

Regulation Review and Impact Analysis Report v. 4.05

as of May 31, 2014

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

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.

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

In addition to this cover page, the report consists of three tables –

- 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.

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.

Regulations with pending due dates for public comments -

- ➤ 4.h. Health Insurance Benefits Agreement and ASC Certification (CMS-370 and CMS-377; comments due 6/2/2014)
- ➤ 110.f. Requirements for Open Payments (CMS-10495; comments due 6/2/2014)
- > 110.i. Self-Referral Disclosure Protocol (CMS-10328; comments due 6/2/2014)
- 191. Blue Button Connector (HHS-OS-0990-New-60D; comments due 6/2/2014)
- 25.t. Psychiatric Unit Criteria Work Sheet (CMS-437; comments due 6/3/2014)
- 110.j. Disclosure for the In-Office Ancillary Services Exception (CMS-10332; comments due 6/3/2014)
- > 7.q. Cooperative Agreement to Support Navigators in FFE (CMS-10463; comments due 6/10/2014)
- > 85.c. Medicaid and CHIP Access to Preventive Services State Survey (CMS-10521; comments due 6/10/2014)
- > 92.w. Provider Non-Discrimination (CMS-9942-NC; comments due 6/10/2014)
- > 82.i. HIPAA Covered Entity and Associate Pre-Audit Survey (HHS-OS-0945-New-30D; comments due 6/11/2014)
- > 1.i. Public Health Agency/Registry Readiness for Meaningful Use (CMS-10499; comments due 6/16/2014)
- ➤ 11.z. Medicare Health Outcomes Survey (CMS-10203; comments due 6/16/2014)
- > 27.c. Reinsurance, Risk Corridors, and Risk Adjustment Standards (CMS-10401; comments due 6/16/2014)
- > 188.b. Fire Safety Requirements for Certain Health Care Facilities (CMS-9942-NC; comments due 6/16/2014)
- > 3.b. DME Competitive Bidding (CMS-10169; comments due 6/17/2014)
- > 39.d. Basic Health Program Report for Exchange Premium (CMS-10510; comments due 6/17/2014)
- > 134.g. Home Office Cost Statement (CMS-287-05; comments due 6/17/2014)
- > 78.f. Request for Applications for the Medicare Care Choices Model (CMS-5512-N; applications due 6/19/2014)
- > 71.c. ESRD Care Model (CMS-5506-N; applications due 6/23/2014)

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

- 100.b.Marketplace Quality Standards (CMS-10520; comments due 6/23/2014)
- 11.aa. Predictive Learning Analytics Tracking Outcome Tool (CMS-10517; comments due 6/24/2014)
- 25.s. Medicare PPS for Inpatient Rehab Facilities for FY 2015 (CMS-1608-P; comments due 6/30/2014)
- 25.u. Medicare PPS for Inpatient Psychiatric Facilities for FY 2015 (CMS-1606-P; comments due 6/30/2014)
- 25.v. Acute Care Hospital IPPS and LTCH PPS for FY 2015, et al. (CMS-1607-P; comments due 6/30/2014)
- 72.d. Medicare PPS and Consolidated Billing for SNFs for FY 2015 (CMS-1605-P; comments due 6/30/2014)
- 78.h. Wage Index and Payment Rates for Hospices for FY 2015, et al. (CMS-1609-P; comments due 7/1/2014)
- > 159.b.Medicare PPS for Federally Qualified Health Centers, et al. (CMS-1443-FC; comments due 7/1/2014)
- > 175.d. Reconciliation of State Invoice and Prior Quarter Adjustment (CMS-304 and CMS-304a; comments due 7/1/2014)
- > 175.e.Medicaid Drug Rebate Program Forms (CMS-368 and CMS-R-144; comments due 7/1/2014)
- 109.c. Health Care Continuation Coverage (DoL/RIN 1210-AB65; comments due 7/7/2014)
- > 185.c. Revisions to HHS OIG Exclusion Authorities (HHS OIG RIN 0936-AA04; comments due 7/8/2014)
- 185.b. Revisions to HHS OIG Civil Monetary Penalty Rules (HHS OIG RIN 0936-AA04; comments due 7/11/2014)
- 13.g. Business Proposal Forms for QIOs (CMS-718-721; comments due 7/15/2014)
- 134.i. Rural Health Clinic/Freestanding FQHC Cost Report (CMS-222-92; comments due 7/15/2014)
- 1.j. Modifications to the EHR Incentive Programs for 2014 (CMS-0052-P; comments due 7/21/2014)
- > 5.c. Health Plan Monitoring System Data Entry for PACE (CMS-10525; comments due 7/22/2014)
- > 3.j. Prior Authorization Process for Certain DMEPOS Items (CMS-6050-P; comments due 7/28/2014)

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

- 184.a. Clinical Laboratory Improvement Amendments Regulations (CMS-R-26; comments submitted 1/6/2014 by ANTHC)
- 31.v. Instructions for the Application for Indian-Specific Exemptions (CMS/no ref. #; comments submitted 1/13/2014 by TTAG)
- 31.w. Cost-Sharing Reductions for Contract Health Services (Draft) (CCIIO/no ref. #; comments submitted 1/14/2014 by TTAG)
- 50.t. QHP Quality Rating System Measures and Methodology (CMS-3288-NC; comments submitted 1/21/2014 by TTAG)
- 39.c. Basic Health Program: Proposed Funding Methodology for 2015 (CMS-2380-PN; comments submitted 1/22/2014 by TTAG)
- 7.ee. 2015 Letter to Issuers in FFMs (CCIIO/no ref. #, comments submitted 2/25/2014 by TTAG)
- 23.g. Imposition of Cost-Sharing Charges Under Medicaid (CMS-R-53; comments submitted 3/17/2014 by TTAG)
- 188. Emergency Preparedness Requirements (CMS-3178-P; comments submitted 3/31/2014 by TTAG)
- 92.u. Exchange and Insurance Market Standards for 2015 and Beyond (CMS-9949-P; comments submitted 4/21/2014)
- 31.x. MEC and Other Rules on the Shared Responsibility Payment (REG-141036-13; comments submitted 4/28/2014 by TTAG)
- 65. Health Care Reform Insurance Web Portal Requirements (CMS-10320; comments submitted 5/12/2014 by TTAG)
- > 50.x. Third Party Payment of QHP Premiums (CMS-9943-IFC; comments submitted 5/13/2014 by TTAG)

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)
- 164.b.Medicare Secondary Payer and "Future Medicals" (CMS-6047-P; sent to OMB 8/1/2013)
- 16.b. Medicaid HCBS Waivers (CMS-2249-F2; approved by OMB 1/14/2014 but not yet published)
- 193. 340B Drug Pricing Program Regulations (HRSA RIN 0906-AB04; sent to OMB 4/9/2014)
- 180. Flu Vaccination Standard for Certain Providers and Suppliers (CMS-3213-F; approved by OMB 4/18/2014 but not yet published)
- 181. Nondiscrimination Provisions (OPM/ RIN 3206-AM77; sent to OMB 5/8/2014)
- > 71.m. Changes to ESRD PPS and QI Program for 2015 (CMS-1614-P; sent to OMB 5/15/2014)

- > 185.d. Revisions to Safe Harbors Under the Anti-Kickback Statute, et al. (HHS OIG/RIN 0936-AA06; sent to OMB 5/15/2014)
- > 52.I. Home Health Agency Conditions of Participation (CMS-3819-P; sent to OMB 5/22/2014)

Recent (final) rules issued -

- 48.e. Computation of MLR (TD 9651; issued 1/7/2014)
- > 82.e. CLIA Program and HIPAA Privacy Rule (CMS-2319-F; issued 2/5/2014)
- ➤ 31.f. Employer Shared Responsibility (TD 9655; issued 2/13/2014)
- 91.b. Waiting Period Limitation and Coverage Requirements (REG-122706-12, DoL/RIN 1210-AB56, CMS-9952-F; issued 2/24/2014)
- ➤ 31.o. Health Insurance Coverage Reporting by Large Employers (TD 9661; issued 3/10/2014)
- > 31.p. Minimum Essential Coverage Reporting (TD 9660; issued 3/10/2014)
- 89.e. Notice of Benefit and Payment Parameters for 2015 (CMS-9954-F; issued 3/11/2014)
- 39.b. Basic Health Program (CMS-2380-F; issued 3/12/2014)
- 39.c. Basic Health Program: Federal Funding Methodology for 2015 (CMS-2380-FN; issued 3/12/2014)
- 7.ee. CCIIO 2015 Letter to Issuers in FFMs (CCIIO/no ref. #, issued 3/14/2014)
- 94. Methodology for Designation of Frontier and Remote Areas (HRSA/no ref. #, issued 5/5/2014)
- > 29.e. Information Reporting for Exchanges (TD 9663, issued 5/7/2014)
- > 31.w. Cost-Sharing Reductions for Contract Health Services (CCIIO/no ref. #, issued 5/9/2014)
- ➣ 50.y. Tax Treatment of Retirement Plan Payment of Premiums (TD 9665; issued 5/12/2014)
- > 81. Efficiency, Transparency, and Burden Reduction (CMS-3267-F; issued 5/12/2014)
- 11.u. CY 2015 Policy and Technical Changes to Parts C and D (CMS-4159-F; issued 5/23/2014)
- 92.u. Exchange and Insurance Market Standards for 2015 and Beyond (CMS-9949-F; issued 5/27/2014)

Contacts: Jackie Engebretson at JEngebretson@nihb.org.

