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, 2010--grandfathered health plans--do 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	

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.
	Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care Act AGENCY: CMS		Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016		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. 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	CMS-10379	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None		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	

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.
	Disclosure and Review Reporting Requirements AGENCY: CMS		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		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. 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	

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.
					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 with changes. http://www.gpo.gov/fdsys/pkg/FR-2014-04-02/pdf/2014-07402.pdf No comments recommended. This PRA request establishes reporting requirements for 1) insurance products in the "single-risk pool" and 2) non-grandfathered plans in the individual and small-group markets operating under the "transitional policy" for plans that otherwise would get canceled. CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03474.pdf 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;		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Annual Eligibility Redetermination, Product Discontinuation, and Renewal Notices; *Use*: 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	

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			issued revision 4/28/2016 Due Date: 2/23/2015; 6/27/2016		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 for 2015" contains the procedures that the Secretary has specified for the 2015 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 QHP issuers in the Exchanges and specifies content for these notices. The accompanying guidance document "Form and Manner of Notices When Discontinuing or Renewing a Product in the Group or Individual Market" provides standard notices for product discontinuation and renewal sent by issuers of individual market QHPs and issuers in the individual market. Issuers in the small group market can use the draft Federal standard small group notices released in the June 26, 2014, bulletin "Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group 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	
92.kk.	Summary of Benefits and	CMS-10407	Issue Date:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of	

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.
	Coverage and Uniform Glossary ACTION: Request for Comment NOTICE: Summary of Benefits and Coverage and Uniform Glossary AGENCY: CMS	See also 31.tt.	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		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 Department of Labor (DoL), and the Department of 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." To implement these disclosure requirements, collection of information requests relate to the provision of the following: summary of benefits and coverage, which includes coverage examples; a uniform glossary of health coverage and medical terms; and a notice of modifications. 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:	

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.
					https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SBC-Template.pdf • Proposed Uniform Glossary: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Uniform-Glossary.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/No-Answers.pdf • Proposed Why This Matters language for SBC "Yes" Answers: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Yes-Answers.pdf • Proposed Instructions for Completing the SBC--Individual Health Insurance Coverage: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/cciio-Individual-Instructions.PDF • Proposed Instructions for Completing the SBC--Group Health Plan Coverage" https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Group-Instructions.pdf • Proposed Guide for Coverage Examples Calculations--Maternity Scenario, Diabetes Scenario, and Foot Fracture: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/coverage_examples_calculator.pdf • Proposed Coverage Examples Narrative--Maternity Scenario: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/maternity-narrative.pdf • Proposed Coverage Examples Narrative--Diabetes Scenario: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/diabetes-narrative.pdf • Proposed Coverage Examples Narrative--Foot 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 documents--which each QHP issuer must release for each plan "variation" offered on 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.
					Marketplace--are 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. No comments recommended.	
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: *Type of Information Collection Request*: New collection; *Title*: Transparency in Coverage Reporting by Qualified Health Plan Issuers; *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 non-grandfathered 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	

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.
					other relevant factors. The Departments also intend to streamline reporting under multiple reporting provisions and reduce unnecessary duplication. The Departments intend to implement any transparency reporting requirements applicable to non-QHP issuers and non-grandfathered group health plans only after notice and comment and after giving those issuers and plans sufficient time, following the publication of final rules, to come into compliance with these requirements. This information collection includes the following data elements: *Appendix A--QHP Issuer Data Collection* • Issuer Name: The full legal name of the issuer, as submitted in the Qualified Health Plan (QHP) application. • 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). *Appendix B--QHP Issuer Data Display*	

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.
					• 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: 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--INFORMATION--Bulletin: Timing of Submission and	CCIIO (no reference number)	Issue Date: 12/23/2015 Due Date: 1/22/2016 NIHB File Date: None Date of		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.	

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.
	Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage AGENCY: CCIIO		Subsequent Agency Action, if any: Issued Final Guidance 2/29/2016		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 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	

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.
					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 (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	
92.ddd.	Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data Bulletin--INFORMATION: 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 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued clarification 3/16/2016		SUMMARY OF 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 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	

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					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-Quality_Quantity_Guidance_for_2015_Benefit_Year_5CR_031516.pdf	
92.eee.	Extension of Transitional Policy Through CY 2017 ACTION: Guidance NOTICE: Insurance Standards Bulletin Series--INFORMATION--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 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 years--to policy years beginning on or before 10/1/2016--in 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 fair health insurance premiums); • Section 2702 (relating to guaranteed availability of coverage); • Section 2703 (relating to guaranteed renewability of coverage); • Section 2704 (relating to the prohibition of pre-existing condition exclusions or	

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.
					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 non-discrimination in health care); • Section 2707 (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). Additionally, CMS does not consider policies subject to the transitional relief out of compliance with section 1312(c) of ACA (relating to the single risk pool requirement). As a reminder, issuers can choose to adopt one or all of these provisions in their renewed policies. 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		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 filings 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	

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:		SUMMARY OF NIHB ANALYSIS:	
92.ggg.	Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data Bulletin--INFORMATION: 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 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. 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: 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,	

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.
					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 SUMMARY OF NIHB ANALYSIS:	
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 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, 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:	
92.jjj.	Marketplace Eligibility Redetermination for 2017 ACTION: Guidance NOTICE: Guidance on Annual Eligibility Redetermination and Re-Enrollment for Marketplace Coverage for 2017	CCIIO (no reference number)	Issue Date: 5/10/2016 Due Date: None NIHB File Date: Date of		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	

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: CCIIO		Subsequent Agency Action, if any:		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 SUMMARY OF NIHB ANALYSIS:	
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: *Type of Information Collection Request*: Extension without change of currently approved collection; *Title*: IHS Forms to Implement the Privacy Rule (45 CFR Parts 160 & 164); *Use*: 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. 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	

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					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 disclosures of their protected health information and the agency's handling of the request. • IHS-917: The rule requires covered entities to permit an individual to request that the covered entity amend protected health information. If the covered entity 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.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
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 Due Date: 5/28/2013; 5/2/2016		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.	
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		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of currently approved collection; *Title*: Self-Referral Disclosure Protocol; *Use*: 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	

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: Issued revision 5/2/2014, 5/6/2016 Due Date: 6/2/2014; 7/5/2016		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 this PRA request. CMS seeks to revise further the currently approved collection. 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.	
111.f.	Mental Health Parity Rules: External Review for MSPP ACTION: Request for Comment	TD 9640 (OMB 1545-2165)	Issue Date: 11/27/2015 Due Date: 1/26/2016		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	

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: 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		NIHB File Date: None Date of Subsequent Agency Action, if any:		benefits and medical/surgical benefits with respect to financial requirements and 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	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	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.
			Rule 3/21/2016 Due Date: 5/20/2016 TSGAC File Date: 5/20/2016		the flexibility necessary to ensure continued access to care for AI/ANs through the Purchased/Referred Care (PRC) programs. Without a mechanism to ensure such flexibility, this proposed rule could operate to deny many AI/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. 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.gpo.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	

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.
					On 4/14/2016, IHS announced that Elizabeth Fowler, Deputy Director of Management 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.m.-4 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 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: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program; *Use*: 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.	
112.h.	Health Care Plan Information for Veterans Choice Program ACTION: Request for Comment NOTICE: Health Care Plan	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Health Care Plan Information for the Veterans Choice Program; *Use*: 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	

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.
	Information for the Veterans Choice Program AGENCY: VA		Date of Subsequent Agency Action, if any: Issued extension 5/15/2015, 5/27/2016 Due Date: 6/15/2015; 7/26/2016		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.	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: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: 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. 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	

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					No comments recommended.	
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: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Submission of Information on Credentials and Licenses by Eligible Entities or Providers; *Use*: 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.l.	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		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	

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: VA		Date of Subsequent Agency Action, if any: Issued correction 4/25/2016		Construction Authorization and Choice Improvement Act of 2014 amended the Choice 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. 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	

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.
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: Date of Subsequent Agency Action, if any: Issued revised policy 4/11/2016 Due Date: 6/10/2016		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 AI/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 NIHB ANALYSIS: 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 AI/AN Tribes and tribal organizations on the revised IHS Contract Support Costs (CSC) policy. IHS seeks to goal is to finalize and implement the revised CSC policy this year. The revised CSC policy is available at http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/	

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.
					2016_Letters/2016IHSCSCPolicy04122016.pdf. The IHS CSC Workgroup recommended improvements and clarifications that IHS incorporated in the revised policy, including the following significant changes: • Introduction--includes Guiding Principles; expands on the definitions • Process--section is renamed "Determining CSC Amounts": o Assumes full funding instead of addressing how to allocate a limited appropriation o 6-3.2.E.1.b--Determination 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). o 6-3.2.E.3--similar 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.
					A template for tribal organization comments on the revised CSC policy and talking points on this policy are embedded below.  TEMPLATE Tribal Comments on Propos  Contract Support Costs Talking Points.p 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.m.-3:45 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.m.-4:30 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.m.-12 p.m.--Open Tribal Leader Comments session Salmon/Whale Room, 4th Floor Tower Building Suquamish Clearwater Casino Resort 15347 Suquamish Way NE Suquamish, Washington 98392	
112.n.	Catastrophic Health Emergency Fund	IHS RIN 0905-AC97	Issue Date: 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.

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
	ACTION: Proposed Rule NOTICE: Catastrophic Health Emergency Fund AGENCY: IHS		Due Date: ~~3/11/2016~~ ~~4/11/2016~~ 5/10/2016 TSGAC File Date: 5/10/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/25/2016, 3/11/3016		agency. This proposed rule would establish: definitions governing CHEF; a requirement 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 analysis 2016-0 This 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	
112.o.	IHS Reimbursement Rates for CY 2016 ACTION: Notice NOTICE: Reimbursement	IHS RIN 0917-ZA30	Issue Date: 3/8/2016 Due Date: None		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	

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.
	Rates for Calendar Year 2016 AGENCY: IHS		NIHB File Date: Date of Subsequent Agency Action, if any:		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. 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 ..... $2,655 Alaska ..... $3,335 Outpatient Per Visit Rate (Excluding Medicare) Lower 48 States ..... $368 Alaska ..... $603 Outpatient Per Visit Rate (Medicare) Lower 48 States ..... $324 Alaska ..... $582 Medicare Part B Inpatient Ancillary Per Diem Rate Lower 48 States ..... $637 Alaska ..... $1,082 Outpatient Surgery Rate (Medicare): Established Medicare rates for freestanding Ambulatory Surgery Centers. Effective Date for CY 2016 Rates: Consistent with previous annual rate revisions, the CY 2016 rates will take effect for services provided on/or after January 1, 2016, to the extent consistent with payment authorities including the applicable Medicaid State plan. SUMMARY OF NIHB ANALYSIS: A TSGAC briefing memo comparing CY 2016 and CY 2015 rates is embedded below.  OMB - IHS Rates for IHCPs 2016-03-10c.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.
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: None Date of Subsequent Agency Action, if any:		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 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 Leader.pdf SUMMARY OF NIHB ANALYSIS: Tribal representatives might wish to comment on this draft FDA Tribal Consultation Policy.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
112.q.	Recognition of Tribal Groups for Representation of VA Claimants ACTION: Request for Information NOTICE: Recognition of Tribal Organizations for Representation of VA Claimants AGENCY: VA	VA (no reference number)	Issue Date: 3/10/2016 Due Date: 4/11/2016 NIHB File Date: 4/11/2016 Date of Subsequent Agency Action, if any:	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 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 AI/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_DTLL_Title38_Part14_030316.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule requires a response, as it is an important item for tribal organizations and AI/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	See Table C.
112.r.	Secondary Authorization Request for VA Community Care ACTION: Request for Comment	VA (OMB 2900-0823)	Issue Date: 5/27/2016 Due Date: 7/26/2016 NIHB File		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Secondary Authorization Request for VA Community Care (VA Form 10-10143e); *Use*: 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	

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: Secondary Authorization Request for VA Community Care AGENCY: VA		Date: Date of Subsequent Agency Action, if any:		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.	
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: *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 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	

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.
					No comments recommended.	
121.m.	Medicare Enrollment Application--DMEPOS 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 Due Date: 1/19/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Medicare Enrollment Application--Durable 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. 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	CMS-855O	Issue Date: 12/11/2015		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Medicare Registration Application; *Use*: CMS-855O serves to gather information from a physician or other eligible professional to help CMS	

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: Medicare Registration Application AGENCY: CMS		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		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.	
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.	

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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.
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.	
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		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	

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 extension 1/24/2013; issued extension 11/23/2015, 3/4/2016 Due Date: 1/22/2016; 4/4/2016		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.	
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 revisions 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,		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. The current rate of 10 3/8%, 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	

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.
			1/27/2016, 4/27/2016		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 the Secretary of the Treasury, is certified for the quarter ended 6/30/2014. 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-2014-09-02/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	

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.
					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 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	
126.a.	Medicare Rural Hospital Flexibility Grant Program ACTION: Request for	HRSA (OMB 0915-0363)	Issue Date: 12/28/2012 Due Date: 60		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination; *Use*: The Medicare Rural Hospital Flexibility Program (Flex), authorized by Section 4201 of the Balanced Budget Act of 1997 (BBA) and reauthorized by Section	

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.
	Comment NOTICE: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination AGENCY: HRSA		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		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 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 SUMMARY OF NIHB ANALYSIS: 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.	
129.b.	Awarding and Administration of MAC Contracts	CMS-1653-NC	Issue Date: 12/21/2015 Due Date:		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	

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: Notice NOTICE: Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts AGENCY: CMS		2/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		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.	
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;		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	

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.
			5/16/2016		CMS on 2/10/2016 issued a revision 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 revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-15/pdf/2016-08784.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 Date: 10/17/2013; 11/3/2015; 3/11/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension without change of a currently approved collection; *Title*: Home Health Agency Cost Report; *Use*: 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 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.
					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, 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.	

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.
					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.	
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	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.
					No comments recommended. CMS on 1/29/2016 issued a revision of this PRA request. 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	CMS-10601	Issue Date: 3/1/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: CMS Innovation Partners Program Applications and Surveys; *Use*: CMS	

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: CMS Innovation Partners Program Applications and Surveys AGENCY: CMS		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		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. 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 No comments recommended.	
136.g.	CMS Quality Measure Development Plan ACTION: Guidance	CMS (no reference number)	Issue Date: 12/18/2016 Due Date: 3/1/2016	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	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.
	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		NIHB File Date: 3/18/2016 Date of Subsequent Agency Action, if any: Issued Final Guidance 5/2/2016		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, 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 MACRA-MDP@hsag.com, or by mail at the below address. Attn: Eric Gilbertson, CMS MACRA Team Health Services Advisory Group, Inc. 3133 East Camelback Road, Suite 240 Phoenix, AZ 85016-4545 https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Draft-CMS-Quality-Measure-Development-Plan-MDP.pdf SUMMARY OF NIHB ANALYSIS: Tribal representatives might wish to submit comments on the CMS Quality Measure Development Plan. SUMMARY OF SUBSEQUENT AGENCY ACTION: This document serves to meet the requirements of the Medicare Access and Children's Health Insurance Program (CHIP)	

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.
					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). 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 Rule NOTICE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the	CMS-5517-P	Issue Date: 5/9/2016 Due Date: 6/27/2016 NIHB File Date: Date of Subsequent		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 Medicare-enrolled 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	

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.
	Physician Fee Schedule, and Criteria for Physician-Focused Payment Models AGENCY: CMS		Agency Action, if any:		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 proposed rule, CMS has rebranded key terminology based on feedback from stakeholders, with the goal of selecting terms more easily identified and understood by stakeholders. https://www.gpo.gov/fdsys/pkg/FR-2016-05-09/pdf/2016-10032.pdf A *Modern Healthcare* article on this proposed rule is available at http://www.modernhealthcare.com/article/20160427/NEWS/160429928. A *HealthcareDive* article on this proposed rule is available at http://www.healthcaredive.com/news/cms-releases-macra-proposed-final-rule/418224/. A *Politico* "Morning eHealth" report that includes several blurbs related to this proposed rule is available at http://www.politico.com/tipsheets/morning-ehealth/2016/05/biden-speaks-at-health-datapalooza-214191. CMS on 3/242016 delivered a presentation on MACRA/MIPS during an ACA Policy Subcommittee Call. The presentation is embedded below.  MACRA Slide Deck_Final_32316_T1 SUMMARY OF NIHB ANALYSIS:	
137.d.	Data Collection for Beneficiaries Receiving Beta Amyloid PET ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries	CMS-10583	Issue Date: 9/25/2015 Due Date: 11/24/2015 NIHB File Date: None		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	

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.
	Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued new request 12/8/2015 Due Date: 1/7/2016		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 No comments recommended.	
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		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Transcatheter Valve Therapy Registry and KCCQ-10; *Use*: 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.	

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, if any:		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.gpo.gov/fdsys/pkg/FR-2016-03-18/pdf/2016-06188.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
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,		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Organ Procurement Organization's (OPOs) HIBASRA at 42 CFR 486.301-486.348; *Use*: 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	

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.
			3/1/2016, 5/6/2016 Due Date: 6/20/2013; 5/2/2016; 6/6/2016		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.	
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: *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 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:	

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 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.	
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 Due Date: 6/17/2013; 1/26/2016		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. 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 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.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
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 Due Date: 6/17/2013; 2/8/2016		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.	
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		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Paid Feeding Assistants in Long-Term Care Facilities and Supporting Regulations at 42 CFR 483.160; *Use*: 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.	

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.
			extension 5/17/2013, 5/26/2016 Due Date: 6/17/2013; 7/25/2016		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.	
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: *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 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.	

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.
					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.	
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 Due Date: 7/1/2013; 7/25/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Collection Requirements for Compendia for Determination of Medically Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen; *Use*: 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 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 a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-05-26/pdf/2016-12476.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.
					No comments recommended.	
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, 3/4/2016 Due Date: 11/2/2015; 4/4/2016		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 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	CMS-10467	Issue Date: 4/4/2013 Due Date: 6/3/2013		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	

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: Evaluation of the Graduate Nurse Education Demonstration Program AGENCY: CMS		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		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 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	
153.m.	CMS/SSA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974: CMS Computer Match No. 2016-12; HHS Computer	CMS (no reference number)	Issue Date: 2/9/2016 Due Date: 30 days (approx. 3/10/2016) NIHB File		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	

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. 1604; SSA Computer Match No. 1097-1899 AGENCY: CMS		Date: None Date of Subsequent Agency Action, if any:		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 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: 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 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 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.	
153.o.	CMS/IRS Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match	CMS (no reference number)	Issue Date: 2/17/2016 Due Date: 30 days (approx. 3/18/2016)		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	

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.
	No. 2016-08; HHS Computer Match No. 1606 AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any:		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, 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.	
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 sequence of notices on data matching undertaken by the federal government 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.
					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 Agency		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 received by CMS through the CMS Federal Data Services Hub from applicants 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.
			Action, if any:		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.	
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.	
154.b.	Medicaid/CHIP Managed Care ACTION: ~~Proposed~~ Final Rule	CMS-2390-~~P~~F	Issue Date: 6/1/2015 Due Date: 7/27/2015	NIHB response: TTAG response:	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 plans (QHPs) and Medicare Advantage (MA) plans; implement statutory provisions;	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.
	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		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		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 prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs)	

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.
					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 Indians without violating the standards in §438.3(d).	

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.
					[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 AI/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/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					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 *Modern Healthcare* article on this final rule is available at http://www.modernhealthcare.com/article/20160425/NEWS/160429951. A 2/19/2016 *Modern Healthcare* 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 AI/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.m.-2 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.
					 DTLL_MedicaidManageCareFinalRule_onlet 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.m.-1:30 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	
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		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	

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.
			extension 4/29/2016 Due Date: 8/23/2013; 6/28/2016		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 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	
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 Due Date:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: Payment Error Rate 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 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 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. 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 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	

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			9/30/2013; 6/7/2016		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 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.	
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		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 findings. At the end of the cycle, states would have submitted 48 forms. CMS has	

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			Due Date: 9/30/2013; 6/7/2016		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.	
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		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 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	

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.
			extension 4/8/2016 Due Date: 6/7/2016		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 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:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: State Medicaid Eligibility Quality Control (MEQC) Sample Selection Lists; *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 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	

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.
			Issued extension 4/8/2016 Due Date: 6/7/2016		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/2016-08106.pdf No comments recommended.	
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		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: Medicaid and Children's Health Insurance (CHIP) Managed Care Claims and Related Information; *Use*: 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 r ate 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.	

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.
			Due Date: 6/7/2016		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 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 No comments recommended.	
161.h.	Medicaid Eligibility Quality Control and PERM Programs ACTION: Proposed Rule NOTICE: Revisions to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement (PERM) Programs AGENCY: CMS	CMS-6068-P	Issue Date: [Pending at OMB as of 4/13/2016 Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would implement changes to the Payment Error Rate Measurement (PERM) and Medicaid Eligibility Quality Control programs to reflect modifications made to the Medicaid and CHIP eligibility processes and systems as required by ACA. This proposed rule also would codify several procedural aspects of the process for estimating improper payments in Medicaid and CHIP. SUMMARY OF NIHB ANALYSIS:	
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 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: Proposed Rule NOTICE: Medicare Secondary Payer and "Future Medicals" AGENCY: CMS		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:	
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-~~IFC~~F	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	

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.
					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	
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 Due Date: 12/2/2013; 6/29/2015; 8/24/2015; 6/28/2016		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 survey in the future. CMS will include a summary of findings from the testing rounds when requesting clearance for the additional two rounds of national	

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			NIHB File Date: 12/2/2013; TTAG also filed comments 12/2/2013		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 AI/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 AI/AN experience, other than one about AI/AN status as part of an examination of the background of respondents. These surveys should include AI/AN-specific elements to ensure that CMS and CCIIO receive feedback from AI/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	

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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	
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. MCBS--an 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 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	

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.
					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: Tribes and Tribal Organizations ACTION: Proposed Rule NOTICE: Federal Employees Health Benefits Program; Tribes and Tribal Organizations AGENCY: OPM	OPM (RIN 3206-AM40)	Issue Date: [Pending at OMB as of 4/22/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would amend the Federal Employees Health Benefits Program (FEHBP) regulations at 5 CFR part 890 to include enrollments for eligible employees of Tribes and tribal organizations under the provisions of ACA. SUMMARY OF NIHB ANALYSIS:	
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		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	

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.
			extension 4/11/2014, issued revision 5/2/2016 Due Date: 5/12/2014; 7/1/2016		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.	
175.b.	Medicaid Drug Use Review Program ACTION: Request for Comment NOTICE: Medicaid Drug Use Review (DUR) 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: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Medicaid Drug Use Review (DUR) Program; *Use*: 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	

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					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 includes no AI/AN-specific or I/T/U-specific sections, questions, or revisions. Among the most significant changes to the survey, CMS has added several questions to the ProDUR section (II) to clarify state data processing and authorization requirements. CMS also has added a question to the 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.	

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.
					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.	
179.d.	Changes to Medicare Appeals Procedures ACTION: Proposed Rule NOTICE: Medicare Program: Changes to the Medicare Claim, Organization Determination, and Coverage Determination Appeals Procedures AGENCY: HHS	HHS RIN 0991-AC02	Issue Date: [Pending at OMB as of 3/1/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would make changes to procedures for Medicare fee-for-service claim appeals, managed care organization determination appeals, and prescription drug plan coverage determination appeals to increase administrative efficiencies. In addition, it would set forth procedures to help position the administrative appeals process to address the increasing number of appeals in a manner responsive to appellant needs for timely determinations on Medicare coverage and payment, while maximizing the efficiencies in administering the appeals programs. 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:	

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.
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	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 performance of its business, including, as addressed in this proposed rule, how HHS will apply the standards of Section 1557 to department-administered health programs and activities. This proposed rule applies to health programs and activities administered by CMS, HRSA, CDC, IHS, and SAMHSA. Examples include tribal hospitals and clinics operated by IHS (about 876 hospitals and clinics) and the National Health Service Corps. http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-22043.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule might have a significant impact on how Indian-specific provisions are enforced and/or permitted. An issue summary for this proposed rule is embedded below.  Nondiscrimination 1557 Issue Summary. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule implements Section 1557 of ACA (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. This final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by HHS and entities established under Title I of ACA. In addition, the HHS Secretary can prescribe the governance, conduct, and performance of department business, including, here, how the department will apply the standards of Section 1557 to HHS-administered health programs and activities. https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.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.
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-~~P~~F	Issue Date: 10/1/2015 Due Date: 11/24/2015 NIHB File Date: 11/24/2015 Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 4/21/2016	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.	See Table C.
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	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 man-made 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	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.
			date extension 2/21/2014; sent Final Rule to OMB 11/3/2015		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 requirements that Tribes currently do not consider applicable. This proposed rule does not include any references to compliance 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	
188.b.	Fire Safety Requirements for Certain Health Care	CMS-3277-~~PF~~	Issue Date: 4/16/2014	TTAG response:	SUMMARY OF AGENCY ACTION: This proposed rule would amend the fire safety standards for Medicare and Medicaid participating hospitals, critical access hospitals	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.
	Facilities ACTION: ~~Proposed~~ Final Rule NOTICE: Medicare and Medicaid Programs; Fire Safet Requirements for Certain Health Care Facilities AGENCY: CMS		Due Date: 6/16/2014 TTAG File Date: 6/16/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 5/4/2016		(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/fdsys/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. CMS-3277-P summary 2014-04-1 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 in CMS 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.	