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

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2014

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 71	
			SECTION II: MEDICARE	Beginning on page 13 of 71	
			SECTION III: HEALTH REFORM	Beginning on page 43 of 71	
			SECTION IV: OTHER	Beginning on page 66 of 71	
			SECTION I: MEDICAID (AND DUAL MEDICAID AND MEDICARE)		
1.g.	Revision to the Definition of Common Meaningful Use Data Set ACTION: Interim Final Rule NOTICE: 2014 Edition Electronic Health Record Certification Criteria: Revision to the Definition of "Common Meaningful Use Data Set" AGENCY: HHS	RIN 0991- AB91	Issue Date: 11/4/2013 Due Date: 1/3/2014 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.h.	Voluntary 2015 Edition EHR Certification Criteria, et al. ACTION: Proposed Rule NOTICE: Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements AGENCY: HHS	HHS RIN 0991- AB92	Issue Date: 2/26/2014 Due Date: 4/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 3/19/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
1.i.	Public Health Agency/Registry Readiness for Meaningful Use ACTION: Request for Comment NOTICE: Public Health Agency/Registry Readiness to Support Meaningful Use AGENCY: CMS	CMS-10499	Issue Date: 2/7/2014 Due Date: 4/8/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 5/16/2013 Due Date: 6/16/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
1.j.	Modifications to the EHR Incentive Programs for 2014 ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition AGENCY: CMS	CMS-0052-P	Issue Date: 5/23/2014 <u>Due Date:</u> 7/21/2014 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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16.b.	Medicaid HCBS Waivers ACTION: Proposed-Final Rule NOTICE: Medicaid; State Plan Home and Community-Based Services, 5- Year Period for Waivers, Provider Payment Reassignment; Setting Requirements AGENCY: CMS	CMS-2249- P2 F2	Issue Date: 5/3/2012 Due Date: 6/4/2012 7/2/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 5/3/2012; Final Rule approved by OMB 1/13/2014	 Summary of Agency action: √ NIHB analysis of action: None. 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
16.d.	Elimination of Cost-Sharing for Dual-Eligibles Receiving HCBS ACTION: Request for Comment NOTICE: Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services AGENCY: CMS	CMS-10344	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/20/2013 Due Date: 1/21/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
16.e.	Community First Choice Option ACTION: Request for Comment NOTICE: Community First Choice Option AGENCY: CMS	CMS-10462	Issue Date: 1/17/2014 Due Date: 3/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/25/2014 Due Date: 4/24/2014	 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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23.e.	State Children's Health Insurance Program ACTION: Request for Comment NOTICE: State Children's Health Insurance Program and Supporting Regulations AGENCY: CMS	CMS-R-308	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/23/2014 Due Date: 2/24/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
23.f.	1932(a) State Plan Amendment Template and Requirements ACTION: Request for Comment NOTICE: 1932(a) State Plan Amendment Template, State Plan Requirements, and Supporting Regulations AGENCY: CMS	CMS-10120	Issue Date: 12/6/2013 Due Date: 2/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/14/2014 Due Date: 3/17/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
23.g.	Imposition of Cost Sharing Charges Under Medicaid ACTION: Request for Comment NOTICE: Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations AGENCY: CMS	CMS-R-53 (OMB approval sought under CMS-10398; see 23.a.)	Issue Date: 1/27/2014 Due Date: 2/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued withdrawal 2/7/2014; re-issued request 2/14/2014 Due Date: 3/17/2014 TTAG File Date: 3/17/2014	 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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28.e.	FMAP Notice for FY 2015 ACTION: Notice NOTICE: Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, CHIP, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2014, Through September 30, 2015 AGENCY: HHS	HHS (no reference number)	Issue Date: 1/21/2014 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:
41.d.	New Safe Harbors ACTION: Notice NOTICE: Solicitation of New Safe Harbors and Special Fraud Alerts AGENCY: HHS OIG	OIG-122-N	Issue Date: 12/27/2013 Due Date: 2/25/2014 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:
44.e.	Multi-Payer Advanced Primary Care Practice Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Multi- Payer Advanced Primary Care Practice (MAPCP) Demonstration: Provider Survey AGENCY: CMS	CMS-10485	Issue Date: 7/12/2013 Due Date: 9/10/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/29/2014 Due Date: 2/28/2014	 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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46.d.	Preliminary DSH Allotments for FY 2014 ACTION: Notice NOTICE: Medicaid Program; Preliminary Disproportionate Share Hospital (DSH) Allotments for Fiscal Year (FY) 2014 and the Preliminary Institutions for Mental Diseases Disproportionate Share Hospital Limits for FY 2014 AGENCY: CMS	CMS-2389-N	Issue Date: 2/28/2014 <u>Due Date:</u> None NIHB File Date: <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
85.c.	Medicaid and CHIP Access to Preventive Services State Survey ACTION: Request for Comment NOTICE: Improving Quality of Care in Medicaid and CHIP through Increased Access to Preventive Services State Survey AGENCY: CMS	CMS-10521	Issue Date: 4/14/2014 Due Date: 6/10/2014 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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147.a.	Statement of Expenditure for Medical Assistance ACTION: Request for Comment NOTICE: Quarterly Statement of Expenditure for Medical Assistance AGENCY: CMS	CMS-64	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 10/4/2013; issued extension 4/11/2014 Due Date: 6/24/2013; 12/3/2013; 5/12/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
147.b.	Statement of Budget for Medical Assistance ACTION: Request for Comment NOTICE: Quarterly Statement of Budget for Medical Assistance AGENCY: CMS	CMS-37	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014 Due Date: 5/12/2014	 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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147.c.	Quarterly CHIP Statement of Expenditures and Budget Report ACTION: Request for Comment NOTICE: Quarterly Children's Health Insurance Program (CHIP) Statement of Expenditures for the Title XXI Program (CMS-21) and State Children's Health Insurance Program Budget Report for the Title XXI Program State Plan Expenditures (CMS-21B) AGENCY: CMS	CMS-21 and CMS-21B	Issue Date: 2/14/2014 Due Date: 4/15/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/25/2014 Due Date: 5/27/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
157.b.	Medicare Secondary Payer and Certain Civil Money Penalties ACTION: Advanced Notice of Proposed Rule Making NOTICE: Medicare Program; Medicare Secondary Payer and Certain Civil Money Penalties AGENCY: CMS	CMS-6061- ANPRM	Issue Date: 12/11/2013 Due Date: 2/10/2014 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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157.c.	Right of Appeal for Medicare Secondary Payer Determination ACTION: Proposed Rule NOTICE: Medicare Program; Right of Appeal for Medicare Secondary Payer Determination Relating to Liability Insurance (Including Self- Insurance), No Fault Insurance, and Workers' Compensation Laws and Plans AGENCY: CMS	CMS-6055-P	Issue Date: 12/27/2013 Due Date: 2/25/2014 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:
171.	Medicaid Emergency Psychiatric Demonstration Evaluation ACTION: Request for Comment NOTICE: Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation AGENCY: CMS	CMS-10487	Issue Date: 7/26/2013 Due Date: 9/24/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/6/2013 Due Date: 1/6/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency 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 Due Date: 5/12/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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175.b.	Medicaid Drug Use Review Program ACTION: Request for Comment NOTICE: Medicaid Drug Use Review Program AGENCY: CMS	CMS-R-153	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/17/2014 Due Date: 4/16/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
175.c.	Submitting Drug Identifying Information to Medicaid Programs ACTION: Request for Comment NOTICE: Medicaid Payment for Prescription DrugsPhysicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs AGENCY: CMS	CMS-10215	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/7/2014 Due Date: 4/7/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
175.d.	Reconciliation of State Invoice and Prior Quarter Adjustment ACTION: Request for Comment NOTICE: Reconciliation of State Invoice and Prior Quarter Adjustment Statement AGENCY: CMS	CMS-304 and CMS-304a	Issue Date: 5/2/2014 Due Date: 7/1/2014 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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175.e.	Medicaid Drug Rebate Program Forms ACTION: Request for Comment NOTICE: Medicaid Drug Rebate Program Forms AGENCY: CMS	CMS-368 and CMS-R-144	Issue Date: 5/2/2014 Due Date: 7/1/2014 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:
176.	EPSDT Participation Report ACTION: Request for Comment NOTICE: Annual EPSDT Participation Report AGENCY: CMS	CMS-416	Issue Date: 8/9/2013 Due Date: 10/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/6/2013 Due Date: 1/6/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
180.	Flu Vaccination Standard for Certain Providers and Suppliers ACTION: 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: √ 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?
188.a.	Emergency Preparedness Requirements ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS		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	 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 Rule NOTICE: Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities AGENCY: CMS	CMS-3277-P	Issue Date: 4/16/2014 Due Date: 6/16/2014 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:
190.	Frontier Community Health Integration Project Demo ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Solicitation for Proposals for the Frontier Community Health Integration Project Demonstration AGENCY: CMS	CMS-5511-N	Issue Date: 2/4/2014 <u>Due Date:</u> 5/5/2014 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency Utilization and Payment Data: Physician and Other Supplier ACTION: Notice NOTICE: Medicare Provider Utilization and Payment Data: Physician and Other Supplier AGENCY: CMS	File Code CMS (no reference number)	Dates (Issue, Due, File, Subsequent Action)¹ Issue Date: 4/9/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	In Table B Is the summary of Agency action included? Is the NIHB analysis included? Summary of Agency action: √ NIHB analysis of action:	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included? NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
			Section II: Medicare		
3.b.	DME Competitive Bidding ACTION: Request for Comment NOTICE: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program AGENCY: CMS	CMS-10169	Issue Date: 7/27/2012 Due Date: 8/27/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/1/2013, 5/10/2013, 4/18/2014 Due Date: 4/30/2013; 6/10/2013; 6/17/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
3.i.	Pass-Through Payment for New Categories of Devices ACTION: Request for Comment NOTICE: Recognition of Pass- Through Payment for Additional (New) Categories of Devices Under the Outpatient Prospective Payment System and Supporting Regulations AGENCY: CMS	CMS-10052	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/20/2013 Due Date: 1/21/2014	 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?
3.j.	Prior Authorization Process for Certain DMEPOS Items ACTION: Proposed Rule NOTICE: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items AGENCY: CMS	CMS-6050-P	Issue Date: 5/28/2014 Due Date: 7/28/2014 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:
3.k.	Methodology for Adjusting Medicare Payments for DMEPOS ACTION: ANPRM NOTICE: Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Using Information From Competitive Bidding Programs AGENCY: CMS		Issue Date: 2/26/2014 <u>Due Date</u> : 3/28/2014 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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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?
3.1.	Payment for New Technology APC Groups Under OPPS ACTION: Request for Comment NOTICE: Recognition of Payment for New Technology Services for New Technology Ambulatory Payment Classification (APC) Groups Under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR part 419 AGENCY: CMS	CMS-10054	Issue Date: 3/3/2014 Due Date: 4/29/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/30/2014 Due Date: 5/30/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
3.m.	FFS Audit Prepayment Review and Prior Authorization Demos ACTION: Request for Comment NOTICE: Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration AGENCY: CMS	CMS-10421	Issue Date: 4/4/2014 <u>Due Date</u> : 4/18/2014 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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Ambulatory Surgical Center Payment System, et al. ACTION: Propesed-Final Rule NOTICE: Medicare and Medicaid Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; EHR Incentive Program; Provider Reimbursement Determinations and Appeals AGENCY: CMS 4.h. Health Insurance Benefits Agreement and ASC Certification ACTION: Request for Comment NOTICE: Health Insurance Benefits Agreement and Ambulatory Surgical Request for Certification or Update of Certification Information Update of Certification Information CMS-370 and CMS-377 Due Date: 9/6/2043 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action: √ NIHB analysis of action: √ NIHB action: √ NIHB action: √ NIHB recommendations included: action: √ NIHB recommendations included: action: √ NIHB recommendations included: action: √ NIHB analysis of action: √ NIHB action: √ NIHB analysis of action: √ NIHB analysis of action: √ NIHB action: √	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?
Agreement and ASC Certification ACTION: Request for Comment NOTICE: Health Insurance Benefits Agreement and Ambulatory Surgical Request for Certification or Update of Certification Information CMS-370 and CMS-377 CMS-370 and CMS-377 Due Date: 6/2/2014 NIHB File Date: Date of Subsequent Agency Action, if any: ■ Subsequent Agency action: ■ Analysis of Agency action: ■ Analysis of Agency action: ■ Analysis of Agency action:	4.d.	Ambulatory Surgical Center Payment System, et al. ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; EHR Incentive Program; Provider Reimbursement Determinations and Appeals		Due Date: 9/6/2013 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction/due date extension 9/6/2013; issued Final Rule 12/10/2013	 action: √ NIHB analysis of action: Summary of subsequent Agency 	Subsequent Agency action:
AGENCY: CMS	4.h.	Agreement and ASC Certification ACTION: Request for Comment NOTICE: Health Insurance Benefits Agreement and Ambulatory Surgical Request for Certification or Update of Certification Information in the Medicare Program		Due Date: 6/2/2014 NIHB File Date: Date of Subsequent Agency	action: √ NIHB analysis of	Subsequent Agency action:

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
5.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; issued extension 10/4/2013; issued extension 12/20/2013 Due Date: 11/8/2010; 12/3/2013; 1/21/2014	 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.b.	PACE State Plan Amendment Preprint ACTION: Request for Comment NOTICE: State Plan Amendment Preprint AGENCY: CMS	CMS-10227	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/13/2013 Due Date: 1/13/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
5.c.	Health Plan Monitoring System Data Entry for PACE ACTION: Request for Comment NOTICE: Health Plan Monitoring System Level I and Level II Data Entry for the Program of All- Inclusive Care for the Elderly AGENCY: CMS	CMS-10525	Issue Date: 5/23/2014 Due Date: 7/22/2014 NIHB File Date: 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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11.d.	Bid Pricing Tool ACTION: Request for Comment NOTICE: BPT for Medicare Advantage and Prescription Drug Plans 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; issued revision 10/4/2013; issued revision 12/20/2013 Due Date: 2/19/2013; 12/3/2013; 1/21/2014	 Summary of Agency action: √ NIHB analysis of action: [To be entered.] 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; issued revision 1/17/2014 Due Date: 2/19/2013; 12/31/2013; 2/18/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
11.s.	Medicare Prescription Drug Benefit Program ACTION: Request for Comment NOTICE: Medicare Prescription Drug Benefit Program AGENCY: CMS	CMS-10141	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/13/2013 Due Date: 1/13/2014	 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.t.	Appeals of Quality Bonus Payment Determinations ACTION: Request for Comment NOTICE: Appeals of Quality Bonus Payment Determinations AGENCY: CMS	CMS-10346	Issue Date: 12/6/2013 Due Date: 2/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/28/2014 Due Date: 3/31/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
11.u.	CY 2015 Policy and Technical Changes to Parts C and D ACTION: Proposed Final Rule NOTICE: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs AGENCY: CMS	CMS-4159-PF	Issue Date: 1/10/2014 Due Date: 3/7/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 5/23/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
11.v.	MA Chronic Care Improvement Program and QI Reporting Tools ACTION: Request for Comment NOTICE: Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools AGENCY: CMS	CMS-10209	Issue Date: 1/10/2014 Due Date: 3/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/2/2014 Due Date: 5/2/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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11.w.	Final Marketing Provisions for Medicare Parts C and D ACTION: Request for Comment NOTICE: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions AGENCY: CMS	CMS-10260	Issue Date: 1/29/2014 Due Date: 2/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
11.x.	Medication Therapy Management Program Improvements ACTION: Request for Comment NOTICE: Medication Therapy Management Program Improvements AGENCY: CMS	CMS-10396	Issue Date: 1/17/2014 Due Date: 3/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014 Due Date: 5/12/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
11.y.	Notice of Changes to Medicare Parts C and D Payment Policies ACTION: Notice NOTICE: Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter AGENCY: CMS	CMS (no reference number)	Issue Date: 2/21/2014 <u>Due Date:</u> 3/7/2014 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u> :	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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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?
11.z.	Medicare Health Outcomes Survey ACTION: Request for Comment NOTICE: Medicare Health Outcomes Survey (HOS) AGENCY: CMS	CMS-10203	Issue Date: 2/28/2014 Due Date: 4/29/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/16/2014 Due Date: 6/16/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
11.aa.	Predictive Learning Analytics Tracking Outcome Tool ACTION: Request for Comment NOTICE: The Predictive Learning Analytics Tracking Outcome (PLATO) AGENCY: CMS	CMS-10517	Issue Date: 4/25/2014 Due Date: 6/24/2014 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:
11.bb.	Independent Charity Patient Assistance Programs ACTION: Notice NOTICE: Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs AGENCY: HHS OIG	HHS OIG (no reference number)	Issue Date: 5/30/2014 <u>Due Date:</u> None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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13.g.	Business Proposal Forms for QIOs ACTION: Request for Comment NOTICE: Business Proposal Forms for Quality Improvement Organizations (QIOs) AGENCY: CMS	CMS-718-721	Issue Date: 5/16/2014 Due Date: 7/15/2014 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.b.	Medicare Inpatient Rates ACTION: Proposed-Final Rule NOTICE: Medicare Program; Hospital IPPS for Acute Care Hospitals and the LTCH PPS and FY 2013 Rates; Hospitals' Resident Caps for GME Payment Purposes; Quality Reporting Requirements for Specific Providers and for ASCs AGENCY: CMS	CMS-1588-PF CMS-1588-F2	Issue Date: 4/24/2012 Due Date: 6/25/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 6/11/2012; issued Final Rule 8/31/2012; issued correction 10/3/2012; issued correction 10/29/2012; issued correction 3/13/2013; issued correction 3/18/2014	 Summary of Agency action: √ NIHB analysis of action: None. Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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25.g.	PPS for Acute and Long-Term Care Hospitals, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Hospital IPPS for Acute Care Hospitals and the Long-Term Care Hospital PPS and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital CoP AGENCY: CMS	CMS-1599- P F CMS-1455-F	Issue Date: 5/10/2013 Due Date: 6/25/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 6/27/2013; issued Final Rule 8/19/2013; issued correction 10/3/2013; issued correction 1/2/2014; issued correction 1/10/2014; issued correction 3/18/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.m.	Geographic Classification Review Board Procedures ACTION: Request for Comment NOTICE: Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations AGENCY: CMS	CMS-R-138	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 12/13/2013 Due Date: 1/13/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.n.	Inpatient Rehab Facilities Quality Reporting Program Evaluation ACTION: Request for Comment NOTICE: Inpatient Rehabilitation Facilities Quality Reporting Program: Program Evaluation AGENCY: CMS	CMS-10503	Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/10/2014 Due Date: 4/9/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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25.0.	Conditions of Participation for Critical Access Hospitals ACTION: Request for Comment NOTICE: Conditions of Participation for Critical Access Hospitals (CAH) and Supporting Regulations AGENCY: CMS	CMS-10239	Issue Date: 12/20/2013 Due Date: 2/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/17/2014 Due Date: 4/16/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.p.	Medicare/Medicaid Psychiatric Hospital Survey Data ACTION: Request for Comment NOTICE: Medicare/Medicaid Psychiatric Hospital Survey Data AGENCY: CMS	CMS-724	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/17/2014 Due Date: 4/16/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.q.	Hospital Conditions of Participation ACTION: Request for Comment NOTICE: Hospital Conditions of Participation and Supporting Regulations AGENCY: CMS	CMS-R-48	Issue Date: 1/31/2014 Due Date: 4/4/2014 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.r.	Extension of Payment Adjustment for Low-Volume Hospitals ACTION: Interim Final Rule NOTICE: Medicare Program; Extension of the Payment Adjustment for Low-Volume Hospitals and the Medicare- Dependent Hospital (MDH) Program Under the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals for Fiscal Year 2014 AGENCY: CMS	CMS-1599- IFC2	Issue Date: 3/18/2014 Due Date: 5/13/2014 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.s.	Medicare PPS for Inpatient Rehab Facilities for FY 2015 ACTION: Proposed Rule NOTICE: Medicare Program; Inpatient Rehabilitation Facility PPS for Federal Fiscal Year 2015 AGENCY: CMS	CMS-1608-P	Issue Date: 5/7/2014 Due Date: 6/30/2014 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.t.	Psychiatric Unit Criteria Work Sheet ACTION: Request for Comment NOTICE: Psychiatric Unit Criteria Work Sheet and Supporting Regulations AGENCY: CMS	CMS-437	Issue Date: 4/4/2014 Due Date: 6/3/2014 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.u.	Medicare PPS for Inpatient Psychiatric Facilities for FY 2015 ACTION: Proposed Rule NOTICE: Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System Update for Fiscal Year Beginning October 1, 2014 (FY 2015) AGENCY: CMS	CMS-1606-P	Issue Date: 5/6/2014 Due Date: 6/30/2014 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.v.	Acute Care Hospital IPPS and LTCH PPS for FY 2015, et al. ACTION: Proposed Rule NOTICE: Medicare Program; Hospital IPPS for Acute Care Hospitals and the Long-Term Care Hospital PPS and Proposed FY 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and EHR Incentive Program AGENCY: CMS	CMS-1607-P	Issue Date: 5/15/2014 Due Date: 6/30/2014 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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32.c.	Bundled Payments for Care Improvement 2014 Winter Period ACTION: Notice NOTICE: Medicare Program; Bundled Payments for Care Improvement Models 2, 3, and 4 2014 Winter Open Period AGENCY: CMS	CMS-5504-N4	Issue Date: 2/14/2014 Due Date: 4/18/2014 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.i.	Home Health PPS Rate Update: Physician Narrative Requirement ACTION: Request for Comment NOTICE: Medicare ProgramHome Health Prospective Payment System Rate Update for CY 2010: Physician Narrative Requirement and Supporting Regulation AGENCY: CMS	CMS-10311	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/20/2013 Due Date: 1/21/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
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	Issue Date: 2/4/2014 <u>Due Date:</u> None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
52.k.	Application for Participation in the IVIG Demonstration ACTION: Request for Comment NOTICE: Application for Participation in the Intravenous Immune Globulin Demonstration AGENCY: CMS	CMS-10518	Issue Date: 3/7/2014 Due Date: 5/6/2014 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:
52.1.	Home Health Agency Conditions of Participation ACTION: Request for Comment NOTICE: Home Health Agency Conditions of Participation AGENCY: CMS	CMS-3819-P	Issue Date: [Pending at OMB as of 5/22/2014] 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:
58.	Medicare Hospital Conditions of Participation ACTION: Final Rule NOTICE: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation AGENCY: CMS	CMS-3244-F	Issue Date: 5/16/2012 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued correcting amendment 2/25/2014	 Summary of Agency action: √ NIHB analysis of action: None. Summary of 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?
70.b.	Revisions to Medicare Payment Policies Under PFS, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for 2014 AGENCY: CMS	CMS-1600- PFC	Issue Date: 7/19/2013 Due Date: 9/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 12/10/2013 Due Date: 1/27/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
70.c.	Policy on FOA Disclosure of Payments to Medicare Physicians ACTION: Notice NOTICE: Modified Policy on Freedom of Information Act Disclosure of Amounts Paid to Individual Physicians Under the Medicare Program AGENCY: CMS	CMS-0041-N	Issue Date: 1/17/2014 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:
71.c.	ESRD Care Model ACTION: Notice NOTICE: Medicare Comprehensive End-Stage Renal Disease Care Model Announcement AGENCY: CMS	CMS-5506-N	Issue Date: 2/6/2013 Due Date: 5/1/2013 7/19/2013 8/30/2013 6/23/2014 NIHB File Date: Date of Subsequent Agency Action, if any: Issued deadline extension 7/17/2013, 8/9/2013, 4/17/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
71.m.	Changes to ESRD PPS and QI Program for 2015 ACTION: Proposed Rule NOTICE: CY 2015 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program AGENCY: CMS	CMS-1614-P	Issue Date: [Pending at OMB as of 5/15/2014] 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:
72.b.	Medicare PPS and Consolidated Billing for SNFs for FY 2014 ACTION: Proposed Final Rule NOTICE: Medicare Program; PPS and Consolidated Billing for Skilled Nursing Facilities for FY 2014 AGENCY: CMS	CMS-1446- P F	Issue Date: 5/6/2013 Due Date: 7/1/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 8/6/2013; issued correction 10/3/2013; issued correction 1/2/2014; issued correction 1/10/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
72.d.	Medicare PPS and Consolidated Billing for SNFs for FY 2015 ACTION: Proposed Rule NOTICE: Medicare Program; PPS and Consolidated Billing for Skilled Nursing Facilities for FY 2015 AGENCY: CMS	CMS-1605-P	Issue Date: 5/6/2014 Due Date: 6/30/2014 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
78.c.	Hospice Request for Certification ACTION: Request for Comment NOTICE: Hospice Request for Certification and Supporting Regulations AGENCY: CMS	CMS-417	Issue Date: 11/1/2013 Due Date: 12/31/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/29/2014 Due Date: 2/28/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
78.d.	Hospice Quality Reporting Program Evaluation ACTION: Request for Comment NOTICE: Hospice Quality Reporting Program: Program Evaluation AGENCY: CMS	CMS-10504	Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/10/2014 Due Date: 4/9/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
78.e.	Hospice Conditions of Participation ACTION: Request for Comment NOTICE: Hospice Conditions of Participation AGENCY: CMS	CMS-10277	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/29/2014 Due Date: 2/28/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2014