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.
					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	
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 -	
194.c.	Enrollment and Re-Certification of Entities in the 340B Program ACTION: Request for Comment NOTICE: Enrollment and Re-Certification of Entities in	HRSA (OMB 0915-0327)	Issue Date: 9/30/2014 Due Date: 12/1/2014 NIHB File Date: None		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").	

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.
	the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations AGENCY: HRSA		Date of Subsequent Agency Action, if any: Issued revision 4/21/2015, 4/8/2016 Due Date: 5/21/2015; 5/9/2016		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, 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.	

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.
194.d.	340B Ceiling Price and CMPs Regulation ACTION: Proposed 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 Due Date: 5/19/2016		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 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.f.	340B Drug Pricing Program Reporting Requirements ACTION: Request for Comment	HRSA (OMB 0915-0176)	Issue Date: 12/23/2015 Due Date: 2/22/2016 NIHB File		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	

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: 340B Drug Pricing Program Reporting Requirements AGENCY: HRSA		Date: None Date of Subsequent Agency Action, if any: Issued revision 5/20/2016 Due Date: 6/20/2016		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 request for a review of the dispute to OPA. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will have the opportunity to provide a response to or a rebuttal of the allegations. HRSA published a notice in 1996 and a policy release in 2011 on manufacturer audit 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	

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					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	
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	

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 NIHB ANALYSIS: 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 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: Public Health Service Act (PHS Act) section 2719 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 NIHB ANALYSIS: 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-	

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.
					CLAS-County-Data.pdf CCIIO on 1/27/2016 issued a revised version of this guidance. https://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 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-~~P~~F	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: This proposed rule would address application of certain requirements set forth in the Public Health Service Act (PHS Act), as amended by 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	

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					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 must comply with the requirements of subpart 2 of part A of title XXVII of the PHS Act, to the same extent that those requirements apply to a health insurance issuer that offers group health insurance. Subpart 2 includes mental health parity requirements added by MHPAEA at section 2726 of the PHS Act (as renumbered; formerly section 2705 of the PHS Act). 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	

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					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 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. <u>Main Provisions of Proposed Rule</u> 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	

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					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 requirement. *E. Compliance with Other Cost-Sharing Rules (§438.910(c)(4))* Section 438.910(c)(4) of this proposed rule would reiterate the requirement that some cost-sharing structures in a state Medicaid program or CHIP may have to change to comply with MHPAEA with a cross-reference to the cost-sharing rules applicable to MCOs, PIHPs, or, PAHPs. *F. Nonquantitative Treatment Limitations (NQTLs) (§438.910(d), §440.395(b)(4), and §457.496(d)(4))* Sections 438.910(d), 440.395(b)(4), and 457.496(d)(4) of this proposed rule would prohibit the imposition of any NQTL to MH/SUD benefits unless certain requirements are met and provides an illustrative list of NQTLs. *G. Application to CHIP and EPSDT Deemed Compliance (§457.496(b))* This section of the proposed rule addresses requirements related to CHIP. *H. Availability of Information (§438.915, §440.395(c), §457. 496(e))* These sections of the proposed rule would apply the requirements imposed on the health insurance issuer through the MHPAEA final regulations regarding availability of information in a similar manner to MCOs and to PIHPs and PAHPs that provide coverage to MCO enrollees. *I. Application to EHBs and other ABP Benefits (§440.395 and §440.347)* This section of the proposed rule addresses parity requirements for ABPs that provide both medical/surgical benefits and MH or SUD benefits, as well as EHB requirements for ABPs.	

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					J. Application of Parity Requirements to the Medicaid State Plan This proposed rule would apply the requirements of section 2726 of the PHS Act incorporated through section 1932 of the Act to the benefits offered by the MCO (or, if benefits are carved out, to all benefits provided to MCO enrollees regardless of service delivery system) but would not apply them to all Medicaid state plan benefit designs. [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-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*	

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.
					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. • 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.	
202.	Health Needs of the AI/AN	IHS (no	Issue Date:		SUMMARY OF AGENCY ACTION: IHS seeks broad public input as it begins efforts to	

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	LGBT Community ACTION: Request for Information NOTICE: Notice of Request for Information AGENCY: IHS	reference number)	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		advance and promote the health needs of the AI/AN Lesbian, Gay, Bisexual, and Transgender (LGBT) community. In summer 2015, IHS will hold a public meeting to garner information from individuals on AI/AN LGBT health issues. Through this meeting, IHS seeks to gain a better understanding of the health care needs of AI/AN LGBT individuals so that it can implement health policy and health care delivery changes to advance the health care needs of the AI/AN LGBT community. IHS aims to increase community access to and engagement with agency leadership and secure a legacy of transparent, accountable, fair, and inclusive decision-making specific to AI/AN LGBT individuals. This request for information seeks public comment on the dimensions of the health needs of the AI/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 AI/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 AI/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.	

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.
					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 AI/AN lesbian, gay, bisexual, transgender and two-spirit (LGBT2S) community. In these teleconferences, participants will have the opportunity comment on several key dimensions of the health needs of the AI/AN LGBT2S community, including but not limited to the following questions: • Are effective models and best practices surrounding the health care of the 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	~~CMS (no reference number)~~	Issue Date: 10/27/2015	TTAG 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 AI/ANs through facilities of IHS or Tribes. Through this policy change,	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.
	ACTION: ~~Request for Information~~ Final Policy NOTICE: Medicaid Services "Received Through" an Indian Health Service/Tribal Facility: A Request for Comment AGENCY: CMS	SHO #16-002	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	TSGAC response:	which would affect all states, CMS seeks to improve access to care for AI/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. NIHB FMAP Memo 2015-10-29.pdf 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 AI/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 AI/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 AI/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 AI/ANs by increasing access to care, strengthening continuity of care, and improving population health. https://www.medicaid.gov/federal-policy-guidance/downloads/sho022616.pdf	
205.	Sharing What Works--BPPPLE Form ACTION: Request for	IHS (OMB 0917-0034)	Issue Date: 10/9/2015 Due Date:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension without change of a currently approved collection; *Title*: IHS Sharing What Works--Best Practice, Promising Practice, and Local Effort (BPPPLE) Form; *Use*: IHS seeks to raise the health status of the AI/AN population to the highest possible level by providing	

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.
	Comment NOTICE: IHS Sharing What Works --Best Practice, Promising Practice, and Local Effort (BPPPLE) Form AGENCY: IHS		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		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 AI/AN communities. 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	AHRQ (no reference number)	Issue Date: 2/10/2016 Due Date: 3/4/2016 NIHB File Date:	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:	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.
	Care Organization Quality Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self-Management AGENCY: AHRQ		3/4/2016 Date of Subsequent Agency Action, if any:		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. 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	

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.
					understandable and less burdensome. https://www.gpo.gov/fdsys/pkg/FR-2016-02-09/pdf/2016-01841.pdf SUMMARY OF NIHB ANALYSIS: Tribal organizations might wish to comment on this rule on information sharing.	
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 Due Date: 4/5/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/29/2016 Due Date: 5/31/2016		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Medicare Probable Fraud Measurement Pilot; *Use*: CMS seeks OMB approval of the collections required for a probable fraud measurement pilot. The probable fraud measurement pilot will establish a baseline estimate of probable fraud in payments for home health care services in the fee-for-service Medicare program. CMS and its agents will collect information from home health agencies (HHAs), the referring physicians, and Medicare beneficiaries selected in a national random sample of home health claims. The pilot will rely on the information collected along with a summary of the service history of the HHA, the referring provider, and the beneficiary to estimate the percentage of total payments associated with probable fraud and the percentage of all claims associated with probable fraud for Medicare fee-for-service home health. 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 4/29/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-10084.pdf	
209.	Reassignment of Personnel in a Public Health Emergency ACTION: Notice NOTICE: Temporary Reassignment of State,	HHS (no reference number)	Issue Date: 4/1/2016 Due Date: None NIHB File Date:		SUMMARY OF AGENCY ACTION: This notice announces the availability of final guidance titled "Guidance for Temporary Reassignment of State, Tribal, and Local Personnel during a Public Health Emergency." Section 201 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) amends section 319 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, upon request by a state or tribal organization or their designee, the temporary reassignment of state, tribal, and local personnel funded through programs	

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.
	Tribal, and Local Personnel During a Public Health Emergency AGENCY: HHS		Date of Subsequent Agency Action, if any: Issued correction 4/12/2016		authorized under the PHS Act to address immediately a public health emergency in the state or Indian Tribe. This final guidance addresses that provision. Discussion: "The PHS Act requires HHS issue proposed guidance on this provision, to be followed by a 60-day public comment period. Consistent with this requirement, a notice appeared in the Federal Register on October 1, 2013 (78 FR 60283) notifying the public that HHS was accepting comments on such proposed guidance. This 60-day public 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 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	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2016

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.
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: Date of Subsequent Agency Action, if any:		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 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	

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 NIHB ANALYSIS: No comments recommended.	
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://s3.amazonaws.com/public-inspection.federalregister.gov/2016-11754.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 http://www.nafoa.org/broadcasts/department-of-labor-releases-overtime-rule-tribal-employers-have-six-months-to-prepare. SUMMARY OF NIHB ANALYSIS:	
212.	Enhancing Retailer Standards in SNAP ACTION: Proposed Rule	USDA FNS RIN 0584-AE27	Issue Date: 2/17/2016 Due Date:	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	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.
	NOTICE: Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP) AGENCY: USDA FNS		~~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		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 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 http://www.cbpp.org/research/food-assistance/house-2017-budget-plan-would-slash-snap-by-more-than-150-billion-over-ten. SUMMARY OF SUBSEQUENT AGENCY ACTION: USDA FNS on 4/5/2016 issued a document that extends the comment period and responds to questions posed by commenters about certain aspects of a proposed rule pertaining to the eligibility of SNAP retail food stores published in the 2/17/2016 FR.	

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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.
					https://www.gpo.gov/fdsys/pkg/FR-2016-04-05/pdf/2016-07793.pdf	

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TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
7.III.	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 recommendations-- 1. Chapter 1, Section 4--Standardized 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-sharing--deductible, 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. 2. Chapter 3, Section 3--Out-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 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.	In the 2/29/2016 Final Letter-- 1. Chapter 1, Section 4--Standardized Options: Not accepted. CCIIO did not address this issue. 2. Chapter 3, Section 3--Out-of-Pocket Cost Comparison Tool: Not accepted. CCIIO did not address this issue.
8.d.	Oklahoma 1115 Waiver Amendment	11-W-00048/6 Issue Date: 3/4/2016	TSGAC recommendations-- CMS should approve the request by the Oklahoma Health Care Authority to amend its section 1115 waiver to incorporate the	No subsequent Agency action taken (as of 5/31/2016).

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TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
	ACTION: Request for Comment NOTICE: §1115(a) SoonerCare Research and Demonstration Waiver Amendment Request AGENCY: N/A	Due Date: 4/14/2016 TSGAC File Date: 4/5/2016 Date of Subsequent Agency Action, if any:	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 AI/ANs who currently lack sufficient access to needed care; • Help the federal government meet its federal trust responsibility for AI/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 necessary--but not provided--specialty care.	
14.c.	Waivers for State Innovation ACTION: Notice NOTICE: Waivers for State Innovation	CMS-9936-N Issue Date: 12/16/2015 Due Date: Open	TSGAC recommendations-- 1. 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 AI/ANs because of changes in Indian-specific and non-Indian	No subsequent Agency action taken (as of 5/31/2016).

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
	AGENCY: CMS/Treasury	TSGAC File Date: 2/23/2016 Date of Subsequent Agency Action, if any:	specific provisions of the law; to ensure that a State Innovation Waiver does not adversely affect AI/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 AI/AN and not remain limited to the overall, or average, impact on the population as a whole. 2. 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 AI/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 AI/ANs, the Agencies should emphasize the importance of maintaining the Indian-specific protections contained in section 1932 under such a waiver. 3. 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 AI/ANs who elect to enroll in Medicaid managed care; to ensure that a State Innovation Waiver does not adversely affect AI/ANs, the Agencies should emphasize the importance of maintaining the Indian-specific protections contained in section 5006 under such a waiver.	
43.	Medicaid Reimbursement for Outpatient	CMS-2345-~~P~~FC	NIHB recommendations (4/2/2012, additional subsequent recommendations appear below)--	In the 2/1/2016 Final Rule--

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TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
	Drugs ACTION: ~~Proposed~~ Final Rule NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS	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	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. 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.	1. 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. 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 AI/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

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				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 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: CMS should retain in the final rule the proposed requirement that dispensing fee calculations take into account special circumstances of I/T/U pharmacies.	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

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				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 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: • 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	No subsequent Agency action taken (as of 4/30/2016).

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			(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 paraprofessionals in compliance with applicable state and federal laws.	
60.I.	Expanding Uses of Medicare Data by Qualified Entities ACTION: Proposed Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities AGENCY: CMS	CMS-5061-P Issue Date: 2/2/2016 Due Date: 3/29/2016 NIHB File Date: 3/29/2016 Date of Subsequent Agency Action, if any:	NIHB recommendations-- 1. Definition of "Authorized User": The Medicare Access and Children's Health Insurance Program Reauthorization Act (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 category--incorporating as well Tribal Epidemiology Centers and Tribal Advisory Committees, such as TTAG--as 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.	No subsequent Agency action taken (as of 5/31/2016).

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			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.	
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,	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 providers (ICHPs). 2. Quarterly Reports to TTAG: CMS should provide TTAG with regular quarterly reports to monitor the use of measures, AI/AN protections, and I/T payments from T-MSIS to ensure the quality, utility, and clarity of the information collected.	No subsequent Agency action taken (as of 5/31/2016).

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		4/12/2016 Due Date: 11/19/2012; 1/2/2013; 2/29/2016; 5/12/2016 TTAG File Date: 2/29/2016		
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,	TTAG recommendations-- 1. Hardship Exemptions: The proposed rule would permit certain individuals, including 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. 2. QHP Certification Process: The proposed rule would grant Federally-Facilitated Exchanges (FFEs) the authority to contract with qualified health plan (QHP) issuers selectively to strengthen oversight, noting that ACA allows FFEs to deny certification of QHPs that meet minimum certification standards but do not serve the "interests of qualified individuals and qualified employers"; as part of this provision, CMS should stipulate that QHP certification process include an evaluation of QHP contracting with Indian health care providers and a review of any complaints against QHPs	In the 3/8/2016 Final Rule-- 1. Hardship Exemptions: Accepted. CMS retained this provision. 2. QHP Certification Process: Not accepted. CMS did not address this issue.

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		if any: Issued Final Rule 3/8/2016	regarding implementation of Indian cost-sharing provisions or other Indian-specific protections. 3. Third-Party Payment of Premiums: The proposed rule would require Tribes 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 delay this requirement as it relates to Tribes. TSGAC recommendations-- 1. 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 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	3. Third-Party Payment of Premiums: Accepted. CMS stated, "We are removing §156.1250(b), the information collection provision, as we believe it will unduly burden Indian tribes, Ryan White HIV/AIDS programs, and government programs to provide such notification to HHS." [81 FR 12320] 1. Application of Federal Requirements on Network Adequacy and ECPs to SBE-FP: Accepted. CMS stated, "Moving forward, the annual Letter to Issuers will include implementing guidance that is specific to SBE-FPs." [81 FR 12246] 2. Standardized Options for Cost-Sharing Protections: Accepted in part.

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			offerings through the Marketplace, and current federal 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.	CMS retained this provision, although on a voluntary basis 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: 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 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.	3. Adjustments Required for Cost-Sharing Payments Advanced to Issuers: Accepted. CMS retained this provision.
			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.	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: CMS should consider the establishment of an additional criterion in the design of rating	5. Size of Rating Areas: Not accepted.

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			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.	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 AI/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 medically necessary health care services under these plan variations.	6. 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]
			7. 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 secure a comparable clarification from IRS.	7. Informing Employers of Employee Financial Assistance Eligibility Determinations: Not accepted. CMS did not address this issue.
			8. 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	8. Special Enrollment Periods: Not Accepted. CMS did not revise this provision, stating, "We are not

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			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).	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]
			9. 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).	9. Termination of Coverage: Accepted in part. CMS retained this provision but did not address the issue of the disenrollment-enrollment administrative process.
			10. Eligibility Standards and Process for Exemptions: The proposed rule would permit certain individuals, including 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.	10. Eligibility Standards and Process for Exemptions: Accepted. See response to TTAG recommendation #1 above.
			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.	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	12. Additional Network Adequacy Standards: Not accepted.

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			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).	CMS did not address this issue.
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;	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). 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	In the 3/21/2016 Final Rule-- 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. 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

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		issued Final Rule 3/21/2016 Due Date: 5/20/2016 TSGAC File Date: 5/20/2016	service from nongovernmental entities, including insurance providers." 3. Need for Exceptions in New Section 136.201(b): Section 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	and provisions have been inserted providing for payment 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] 3. Need for Exceptions in New Section 136.201(b): • 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

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				consistent with 25 U.S.C. 458aaa-16(e), which 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. 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.	• 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

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				provider or supplier or its agent by the I/T/U, the I/T/U 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: 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.	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

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				composed of technical experts who have a deep 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]
			TSGAC recommendations (5/20/2016)-- 1. 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. 2. 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, but only to the extent that the tribally operated programs opt-in to the requirements of the	No subsequent Agency action taken (as of 5/31/2016).

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			rule, with this decision expected to occur through a modification to the existing annual funding agreement of a Tribe--a 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.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 TSGAC File Date: 5/10/2016 Date of Subsequent Agency Action, if any: Issued	TSGAC recommendations-- 1. 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. 2. 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	No subsequent Agency action taken (as of 5/31/2016).

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		due date extension 2/25/2016, 3/11/3016	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." 3. Lack of Procedure Governing the Awarding of CHEF 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. 4. 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.	
112.q.	Recognition of Tribal Groups for Representation of VA Claimants ACTION: Request for Information NOTICE:	VA (no reference number) Issue Date: 3/10/2016 Due Date: 4/11/2016	NIHB recommendations-- 1. 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.	No subsequent Agency action taken (as of 5/31/2016).

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	Recognition of Tribal Organizations for Representation of VA Claimants AGENCY: VA	NIHB File Date: 4/11/2016 Date of Subsequent Agency Action, if any:	2. Requirements for Tribal Organizations Becoming 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 AI/AN veterans and to better fit the unique circumstances of how tribal nations serve their veterans. 3. 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. 4. 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 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.	

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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	TTAG recommendations-- 1. 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. 2. 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 5/31/2016).

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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 recommendations-- 1. 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. 2. Policy Option 1: Option 1 would require EP health IT developers to certify Health IT Modules to all CQMs in the 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	No subsequent Agency action taken (as of 5/31/2016).

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			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 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	NIHB recommendations-- 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; • b. Develop new patient experience surveys for implementation across multiple programs and settings	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 *Performance Measurement for Rural 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.

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			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;	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 responding to the surveys." [page 39]
			• c. Collaborate with AI/AN groups and associations to develop quantifiable measures important to both patients and providers within Indian Country to reflect the health of the AI/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	• c. Not accepted. CMS did not address this issue. • d. Not accepted. CMS did not address this issue.

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			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. 2. 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 AI/ANs.	2. Tribal Consultation: Not accepted. CMS did not address this issue.
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	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	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 AI/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

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	Related to Third Party Liability AGENCY: CMS	Final Rule 5/6/2016		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 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]
			2. Section 483.14(b)(1)--Network Adequacy: Proposed §	2. Section 483.14(b)(1)--Network Adequacy: Not accepted.

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			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) 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.	CMS stated, "We decline to require managed care plans to offer a network provider agreement to all IHCPs as we 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 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]

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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 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. 4. Section 483.14(b)(5)--Access to Services in States with Few or No IHCPs: Proposed § 483.14(b)(5) provides that, in	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), 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: Not accepted.

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			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."	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 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: 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-PAHPs--must meet the requirements identified in proposed § 438.9(b), the special provisions applicable to other MCE contracts involving	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]

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			AI/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 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 have the right to payment at either the rate set out in the State plan or the encounter rate, whichever is higher. 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	6. 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 rate published in the Federal Register annually by the 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: 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

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			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.	§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 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 QHP--a goal indicated in the preamble--CMS in the final rule should provide monthly special enrollment periods during which AI/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 AI/ANs, many of whom live in remote areas with no Internet access and slow mail delivery.	8. Enrollment Protections: • a. Monthly Special Enrollment Periods: Not accepted. CMS did not address this issue. • b. Initial Selection Period: Not accepted. CMS did not address this issue.
			9. Section 438.71--Beneficiary Support System:	9. Section 438.71--Beneficiary Support System: Not

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			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.	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 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: 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	10. Suspension of Payments to a Network Provider: Not accepted. CMS did not make this change.

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			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 AI/ANs also need information that clearly states they can continue to access their IHCP whether they in-network or out-of-network and that explains other 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 recovery--an issue that has meaning for AI/ANs tied to historical trauma and federal Indian law--as 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 438.4--Capitation 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	11. Section 438.10--Information Standards: Not accepted. CMS noted, "We appreciate the suggested topics to enhance §438.10(g)(2) but found most of them duplicative of an existing provision."[page 857] 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 438.4--Capitation 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

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			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 potential to significantly impact both AI/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 AI/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.	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. 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 Survey Data Collection ACTION: Request for Comment	CMS-10488 Issue Date: 6/28/2013 Due Date: 8/27/2013	NIHB/TTAG recommendations-- 1. Questions Specific to AI/ANs--Marketplace Survey: To address questions specific to the experiences of AI/ANs, 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	In the 4/28/2015 and 7/24/2015 revisions (review of 4/29/2016 revisions TBE): 1. Questions Specific to AI/ANs--Marketplace Survey: N/A. CMS did not include a revised version of the Marketplace Survey in this PRA request.

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
	NOTICE: Enrollee Satisfaction Survey Data Collection AGENCY: CMS	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 Due Date: 12/2/2013; 6/29/2015; 8/24/2015; 6/28/2016 NIHB File Date: 12/2/2013; TTAG also filed comments 12/2/2013	solicit responses to the below questions. • a. Whether the Marketplace provides specific information on how it determines "Indian" status for both 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 AI/AN status, as well as the ease of uploading or otherwise providing these documents; • c. Whether the Marketplace informs AI/ANs of their eligibility for a special monthly enrollment period; • d. Whether the Marketplace explains (1) the existence of AI/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 AI/AN can establish eligibility for any relevant cost-sharing protection; • e. Whether the Marketplace specifically explains (1) how AI/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 AI/AN individual has experienced with any enrollment assisters or similar Marketplace personnel concerning AI/AN-specific enrollment issues.	

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TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
			2. Questions Specific to AI/ANs--QHP Survey: To address questions specific to the experiences of AI/ANs, 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. • a. How the QHP interacts with both the individual AI/AN and health care providers to ensure that AI/ANs do not have cost-sharing for which ACA exempts them; • b. Whether the individual AI/AN has ever had cost-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	2. Questions Specific to AI/ANs--QHP Survey: • a. Not accepted. • b. Not accepted. • c. Not accepted. • d. Not accepted. • e. Not accepted. 3. AI/AN Survey Responses: N/A. Unable to determine whether CMS addressed this issue. 4. Question Wording and Answers:

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
			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 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. AI/AN,' *regardless of any other race or ethnicity they check*, CMS should ask:]	• a. Not accepted.

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TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
			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? 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	HHS OCR	TSGAC recommendations--	In the 5/18/2016 Final Rule--

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TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
	Under ACA ACTION: ~~Proposed~~ Final Rule NOTICE: Nondiscrimination in Health Programs and Activities AGENCY: 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	1. 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. 2. Applicability Provisions: CMS should revise the proposed applicability provisions in part 92.2 to include Indian health programs. 3. Exceptions to Nondiscrimination Provisions: CMS should explicitly refer to Indian health programs in the text of the 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.	1. Indian Health Program Protections: Not accepted. See HHS OCR response below. 2. Applicability Provisions: Not accepted. See HHS OCR response below. 3. Exceptions to Nondiscrimination Provisions: Not accepted. 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]
188.b.	Fire Safety	CMS-3277-~~P~~F	TTAG recommendations--	In the 5/4/2016 Final Rule--

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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
	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	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	1. 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. 2. 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. 3. 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. 4. Window Requirements: The proposed rule would require that every health care occupancy patient sleeping room have	1. Occupancy Standards: Not accepted. CMS did not address this issue. 2. 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] 3. 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: Accepted. CMS stated, "We agree with commenters that requiring existing facilities to change their existing window structures

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
			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.	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 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,	TTAG/TSGAC recommendations-- 1. Paragraph 1--Modifying the Second Condition: CMS should-- • 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.	In the 2/26/2016 Final Policy-- 1. Paragraph 1--Modifying the Second Condition: CMS should-- • 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 "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

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TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
		if any: Issued Final Policy 2/26/2016	• d. Implement this proposal in a manner that protects the general 100 percent FMAP rule for Indians in the Medicaid Expansion population. • e. Retain and highlight that services covered include "transportation services, as well as emergency 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)." 2. Comments in Response to Paragraph 2--Modifying the Third Condition: CMS should-- • a. Retain this proposal (with clarifications). • b. Revise the phrase "who provides items or services not within the scope of a Medicaid "facilities services" benefit but within the IHS/tribal facility authority ..." to ensure that it is not susceptible to an interpretation intended to disqualify Medicaid facilities services benefits and that it expresses clearly the intention for consistency with the policy change proposed in Paragraph 1.	facility that are described in this SHO are present." [page 7] However, CMS did not address the issue of section 1915 waivers. • d. Not accepted. CMS did not address this issue. • e. Accepted. CMS addressed this issue as recommended. 2. Comments in Response to Paragraph 2--Modifying the Third Condition: CMS should-- • a. Accepted in part. CMS retained this proposal with some clarifications. • b. Accepted. CMS removed this language.