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?
78.f.	Request for Applications for the Medicare Care Choices Model ACTION: Notice NOTICE: Medicare Program; Request for Applications for the Medicare Care Choices Model AGENCY: CMS	CMS-5512-N	Issue Date: 3/21/2014 Due Date: 6/19/2014 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:
78.g.	Report of New System of Records (Hospice Item Set) ACTION: Notice NOTICE: Privacy Act of 1974, Report of New System of Records AGENCY: CMS	CMS (no reference number)	Issue Date: 4/8/2014 <u>Due Date</u> : 30 days (approx. 5/8/2014) <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
78.h.	Wage Index and Payment Rates for Hospices for FY 2015, et al. ACTION: Proposed Rule NOTICE: Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice AGENCY: CMS	CMS-1609-P	Issue Date: 5/8/2014 Due Date: 7/1/2014 NIHB File Date: Date of Subsequent Agency Action, if any	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
81.	Efficiency, Transparency, and Burden Reduction ACTION: Proposed-Final Rule NOTICE: Medicare and Medicaid Programs; Part IIRegulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction AGENCY: CMS	CMS-3267-PF	Issue Date: 2/7/2013 Due Date: 4/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 5/12/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
110.f.	Requirements for Open Payments ACTION: Request for Comment NOTICE: Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments AGENCY: CMS	CMS-10495	Issue Date: 7/22/2013 Due Date: 9/20/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued new request 11/8/2013; issued revision 5/5/2014 Due Date: 12/9/2013; 6/2/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
110.g.	Procedures for Advisory Opinions on Physician Referrals ACTION: Request for Comment NOTICE: Procedures for Advisory Opinions Concerning Physicians' Referrals and Supporting Regulations AGENCY: CMS	CMS-R-216	Issue Date: 11/8/2013 Due Date: 1/7/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/17/2014 Due Date: 2/18/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
110.h.	Hospital Disclosures Regarding Physician Ownership ACTION: Request for Comment NOTICE: Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership AGENCY: CMS	CMS-10225	Issue Date: 12/13/2013 Due Date: 2/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/10/2014 Due Date: 4/9/2014	 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 Due Date: 6/2/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
110.j.	Disclosure for the In-Office Ancillary Services Exception ACTION: Request for Comment NOTICE: Disclosure for the In- Office Ancillary Services Exception AGENCY: CMS	CMS-10332	Issue Date: 4/4/2014 Due Date: 6/3/2014 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
113.	Additional Medicare Tax ACTION: Proposed Final Rule NOTICE: Rules Relating to Additional Medicare Tax AGENCY: IRS	REG-130074- 11 TD 9645	Issue Date: 12/5/2012 Due Date: 3/5/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 1/30/2013; issued Final Rule 11/29/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
121.g.	Health Insurance Benefit Agreement ACTION: Request for Comment NOTICE: Health Insurance Benefit Agreement AGENCY: CMS	CMS-1561	Issue Date: 11/1/2013 Due Date: 12/31/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/17/2014 Due Date: 2/18/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
121.h.	Medicare Enrollment Application: Part A Institutional Providers ACTION: Request for Comment NOTICE: Medicare Enrollment Application: Part A Institutional Providers AGENCY: CMS	CMS-855A	Issue Date: 11/15/2013 Due Date: 1/14/2014 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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126.b.	Evaluation of the Rural Community Hospital Demo ACTION: Request for Comment NOTICE: Evaluation of the Rural Community Hospital Demonstration AGENCY: CMS	CMS-10508	Issue Date: 11/15/2013 Due Date: 1/14/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Date of Subsequent Agency Action, if any: Issued new request 1/23/2014 Due Date: 2/24/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
132.e.	Outpatient/Ambulatory Surgery Experience of Care Survey ACTION: Request for Comment NOTICE: Outpatient and Ambulatory Surgery Experience of Care Survey AGENCY: CMS	CMS-10500	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/27/2013 Due Date: 1/27/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
134.f.	Outpatient Rehab Facility/CMHC Cost Report ACTION: Request for Comment NOTICE: Outpatient Rehabilitation Facility, Community Mental Health Center Cost Report and Supporting Regulations AGENCY: CMS	CMS-2088-92	Issue Date: 10/23/2013 Due Date: 12/23/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/2/2014 Due Date: 2/3/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2014

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?
134.g.	Organ Procurement Organization Laboratory Cost Report ACTION: Request for Comment NOTICE: Organ Procurement Organization/Histocompatibility Laboratory Cost Report AGENCY: CMS	CMS-216-94	Issue Date: 3/25/2014 Due Date: 5/23/2014 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.h.	Home Office Cost Statement ACTION: Request for Comment NOTICE: Home Office Cost Statement Form AGENCY: CMS	CMS-287-05	Issue Date: 4/18/2014 Due Date: 6/17/2014 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:
134.i.	Rural Health Clinic/Freestanding FQHC Cost Report ACTION: Request for Comment NOTICE: Independent Rural Health Clinic/Freestanding Federally Qualified Health Center Cost Report AGENCY: CMS	CMS-222-92	Issue Date: 5/16/2014 Due Date: 7/15/2014 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2014

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
136.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:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
151.a.	Request for Employment Information ACTION: Request for Comment NOTICE: Request for Employment Information AGENCY: CMS	CMS-R-297	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/26/2013; issued revision 1/2/2014 Due Date: 8/26/2013; 2/3/2014	 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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159.b.	Medicare PPS for Federally Qualified Health Centers, et al. ACTION: Proposed-Final Rule NOTICE: Medicare Program; PPS for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral AGENCY: CMS	CMS-1443- PFC	Issue Date: 9/23/2013 Due Date: 11/18/2013 ANTHC File Date: 11/18/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 5/2/2014 Due Date: 7/1/2013	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 ANTHC recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
159.c.	CoPs for Community Mental Health Centers ACTION: Request for Comment NOTICE: Conditions of Participation for Community Mental Health Centers and Supporting Regulations in 42 CFR 485 AGENCY: CMS	CMS-10506	Issue Date: 3/10/2014 Due Date: 4/9/2014 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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164.b.	Medicare Secondary Payer and "Future Medicals" ACTION: Proposed Rule NOTICE: Medicare Secondary Payer and "Future Medicals" AGENCY: CMS	CMS-6047	Issue Date: [Pending at OMB as of 8/1/2013] 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
165.c.	Application for Medicare Part B Enrollment ACTION: Request for Comment NOTICE: Application for Enrollment in Medicare the Medical Insurance Program AGENCY: CMS	CMS-40B	Issue Date: 10/23/2013 Due Date: 12/23/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/2/2014 Due Date: 2/3/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
165.d.	Application for Hospital Insurance ACTION: Request for Comment NOTICE: Application for Hospital Insurance and Supporting Regulations AGENCY: CMS	CMS-18F5	Issue Date: 12/6/2013 Due Date: 2/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/14/2014 Due Date: 3/17/2014	 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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184.a.	Clinical Laboratory Improvement Amendments Regulations ACTION: Request for Comment NOTICE: Clinical Laboratory Improvement Amendments (CLIA) Regulations AGENCY: CMS	CMS-R-26	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/6/2013 Due Date: 1/6/2014 ANTHC File Date: 1/6/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 ANTHC recommendations included: √ Subsequent Agency action: Analysis of Agency action:
184.b.	CLIA Application Form ACTION: Request for Comment NOTICE: Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations AGENCY: CMS	CMS-116	Issue Date: 12/13/2013 Due Date: 2/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/24/2014 Due Date: 3/26/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
184.c.	CLIA Budget Workload Reports ACTION: Request for Comment NOTICE: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations AGENCY: CMS	CMS-102 and CMS-105	Issue Date: 1/10/2014 Due Date: 3/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014 Due Date: 5/12/2014	 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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191.a.	HCPCSLevel II Code Modification Request Process ACTION: Request for Comment NOTICE: Healthcare Common Procedure Coding System (HCPCS)Level II Code Modification Request Process AGENCY: CMS	CMS-10224	Issue Date: 3/25/2014 Due Date: 5/23/2014 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:
191.b.	New Clinical Diagnostic Lab Test Codes for CY 2015 ACTION: Notice NOTICE: Medicare Program; Public Meeting on July 14, 2014 Regarding New Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2015 AGENCY: CMS	CMS-1610-N	Issue Date: 3/25/2014 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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6.g.	Policy Sales to Medicare Beneficiaries Losing Coverage Due to High Risk Pool Closures ACTION: Guidance NOTICE: The Sale of Individual Market Policies to Medicare Beneficiaries Under 65 Losing Coverage Due to High Risk Pool Closures AGENCY: CMS	CMS (no reference number)	Section III: HEALTH REFORM Issue Date: 1/10/2014 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:
6.h.	Special Enrollment Period for PCIP Enrollees ACTION: Guidance NOTICE: Special Enrollment Period for Individuals Losing Coverage through the Pre-Existing Condition Insurance Program (PCIP) AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 4/24/2014 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:
7.1.	Stand-Alone Dental Plans in Federally-Facilitated Exchanges ACTION: Guidance NOTICE: Issuers of Stand-Alone Dental Plans: Intent to Offer in FFE States AGENCY: HHS	HHS (no reference number)	Issue Date: 1/28/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 5/6/2014	 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?
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 Due Date: 8/26/2013; 6/10/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
7.y.	Blueprint for Approval of Health Insurance Marketplaces ACTION: Request for Comment NOTICE: Blueprint for Approval of Affordable Health Insurance Marketplaces AGENCY: CMS	CMS-10416	Issue Date: 8/16/2013 Due Date: 10/15/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 3/7/2014 Due Date: 4/7/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
7.bb.	Program Integrity; Amendments to the HHS Notice of Benefit and Payment Parameters ACTION: Final Rule NOTICE: Patient Protection and Affordable Care Act; Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 AGENCY: CMS	CMS-9957-F2 CMS-9964-F3 See also 7.s., 89.a., and 89.b.	Issue Date: 10/30/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued correction 12/31/2013	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
7.ee.	2015 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft-2015 Letter to Issuers in the Federally-Facilitated Marketplaces AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/4/2014 Due Date: 2/25/2014 TTAG File Date: 2/25/2014; NIHB and TSGAC also filed comments 2/15/2014 Date of Subsequent Agency Action, if any: Issued Final Letter 3/14/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
7.ff.	Enrollment and Termination Policies for Marketplace Issuers ACTION: Guidance NOTICE: Affordable Exchanges Guidance: Bulletins on Enrollment and Termination Policies and Processes for FFM and SPM Issuers AGENCY: CCIIO	CCIIO (no reference number) See also 7.aa. and 7.dd.	Issue Date: 2/6/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
7.gg.	Casework Guidance for Issuers in FFMs ACTION: Guidance NOTICE: Casework Guidance for Issuers in Federally-Facilitated Marketplaces, Including State Partnership Marketplaces AGENCY: CCIIO	CCIIO (no reference number) See also 7.s.	Issue Date: 3/13/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
7.hh.	Guidance on Individuals "In Line" for FFM ACTION: Guidance NOTICE: Affordable Exchanges Guidance: Guidance for Issuers on People "In Line" for the Federally- Facilitated Marketplace at the end of the Initial Open Enrollment Period AGENCY: CCIIO	CCIIO (no reference number) See also 7.ii.	Issue Date: 3/26/2014 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.ii.	Guidance on Special Enrollment Periods for Complex Cases ACTION: Guidance NOTICE: Affordable Exchanges Guidance: Guidance for Issuers on Special Enrollment Periods for Complex Cases in the Federally- facilitated Marketplace after the Initial Open Enrollment Period AGENCY: CCIIO	CCIIO (no reference number) See also 7.hh.	Issue Date: 3/26/2014 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.jj.	SEPs and Hardship Exemptions for Certain Individuals ACTION: Guidance NOTICE: Special Enrollment Periods and Hardship Exemptions for Persons Meeting Certain Criteria AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 5/2/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
27.c.	Reinsurance, Risk Corridors, and Risk Adjustment Standards ACTION: Request for Comment NOTICE: Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment AGENCY: CMS	CMS-10401	Issue Date: 1/25/2013 Due Date: 3/26/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 5/24/2013; issued revision 5/16/2014 Due Date: 6/24/2013; 6/16/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
27.f.	Risk Corridors and Budget Neutrality ACTION: Guidance NOTICE: Risk Corridors and Budget Neutrality AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 4/11/2014 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.g.	Reinsurance Contributions Process ACTION: Guidance NOTICE: Reinsurance Contributions Process AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 5/22/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
29.e.	Information Reporting for Exchanges ACTION: Proposed-Final Rule NOTICE: Information Reporting for Affordable Insurance Exchanges AGENCY: IRS	REG-140789- 12 TD 9663	Issue Date: 7/2/2013 Due Date: 9/3/2013 TTAG File Date: 9/3/2013; TSGAC and ANTHC also filed comments 9/3/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 5/7/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
29.g.	Payment Collections Operations Contingency Plan ACTION: Request for Comment NOTICE: Payment Collections Operations Contingency Plan AGENCY: CMS	CMS-10515	Issue Date: 12/27/2013 Due Date: 1/27/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/31/2014 Due Date: 4/4/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
29.h.	Verification of Income for Tax Credits and Cost Sharing ACTION: Guidance NOTICE: Verification of Household Income and Other Qualifications for the Provision of Affordable Care Act Premium Tax Credits and Cost- Sharing Reductions AGENCY: HHS	HHS (no reference number)	Issue Date: 12/31/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
29.i.	Victims of Domestic Abuse ACTION: Guidance NOTICE: Victims of Domestic Abuse AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/31/2014 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.f.	Employer Shared Responsibility ACTION: Proposed-Final Rule NOTICE: Shared Responsibility for Employers Regarding Health Coverage AGENCY: IRS	REG-138006- 12 TD 9655	Issue Date: 1/2/2013 Due Date: 3/18/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 3/15/2013; issued Final Rule 2/12/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
31.0.	Health Insurance Coverage Reporting by Large Employers ACTION: Proposed-Final Rule NOTICE: Information Reporting by Applicable Large Employers on Health Insurance Coverage Offered Under Employer-Sponsored Plans AGENCY: IRS	REG-136630- 12 TD 9661	Issue Date: 9/9/2013 Due Date: 11/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/10/2014	 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?
31.p.	Minimum Essential Coverage Reporting ACTION: Proposed-Final Rule NOTICE: Information Reporting of Minimum Essential Coverage AGENCY: IRS	REG-132455- 44 TD 9660	Issue Date: 9/9/2013 Due Date: 11/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/10/2014; issued corrections 4/30/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
31.t.	Amendments to Excepted Benefits ACTION: Proposed Rule NOTICE: Amendments to Excepted Benefits AGENCY: IRS/DoL/CMS	REG-143172- 13 DoL RIN 1210- AB60 CMS-9946-P	Issue Date: 12/24/2013 Due Date: 2/24/2014 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.u.	Options Available for Consumers with Cancelled Policies ACTION: Guidance NOTICE: Options Available for Consumers with Cancelled Policies AGENCY: CCIIO	CCIIO (no reference number) See also 7.dd.	Issue Date: 12/19/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued clarification 1/3/2014	 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.v.	Instructions for the Application for Indian-Specific Exemptions ACTION: Guidance NOTICE: Instructions for the Application for Exemption for American Indians and Alaska Natives and Other Individuals who are Eligible to Receive Services from an Indian Health Care Provider AGENCY: CMS	CMS (no reference number) See also 31.q.	Issue Date: 1/10/2014 Due Date: 1/13/2014 TTAG File Date: 1/13/2014 Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ TTAG analysis of action: √ 	 TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action:
31.w.	Q&A on Cost-Sharing Reductions for Contract Health Services ACTION: Guidance NOTICE: Question and Answer on Cost-Sharing Reductions for Contract Health Services AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/8/2014 Due Date: 1/14/2014 TTAG File Date: 1/14/2013 Date of Subsequent Agency Action, if any: Issued Final Guidance 2/18/2014; sent revised Guidance to TTAG for review 4/2/2014; issued revised Final Guidance 5/9/2014	 Summary of Agency action: √ TTAG analysis of action: √ Summary of subsequent Agency action: √ 	 TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
31.x.	MEC and Other Rules on the Shared Responsibility Payment ACTION: Proposed Rule NOTICE: Minimum Essential Coverage and Other Rules Regarding the Shared Responsibility Payment for Individuals AGENCY: IRS	REG-141036- 13	Issue Date: 1/27/2014 Due Date: 4/28/2014 TTAG File Date: 4/28/2014 Date of Subsequent Agency Action, if any: Issued hearing cancellation 5/16/2014	 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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39.b.	Basic Health Program ACTION: Proposed-Final Rule NOTICE: Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity AGENCY: CMS	CMS-2380-PF	Issue Date: 9/25/2013 Due Date: 11/25/2013 NIHB File Date: 11/22/2013; ANTHC, TSGAC, and TTAG also filed comments 11/22/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 3/12/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
39.c.	Basic Health Program: Federal Funding Methodology for 2015 ACTION: Proposed-Final Methodology NOTICE: Basic Health Program: Proposed-Federal Funding Methodology for Program Year 2015 AGENCY: CMS	CMS-2380- PFN	Issue Date: 12/23/2013 Due Date: 1/22/2014 TTAG File Date: 1/22/2014; TSGAC also filed comments 1/22/2014 Date of Subsequent Agency Action, if any: Issued Final Methodology 3/12/2014	 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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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2014