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
			• 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 AI/AN individual" or similar such conditions; and not require that an AI/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.
			• 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.	• e. Not accepted. CMS did not address this issue.

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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
			• 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.	• 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 3--Modifying the Fourth Condition: CMS should retain this proposal.	3. Paragraph 3--Modifying the Fourth Condition: Accepted. CMS retained this proposal.
			4. Paragraph 4--Application to Fee-for-Service: CMS should-- • a. Retain this proposal.	4. Paragraph 4--Application to Fee-for-Service: • 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.
			5. Paragraph 5--Application to Managed Care: CMS should-- • a. Retain this proposal (with clarifications).	5. Paragraph 5--Application to Managed Care: • a. Accepted in part.

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
			• 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.	CMS retained this proposal with some clarifications. • 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 Measures Assessing Health Care Organization Quality	AHRQ (no reference number) Issue Date: 2/10/2016 Due Date: 3/4/2016 NIHB File Date: 3/4/2016	NIHB recommendations-- 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 AI/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 5/31/2016).

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
	Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self-Management AGENCY: AHRQ	Date of Subsequent Agency Action, if any:		
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/	TSGAC recommendations-- 1. Technical Assistance and Grants: USDA currently has only one rural development grant exclusively available to AI/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. 2. 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 increasing their access to fresh foods, the department should fund FRTEP at $10 million annually. 3. Flexible Compliance Timelines and Requirements: If the	No subsequent Agency action taken (as of 5/31/2016).

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 5/31/2016

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
		clarification 4/5/2016	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. 4. 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.	

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RRIAR INDEX: HEALTH REFORM
UPDATED THROUGH 5/31/2016

RRIAR Index: Health Reform[1]						
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.						
Terms	RRIAR Entry Numbers (Page Numbers)[2] Red = Table B Blue = Table C					Other Citations
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.05)	
Indian-specific ACA provisions						
Cost-sharing reductions						
Eligibility				7.ccc. (29/10), 89.a. (/34), 89.k. (210/42)		
General	7.a. (18/16), 7.c. (24/67), 7.g. (29/76), 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. (133/14), 31.x. (135/16)	7.ww. (26), 7.xx. (27), 27.n. (97), 89.h. (203/35)	50.h. (81)	

[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).

[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.

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.

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RRIAR INDEX: HEALTH REFORM
UPDATED THROUGH 5/31/2016

RRIAR Index: Health Reform[1]

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.

Terms	RRIAR Entry Numbers (Page Numbers)[2] Red = Table B Blue = Table C					Other Citations
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.05)	
Referrals		111.c. (240/102)		89.l. (211/48)		
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. (78), 50.h. (81)	
Employer mandate				31.ccc. (136/26)	31.iii. (66)	
Essential community providers	7.a. (18/16), 7.b. (21/22)	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. (14), 7.lll. (16/1)	
Exemption from tax penalty		31.e. (94/40), 31.g. (103/44), 31.q. (114/47)	7.mm. (42), 31.v. (133/13)	7.ww. (26), 89.h. (203/35)		
Fees	116. (154)	89.a. (194/79)		145.c. (279)		
Implementation of section 402 of IHCIA			50.q. (173), 50.r. (175), 50.x. (179/30)			
Indian addendum	7.b. (21/22)	50.c. (135/54), 111.a. (237/94), 111.b. (238/96)	7.ee. (29/4)	7.vv. (24/9), 89.h. (203/35)	7.lll. (16/1)	
Issuer regulations (Indian-specific concerns)	7.a. (18/16), 7.b. (21/22), 7.g. (29/76)	7.n. (23/1), 89.a. (194/79), 89.b. (195/87),	7.ee. (29/4), 50.t. (176/29), 65. (199/36),	7.vv. (24/9), 31.pp. (119/21), 89.h. (203/35),	7.lll. (16/1), 168. (204/35)	

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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.05)	
Premium sponsorship	7.a. (18/16), 7.b. (21/22), 7.g. (29/76), 29.a. (70/112)	111.a. (237/94) 50.d. (136/61), 111.a. (237/94), 111.b. (238/96)	92.u. (242/49), 92.cc. (255) 7.b. (3), 7.ee. (29/4), 50.q. (173), 50.r. (175), 50.x. (179/30), 65. (199/36)	92.ll. (218/54), 7.vv. (24/9)	7.lll. (16/1)	
Tribal consultation			64.a. (196/31), 64.b (198/33)	64.c. (173/30)		
Tribal employer/organization participation in FEHBP			174.d. (317)		174.g. (207)	
Tobacco use (ceremonial)		50.d. (136/61), 50.f. (64), 50.h. (68), 92.a. (202/91)			50.f. (78), 50.h. (81)	
1311 Funding for Change orders		67.c. (164)	67.d. (202), 67.f. (203)	50.bb. (156), 67.g. (176)		
Basic Health Program	39.a. (80/123)		39.b. (155/19), 39.c. (157/23), 39.d. (159)	39.e. (138)	39.f. (68)	
Consumer assistance grants					67.a. (95)	
Consumer Operated and Oriented Plan (CO-OP) Program	12.a. (44), 12.b. (46/94)	12.c. (58)		12.d. (64), 12.e. (65)	7.www. (25), 12.f. (40)	
Cost-sharing reductions	7.a. (18/16), 45. (87)	29.f. (89), 50.d. (136/61), 50.h. (68),	29.g. (107/12), 29.h. (108), 31.w. (133/14),	27.n. (97), 89.k. (210/42), 89.l. (211/48),	50.h. (81), 89.d. (115), 89.g. (117),	

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		50.n. (146), 89.a. (194/79), 89.b. (195/87), 89.f. (201), 111.c. (240/102)	50.w (178),	92.uu. (225)	89.n. (117), 89.o. (124), 89.p. (124), 89.q. (125)	
Early retiree reinsurance program		88.a. (193), 88.b. (194)				
Electronic funds transfers	63.a. (113)	63.b. (159)				
Employer requirements (see also Shared responsibility)						
Coverage		31.i. (107), 92.l. (211), 92.m. (212)	92.bb. (254), 92.jj. (266)	31.ccc. (136/26)	29.d. (59), 31.iii. (66)	
Excise tax				31.ss. (124/22), 31.aaa. (132/26)		
Notices		7.x. (34), 7.z. (36)				
Reporting		31.k. (108)	31.o. (129), 31.p. (130), 31.z. (137), 31.cc. (142), 31.jj. (148)	31.yy. (130), 31.ccc. (136/26), 31.eee. (137)		
Self-funded, non-federal governmental plans			92.ee. (259)			
Employer tax credits			31.m. (127), 31.n. (128)			
Essential health benefits						
Excepted benefits		31.i. (107)	31.t. (131)	31.oo. (117),		

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General				31.qq. (122) 31.vv. (127), 31.zz (131)		
Preventive services	31.a. (74/115), 31.b. (77)	31.c. (91), 31.j. (108)	31.y. (136), 31.ee. (144), 31.ff. (145)	31.dd. (108), 31.gg. (110), 31.ll. (112), 31.xx. (128)	92.iii. (143)	
Standards	7.g. (29/76), 31.a. (74/115), 45. (87), 50.b. (98)	31.d. (93)	92.aa. (253)		31.kkk. (67)	
Exchanges						
Federally-facilitated and state-partnership						
Benefit and payment parameters (see Notice of Benefit and Payment Parameters)						
Blueprint for approval	7.f. (29)		7.y. (27)			
Certified application counselors		7.o. (26/3), 7.u. (32/12), 28.c. (84/30)	92.u. (242/49), 7.oo. (44)			
Eligibility and enrollment	7.c. (24/67), 7.g. (29/76)	7.s. (30/11), 7.w. (34), 7.aa. (37), 7.cc. (39), 7.dd. (40), 50.d. (136/61), 50.h. (68), 50.k. (143/73)	7.ff. (33), 7.qq. (47), 7.rr. (48), 7.uu. (51), 67.e. (202), 92.dd. (257/52)	7.eee. (35), 7.hhh. (37), 7.ppp. (45), 92.oo. (220)	7.ttt. (23), 7.yyy. (27), 31.jjj. (66), 50.h. (81), 92.hh. (131), 92.jjj. (143)	

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Enrollee satisfaction	7.a. (18/16)				7.xxx. (27), 168. (204/35)	
Establishment					7.mmm. (19), 7.nnn. (20)	
General	7.a. (18/16), 7.b. (21/22), 7.e. (27)	7.i. (19), 89.c. (198/89)	7.b. (3), 7.ss. (50) 92.u. (242/49)			
Guidance (other)						
Agent/broker		7.r. (29)				
General	7.g. (29/76)		31.u. (132)			
Issuer		7.n. (23/1)	7.ee. (29/4), 7.gg. (35), 7.hh. (36)	7.vv. (24/9), 7.bbb. (29)	7.lll. (16/1), 7.rrr. (21)	
Health insurance affordability programs (see Cost-sharing reductions and Premium tax credits)						
Information collection/reporting/ security/transactions		7.j. (20), 7.k. (21), 7.m. (22), 29.e. (89/39), 68. (164)	29.o. (117), 29.p. (118), 31.cc. (142)	7.ddd. (33), 50.e. (147), 89.i. (207)	7.kkk. (14)	
Language access					7.uuu. (24)	
Minimum acceptable risk standards				7.iii. (39)		
Navigators and non-Navigator assistance personnel	7.a. (18/16)	7.o. (26/3), 7.p. (27)	7.oo. (44)	7.v. (22), 7.kk. (23)	7.q. (12)	

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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.05)	
Out-of-pocket costs				7.ccc. (29/10)		
Outreach	7.a. (18/16), 7.g. (29/76)		7.pp. (46)		67.b. (96)	
Policy-based payments				7.qqq. (47)	7.sss. (22)	
Program integrity		7.s. (30/11)				
Quality	100.a. (144)		100.b. (271)		7.xxx. (27)	
Special enrollment periods		31.h. (105)	6.h. (22), 7.ii. (38), 7.jj. (38), 29.i. (108)	7.yy. (27), 7.aaa. (28), 29.r. (107)	7.vvv. (25), 7.www. (25)	
Stand-alone dental plans		7.u. (32/12)			7.l. (11)	
Web portal	7.g. (29/76)		65. (199/36)		7.ooo. (21)	
State-based						
General		7.dd. (40), 50.u. (150)	50.o. (172), 50.s. (175)	7.t. (20)		
Shared responsibility payment exemptions				50.cc. (157)		
State alternative applications		50.k. (143/73), 50.l. (144)				
Federal Employees Health Benefits Program (FEHBP)		174.a. (323), 174.b. (325)	174.c. (315), 174.d. (317), 174.e. (318)	174.f. (290)	174.g. (207)	
Health insurance market rules						
Regulations						
90-day waiting period	91.a. (138)		91.b. (231), 91.c. (231)			
Age curves		92.c. (205)				

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Appeals and external review	90. (138)	128.a. (259), 128.b. (261), 128.c. (261), 128.d. (262)		92.bbb. (232), 128.e. (263), 128.f. (263)		
Contraceptive services		31.i. (107)	31.y. (136), 31.ee. (144), 31.ff. (145)	31.dd. (108), 31.gg. (110), 31.ll. (112), 31.nn. (117), 31.xx. (128)	92.iii. (143)	
Cost-sharing limitations				89.j. (207)		
General		92.a. (202/91)	92.u. (242/49), 92.dd. (257/52) 92.ff. (260)			
Geographic rating areas		92.c. (205)				
Grandfathered health plans			92.h. (234), 92.n. (237)	92.bbb. (232)	92.e. (128)	
Information reporting		31.k. (108), 31.l. (110), 92.c. (205)	31.aa. (138), 31.cc. (142), 31.ii. (147), 92.g. (232), 145.b. (302),	31.kk. (112), 31.yy. (130), 31.eee. (137), 92.pp. (221), 92.qq. (221), 92.rr. (222), 92.uu. (225), 92.xx. (228)	92.b. (125), 92.ddd. (139), 92.eee. (140), 92.ggg. (142), 92.yy. (135)	
Mental health parity/services	31.a. (74/115)		92.t. (241)	92.aaa. (231)	92.iii. (143)	
Network/provider issues			92.w. (249/51), 92.cc. (255), 145.a. (301)	89.j. (207), 92.ll. (218/54) 145.c. (279),	92.fff. (141)	

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PACE Act				145.d. (279) 50.ee. (159), 92.zz. (231)		
Preventive services (see Essential health benefits)						
Product modification/withdrawal				92.vv. (225)		
Rate review		92.o. (213)	92.g. (232)	92.mm. (218), 92.nn. (219), 92.ss. (223)	92.s. (129), 92.ccc. (137)	
Reference pricing			92.gg. (261)			
Same-sex spouses			92.z. (252)			
Stop-loss insurance	56. (106)					
Student insurance	51.a. (101)			51.b. (159)	51.c. (84), 51.d. (85)	
Transitional policy			92.x. (250), 92.aa. (253)		92.eee. (140)	
Unique plan identifiers	77.a. (125)			77.e. (190)		
Notices						
Annual/lifetime limits		92.j. (210)		92.bbb. (232)	92.d. (127)	
Coverage (Summary of Benefits and Coverage)		122.c. (254)		31.pp. (119/21), 31.uu. (126), 31.bbb. (133)	31.tt. (61), 31.ggg. (64), 31.hhh. (65), 92.kk. (132)	
Enrollment opportunity		92.j. (210)		92.v. (215)		

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Market discontinuation/renewal		92.f. (207)	92.y. (251)	92.ww. (227)	92.hhh. (142)	
Patient protection		92.j. (210)	92.k. (236), 92.r. (238)	92.bbb. (232)	92.d. (127)	
Pre-existing condition exclusion		122.b. (254)		92.bbb. (232)		
Rescission		92.j. (210)	92.i. (235), 92.q. (237)	92.bbb. (232)	92.d. (127)	
Special enrollment rights		122.a. (253)				
Transition		92.p. (214)				
High-risk pools (see Pre-Existing Condition Insurance Plan)						
Issuer Letters (CCIIO)						
2014 Issuer Letter		7.n. (23/1)				
2015 Issuer Letter			7.ee. (29/4)			
2016 Issuer Letter				7.vv. (24/9)		
2017 Issuer Letter					7.lll. (16/1)	
Marketplaces (see Exchanges)						
Medical loss ratio						
General requirements	48.a. (96)	48.d. (131), 48.g. (133), 89.a. (194/79)	48.e. (169)	27.n. (97), 48.h. (145), 48.i. (145)	48.b. (73)	
Medicare Parts C and D		48.c. (131), 48.f. (132)				
Medicaid/CHIP						
Application of essential health benefits	31.a. (74/115)					
Community First Choice Option	16.a. (49/100)					

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Eligibility/enrollment under ACA	7.a. (18/16), 7.c. (24/67), 7.g. (29/76)	28.a. (82/24), 28.c. (84/30)	28.e. (104)			
Federal Medical Assistance Percentage rates		28.d. (85/38)				
Medicare						
Accountable Care Organization standards	10.b. (138/82)					
Federally Qualified Health Center payments			159.b. (310/60)			
Minimum essential coverage		31.e. (94/40), 31.q. (114/47), 31.s. (117)	29.m. (113), 31.p. (130), 31.x. (135/16), 92.aa. (253)	31.rr. (123)	31.fff. (63)	
Multi-State Plan Program		111.a. (237/94), 111.b. (238/96), 111.c. (240/102), 111.d. (241)		111.e. (240)	111.f. (147)	
Nondiscrimination		99.b. (221/94), 111.b. (238/96)		181.b. (291/72)		
Notice of Benefit and Payment Parameters						
2014		89.a. (194/79), 89.b. (195/87)	7.bb.(28)			
2015			89.e. (225)			
2016				89.h. (203/35)		
2017					89.m. (119/9)	
Patient-Centered Outcomes Research Trust Fund	116. (154)					
Pre-Existing Condition Insurance Plan	6.a. (16/15), 6.b.	6.c., (17),	6.g. (22),		6.i. (10)	

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	(17)	6.d. (18), 6.e. (18), 6.f. (19)	6.h. (22)			
Premium tax credits						
General	29.a. (70/112)	29.b. (86), 29.c. (87), 29.f. (89), 50.d. (136/61), 50.h. (68), 50.n. (146)	29.g. (107/12), 29.h. (108), 29.j. (109), 29.k. (110), 29.l. (113), 29.m. (113), 29.n. (115), 50.w. (178)	29.q. (106), 92.uu. (225)	29.d. (59), 50.h. (81),	
Relation to cost-sharing reduction eligibility				89.a. (/34)		
Prescription drug fee			198.a. (347), 198.b. (347)	198.c. (306)		
Qualified health plans						
Accreditation	50.b. (98)	31.d. (93), 50.j. (142)		7.bbb. (29)	7.rrr. (21), 31.hhh. (65)	
Actuarial value	45. (87)	31.d. (93), 89.a. (194/79), 89.b. (195/87)	31.hh. (147), 92.aa. (253), 92.ii. (264)	31.mm. (114)	31.ddd. (61)	
Enrollee satisfaction					168. (204/35)	
Essential community providers	7.a. (18/16), 7.b. (21/22)	7.i. (19), 7.n. (23/1), 50.c. (135/54), 111.b. (238/96)	7.ee. (29/4), 92.cc. (255)	7.ddd. (33), 50.e. (147)	7.kkk. (14)	

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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.						
Terms	RRIAR Entry Numbers (Page Numbers)[2] Red = Table B Blue = Table C					Other Citations
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.05)	
General	7.b. (21/22)	50.p. (147), 89.c. (198/89)	7.b. (3)			
Guaranteed availability			92.aa. (253)			
Network adequacy					7.jjj. (13)	
Quality improvement/rating system			50.t. (176/29)	92.tt. (224)		
State evaluation		50.i. (142)				
Third-party payments	7.a. (18/16), 7.b. (21/22), 7.g. (29/76), 29.a. (70/112)		50.q. (173), 50.x. (179/30), 50.y. (182)			
Reinsurance, risk corridors, and risk adjustment	7.a. (18/16), 27.a. (65/104)	27.b. (77), 27.d. (79), 27.e. (80)	27.c. (100), 27.f. (101), 27.g. (102), 27.h. (102), 27.j. (104)	27.i. (93), 27.k. (94), 27.l. (95), 27.m. (96), 27.n. (97), 27.o. (98), 27.p. (98), 27.q. (98), 27.r. (100), 27.s. (100), 27.t. (101)	27.u. (58), 27.v. (59)	
Shared responsibility payments						
Employers		31.k. (108)	31.f. (120)	31.ccc. (136/26)	31.iii. (66)	
Exemptions		31.e. (94/40), 31.h. (105), 31.q. (114/47)	7.jj. (38), 7.ll. (41), 7.mm. (42), 7.nn. (43), 7.tt. (51),	50.cc. (157)		

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RRIAR INDEX: HEALTH REFORM
UPDATED THROUGH 5/31/2016

RRIAR Index: Health Reform[1]						
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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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.05)	
Individuals		31.g. (103/44), 31.r. (116)	29.m. (113), 31.v. (133/13), 31.bb. (139/18), 31.x. (135/16)			
Small Business Health Options Program (SHOP)						
Aggregation of premiums			50.z. (183)			
Direct Enrollment				50.bb. (156)	50.ff. (83)	
General	7.c. (24/67)	7.s. (30/11), 7.dd. (40), 50.f. (64), 50.g. (66), 89.c. (198/89)	7.ee. (29/4), 50.z. (183)	7.vv. (24/9), 7.hhh. (37), 50.dd. (159)	7.lll. (16/1), 50.f. (78), 50.g. (79), 50.aa. (83)	
State alternative applications		50.m. (145)				
Waivers for state innovation	14.a. (49/98)			14.b. (66)	14.c. (40/2)	
Wellness programs		99.a. (220)	99.c. (269)	99.d. (233), 99.e. (235)		

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RRIAR NUMBER REFERENCE GUIDE: HEALTH REFORM
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RRIAR Number	Action	Short Title	Agency
6.a.	Interim Final Rule	High-Risk Pool Eligibility	CCIIO (OCIIO)
6.b.	Interim Final Rule	Pre-Existing Condition Insurance Plan Program	CMS
6.c.	Request for Comment	Pre-Existing Condition Insurance Plan Authorization	CMS
6.d.	Request for Comment	Matching Grants to States for the Operation of High Risk Pools	CMS
6.e.	Request for Comment	Pre-Existing Health Insurance Plan	CMS
6.f.	Interim Final Rule	Pre-Existing Health Insurance Plan Program (Payment Rates)	CMS
6.g.	Guidance	Policy Sales to Medicare Beneficiaries Losing Coverage Due to High Risk Pool Closures	CMS
6.h.	Guidance	Special Enrollment Period for PCIP Enrollees	CCIIO
6.i.	Interim Final Rule	Pre-Existing Health Insurance Plan Program Updates	CMS
7.a.	Request for Comment	ACA Exchange Rules	CCIIO (OCIIO)
7.b.	Final/Interim Final Rule	Establishment of Exchange/QHP	CMS
7.c.	Final Rule	Exchange: Eligibility Determinations	CMS
7.d.	N/A	Definition of Indian (Response to CMS/IRS Regulations)	N/A
7.e.	Request for Comment	Exchange: Cooperative Agreements	CMS
7.f.	Request for Comment	Exchange: Blueprint Application	CMS
7.g.	Request for Comment	Exchange: General Guidelines	CMS
7.i.	Guidance	Guidance on the State Partnership Exchange	CCIIO
7.j.	Notice	New System of Records: Exchanges	CMS
7.k.	Request for Comment	Agent/Broker Data Collection in Federally-Facilitated Exchanges	CMS
7.l.	Guidance	Stand-Alone Dental Plans in Federally-Facilitated Exchanges	HHS
7.m.	Guidance	Data Transactions in Federally-Facilitated Exchanges	CMS
7.n.	Guidance	Federally-Facilitated and State Partnership Exchanges	CCIIO
7.o.	Final Rule	Standards for FFE Navigators and Assistance Personnel	CMS
7.p.	Notice	Cooperative Agreement to Support Navigators in FFE	CCIIO
7.q.	Request for Comment	Cooperative Agreement to Support Navigators in FFE	CMS
7.r.	Guidance	Role of Agents, Brokers, and Web-Brokers in Marketplaces	CCIIO
7.s.	Final Rule	Program Integrity: Exchange, SHOP, and Eligibility Appeals	CMS
7.t.	Request for Comment	Cooperative Agreement to Support State Exchanges	CMS
7.u.	Guidance	Certified Application Counselor Program for FFE	CCIIO
7.v.	Request for Comment	Consumer Assistance Tools and Programs of Exchanges	CMS
7.w.	Request for Comment	Enrollment Assistance Program	CMS
7.x.	Request for Comment	Notice to Employees of Coverage Options	DoL
7.y.	Request for Comment	Blueprint for Approval of Health Insurance Marketplaces	CMS
7.z.	Guidance	Employer Notification Requirements Under ACA	DoL