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?
39.d.	Basic Health Program Report for Exchange Premium ACTION: Request for Comment NOTICE: Basic Health Program Report for Health Insurance Exchange Premium AGENCY: CMS	CMS-10510	Issue Date: 12/23/2013 Due Date: 1/2/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 12/27/2013; issued extension 4/18/2014 Due Date: 6/17/2014	 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; issued revision 11/22/2013; issued revision 1/31/2014 Due Date: 3/25/2013; 1/21/2014; 3/5/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
48.e.	Computation of MLR ACTION: Proposed-Final Rule NOTICE: Computation of, and Rules Relating to, Medical Loss Ratio AGENCY: IRS	REG-126633- 12 TD 9651	Issue Date: 5/13/2013 Due Date: 8/12/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 1/7/2014	 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.e.	Initial Plan Data Collection to Support QHP Certification ACTION: Request for Comment NOTICE: Initial Plan Data Collection to Support Qualified Health Plan Certification and Other Financial Management and Exchange Operations AGENCY: CMS	CMS-10433	Issue Date: 11/21/2012 Due Date: 12/21/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 11/1/2013; issued revision 2/10/2014 Due Date: 12/31/2013; 3/12/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
50.o.	State Health Insurance Exchange Incident Report ACTION: Request for Comment NOTICE: State Health Insurance Exchange Incident Report AGENCY: CMS	CMS-10496	Issue Date: 8/21/2013 Due Date: 9/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/20/2013; issued extension 2/28/2014 Due Date: 2/18/2014; 3/31/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
50.q.	Third Party Payments of Premiums for QHPs ACTION: Guidance NOTICE: FAQ: Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces AGENCY: CCIIO	CCIIO (no reference number) See also 50.r.	Issue Date: 11/4/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued clarification 2/7/2014	 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.r.	Implementation of Section 402 of IHCIA ACTION: Guidance NOTICE: Tribal Leader Letter: Implementation of Section 402 of the Indian Health Care Improvement Act AGENCY: IHS		Issue Date: 10/24/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ TSGAC analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
50.s.	State-Based Marketplace Annual Report ACTION: Request for Comment NOTICE: State-Based Marketplace Annual Report (SMAR) AGENCY: CMS	CMS-10507	Issue Date: 11/15/2013 Due Date: 1/14/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/31/2014 Due Date: 3/5/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
50.t.	QHP Quality Rating System Measures and Methodology ACTION: Request for Comment NOTICE: Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS), Framework Measures and Methodology AGENCY: CMS	CMS-3288-NC	Issue Date: 11/22/2013 Due Date: 1/21/2014 TTAG File Date: 1/21/2014 Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action:

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50.v.	Medical Expenditure Panel SurveyInsurance Component ACTION: Request for Comment NOTICE: Medical Expenditure Panel SurveyInsurance Component AGENCY: AHRQ	AHRQ (OMB 0935-0110)	Issue Date: 1/10/2014 Due Date: 3/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/31/2014 Due Date: 4/30/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
50.w.	Retroactive Advance Payments of PTCs and CSRs Due to Exceptional Circumstances ACTION: Guidance NOTICE: CMS Bulletin to Marketplaces on Availability of Retroactive Advance Payments of the PTC and CSRs in 2014 Due to Exceptional Circumstances AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/27/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued clarification 3/14/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
50.x.	Third Party Payment of QHP Premiums ACTION: Interim Final Rule NOTICE: Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums AGENCY: CMS	CMS-9943-IFC	Issue Date: 3/19/2014 Due Date: 5/13/2014 TTAG File Date: 5/13/2014 Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action:

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50.y.	Tax Treatment of Retirement Plan Payment of Premiums ACTION: Final Rule NOTICE: Tax Treatment of Qualified Retirement Plan Payment of Accident or Health Insurance Premiums AGENCY: IRS	TD 9665	Issue Date: 5/12/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
54.	ESI Coverage Verification ACTION: Notice NOTICE: Employer-Sponsored Coverage Verification: Preliminary Informational Statement AGENCY: CMS	CMS RIN 0938- ZB09	Issue Date: [Approved by OMB 4/26/2012] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
63.c.	Certification of Compliance for Health Plans ACTION: Proposed Rule NOTICE: Administrative Simplification: Certification of Compliance for Health Plans AGENCY: CMS	CMS-0037-P	Issue Date: 1/2/2014 Due Date: 3/3/2014 4/3/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 3/5/2014	 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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65.	Health Care Reform Insurance Web Portal Requirements ACTION: Request for Comment NOTICE: Health Care Reform Insurance Web Portal Requirements AGENCY: CMS	CMS-10320	Issue Date: 8/15/2012 Due Date: 9/13/2012 TTAG File Date: 9/13/2012; ANTHC also filed comments 9/13/2012 Date of Subsequent Agency Action, if any: Issued revision 2/3/2014; issued revision 4/11/2014 Due Date: 4/1/2014; 5/12/2014 TTAG File Date: 5/12/2014	 Summary of Agency action: √ TTAG analysis of action: √ Summary of subsequent Agency action: √ 	 TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
67.d.	Use of 1311 Funds and No Cost Extensions ACTION: Guidance NOTICE: FAQs on the Use of 1311 Funds and No Cost Extensions AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/14/2014 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.e.	Notice of Benefit and Payment Parameters for 2015 ACTION: Proposed-Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015 AGENCY: CMS	CMS-9954-PF	Issue Date: 12/2/2013 Due Date: 12/26/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/11/2014	 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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91.b.	Waiting Period Limitation and Coverage Requirements ACTION: Proposed-Final Rule NOTICE: Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under ACA AGENCY: IRS/DoL/CMS	REG-122706- 12 DoL (RIN 1210-AB56) CMS-9952- P F	Issue Date: 3/21/2013 Due Date: 5/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/24/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
91.c.	Waiting Period Limitation ACTION: Proposed Rule NOTICE: Ninety-Day Waiting Period Limitation AGENCY: IRS/DoL/CMS	REG-122706- 12 DoL (RIN 1210-AB61) CMS-9952-P2	Issue Date: 2/24/2014 Due Date: 4/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.h.	Disclosure and Recordkeeping for Grandfathered Health Plans ACTION: Request for Comment NOTICE: Affordable Care Act Grandfathered Health Plan Disclosure, Recordkeeping Requirement, and Change in Carrier Disclosure AGENCY: DoL	DoL (OMB 1210-0140)	Issue Date: 5/22/2013 Due Date: 7/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 11/29/2013 Due Date: 1/2/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action)¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
92.i.	ACA Notice of Rescission ACTION: Request for Comment NOTICE: Affordable Care Act Notice of Rescission AGENCY: Treasury	TD 9491 (OMB 1545-2180)	Issue Date: 6/27/2013 Due Date: 8/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2014 Due Date: 3/31/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.k.	ACA Notice of Patient Protection ACTION: Request for Comment NOTICE: Affordable Care Act Notice of Patient Protection AGENCY: IRS	REG-120399- 10 (OMB 1545- 2181)	Issue Date: 9/4/2013 Due Date: 11/4/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2014 Due Date: 3/31/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.n.	Rules for Group Health Plans Related to Grandfather Status ACTION: Request for Comment NOTICE: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act AGENCY: IRS	REG-118412- 10 (OMB 1545- 2178)	Issue Date: 10/29/2013 Due Date: 12/30/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/27/2014 Due Date: 3/31/2014	 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.q.	ACA Advance Notice of Rescission ACTION: Request for Comment NOTICE: Affordable Care Act Advance Notice of Rescission AGENCY: DoL	DoL (OMB 1210-0141)	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/19/2014 Due Date: 3/21/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.r.	ACA Patient Protection Notice ACTION: Request for Comment NOTICE: Affordable Care Act Patient Protection Notice AGENCY: DoL	DoL (OMB 1210-0142)	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/28/2014 Due Date: 3/31/2014	 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 Due Date: 5/2/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
92.t.	ACA Implementation: Market Reform and Mental Health Parity ACTION: Guidance NOTICE: Affordable Care Act Implementation FAQs: Market Reform Provisions and Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/9/2014 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.u.	Exchange and Insurance Market Standards for 2015 and Beyond ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond AGENCY: CMS	CMS-9949- P F	Issue Date: 3/21/2014 Due Date: 4/21/2014 NIHB File Date: 4/21/2014; TTAG also filed comments 4/21/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 5/27/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
92.v.	Q&A on Outreach by Medicaid MCOs to Former Enrollees ACTION: Guidance NOTICE: Question and Answer on Outreach by Medicaid Managed Care Contractors and Health Insurance Issuers to Former Enrollees AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/21/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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92.w.	Provider Non-Discrimination ACTION: Request for Information NOTICE: Request for Information Regarding Provider Non- Discrimination AGENCY: CMS/IRS/DoL	CMS-9942-NC	Issue Date: 3/12/2014 Due Date: 6/10/2014 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.x.	Extension of Transitional Policy for Non-Grandfathered Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin SeriesExtension of Transitional Policy through October 1, 2016: Extended Transition to ACA-Compliant Policies AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/5/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.y.	Draft Notices When Discontinuing or Renewing a Product ACTION: Guidance NOTICE: Insurance Standards Bulletin Series: Draft Notices When Discontinuing or Renewing a Product in the Group or Individual Market AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/14/2014 Due Date: 4/18/2014 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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92.z.	Coverage of Same-Sex Spouses ACTION: Guidance NOTICE: Frequently Asked Question on Coverage of Same- Sex Spouses AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/14/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.aa.	Health Insurance Market Reforms and Marketplace Standards ACTION: Guidance NOTICE: Frequently Asked Questions on Health Insurance Market Reforms and Marketplace Standards AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 5/16/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.bb.	Employer Health Care Arrangements (Q&A) ACTION: Guidance NOTICE: Employer Health Care Arrangements AGENCY: IRS	IRS (no reference number) See also 92.I.	Issue Date: 5/13/2014 <u>Due Date:</u> None NIHB File Date: <u>Date of Subsequent Agency</u> <u>Action, if any</u> :	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
99.c.	Evaluation of Wellness and Prevention Programs ACTION: Request for Comment NOTICE: Prospective Evaluation of Evidence-Based Community Wellness and Prevention Programs AGENCY: CMS	CMS-10509	Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/18/2014 Due Date: 5/19/2014	 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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100.b.	Marketplace Quality Standards ACTION: Request for Comment NOTICE: Marketplace Quality Standards AGENCY: CMS	CMS-10520	Issue Date: 5/23/2014 Due Date: 6/23/2014 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.b.	IHS Reimbursement Rates for CY 2014 ACTION: Notice NOTICE: Reimbursement Rates for Calendar Year 2014 AGENCY: IHS	IHS RIN 0917- ZA28	Issue Date: 3/31/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
135.d.	Evaluation ACTION: Request for Comment NOTICE: Long Term Care Hospital Quality Reporting Program: Program Evaluation AGENCY: CMS	CMS-10502	Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/10/2014 Due Date: 4/9/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
145.a.	Health Insurance Providers Fee ACTION: Proposed-Final Rule NOTICE: Health Insurance Providers Fee AGENCY: IRS	REG-118315- 12 TD 9643	Issue Date: 3/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 3/22/2013; issued Final Rule 11/29/2013; issued correction 1/22/2014	 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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145.b.	Report of Health Insurance Provider Information ACTION: Request for Comment NOTICE: Report of Health Insurance Provider Information AGENCY: IRS	Form 8963	Issue Date: 11/21/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/29/2014 Due Date: 2/28/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
	OLIA D. LUIDAA		SECTION IV: OTHER		
82.e.	CLIA Program and HIPAA Privacy Rule ACTION: Final Rule NOTICE: CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports AGENCY: CMS	CMS-2319-F	Issue Date: 2/5/2014 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:
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 Due Date: 3/5/2014	 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.i.	HIPAA Covered Entity and Associate Pre-Audit Survey ACTION: Request for Comment NOTICE: HIPAA Covered Entity and Business Associate Pre-Audit Survey AGENCY: HHS OCR	HHS-OS- 21435-60D HHS-OS-0945- New-30D	Issue Date: 2/24/2014 Due Date: 4/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 5/12/2014 Due Date: 6/11/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
94.	Methodology for Designation of Frontier and Remote Areas ACTION: Notice NOTICE: Methodology for Designation of Frontier and Remote Areas AGENCY: HRSA	HRSA (no reference number)	Issue Date: 11/5/2012 Due Date: 1/4/2013 NIHB File Date: 1/4/2013 Date of Subsequent Agency Action, if any: Issued Final Notice 5/5/2014	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
109.c.	Health Care Continuation Coverage ACTION: Proposed Rule NOTICE: Health Care Continuation Coverage AGENCY: DoL	DoL RIN 1210- AB65	Issue Date: 5/7/2014 Due Date: 7/7/2014 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.j.	CMS/VA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974: CMS Computer Matching Program Match No. 2013-01; HHS Computer Matching Program Match No. 1312 AGENCY: CMS	CMS (no reference number)	Issue Date: 12/5/2013 Due Date: 30 days (approx. 1/6/2014) NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
153.k.	CMS/SSA/IRS Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974, CMS Computer Match No. 2013-03, HHS Computer Match No. 1314, SSA Computer Match No. 1048, IRS Project No. 241 AGENCY: CMS	CMS (no reference number)	Issue Date: 1/28/2014 Due Date: 30 days (approx. 2/27/2014) 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:
181.	Nondiscrimination Provisions ACTION: Proposed Rule NOTICE: Nondiscrimination Provisions AGENCY: OPM	OPM RIN 3206- AM77	Issue Date: 9/4/2013 Due Date: 11/4/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 5/8/2014	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 5/31/2014