RRIAR Number	Action	Short Title	Agency
7.aa.	Guidance	Federally Facilitated Marketplace Enrollment Operational Policy	CCIIO
7.bb.	Final Rule	Program Integrity; Amendments to the HHS Notice of Benefit and Payment Parameters	CMS
7.cc.	Guidance	Using Account Transfer Flat Files to Enroll Individuals	CCIIO
7.dd.	Final Rule	Maximizing Coverage Under ACA	CMS
7.ee.	Guidance	2015 Letter to Issuers in FFMs	CCIIO
7.ff.	Guidance	Enrollment and Termination Policies for Marketplace Issuers	CCIIO
7.gg.	Guidance	Casework Guidance for Issuers in FFMs	CCIIO
7.hh.	Guidance	Guidance on Individuals “In Line” for FFM	CCIIO
7.ii.	Guidance	Guidance on Special Enrollment Periods for Complex Cases	CCIIO
7.jj.	Guidance	SEPs and Hardship Exemptions for Certain Individuals	CCIIO
7.kk.	Request for Comment	Standards for Navigators and Non-Navigator Personnel	CMS
7.ll.	Guidance	Filing Threshold Hardship Exemption	CCIIO
7.mm.	Guidance	Exemption for Individuals Eligible for Indian Provider Services	CCIIO
7.nn.	Guidance	Hardship Exemptions, Age Offs, and Catastrophic Coverage	CCIIO
7.oo.	Guidance	Information and Tips for Assisters: Working with AI/ANs	CCIIO
7.pp.	Guidance	Effort to Help Marketplace Enrollees Stay Covered	CCIIO
7.qq.	Guidance	Options for Paper-Based Marketplace Eligibility Appeals	CCIIO
7.rr.	Guidance	Termination of Enrollment in FFM Due to Death	CCIIO
7.ss.	Notice	Health Insurance Marketplace Public Use Files	CCIIO
7.tt.	Guidance	Hardship Exemptions for Persons Meeting Certain Criteria	CCIIO
7.uu.	Guidance	Guidance for Issuers on 2015 Reenrollment in the FFM	CCIIO
7.vv.	Guidance	2016 Letter to Issuers in FFMs	CCIIO
7.ww.	Guidance	Special Protections for AI/ANs	CMS
7.xx.	Guidance	AI/AN Trust Income and MAGI	CMS
7.yy.	Notice	Special Enrollment Period for Tax Season	CMS
7.zz.	Guidance	Hardship Exemptions for Persons Meeting Certain Criteria	CCIIO
7.aaa.	Guidance	Ending Special Enrollment Periods for Coverage in 2014	CCIIO
7.bbb.	Guidance	Key Dates in 2015: QHP Certification in the FFM, et al.	CCIIO
7.ccc.	Guidance	Out-of-Pocket Cost Comparison Tool for FFMs	CCIIO
7.ddd.	Request for Comment	ECP Data Collection to Support QHP Certification for PY 2017	CMS
7.eee.	Guidance	2016 Reenrollment in the FFM	CCIIO
7.fff.	Guidance	FAQs Regarding the FFM 2016 Employer Notice Program	CCIIO
7.ggg.	Guidance	Periodic Data Matching in the FFM	CCIIO
7.hhh.	Guidance	FFM and Federally-Facilitated SHOP Enrollment Manual	CCIIO

RRIAR Number	Action	Short Title	Agency
7.iii.	Guidance	FAQ on Minimum Acceptable Risk Standards for Exchanges	CCIIO
7.jjj.	Request for Comment	Establishment of QHPs and Exchanges	CMS
7.kkk.	Notice	ECP Petition for 2017	CCIIO
7.lll.	Guidance	2017 Letter to Issuers in FFMs	CCIIO
7.mmm.	Request for Comment	Establishment of an Exchange by a State and QHPs	CMS
7.nnn.	Request for Comment	Establishment of Exchanges and QHPs--Standards for Employers	CMS
7.ooo.	Request for Comment	CMS Healthcare.gov Site Wide Online Survey	CMS
7.ppp.	Guidance	Unaffiliated Issuer Enrollments and 2016 Reenrollment in FFMs	CCIIO
7.qqq.	Guidance	Policy-Based Payments: Approach for 2016	CCIIO
7.rrr.	Guidance	Key Dates for CY 2016: QHP Certification in the FFM, et al.	CCIIO
7.sss.	Guidance	April 2016 Transition of Issuers to Policy-Based Payments	CCIIO
7.ttt.	Guidance	Marketplace Eligibility Appeals--Paper-Based Processes	CCIIO
7.uuu.	Guidance	Ensuring Meaningful Access by Limited-English Speakers	CCIIO
7.vvv.	Guidance	Ending Special Enrollment Periods for Coverage in 2015	CCIIO
7.www.	Interim Final Rule	Amendments to SEPs and the CO-OP Program	CMS
7.xxx.	Guidance	Display of QRS Star Ratings and QHP Enrollee Survey Results	CCIIO
7.yyy.	Guidance	FAQs on Incarceration and the Marketplace	CCIIO
10.b.	Final Rule	ACO Standards	CMS
12.a.	Request for Comment	Co-Op Plans (Section 1322 of ACA)	CCIIO (OCIIO)
12.b.	Final Rule	Co-Op Plans (Section 1322 of ACA)	CMS
12.c.	Guidance	CO-OP Program Contingency Fund	CCIIO
12.d.	Request for Comment	Consumer Operated and Oriented Program	CMS
12.e.	Guidance	CO-OP Program Guidance Manual	CCIIO
12.f.	Guidance	FAQs on the CO-OP Program	CCIIO
14.a.	Final Rule	ACA Waivers for State Innovation	Treasury/CMS
14.b.	Guidance	Fact Sheet/FAQs on Section 1332 State Innovation Waivers	CCIIO
14.c.	Notice	Waivers for State Innovation	CMS/Treasury
16.a.	Final Rule	New Medicaid Community First Choice Option	CMS
27.a.	Final Rule	Risk Adjustment Standards in ACA	CMS
27.b.	Guidance	HHS Risk Adjustment Model Algorithm	CCIIO
27.c.	Request for Comment	Reinsurance, Risk Corridors, and Risk Adjustment Standards	CMS
27.d.	Guidance	HHS-Developed Risk Adjustment Model Algorithm	CCIIO
27.e.	Guidance	Reinsurance Enrollment Count	CCIIO
27.f.	Guidance	Risk Corridors and Budget Neutrality	CCIIO

RRIAR Number	Action	Short Title	Agency
27.g.	Guidance	Reinsurance Contributions Process	CCIIO
27.h.	Guidance	HHS-Developed Risk Adjustment Model Algorithm	CMS
27.i.	Request for Comment	Risk Corridors Transitional Policy	CMS
27.j.	Guidance	Transitional Reinsurance Program Annual Form	CCIIO
27.k.	Guidance	Transitional Reinsurance Program Collections for 2014	CCIIO
27.l.	Guidance	Transitional Reinsurance Program--Timing of Refunds	CCIIO
27.m.	Guidance	Transitional Adjustment for 2014 Risk Corridors Program	CCIIO
27.n.	Guidance	CSR Amounts in Risk Corridors and MLR Reporting	CCIIO
27.o.	Guidance	Risk Corridors Program Results	CCIIO
27.p.	Guidance	FY 2016 ICD-10 Crosswalk for HHS Risk Adjustment Model	CCIIO
27.q.	Guidance	Adjustment of Risk Adjustment Transfers	CCIIO
27.r.	Guidance	Early Reinsurance Payments for the 2015 Benefit Year	CCIIO
27.s.	Guidance	HHS-Developed Risk Adjustment Model Algorithm Software	CCIIO
27.t.	Guidance	Risk Corridors Payments for the 2014 Benefit Year	CCIIO
27.u.	Guidance	Transitional Reinsurance Program Collections for 2015	CCIIO
27.v.	Notice	New System of Records (Risk Adjustment Data Validation)	CMS
28.a.	Final Rule	Medicaid Eligibility Under ACA	CMS
28.c.	Final Rule	Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, etc.	CMS
28.d.	Final Rule	Increased FMAP Changes Under ACA	CMS
28.e.	Request for Comment	Medicaid Implementation Advanced Planning Document	CMS
29.a.	Final Rule	Premium Subsidies and Tax Credits	IRS
29.b.	Final Rule	Health Insurance Premium Tax Credit	Treasury
29.c.	Request for Comment	Health Insurance Premium Tax Credit	IRS
29.d.	Final Rule	Minimum Value of Eligible Employer-Sponsored Plans	IRS
29.e.	Final Rule	Information Reporting for Exchanges	IRS
29.f.	Guidance	IRS Ruling 2013-17 and Advance Premium Tax Credits	CCIIO
29.g.	Request for Comment	Payment Collections Operations Contingency Plan	CMS
29.h.	Guidance	Verification of Income for Tax Credits and Cost Sharing	HHS
29.i.	Guidance	Victims of Domestic Abuse	CCIIO
29.j.	Final/Temporary Rule	Rules Regarding the Health Insurance Premium Tax Credit	IRS
29.k.	Proposed Rule	Rules Regarding the Health Insurance Premium Tax Credit	IRS
29.l.	Guidance	Determining the Deduction for the Premium Tax Credit	IRS
29.m.	Guidance	Revisions to Calculating the Premium Tax Credit, et al.	IRS
29.n.	Notice	Premium Tax Credit	IRS

RRIAR Number	Action	Short Title	Agency
29.o.	Notice	Health Insurance Marketplace Statement	IRS
29.p.	Request for Comment	Health Insurance Premium Tax Credit	IRS
29.q.	Guidance	Penalty Relief Related to Advance Payments of PTC	IRS
29.r.	Guidance	Victims of Domestic Abuse and Spousal Abandonment	CCIIO
31.a.	Guidance	Essential Health Benefits Bulletin	CCIIO
31.b.	Interim Final Rule	Preventive Health Services	IRS/DoL/CMS
31.c.	Final Rule	Coverage of Certain Preventive Services Under ACA	IRS/DoL/CMS
31.d.	Final Rule	Standards on EHB, Actuarial Value, and Accreditation	CMS
31.e.	Final Rule	Exchanges: Eligibility for Exemptions and Minimum Essential Coverage Provisions	CMS
31.f.	Final Rule	Employer Shared Responsibility	IRS
31.g.	Final Rule	Shared Responsibility for Not Maintaining Essential Coverage	IRS
31.h.	Guidance	Hardship Exemption Criteria and Special Enrollment Periods	CCIIO
31.i.	Guidance	Safe Harbor for Coverage of Contraceptive Services	CCIIO
31.j.	Guidance	Women's Preventive Services Guidelines	HRSA
31.k.	Guidance	Employer and Insurer Reporting and Shared Responsibility	IRS
31.l.	Request for Comment	Data Submission for the FFE User Fee Adjustment	CMS
31.m.	Final Rule	Tax Credit for Health Insurance Expenses of Small Employers	IRS
31.n.	Request for Comment	Credit for Small Employer Health Insurance Premiums	IRS
31.o.	Final Rule	Health Insurance Coverage Reporting by Large Employers	IRS
31.p.	Final Rule	Minimum Essential Coverage Reporting	IRS
31.q.	Request for Comment	Exchange Functions: Eligibility for Exemptions	CMS
31.r.	Guidance	Shared Responsibility Provision	CCIIO
31.s.	Guidance	Obtaining Recognition as Minimum Essential Coverage	CCIIO
31.t.	Final Rule	Amendments to Excepted Benefits	IRS/DoL/CMS
31.u.	Guidance	Options Available for Consumers with Cancelled Policies	CCIIO
31.v.	Guidance	Instructions for the Application for Indian-Specific Exemptions	CMS
31.w.	Guidance	Q&A on Cost-Sharing Reductions for Contract Health Services	CCIIO
31.x.	Final Rule	MEC and Other Rules on the Shared Responsibility Payment	IRS
31.y.	Guidance	Disclosure with Respect to Preventive Services	CCIIO
31.z.	Notice	Reporting on Employer Health Insurance Offer and Coverage	IRS
31.aa.	Notice	Reporting on Health Coverage by Insurers	IRS
31.bb.	Notice	Health Coverage Exemptions	IRS
31.cc.	Request for Comment	Application for Filing ACA Information Returns	IRS
31.dd.	Final Rule	Coverage of Certain Preventive Services Under ACA	IRS/DoL/CMS

RRIAR Number	Action	Short Title	Agency
31.ee.	Interim Final Rule	Coverage of Certain Preventive Services Under ACA	IRS/DoL/CMS
31.ff.	Proposed Rule	Coverage of Certain Preventive Services Under ACA	IRS
31.gg.	Request for Comment	EBSA Form 700--Certification	DoL
31.hh.	Guidance	State-Specific Data for the Actuarial Value Calculator	CCIIO
31.ii.	Request for Comment	Reporting of Minimum Essential Coverage	IRS
31.jj.	Request for Comment	Information Reporting by Employers on Health Coverage	IRS
31.kk.	Request for Comment	ACA Uniform Explanation of Coverage Documents	IRS
31.ll.	Request for Comment	Data Submission for the FFE User Fee Adjustment	CMS
31.mm.	Guidance	2016 Actuarial Value Calculator	CCIIO
31.nn.	Request for Comment	Notification of Objection to Covering Contraceptive Services	CMS
31.oo.	Final Rule	Amendments to Excepted Benefits	IRS/DoL/CMS
31.pp.	Final Rule	Summary of Benefits and Coverage and Uniform Glossary	IRS/DoL/CMS
31.qq.	Guidance	FAQ About Excepted Benefits	CCIIO
31.rr.	Guidance	Minimum Essential Coverage Application Review Process	CCIIO
31.ss.	Guidance	Excise Tax on High Cost Employer Health Coverage	IRS
31.tt.	Request for Comment	Summary of Benefits and Coverage and Uniform Glossary	DoL
31.uu.	Guidance	ACA Implementation FAQs (SBC)	CCIIO
31.vv.	Guidance	EHBs: List of the Largest Three Small Group Products by State	CCIIO
31.xx.	Guidance	ACA Implementation FAQs (Preventive Services)	CCIIO
31.yy.	Guidance	ACA Information Returns Reference Guide	IRS
31.zz.	Guidance	EHB Benchmark Plans for 2017 and Beyond	CCIIO
31.aaa.	Guidance	Excise Tax on High Cost Employer Health Coverage	IRS
31.bbb.	Guidance	SBC Online Posting of Documents	CCIIO
31.ccc.	Letters to IRS	Relief from ACA Employer Mandate on Tribes	TSGAC
31.ddd.	Guidance	2017 Actuarial Value Calculator	CCIIO
31.eee.	Guidance	Extension of Due Dates for 2015 Information Reporting	IRS
31.fff.	Request for Comment	Minimum Essential Coverage Calculation Report and Notices	CMS
31.ggg.	Guidance	FAQs on ACA Implementation (SBC)	CCIIO
31.hhh.	Guidance	FAQs on SBC Related to Rate Filing and QHP Certification	CCIIO
31.iii.	Notice	Tribal Consultation on ACA Employer Shared Responsibility	IRS
31.jjj.	Request for Comment	EHBs in ABPs, Eligibility Notices, et al.	CMS
31.kkk.	Guidance	FAQs on Health Insurance Market Reforms (EHBs)	CCIIO
39.a.	Request for Information	Basic Health Program	CMS
39.b.	Final Rule	Basic Health Program	CMS

RRIAR Number	Action	Short Title	Agency
39.c.	Final Methodology	Basic Health Program: Federal Funding Methodology for 2015	CMS
39.d.	Request for Comment	Basic Health Program Report for Exchange Premium	CMS
39.e.	Final Methodology	Basic Health Program: Federal Funding Methodology for 2016	CMS
39.f.	Final Methodology	Basic Health Program: Federal Funding Methodology for 2017	CMS
45.	Guidance	Actuarial Value and Cost-Sharing	CMS
48.a.	Final Rule	Medical Loss Ratio Requirements	CMS
48.b.	Request for Comment	Medical Loss Ratio Rebate Calculation Report and Notices	CMS
48.c.	Final Rule	MLR Requirements for Medicare Part C and Part D	CMS
48.d.	Guidance	Medical Loss Ratio Reporting and Rebate Requirements	CCIIO
48.e.	Final Rule	Computation of MLR	IRS
48.f.	Request for Comment	Medical Loss Ratio Report for MA Plans and PDPs	CMS
48.g.	Guidance	Medical Loss Ratio Reporting and Rebate Requirements	CCIIO
48.h.	Guidance	Q&A on MLR Reporting and Rebate Requirements	CCIIO
48.i.	Guidance	Q&A on MLR Reporting and Rebate Requirements for 2014	CCIIO
50.b.	Final Rule	EHB and QHP Standards	CMS
50.c.	Guidance	Model Qualified Health Plan Addendum (Indian Addendum)	CMS/IHS
50.d.	Request for Comment	Data Elements for Exchange Application	CMS
50.e.	Request for Comment	Initial Plan Data Collection to Support QHP Certification	CMS
50.f.	Request for Comment	Eligibility and Enrollment for Employees in SHOP	CMS
50.g.	Request for Comment	Eligibility and Enrollment for Small Businesses in SHOP	CMS
50.h.	Request for Comment	Eligibility for Insurance Affordability Programs and Enrollment	CMS
50.i.	Guidance	State Evaluation of Plan Management Activities	CCIIO
50.j.	Request for Comment	Recognized Accrediting Entities Data Collection	CMS
50.k.	Guidance	Model Eligibility Application	CCIIO
50.l.	Guidance	State Alternative Applications for Health Coverage	CCIIO
50.m.	Guidance	State Alternative Applications for Health Coverage Through SHOP	CCIIO
50.n.	Final Rule	Disclosures for Health Insurance Affordability Program Eligibility	Treasury
50.o.	Request for Comment	State Health Insurance Exchange Incident Report	CMS
50.p.	Guidance	QHP Webinar Series FAQs	CMS
50.q.	Guidance	Third Party Payments of Premiums for QHPs	CCIIO
50.r.	Guidance	Implementation of Section 402 of IHCIA	IHS
50.s.	Request for Comment	State-Based Marketplace Annual Report	CMS
50.t.	Request for Comment	QHP Quality Rating System Measures and Methodology	CMS
50.u.	Guidance	State-Based Marketplace Annual Reporting Tool	CCIIO

RRIAR Number	Action	Short Title	Agency
50.w.	Guidance	Retroactive Advance Payments of PTCs and CSRs Due to Exceptional Circumstances	CCIIO
50.x.	Interim Final Rule	Third Party Payment of QHP Premiums	CMS
50.y.	Final Rule	Tax Treatment of Retirement Plan Payment of Premiums	IRS
50.z.	Guidance	Implementation of Employee Choice in SHOP in 2015	CCIIO
50.aa.	Request for Comment	SHOP Effective Date and Termination Notice Requirements	CMS
50.bb.	Guidance	FAQs on Flexibilities for State-Based SHOP Direct Enrollment	CCIIO
50.cc.	Guidance	FAQs on SBM Options for Shared Responsibility Exemptions	CCIIO
50.dd.	Guidance	FAQs on Agents and Brokers Operating in SHOP	CCIIO
50.ee.	Guidance	FAQs on the Impact of PACE Act on State Small Group Expansion	CCIIO
50.ff.	Guidance	State-Based SHOP Direct Enrollment Transition	CCIIO
51.a.	Final Rule	Student Insurance Coverage	CMS
51.b.	Guidance	FAQ on Rate Review of Student Health Plans	CCIIO
51.c.	Guidance	Application of Market Reforms to Student Health Coverage	CCIIO
51.d.	Request for Comment	Student Health Insurance Coverage	CMS
54.	Notice	ESI Coverage Verification	CMS
56.	Request for Information	Stop-Loss Insurance	IRS/DoL/CMS
63.a.	Interim Final Rule	Health Care EFT Standards	HHS
63.b.	Request for Comment	Electronic Funds Transfers Authorization Agreement	CMS
64.a.	Notice	Policy on Conferring with Urban Indian Organizations	IHS
64.b.	Notice	CMS Tribal Consultation Policy	CMS
64.c.	Notice	Tribal Consultation Policy	Treasury
65.	Request for Comment	Health Care Reform Insurance Web Portal Requirements	CMS
67.a.	Request for Comment	State Consumer Assistance Grants	CMS
67.b.	Request for Comment	Research on Outreach for Health Insurance Marketplace	CMS
67.c.	Guidance	Use of 1311 Funding for Change Orders	CCIIO
67.d.	Guidance	Use of 1311 Funds and No Cost Extensions	CCIIO
67.e.	Guidance	Consumer Assistance for Marketplace Enrollment	CCIIO
67.f.	Guidance	Use of 1311 Funds, et al.	CCIIO
67.g.	Guidance	FAQs on Use of 1311 Funds for Establishment Activities	CCIIO
68.	Request for Comment	Security of Electronic Health Information	CMS
77.a.	Final Rule	Unique Plan Identifiers	CMS
77.e.	Request for Information	Requirements for the Health Plan Identifier	CMS
88.a.	Request for Comment	Early Retiree Reinsurance Program Survey	CMS
88.b.	Notice	Early Retiree Reinsurance Program	CMS

RRIAR Number	Action	Short Title	Agency
89.a.	Final Rule	Notice of Benefit and Payment Parameters for 2014	CMS
89.b.	Interim Final Rule	Amendments to the Notice of Benefit and Payment Parameters	CMS
89.c.	Final Rule	Small Business Health Options Program	CMS
89.d.	Request for Comment	Cost-Sharing Reductions Reconciliation Methodology	CMS
89.e.	Final Rule	Notice of Benefit and Payment Parameters for 2015	CMS
89.f.	Guidance	Choice of Methodology for Cost-Sharing Reduction Reconciliation	CCIIO
89.g.	Request for Comment	Cost Sharing Reduction Reconciliation	CMS
89.h.	Final Rule	Notice of Benefit and Payment Parameters for 2016	CMS
89.i.	Request for Comment	Information Collection for Machine-Readable Data for QHPs	CMS
89.j.	Guidance	ACA Implementation FAQs (Cost-Sharing Limitations)	CCIIO
89.k.	Letter to CCIIO	Eligibility Determinations for Indian-Specific CSVs	TTAG
89.l	Request for Information	Referrals for Cost-Sharing Protections Under Limited CSVs	CMS
89.m.	Final Rule	Notice of Benefit and Payment Parameters for 2017	CMS
89.n.	Guidance	Manual for Reconciliation of Advance Payment of CSRs	CCIIO
89.o.	Guidance	CSR Reconciliation Issuer to MIDAS Attestation	CCIIO
89.p.	Guidance	CSR Reconciliation Issuer to MIDAS Inbound Specification	CCIIO
89.q.	Guidance	Data Submission Deadline for CSR Reconciliation	CCIIO
90.	Guidance	Adverse Benefit Determinations	CCIIO
91.a.	Guidance	Waiting Period Limitation Under Public Health Service Act	CCIIO
91.b.	Final Rule	Waiting Period Limitation and Coverage Requirements	IRS/DoL/CMS
91.c.	Final Rule	Waiting Period Limitation	IRS/DoL/CMS
92.a.	Final Rule	Health Insurance Market Rules	CMS
92.b.	Request for Comment	Compliance with Individual and Group Market Reforms	CMS
92.c.	Guidance	Age Curves, Geographical Rating Areas, and State Reporting	CMS
92.d.	Request for Comment	Patient Protection Notices and Disclosure Requirements	CMS
92.e.	Request for Comment	Disclosure and Recordkeeping for Grandfathered Health Plans	CMS
92.f.	Guidance	Model Language for Individual Market Renewal Notices	CMS
92.g.	Request for Comment	Reporting for Grants to Support Health Insurance Rate Review	CMS
92.h.	Request for Comment	Disclosure and Recordkeeping for Grandfathered Health Plans	DoL
92.i.	Request for Comment	ACA Notice of Rescission	Treasury
92.j.	Request for Comment	Enrollment Opportunity Notice Relating to Lifetime Limits	Treasury
92.k.	Request for Comment	ACA Notice of Patient Protection	IRS
92.l.	Guidance	Application of ACA Provisions to HRAs, Health FSAs, et al.	IRS/DoL
92.m.	Guidance	Application of ACA Provisions to Certain Healthcare Arrangements	CCIIO

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92.n.	Request for Comment	Rules for Group Health Plans Related to Grandfather Status	IRS
92.o.	Guidance	State Reporting for Plan or Policy Years Beginning in 2015	CCIIO
92.p.	Guidance	Standard Notices for Transition to ACA Compliant Policies	CCIIO
92.q.	Request for Comment	ACA Advance Notice of Rescission	DoL
92.r.	Request for Comment	ACA Patient Protection Notice	DoL
92.s.	Request for Comment	Rate Increase Disclosure and Review Reporting Requirements	CMS
92.t.	Guidance	ACA Implementation: Market Reform and Mental Health Parity	CCIIO
92.u.	Final Rule	Exchange and Insurance Market Standards for 2015 and Beyond	CMS
92.v.	Guidance	Q&A on Outreach by Medicaid MCOs to Former Enrollees	CCIIO
92.w.	Request for Information	Provider Non-Discrimination	CMS/IRS/DoL
92.x.	Guidance	Extension of Transitional Policy for Non-Grandfathered Coverage	CCIIO
92.y.	Guidance	Draft Notices When Discontinuing or Renewing a Product	CCIIO
92.z.	Guidance	Coverage of Same-Sex Spouses	CCIIO
92.aa.	Guidance	Health Insurance Market Reforms and Marketplace Standards	CCIIO
92.bb.	Guidance	Employer Health Care Arrangements (Q&A)	IRS
92.cc.	Guidance	FAQs on Essential Community Providers	CCIIO
92.dd.	Final Rule	Eligibility Determinations for Exchange Participation	CMS
92.ee.	Guidance	Self-Funded, Non-Federal Governmental Plans	CCIIO
92.ff.	Final Rule	Deduction Limitation for Remuneration by Insurers	IRS
92.gg.	Guidance	FAQs About ACA Implementation (Reference Pricing)	CCIIO
92.hh.	Request for Comment	Annual Eligibility Redetermination Notices, et al.	CMS
92.ii.	Guidance	Group Plans that Fail to Cover In-Patient Hospitalization Services	CCIIO
92.jj.	Guidance	ACA Implementation (Premium Reimbursement Arrangements)	CCIIO
92.kk.	Request for Comment	Summary of Benefits and Coverage and Uniform Glossary	CMS
92.ll.	Request for Comment	Health Benefit Plan Network Access and Adequacy Model Act	NAIC
92.mm.	Guidance	Rate Review Requirements	CCIIO
92.nn.	Guidance	Rate Filing Justifications for Single Risk Pool Coverage	CCIIO
92.oo.	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

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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
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
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
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

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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: Tribes and Tribal Organizations	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