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?
185.a.	Healthcare Fraud Prevention Partnership: Data Sharing ACTION: Request for Comment NOTICE: Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange AGENCY: CMS	CMS-10501	Issue Date: 10/23/2013 Due Date: 12/23/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/10/2014 Due Date: 2/10/2014	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
185.b.	Revisions to HHS OIG Civil Monetary Penalty Rules ACTION: Request for Comment NOTICE: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules AGENCY: HHS OIG	HHS OIG RIN 0936- AA04	Issue Date: 5/12/2014 <u>Due Date</u> : 7/11/2014 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:
185.c.	Revisions to HHS OIG Exclusion Authorities ACTION: Request for Comment NOTICE: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities AGENCY: HHS OIG	HHS OIG RIN 0936- AA05	Issue Date: 5/9/2014 <u>Due Date</u> : 7/8/2014 <u>NIHB File Date</u> : <u>Date of Subsequent Agency</u> <u>Action, if any</u> :	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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National Indian Health Board Table A: Regulations Included to Date in RRIAR Tables B and C Updated through 5/31/2014

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?
185.d.	Revisions to Safe Harbors Under the Anti-Kickback Statute, et al. ACTION: Request for Comment NOTICE: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing AGENCY: HHS OIG	HHS OIG RIN 0936- AA06	Issue Date: [Pending at OMB as of 5/15/2014] 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:
186.	DSW Resource Center Core Competencies Survey ACTION: Request for Comment NOTICE: Direct Service Workforce (DSW) Resource Center (RC) Core Competencies (CC) Survey Instrument AGENCY: CMS	CMS-10512	Issue Date: 11/29/2013 Due Date: 1/28/2014 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:
189.	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: 1/22/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

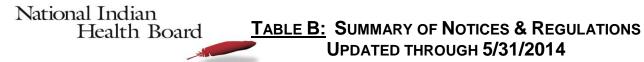
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National Indian Health Board Table A: Regulations Included to Date in RRIAR Tables B and C Updated through 5/31/2014

R	RIAR 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?
1	92.	Blue Button Connector ACTION: Request for Comment NOTICE: The Blue Button Connector AGENCY: HHS	HHS-OS-0990- New-60D	Issue Date: 4/2/2014 Due Date: 6/2/2014 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	94.	340B Drug Pricing Program Regulations ACTION: Proposed Rule NOTICE: 340B Drug Pricing Program Regulations AGENCY: HRSA	HRSA RIN 0906- AB04	Issue Date: [Pending at OMB as of 4/9/2014] 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:



Ref.	Short Title/Current Status of Regulation/Title/ 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.g.	Revision to the Definition of Common Meaningful Use Data Set ACTION: Interim Final Rule NOTICE: 2014 Edition Electronic Health Record Certification Criteria: Revision to the Definition of "Common Meaningful Use Data Set" AGENCY: HHS	HHS RIN 0991- AB91	Issue Date: 11/4/2012 Due Date: 1/3/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This interim final rule with comment period revises one paragraph in the Common Meaningful Use (MU) Data Set definition at 45 CFR 170.102 to allow more flexibility with respect to the representation of dental procedures data for electronic health record (EHR) technology testing and certification. http://www.gpo.gov/fdsys/pkg/FR-2013-11-04/pdf/2013-26290.pdf SUMMARY OF NIHB ANALYSIS: I/T/Us might have an interest in the revision to the definition pertaining to dental procedures and EHRs.	
1.h.	Voluntary 2015 Edition EHR Certification Criteria, et al. ACTION: Proposed Rule NOTICE: Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements AGENCY: HHS	HHS RIN 0991- AB92	Issue Date: 2/26/2014 Due Date: 4/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 3/19/2014		SUMMARY OF AGENCY ACTION: This notice of proposed rulemaking introduces the beginning of the more frequent approach by the HHS Office of National Coordinator for Health Information Technology (ONC) to health information technology certification regulations. Under this approach, ONC intends to update certification criteria editions every 12 to 18 months to provide smaller, more incremental regulatory changes and policy proposals. This approach gives stakeholders greater and earlier visibility into our regulatory direction before they must comply, provides more time for public input on policy proposals under consideration for future rulemakings, and enables certification processes to more quickly adopt newer industry standards that can enhance interoperability. The 2015 Edition EHR certification criteria outlined in this proposed rule would remain voluntary. No EHR technology developer that has certified its EHR technology to the 2014 Edition would need to recertify to the 2015 Edition for its customers to participate in the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs). Furthermore, eligible professionals, eligible hospitals, and critical access hospitals that participate in the EHR Incentive Programs would not need to "upgrade" to EHR technology certified to 2015 Edition to have EHR technology that meets the Certified EHR Technology (CEHRT) definition. Instead, the 2015 Edition EHR	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					certification criteria would accomplish three policy objectives. They would: 1) enable a more efficient and effective response to stakeholder feedback; 2) incorporate "bug fixes" to improve on 2014 Edition EHR certification criteria in ways designed to make rules clearer and easier to implement; and 3) reference newer standards and implementation specifications that reflect ONC commitment to promoting innovation and enhancing interoperability.	
					This proposed rule also includes specific revisions to the ONC HIT Certification Program. These proposals focus on: improving regulatory clarity; simplifying the certification of EHR Modules designed for purposes other than achieving meaningful use; and discontinuing the use of the Complete EHR definition starting with the 2015 Edition.	
					SUMMARY OF NIHB ANALYSIS: Although this proposed rule would make the certification criteria voluntary for 2015, it offers an opportunity to comment on criteria likely to become mandatory in the future.	
					SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/19/2014 issued a notice to correct the preamble text and gap certification table for four certification criteria that ONC omitted from the list of certification criteria eligible for gap certification for the 2015 Edition EHR certification criteria and to provide information on inactive Web links that appear in this proposed rule.	
					http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-06041.pdf	
1.i.	Public Health Agency/Registry Readiness for Meaningful Use	CMS-10499	<u>Issue Date:</u> 2/7/2014 <u>Due Date:</u> 4/8/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Public Health Agency/Registry Readiness to Support Meaningful Use; Use: The Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs provide incentives for the meaningful use of Certified Electronic Health Record Technology (CEHRT). CMS defined meaningful use as a set of objectives and measures	
	ACTION: Request for Comment		NIHB File Date: None		in either Stage 1 or Stage 2, depending on how long an eligible provider has participated in the program. Both Stage 1 (3 objectives) and Stage 2 (5 objectives) of meaningful use contain objectives and measures that require eligible providers to determine	
	NOTICE: Public Health Agency/Registry Readiness to Support Meaningful Use		Date: None Date of Subsequent		the readiness of public health agencies and registries to receive electronic data from CEHRT. Public comments on the notice of proposed rulemaking for Stage 2 of meaningful use (77 FR 13697) asserted that the burden for each individual eligible	



Ref.	Short Title/Current Status of Regulation/Title/ 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		Agency Action, if any: Issued new request 5/16/2013 Due Date: 6/16/2014		provider to determine the readiness of multiple public health agencies and registries would decrease to almost zero if CMS maintained a database on the readiness of public health agencies and registries. In the final rule for Stage 2 of meaningful use (77 FR 53967), CMS agreed that the burden on eligible providers, public health agencies, and registries would decrease greatly and established that it would create such a database, which would serve as the definitive information source for determining public health agency and registry readiness to receive electronic data associated with the public health meaningful use objectives. CMS will make the information publicly available on its Web site (www.cms.gov/EHRincentiveprograms) to provide a centralized repository of this information to eligible providers and eliminate multiple individual inquiries to multiple public health agencies and registries. http://www.gpo.gov/fdsys/pkg/FR-2014-02-07/pdf/2014-02673.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/16/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-05-16/pdf/2014-11388.pdf	
1.j.	Modifications to the EHR Incentive Programs for 2014 ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified	CMS-0052-P	Issue Date: 5/23/2014 Due Date: 7/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would change the meaningful use stage timeline and the definition of certified electronic health record technology (CEHRT). It also would change the requirements for the reporting of clinical quality measures for 2014. http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11944.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.
	EHR Technology Definition AGENCY: CMS					
3.b.	DME Competitive Bidding ACTION: Request for Comment NOTICE: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program AGENCY: CMS	CMS-10169	Issue Date: 7/27/2012 Due Date: 8/27/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/1/2013, 5/10/2013, 4/18/2014 Due Date: 4/30/2013; 6/10/2013; 6/17/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program; Use: CMS will conduct competitive bidding programs in which certain suppliers will receive contracts to provide competitively bid DMEPOS items to Medicare beneficiaries in a competitive bidding area (CBA). In 2007, CMS conducted its first round of bidding, which was implemented on 7/1/2008. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contract and prices became effective on 1/1/2011. The Medicare Modernization Act (MMA) requires the HHS Secretary to recomplete contracts not less often than once every 3 years; CMS has begun preparing to re-compete competitive bidding contracts in the Round 1 Rebid areas. In response to comments on the 60-day FR notice published on 5/7/2012 (77 FR 26763), CMS has revised the Application for Suppliers/Networks collection instrument by clarifying, removing, and renumbering a few questions. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/1/2013 issued a revision of this PRA request. The most recent approval for this information collection request (ICR) occurred on 10/10/2012. Since then, CMS has decided to update sequentially the paperwork burden necessary to administer the program as it expands nationally and cycles through multiple rounds of competition. Specifically, CMS seeks to update burden estimates for certain contract maintenance forms for Round 2 and the national mail-order competition. These include Form C and the Contract Supplier's Disclosure of Subcontractors form. CMS also requests approval of two additional forms: the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, which the agency will use in all rounds of competition. Finally, CMS has retained without changes Forms A, B, and D and their associated burden under this ICR. CMS has completed collection for Forms A and	



Ref.	Short Title/Current Status of Regulation/Title/ 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-2013-03-01/pdf/2013-04752.pdf CMS on 5/10/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11033.pdf CMS on 4/18/2014 issued a revision of this PRA request. OMB issued the most recent approval for this information collection request (ICR) on 6/10/2013. That ICR included the estimated burden to collect the information in bidding Forms A and B for the Round 1 Recompete. In this ICR, CMS seeks approval to collect the information in Forms A and B for competitions that will occur before 2017. For these upcoming competitions, CMS will publish a slightly modified version of the Request for Bids (RFB) instructions and accompanying Forms A and B to allow suppliers to identify and understand the requirements of the program better. CMS decided to modify the RFB instructions and forms based on its experience from the last round of competition. The end result will produce more complete and accurate information to evaluate suppliers. CMS has added no new collection requirements to the modified RFB instructions or Form A or B. Finally, CMS has retained without change the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, the Subcontracting Disclosure Form, and Forms C and D, as well as their associated burden under this ICR. CMS intends to continue use of these forms on an ongoing basis. http://www.gpo.gov/fdsys/pkg/FR-2014-04-18/pdf/2014-08898.pdf	
3.i.	Pass-Through Payment for New Categories of Devices ACTION: Request for Comment NOTICE: Recognition of Pass-Through Payment for Additional (New) Categories	CMS-10052	<u>Issue Date:</u> 10/4/2013 <u>Due Date:</u> 12/3/2013 <u>NIHB File</u> <u>Date</u> : None		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Recognition of Pass-Through Payment for Additional (New) Categories of Devices Under the Outpatient Prospective Payment System and Supporting Regulations; Use: Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient prospective payment system (OPPS). After CMS receives all requested information, it evaluates the information to determine if justification exists for the creation of an additional category of medical devices for transitional pass-through payments. 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.
	of Devices Under the Outpatient Prospective Payment System and Supporting Regulations AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued extension 12/20/2013 Due Date: 1/21/2014		might request additional information related to the proposed new device category, as needed. CMS advises the applicant of its decision and updates the OPPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/20/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf	
3.j.	Prior Authorization Process for Certain DMEPOS Items ACTION: Proposed Rule NOTICE: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items AGENCY: CMS	CMS-6050-P	Issue Date: 5/28/2014 Due Date: 7/28/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would establish a prior authorization process for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items frequently subject to unnecessary utilization and would add a contractor decision regarding prior authorization of coverage of DMEPOS items to the list of actions not considered initial determinations and therefore not appealable. http://www.gpo.gov/fdsys/pkg/FR-2014-05-28/pdf/2014-12245.pdf SUMMARY OF NIHB ANALYSIS:	
3.k.	Methodology for Adjusting Medicare Payments for DMEPOS ACTION: ANPRM NOTICE: Medicare Program; Methodology for	CMS-1460- ANPRM	Issue Date: 2/26/2014 Due Date: 3/28/2014 NIHB File Date: None		SUMMARY OF AGENCY ACTION: This advance notice of proposed rulemaking (ANPRM) solicits public comments on different methodologies CMS might consider using with regard to applying information from the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding programs to adjust Medicare fee schedule payment amounts or other Medicare payment amounts for DMEPOS items and services furnished in areas not included in these competitive bidding programs. In addition, CMS also requests comments on a different matter regarding ideas for potentially changing the payment methodologies used under the competitive bidding	



Ref.	Short Title/Current Status of Regulation/Title/ Agency Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Using Information From Competitive Bidding Programs AGENCY: CMS	File Code	Issue Date; Due Date & File Date Date of Subsequent Agency Action, if any:	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis programs for certain durable medical equipment and enteral nutrition. SUMMARY OF NIHB ANALYSIS:	NIHB Recs.
3.1.	Payment for New Technology APC Groups Under OPPS ACTION: Request for Comment NOTICE: Recognition of Payment for New Technology Services for New Technology Ambulatory Payment Classification (APC) Groups Under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR part 419 AGENCY: CMS	CMS-10054	Issue Date: 3/3/2014 Due Date: 4/29/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/30/2014 Due Date: 5/30/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of currently approved collection; Title: Recognition of Payment for New Technology Services for New Technology Ambulatory Payment Classification (APC) Groups Under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR part 419; Use: CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. CMS must continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies, and others that bring to our attention specific services they wish the agency to evaluate for New Technology APC payment. http://www.gpo.gov/fdsys/pkg/FR-2014-03-03/pdf/2014-04613.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/30/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-30/pdf/2014-09970.pdf	
3.m.	FFS Audit Prepayment Review and Prior Authorization Demos ACTION: Request for Comment	CMS-10421	<u>Issue Date:</u> 4/4/2014 <u>Due Date:</u> 4/18/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration; Use: On 7/23/2012, OMB approved the collections required for two demonstrations of prepayment review and prior authorization. The first demonstration allows Medicare Recovery Auditors to review claims on a pre-payment basis in certain States. The second demonstration established	



Agency File Date NOTICE: Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration Demonstration Demonstration AGENCY: CMS NOTICE: Fee-for-Service Recovery Audit Prepayment Review Demonstration, CMS and its agents request additional documentation, including medical records, to support submitted claims. As discussed in more detail in Chapter 3 of the Program Integrity Manual, additional documentation includes any medical documentation, beyond what appears on the face of the claim that supports the item or service billed. For Medicare to consider coverage and payment for any item or service, the information submitted by the provider or supplier	 				
NOTICE: Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration Demonstration Demonstration AGENCY: CMS Date: None Date: None For the Recovery Audit Prepayment Review Demonstration, CMS and its agents request additional documentation, including medical records, to support submitted claims. As discussed in more detail in Chapter 3 of the Program Integrity Manual, additional documentation includes any medical documentation, beyond what appears on the face of the claim that supports the item or service billed. For Medicare to consider coverage and payment for any item or service, the information submitted by the provider or supplier	of Regulation/Title/	File Code	Due Date &		NIHB Recs.
test, it is a support of the contractor specifies documentation the prequire in accordance with Medicare rules and policies. In addition, providers and suppliers can supply additional documentation not explicitly listed by the contractor. CMS and its agents might request this supporting information on a routine basis in instances where diagnoses on a claim do not clearly indicate medical necessity, or in instances of suspected fraud. For the Prior Authorization of PMDs Demonstration, CMS has piloted prior authorization for PMDs. Prior authorization allows submission for review of the applicable documentation that supports a claim before delivery of the item or rendering of the service. CMS has begun this demonstration in California, Florida, Illinois, Michigan, New York, North Carolina and Texas based on beneficiary address as reported to the Social Security Administration and recorded in the Common Working File (CWF). For the demonstration, the (ordering) physician or treating practitioner can complete a prior authorization request and submit it to the appropriate DME MAC for an initial decision. The supplier also can submit the request on behalf of the physician or treating practitioner. Under this demonstration, the submitter will submit to the DME MAC a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item. With this emergency FR notice, CMS announces its plans to expand the demonstration from the seven aforementioned States to 12 new States, bringing the total number of participating States to 19; however, the original demonstration requirements will remain the same in all 19 States. The new States include Pennsylvania, Ohio, Louisiana, Missouri, Maryland, New Jersey, Indiana, Kentucky, Georgia, Tennessee, Washington, and Arizona.	Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration		Date: None Date of Subsequent Agency	For the Recovery Audit Prepayment Review Demonstration, CMS and its agents request additional documentation, including medical records, to support submitted claims. As discussed in more detail in Chapter 3 of the Program Integrity Manual, additional documentation includes any medical documentation, beyond what appears on the face of the claim that supports the item or service billed. For Medicare to consider coverage and payment for any item or service, the information submitted by the provider or supplier (e.g., claims) must include supporting documentation from patient medical records. When conducting complex medical review, the contractor specifies documentation they require in accordance with Medicare rules and policies. In addition, providers and suppliers can supply additional documentation not explicitly listed by the contractor. CMS and its agents might request this supporting information on a routine basis in instances where diagnoses on a claim do not clearly indicate medical necessity, or in instances of suspected fraud. For the Prior Authorization of PMDs Demonstration, CMS has piloted prior authorization for PMDs. Prior authorization allows submission for review of the applicable documentation that supports a claim before delivery of the item or rendering of the service. CMS has begun this demonstration in California, Florida, Illinois, Michigan, New York, North Carolina and Texas based on beneficiary address as reported to the Social Security Administration and recorded in the Common Working File (CWF). For the demonstration, the (ordering) physician or treating practitioner can complete a prior authorization request and submit it to the appropriate DME MAC for an initial decision. The supplier also can submit the request on behalf of the physician or treating practitioner. Under this demonstration, the submitter will submit to the DME MAC a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item. With this emergency FR notice, CMS announces it	



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					SUMMARY OF NIHB ANALYSIS:	
4.d.	Medicare Hospital OPPS, Ambulatory Surgical Center Payment System, et al. ACTION: Proposed-Final Rule NOTICE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals AGENCY: CMS	CMS-1601- PFC	Issue Date: 7/19/2013 Due Date: 9/6/2013 9/16/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction/due date extension 9/6/2013; issued Final Rule 12/10/2013 Due Date: 1/27/2014		SUMMARY OF AGENCY ACTION: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2014 to implement applicable statutory requirements and changes arising from continuing experience with these systems. In this proposed rule, CMS describes the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program. This proposed rule also would change the conditions for coverage (CfCs) for organ procurement organizations (OPOs); revise the Quality Improvement Organization (QIO) regulations; change the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and make changes relating to provider reimbursement determinations and appeals. http://www.gpo.gov/fdsys/pkg/FR-2013-07-19/pdf/2013-16555.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/6/2013 issued a document (CMS-1601-CN) to correct technical errors that appeared in the proposed rule published in the 7/19/2013 FR. This document also extends the comment period for 10 days for the technical corrections set forth in this correcting document. http://www.gpo.gov/fdsys/pkg/FR-2013-09-06/pdf/2013-21849.pdf CMS on 12/10/2013 issued a final rule with comment period that revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory requirements and changes arising from continuing CMS experience with these systems. In this final rule with comment period, CMS describes the changes to the amounts 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.
					factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Hospital Value-Based Purchasing (VBP) Program. In addition, this final rule with comment period makes changes to the conditions for coverage (CfCs) for organ procurement organizations (OPOs); the Quality Improvement Organization (QIO) regulations; the Medicare fee-for-service Electronic Health Record (EHR) Incentive Program; and provider reimbursement determinations and appeals. CMS will consider comments on the payment classification assigned to HCPCS codes identified in Addenda B, AA, and BB of this final rule with comment period with the "NI" comment indicator and on other areas specified throughout this rule. http://www.gpo.gov/fdsys/pkg/FR-2013-12-10/pdf/2013-28737.pdf	
4.h.	Health Insurance Benefits Agreement and ASC Certification ACTION: Request for Comment NOTICE: Health Insurance Benefits Agreement and Ambulatory Surgical Request for Certification or Update of Certification Information in the Medicare Program AGENCY: CMS	CMS-370 and CMS- 377	Issue Date: 4/2/2014 Due Date: 6/2/2014 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: Health Insurance Benefits Agreement and Ambulatory Surgical Request for Certification or Update of Certification Information in the Medicare Program; Use: CMS uses CMS-370 to establish eligibility for payment. This agreement, upon submission by the ambulatory surgical center (ASC) and acceptance for filing by the HHS Secretary, shall bind both the ASC and the Secretary. Either party can terminate this agreement in accordance with regulations. In the event of termination, the ASC will not receive payment for services furnished on or after the effective date of termination. CMS uses CMS-377 to collect facility-specific characteristics that facilitate oversight of ASCs. ASCs submit CMS-377 when they request initial certification of compliance with the conditions for coverage or to update their existing certification information. State agencies that conduct certification surveys on behalf of CMS also use CMS-377 to maintain information on facility characteristics that facilitate conducting surveys, e.g., determining the size and the composition of the survey team on the basis of the number of operating and procedure rooms and the types of surgical procedures performed in the ASC.	



http://www.gpo.gov/fdsys/pkg/FR-2014-04-02/pdf/2014-07405.pdf SUMMARY OF NIHB ANALYSIS:	
Sa. PACE Information Request ACTION: Request for Comment NOTICE: Medicare and Medicaid: Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS NOTICE: Medicare and Medicaid: Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS Subsequent Agency Action, if any: Issued extension 10/8/2010; issued extension 10/4/2013; issued extension 12/20/2013 Due Date: 11/8/2010; 12/3/2013; 1/21/2014 PACE Information Request SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Exter a currently approved collection; Title: Programs for All-Inclusive Care of the Elderly (PACE) and Supporting Regulations; Use: The PACE organizations must demons their ability to provide quality community-based care for the firal elderly who meet state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state nursing home eligibility standards using capitated payments from Medicare and Medicaid earle state. The Payment from Medicare and Medicaid earle state. The Payment from Medicare and Medica	ate neir id the care on of CE ital, l e



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5.b.	PACE State Plan Amendment Preprint ACTION: Request for Comment NOTICE: State Plan Amendment Preprint AGENCY: CMS	CMS-10227	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/13/2013 Due Date: 1/13/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: PACE State Plan Amendment Preprint; Use: If a state elects to offer PACE as an optional Medicaid benefit, it must complete a state plan amendment preprint packet described as "Enclosures #3, 4, 5, 6, and 7." CMS uses the information, collected from the state on a one-time basis, to determine if the state has properly elected to cover PACE services as a state plan option. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/13/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-13/pdf/2013-29726.pdf CMS-10227 and a Supporting Statement for this PRA request are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1239083.html.	
5.c.	Health Plan Monitoring System Data Entry for PACE ACTION: Request for Comment NOTICE: Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly AGENCY: CMS	CMS-10525	Issue Date: 5/23/2014 Due Date: 7/22/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Existing collection in use without an OMB control number; Title: Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly; Use: This information collection would require Program of All-Inclusive Care for the Elderly (PACE) organizations to enter Level I and Level II data into the CMS Health Plan Monitoring System. CMS will use the collected information to develop a quality improvement strategy for PACE. http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11947.pdf SUMMARY OF NIHB ANALYSIS:	



Ref.	Short Title/Current Status of Regulation/Title/ 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.g.	Policy Sales to Medicare Beneficiaries Losing Coverage Due to High Risk Pool Closures ACTION: Guidance NOTICE: The Sale of Individual Market Policies to Medicare Beneficiaries Under 65 Losing Coverage Due to High Risk Pool Closures AGENCY: CMS	CMS (no reference number)	Issue Date: 1/10/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This bulletin sets forth circumstances under which the HHS Secretary has determined that issuers can sell individual market health insurance policies to certain Medicare beneficiaries younger than age 65 who lose state high risk pool coverage. As this bulletin explains, for sales to these individuals, HHS will not enforce the anti-duplication provisions of section 1882(d)(3)(A) of the Social Security Act (the Act) from 1/10/2014 to 12/31/2015. http://www.cms.gov/Medicare/Health-Plans/Medigap/Downloads/Sale-of-Individual-Market-Policies-to-Certain-Medicare-Beneficiaries.pdf SUMMARY OF NIHB ANALYSIS:	
6.h.	Special Enrollment Period for PCIP Enrollees ACTION: Guidance NOTICE: Special Enrollment Period for Individuals Losing Coverage through the Pre-Existing Condition Insurance Program (PCIP) AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 4/24/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Benefits coverage for current enrollees in the Pre-Existing Condition Insurance Plan (PCIP) will end on 4/30/2014. CMS, which offered transitional coverage to PCIP enrollees who, on 1/1/2014, had not yet enrolled in other coverage, will not extend this transitional coverage to May 2014. The open enrollment period for an individual Marketplace plan for the 2014 coverage year ended on 3/31/2014. To ensure that eligible individuals who will lose coverage through PCIP can avoid a lapse in coverage, this bulletin provides a special enrollment period (SEP) for a qualified health plan offered through the Federally-Facilitated Marketplace in 2014. State-Based Marketplaces are adopting a similar SEP. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/PCIP-bulletin-4-24-14.pdf A fact sheet on the SEP for PCIP enrollees is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/PCIP-fact-sheet-4-24-2014.pdf. SUMMARY OF NIHB ANALYSIS:	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
7.1.	Stand-Alone Dental Plans in Federally-Facilitated Exchanges ACTION: Guidance NOTICE: Issuers of Stand-Alone Dental Plans: Intent to Offer in FFE States AGENCY: HHS	HHS (no reference number)	Issue Date: 1/28/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 5/6/2014		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	
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	CMS-10463	Issue Date: 4/12/2013 Due Date: 6/11/2013 NIHB File Date: None Date of Subsequent Agency		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	



Ref.	Short Title/Current Status of Regulation/Title/ 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 reinstatement 7/26/2013; issued revision 4/11/2014 Due Date: 8/26/2013; 6/10/2014		receiving funds. SUMMARY OF NIHB ANALYSIS: This PRA request relates to CCIIO CA-NAV-13-001 (see 7.p.). No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/26/2013 issued a reinstatement of this PRA request with changes. In response to a 60-day notice on this information collection published in the 4/12/2013 FR (78 FR 21957), several commenters suggested changes to the reporting requirements, and CMS incorporated them where appropriate. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf 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	
7.y.	Blueprint for Approval of Health Insurance Marketplaces ACTION: Request for Comment NOTICE: Blueprint for Approval of Affordable Health Insurance Marketplaces AGENCY: CMS	CMS-10416	Issue Date: 8/16/2013 Due Date: 10/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/7/2014 Due Date: 4/7/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Blueprint for Approval of Affordable Health Insurance Marketplaces; Use: All states (which include the 50 States and the District of Columbia) have the opportunity under Section 1311(b) of ACA to establish an Exchange (Marketplace). The original information collection request for the State Marketplace Blueprint Data Collection Tool specified a single reporting tool for all the various Marketplace types. This request revises the collection process by having separate collection tools for each type of Marketplace with the goal of reducing the burden. In addition, at the time of the original request, the tool had a paper-based component. During the intervening time, CMS has completed the online implementation of the tool and will transition all future applications to that system. Given the innovative nature of Marketplaces and the statutorily prescribed relationship between the HHS Secretary and states in their development and operation, the Secretary must work closely with states to provide necessary guidance and technical assistance to ensure states can meet the prescribed timelines, federal requirements, and goals of the statute. States seeking to establish a Marketplace must build a Marketplace that meets the requirements set out in section 1311(d) of ACA and 45 CFR 155.105. To ensure that 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.
	rigoloy				state seeking approval as a state-based Marketplace, state-based SHOP, or State Partnership Marketplace in the Federally-Facilitated Marketplace meet all applicable requirements, the HHS Secretary will require a state to submit a Blueprint for approval and to demonstrate operational readiness through virtual or onsite readiness review. Submission of the Blueprint Application will occur online. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-19963.pdf SUMMARY OF NIHB ANALYSIS: This PRA request separates information collections depending on the type of Exchange (State-based or Partnership). This might provide an opportunity to revisit the issue of tribal consultation requirements and certifications. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/7/2013 issued a revision of this PRA request. This information collection request reduces the number of potential respondents in the original request due to various states electing to rely on FFM. Also, at the time of the original request, the tool had a paper-based component. During the intervening time, CMS has developed the online implementation of the tool and will transition all future applications to that system. http://www.gpo.gov/fdsys/pkg/FR-2014-03-07/pdf/2014-05000.pdf Tribal representatives might want to review and submit (or re-submit) prior comments on this version of the Blueprint.	
					this version of the Bluephint.	
7.bb.	Program Integrity; Amendments to the HHS Notice of Benefit and Payment Parameters ACTION: Final Rule NOTICE: Patient Protection and Affordable Care Act; Program Integrity: Exchange, Premium Stabilization Programs, and	CMS-9957- F2 CMS-9964- F3 See also 7.s., 89.a., and 89.b.	Issue Date: 10/30/2013 Due Date: None NIHB File Date: Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: This final rule implements provisions of ACA. Specifically, this final rule outlines financial integrity and oversight standards with respect to Affordable Insurance Exchanges, qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFEs), and States with regard to the operation of risk adjustment and reinsurance programs. It also establishes additional standards for special enrollment periods, survey vendors that might conduct enrollee satisfaction surveys on behalf of QHP issuers, and issuer participation in an FFE, and makes certain amendments to definitions and standards related to the market reform rules. These standards, which include financial integrity provisions and protections against fraud and abuse, are consistent with Title I of ACA. This final rule also amends and adopts as final interim provisions set forth in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the Federal Register on March 11,	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 AGENCY: CMS		Action, if any: Issued correction 12/31/2013		2013, related to risk corridors and cost-sharing reduction reconciliation. http://www.gpo.gov/fdsys/pkg/FR-2013-10-30/pdf/2013-25326.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/31/2013 issued a document (CMS-9957-CN; 9964-CN) that corrects an error that appeared in the final rule published in the 10/30/2013 FR. On page 65095, CMS added subpart M "Oversight and Program Integrity Standards for State Exchanges" to the regulations text at 45 CFR ` 155. Although subpart M applies to all Exchanges, including Small Business Health Options Program (SHOP) Exchanges, as a result of an oversight, CMS inadvertently omitted cross-referencing new subpart M at § 155.705(a) of the regulations in part 155, subpart H.—Exchange Functions: Small Business Health Options Program. Accordingly, CMS has revised § 155.705(a) so that the regulations in part 155 consistently reflect its policy that all Exchanges, including SHOP Exchanges, must carry out the required functions of an Exchange set forth at subpart M. CMS has correcting § 155.705(a) by adding a cross reference to subpart M, so that the provision reads, "Exchange functions that apply to SHOP". The SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, K, and M of this part, except:" http://www.gpo.gov/fdsys/pkg/FR-2013-12-31/pdf/2013-31319.pdf	
7.ee.	2015 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft-2015 Letter to Issuers in the Federally-Facilitated Marketplaces AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/4/2014 Due Date: 2/25/2014 TTAG File Date: 2/25/2014; NIHB and TSGAC also filed	TTAG response: NIHB response: TSGAC response:	SUMMARY OF AGENCY ACTION: This draft 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 a Federally-Facilitated Marketplace (FFM) and/or Federally-Facilitated Small Business Health Options Program (FF-SHOP) with operational and technical guidance to help them successfully participate in the Marketplaces. Unless otherwise specified, references to the Marketplaces or FFMs include the FF-SHOP. As indicated in previous guidance, states that perform plan management functions in an FFM have some flexibility in assessing compliance with certification standards and adjusting processes. Throughout this Letter, CMS identifies the areas in which states performing plan management functions in an FFM have flexibility to follow an approach	See Table C.



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			comments 2/15/2014 Date of Subsequent Agency Action, if any: Issued Final Letter 3/14/2014		different from that articulated in this guidance. CMS notes that the policies articulated in this Letter apply to QHP issuers starting in the 2015 certification year and beyond, until or unless subsequent guidance or regulations supersedes them. In the future, CMS intends to issue similar letters and other guidance to provide operational updates to QHP issuers but does not intend to issue these letters on more than an annual basis. CMS welcomes comments on this proposed guidance. However, to the extent that this guidance merely summarizes policies proposed through other rulemaking processes not yet finalized, such as the rulemaking process for the HHS Notice of Benefit and Payment Parameters for 2015 (2015 Payment Notice), CMS notes that issuers have already had or will have an opportunity to comment on those underlying policies through these ongoing rulemaking processes. CMS does not seek any additional comments on the substance of the underlying policies proposed in un-finalized rulemakings through the comment process for this Letter. Please send comments on other aspects of this Letter to FFEcomments@cms.hhs.gov by 2/25/2014. Comments will prove most helpful if commenters organize them by subsections of this document. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf CMS provided an overview and answer questions on the ACA Tribal Outreach Call on 2/11/2014. SUMMARY OF NIHB ANALYSIS: On 2/4/2014, the Center for Consumer Information and Insurance Oversight (CCIIO) in the Centers for Medicare and Medicaid Services (CMS) of the federal Department of Health and Human Services (HHS) released a "Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces" (2015 Issuer Letter). Comments are due back to CCIIO by 2/25/2014. On 2/11/2014, there was a national "All Tribes Call" hosted by CMS to explain the document and answer questions. During the call, CMS staff responded to questions from tribal representatives and indicated that issuers complied wit	



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					QHPs.) In the other five states, CMS certified the plans as being compliant on the requirement for QHPs to offer contracts to IHCPs, again by issuers attesting to complying with this provision.	
					Tribal representatives indicated to CMS staff that the experience in the field has been different from what CMS was reporting. Namely, in general, issuers have not been uniformly offering contracts to IHCPs. A tribal representative from Washington State reviewed in detail the experience with QHPs operating in the State's Marketplace. CMS representatives responded that it would be beneficial to have further discussions on the issue of issuer compliance with this requirement. Comments by tribal representatives will, among other topics, focus on the need for increased oversight to ensure QHP compliance with the CMS-established standards.	
					Analysis of 2015 CCIIO Issuer Letter:	
					SUMMARY OF SUBSEQUENT AGENCY ACTION: This Final 2015 Letter to Issuers in the Federally-Facilitated Marketplaces provides issuers seeking to offer QHPs, including stand-alone dental plans (SADPs), in a Federally-facilitated Marketplace (FFM) and/or Federally-facilitated Small Business Health Options Program (FF-SHOP), with operational and technical guidance to help them successfully participate in the Marketplaces. Except where noted, it finalizes the policies in the Draft 2015 Letter to Issuers in the Federally-Facilitated Marketplaces published on 2/4/2014. Unless otherwise specified, references to the Marketplaces or FFMs include the FF-SHOP.	
					Analysis : A comparison of the TTAG comments on the draft Letter to Issuers and the final Letter to Issuers appears in the document embedded below.	
					Review of Final CCIIO 2015 Issuer Le	
					On the issue of HHS requiring QHPs to make available to HHS a provider directory, some conflicting information has surfaced. First, in the draft Letter to Issuers, CMS required it; then, in the final Letter to Issuers and subsequent comments, CMS seemed	



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Ref. #	of Regulation/Title/ Agency	File Code	Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	_	File Code			to withdraw the requirement. More recent media reporting indicates that CMS might implement the requirement. A recent <i>Politico</i> article appears below. CMS Backtracks On Provider Lists, Now Tells Health Plans They Are Required for 2015 Posted: March 24, 2014 CMS told health plans during a Monday conference call that it has not shelved the requirement that qualified health plan (QHP) issuers in the federally-facilitated exchange hand over a list of the providers in their network as part of the QHP certification process, a health plan source tells <i>Inside Health Policy</i> . The plans were apparently informed that they would need to provide the list despite the conflicting language in the final letter to FFE plans, and the agency's previous confirmation to <i>Inside Health Policy</i> that while the agency hoped to collect the provider data as soon as possible it would not be a requirement for 2015. CMS last week did not say why the agency backed off the proposal, but advocates suggested it was likely due to technical issues. If that was the case, CMS may now believe that it does have the technical capabilities to collect the data, and perhaps does not want to fully abandon the proposal. "We are continuing to work on a process for collecting provider network lists, and hope to be able to do so soon," a CMS official told <i>IHP</i> Monday. Insurers had opposed the requirement, saying that it would be very difficult to implement, particularly in 2015 with the QHP submission date only two months away, but consumer advocates strongly supported the requirement. Confusion over whether the lists would be a requirement for this year came after the final letter did not include a sentence from the draft version that specifically said the lists must be submitted, yet did include language suggesting the agency would soon release guidance on how it intended to collect the provider information as part of certification and	NIHB Recs.
					recertification instructions. The final letter also stressed that in the future the agency would like to collect the information in a way that it could be reviewed for network adequacy and also be searched by consumers shopping for plans via healthcare.gov.	
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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.
					CMS last week told <i>IHP</i> that the correct interpretation of the letter is that the list would not be required for 2015, but would be in future years. The agency hopes to collect the data very soon, but wants to ensure that the process for collecting and analyzing the information is as efficient as possible, CMS told <i>IHP</i> . While CMS will not be collecting information using the process anticipated in the draft letter, issuers will still be submitting network adequacy data as part of the QHP application process. CMS will review this data and assess its adequacy for 2015, and will also use it to help refine the review process for future benefit years, CMS said last week. Amy Lotven (alotven@iwpnews.com This e-mail address is being protected from spambots. You need JavaScript enabled to view it)	
7.ff.	Enrollment and Termination Policies for Marketplace Issuers ACTION: Guidance NOTICE: Affordable Exchanges Guidance: Bulletins on Enrollment and Termination Policies and Processes for FFM and SPM Issuers AGENCY: CCIIO	CCIIO (no reference number) See also 7.aa. and 7.dd.	Issue Date: 2/6/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: CMS has finalized a series of processes and policies regarding enrollment and termination for issuers participating in Marketplaces using the CMS system, including Federally-Facilitated Marketplaces (FFMs) and State Partnership Marketplaces (SPMs). This set of guidance covers a variety of topics related to the ability of consumers or issuers to make changes to information or plan selections based on changes in life circumstances or as the result of receiving a special enrollment period. New functionality in the FFM will allow consumers to make certain changes to their application. The attached guidance represents a series of bulletins and FAQs related to consumer changes where new functionality is available. This guidance outlines interim processes for situations where functionality is not yet available, such as special enrollment periods (SEPs). This guidance works in conjunction with previously issued guidance, including the 12/12/2013 Interim Final Rule (link below); the FFM Enrollment Operational Policy and Guidance draft issued on 10/3/2013 (link below); and all previously released bulletins except where otherwise indicated. This guidance includes the following bulletins: Bulletin #2: Functionality for Consumer-Initiated Application and Enrollment Changes; Bulletin #3: Special Enrollment Periods: Effective Dates and Processes; Bulletin #4: Enrollee-Initiated Terminations;	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
#	_			Response	Bulletin #5: Flexibility During the Initial Open Enrollment Period to Change Plans Offered by the Same Issuer at the Same Metal Level; and Bulletin #6: Clarifications of the Instructions Presented in the December 12, 2013, Interim Final Rule and Bulletin #001. http://www.healthreformgps.org/wp-content/uploads/provider-networks-2-11.pdf The 12/12/2013 Interim Final Rule is available at http://www.gpo.gov/fdsys/pkg/FR-2013-12-17/pdf/2013-29918.pdf. The FFM Enrollment Operational Policy and Guidance draft is available at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR OperationsPolicyandGuidance 5CR 100313.pdf. According to a February 7, 2014, Washington Post article: In a 14-page memo sent to health insurers on 2/6/2014, CMS announced it will temporarily allow consumers who have obtained coverage through the new online Marketplace to switch health plans before 3/31/2014, provided they remain with the same insurer and generally the same level of coverage. Specifically, the memo states that consumers can switch health plans if they want to "move to a plan with a more inclusive provider network" or fit within "other isolated circumstances," which CMS did not define. CMS will allow consumers more flexibility and a longer opportunity to obtain a new health plan if they can prove that HealthCare.gov displayed inaccurate information about the benefits that their current plan offers, according to the memo. In addition, the memo states that CMS has added to HealthCare.gov a "Report a Life Change" button, which will allow consumers to adjust their health plans if they have added members to their family, moved, gotten released from prison, or undergone other changes that affect the coverage they want. The memo also indicates that consumers, during open enrollment periods this year and in the future, might have the ability to switch health plans by refusing to pay their premium to prompt their insurer to cancel their policy. In that circumstance, consumers can apply for a new health plan, the	
					The Post article is available at http://www.washingtonpost.com/national/health-science/administration-will-allow-people-to-switch-obamacare-plans-to-a-limited-	



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					 degree/2014/02/07/56c8bfd2-9015-11e3-b227-12a45d109e03_story.html. SUMMARY OF NIHB ANALYSIS: Details on effective dates for coverage for individuals eligible for Special Enrollment Periods (SEPs): If eligible for a Special Enrollment Period due to loss of minimum essential coverage (MEC), an individual can enroll in a Marketplace plan at any time during a month, with the coverage taking effect on the 1st of the following month (i.e., not required to enroll by the 15th of the month). For most other SEPs, an individual must enroll by the 15th of the month, etc. For instance, individuals with a status as an Indian must enroll by the 15th of the month for coverage to take effect by the 1st of the following month. For births and adoptions, coverage takes effect on the day of the birth or adoption. For future loss of MEC as much as 60 days in the future, an individual can enroll for coverage that will become effective on the 1st of the month following the loss of coverage. 			
					ווים וטסט טו טטעפומטים.			
7.gg.	Casework Guidance for Issuers in FFMs ACTION: Guidance NOTICE: Casework Guidance for Issuers in Federally-Facilitated Marketplaces, Including State Partnership Marketplaces AGENCY: CCIIO	CCIIO (no reference number) See also 7.s.	Issue Date: 3/13/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In the Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule (7.s.), HHS outlined standards for Qualified Health Plan (QHP) issuers in Federally-facilitated Marketplaces (FFMs) with regard to the resolution of cases. HHS has defined a case as a communication brought by a complainant that expresses dissatisfaction with a specific individual or entity subject to state or federal laws regulating insurance, concerning the activities of the individual or entity related to the offering of insurance, other than a communication with respect to an adverse benefit determination. This guidance provides additional information to QHP issuers in FFMs on casework handling procedures, as well as HHS expectations of QHP issuers operating in FFMs, including Stand-alone Dental Plan (SADP) issuers. As FFMs mature, HHS envisions refinement of this guidance to meet evolving program needs and allow better monitoring of the consumer experience. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/casework-guidance-03132014.pdf SUMMARY OF NIHB ANALYSIS: The casework referenced in this guidance pertains to complaints against a health plan (i.e., issues other than an adverse benefit determination			



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					subject to the internal and external appeals processes). QHP issuers must investigate and resolve cases brought directly by complainants or their authorized representative and should not refer consumers and other stakeholders to HHS or the Health Insurance Marketplace (HIM) Call Center for matters within their control to resolve. Through the HHS-established Health Insurance Casework System (HICS), when appropriate, complaints filed with HHS are forwarded to the QHP, and the QHP must work with HHS to resolve issues. Otherwise, this guidance indicates: "HHS will work with consumers and their authorized representatives directly if it becomes apparent that the QHP issuer is not working to resolve the concern, dispute, or grievance pursuant to the regulatory timeframes." HICS, similar to the system used by HHS with Medicare Advantage and Part D drug plans, is used with the Federally-Facilitated Marketplace. The QHP must resolve "urgent" issues within 72 hours and other complaints within 15 calendar days; the QHP must notify the complainant within 3 days of resolving the issue(s). MMPC and other tribal representatives might want to: • Map out the process to file a complaint and receive a response to make this process transparent (and circulate the findings to the MMPC list); and • Use the process to clarify with QHPs, through CMS/CCIIO, that 100% costsharing applies when a provider is out of network. See the Q&A memo below on "How to file a complaint about Marketplace coverage?" How Do I File a Complaint about Marketplace coverage?"	
7.hh.	Guidance on Individuals "In Line" for FFM ACTION: Guidance NOTICE: Affordable	CCIIO (no reference number) See also 7.ii.	Issue Date: 3/26/2014 Due Date: None		SUMMARY OF AGENCY ACTION: The law and regulations provide for special enrollment periods (SEPs), which are described in 45 CFR 155.420(d) and include, for example, life changes and errors in enrollment. SEPs permit individuals to enroll in a qualified health plan outside of open enrollment. This guidance describes treatment for consumers in the Federally-facilitated Marketplaces (FFMs) who are "in line" as of 3/31/2014.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Exchanges Guidance: Guidance for Issuers on People "In Line" for the Federally-Facilitated Marketplace at the end of the Initial Open Enrollment Period AGENCY: CCIIO		NIHB File Date: Date of Subsequent Agency Action, if any:		http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/in-line-SEP-3-26-2014.pdf SUMMARY OF NIHB ANALYSIS: Individuals who are included under this guidance and complete the application/enrollment process will have a 5/1/2014 coverage effective date, as if they completed enrollment by 3/31/2014. Individuals who applied prior to 3/31/2014 to the FFM are included under this guidance. Individuals who applied through a paper application that was received by 4/7/2014 are included under this guidance. CMS will process information related to paper applications received by 4/7/2014 to capture consumers who were "in line" with paper applications or whose applications were pending submission or review of supporting documentation on March 31. These consumers will have the ability to select a plan through 4/30/2014 to allow them time to receive an eligibility notice, with coverage effective 5/1/2014. Issuers will receive direction to effectuate accelerated effective dates for this group of consumers through the Health Insurance Casework System (HICS). This guidance applies to the FFM, including State Partnership Marketplaces, and works in conjunction with previously published guidance on SEPs. State-based Marketplaces can elect to offer similar SEPs. In total, CMS appears to offer a variety of justifications for individuals to request processing of their application past the 3/31/2014 deadline. Although exceptions might exist, individuals who could not complete enrollment by 3/31/2014for a variety of reasonswill have a coverage effective date of 5/1/2014. In addition to options for individuals unable to complete an application by 3/31/2014, CMS has established a host of SEPs, including the Monthly SEPs for qualifying Al/ANs (see 7.ii.) A summary of this CCIIO guidance document and the guidance document on Special Enrollment Periods for Complex Cases (7.ii) is imbedded here.	



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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.
					Memo- Q&A - Can I Apply After March 31	
7.ii.	Guidance on Special Enrollment Periods for Complex Cases ACTION: Guidance NOTICE: Affordable Exchanges Guidance: Guidance for Issuers on Special Enrollment Periods for Complex Cases in the Federally-facilitated Marketplace after the Initial Open Enrollment Period AGENCY: CCIIO	CCIIO (no reference number) See also 7.hh.	Issue Date: 3/26/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This guidance lists the special enrollment periods (SEPs), authorized under 45 CFR 155.420, that CMS will provide for consumers to enroll in Marketplace coverage after open enrollment closes on March 31. This list includes SEPs that the Federally-facilitated Marketplace (FFM) has begun processing to allow a consumer to select a plan outside of the open enrollment period, including those for life changes, benefit display errors, misrepresentation, and some exceptional circumstances. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/complex-cases-SEP-3-26-2014.pdf A PowerPoint presentation prepared by the Center on Budget and Policy Priorities on SEPs is available at http://www.healthreformbeyondthebasics.org/events/ (this presentation does not include all of the provisions raised in this guidance). SUMMARY OF NIHB ANALYSIS:	
7.jj.	SEPs and Hardship Exemptions for Certain Individuals ACTION: Guidance NOTICE: Special Enrollment Periods and Hardship Exemptions for Persons Meeting Certain Criteria AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 5/2/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		 SUMMARY OF AGENCY ACTION: This guidance provides information related to three types of special enrollment periods (SEPs) for individuals seeking to enroll in qualified health plans (QHPs) through the Federally-facilitated Marketplace (FFM). CCIIO encourages State-based Marketplaces (SBMs) to adopt similar special enrollment periods. This guidance also contains information about two hardship exemptions available for eligible consumers in FFM and SBM states. 1. HHS will extend a hardship exemption for all months prior to the effective date of coverage for those individuals who obtained MEC effective on or before 5/1/2014 outside of the Marketplace as has already been offered for person who secured coverage through a Marketplace. This hardship exemption is available to consumers in states with a Federally-facilitated Marketplace or a State-based Marketplace. Individuals are not required to submit an exemption application 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.
					 Marketplace. This hardship exemption is available to consumers in states with a Federally-facilitated Marketplace or a State-based Marketplace. Individuals are not required to submit an exemption application to the Marketplace. In accordance with 45 CFR 155.420(d)(9), HHS is providing an additional special enrollment period based on exceptional circumstances so that persons eligible for COBRA and COBRA beneficiaries are able to select QHPs in the FFM. Affected individuals have 60 days from the date of this bulletin, that is, through 7/1/2014, to select QHPs in the FFM. Special Enrollment Periods for Individuals Whose Individual Market Plans are Renewing Outside of Open Enrollment: consumers may have reasonably expected to have an option not to renew non-calendar year individual market policies and to receive a special enrollment period in the FFM outside of the open enrollment period. Therefore, at this time, in accordance with 45 CFR 155.420(d)(9), HHS will provide special enrollment periods consistent with 45 CFR 147.104(b)(2). Affected individual market consumers will be able to report to the FFM that they will not renew their plan up to 60 days before the renewal date, and can get coverage in the FFM effective the first of the month following the renewal date. Consumers will also have 60 days from the renewal date to select QHPs in the FFM. If a QHP is selected after the renewal date, coverage will be prospective based on the date of plan selection. These individuals should indicate "loss of other coverage" on their Marketplace application, if they would like to apply for and enroll in a QHP offered by the Marketplace plan, if otherwise eligible. Special Enrollment Periods and Hardship Exemption for AmeriCorps/ VISTA/National Civilian Community Corps Members: HHS has determined that the following individuals and their dependents, as described in 45 CFR 155.420(a)(2), have experienced "exceptional circumstances" and are eligible for a special e	
					Affected AmeriCorps State and National, VISTA, and NCCC members have 60 days from their triggering event, defined as either the date they begin service, or	



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					the date they lose access to short-term limited duration coverage or self-funded coverage from these programs, to select QHPs through the FFM. In addition, in recognition of the need for a transition period, HHS is exercising its authority to establish an additional hardship exemption for calendar year 2014 for certain individuals engaged in service in AmeriCorps State and National, VISTA, or NCCC programs. Consumers in all states except Connecticut will need to request the hardship exemption certification using the hardship exemption form available at HealthCare.gov/exemptions, selecting reason #14, and filling in "AmeriCorps", VISTA" or "NCCC" as the reason. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SEP-and-hardship-FAQ-5-1-2014.pdf SUMMARY OF NIHB ANALYSIS:	
11.d.	Bid Pricing Tool ACTION: Request for Comment NOTICE: BPT for Medicare Advantage and Prescription Drug Plans 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; issued revision 10/4/2013;		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); Use: Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) must submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by the Centers for Medicare & Medicaid Services (CMS). MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid, with the information provided in the BPT used as the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development, administrative expenses, profit levels, and projected plan enrollment information. CMS reviews and analyzes the information provided in the BPT and decides whether to approve the plan pricing proposed by each organization. CMS is requesting to continue its use of the BPT for the collection of information for CY 2014 through CY 2016. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/17/2013 issued a revision of this PRA request.	



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			issued revision 12/20/2013 <u>Due Date:</u> 2/19/2013; 12/3/2013; 1/21/2014		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	
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; issued revision 1/17/2014 Due Date: 2/19/2013; 12/31/2013; 2/18/2014		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	



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					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	
11.s.	Medicare Prescription Drug Benefit Program ACTION: Request for Comment NOTICE: Medicare Prescription Drug Benefit Program AGENCY: CMS	CMS-10141	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/13/2013 Due Date: 1/13/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Prescription Drug Benefit Program; Use: Part D plans use the information to comply with the eligibility and associated Part D participating requirements. CMS uses the information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure disclosure of correct information to potential and current enrollees. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/13/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-13/pdf/2013-29726.pdf Several documents related to CMS-10141 (listed below) are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1210554.html. Attachment 1a: Compensation Certification Attachment 2a: Description of Compensation Structure for Plans Using Contracted Marketing Organizations Attachment 4: Compensation Structure for Writing Agents by Contract/PBP Number Supporting Statement	



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11.t.	Appeals of Quality Bonus Payment Determinations ACTION: Request for Comment NOTICE: Appeals of Quality Bonus Payment Determinations AGENCY: CMS	CMS-10346	Issue Date: 12/6/2013 Due Date: 2/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/28/2014 Due Date: 3/31/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Appeals of Quality Bonus Payment Determinations; Use: Section 1853(o) of the Social Security Act (the Act) requires CMS to make quality bonus payments (QBPs) to Medicare Advantage (MA) organizations that achieve performance rating scores of at least 4 stars under a 5-star rating system. While CMS has applied a Star Rating system to MA organizations for a number of years, prior to the QBP program, it used these Star Ratings only to provide additional information for beneficiaries to consider in making their Part C and D plan elections. Beginning in 2012, the Star Ratings CMS assign for purposes of QBPs directly affect the monthly payment amount MA organizations receive under their contracts. Additionally, section 1854(b)(1)(C)(v) of the Act, as added by AcA, requires CMS to change the share of savings that MA organizations must provide to enrollees as the beneficiary rebate specified at § 422.266(a) based on the level of a Star Rating for quality performance. While the statute does not specify an administrative review process for appealing low QBP Star Ratings, CMS has implemented an appeals process in accordance with its authority to establish MA program standards by regulation at section 1856(b)(1) of the Act. Under this process, MA organizations can seek review of their QBP Star Rating determinations. This review process also applies to the determinations CMS made where the Star Rating sets the QBP status of an MA organization at ineligible for rebate retention. The reconsideration official and potentially the hearing officer will consider the information collected from MA organizations can seek review of their QBP Star Rating determinations. This review process also applies to the determinations of eligibility for a QBP. While the statute does not specify an administrative review process for appealing low QBP Star Ratings, CMS has implemented an appeals process in accordance with its author	



Ref. #	Short Title/Current Status of Regulation/Title/ 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 2/28/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04327.pdf No comments recommended.	
11.u.	CY 2015 Policy and Technical Changes to Parts C and D ACTION: Proposed Final Rule NOTICE: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs AGENCY: CMS	CMS-4159- PF	Issue Date: 1/10/2014 Due Date: 3/7/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 5/23/2014		SUMMARY OF AGENCY ACTION: This proposed rule would revise Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; exclude plans that perform poorly; improve program efficiencies; and clarify program requirements. This proposed rule also includes several provisions designed to improve payment accuracy. http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule could serve as the vehicle for regulations that would require all MA plans to offer a contract to each I/T/U facility with an Indian Addendum. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule will revise MA program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements, improve program efficiencies, and clarify program requirements. This final rule also includes several provisions designed to improve payment accuracy. http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf Analysis: Tribal organizations did not file comments on the proposed rule. This final rule does not include any Indian-specific provisions. In the proposed rule, CMS included a discussion about Al/ANs and IHS as part of its reasoning for proposed revisions to the eligibility criteria for Medication Therapy Management (MTM) programs under Part D (§ 423.153(d)).	



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	Agency		THE Date		The proposed revisions focused on three areas: multiple chronic diseases, multiple Part D drugs, and the annual cost threshold. A summary of the proposed revisions in each of these areas appears below. • Multiple chronic diseases: CMS proposed to revise its interpretation of "multiple chronic diseases" to require sponsors to target enrollees having two or more chronic diseases for MTM services. CMS also proposed to require that at least one of the chronic diseases that a beneficiary has to satisfy the eligibility criteria must appear on the list of core chronic diseases. In addition, CMS proposed to redefine the core diseases by combining hypertension and congestive heart failure under the umbrella of "cardiovascular disease," which also would encompass congestive heart failure; acute myocardial infarction; cerebral hemorrhage; and effects of stroke, vascular disease, specified heart arrhythmias, and hypertensive heart disease. The list of core chronic diseases would become cardiovascular disease, diabetes, dyslipidemia, respiratory disease, bone disease-arthritis, mental health, Alzheimer's disease, and end stage renal disease • Multiple Part D drugs: CMS proposed to revise its interpretation of "multiple Part D drugs" to require sponsors to target enrollees taking two or more Part D covered drugs for MTM services. CMS also proposed to restrict the flexibility previously available to sponsors by requiring that they consider any Part D covered drug. • Annual cost threshold: CMS proposed setting the annual amount in Part D drug costs at an amount that represents the intersection of multiple conditions and multiple drugs. Specifically, CMS proposed setting the threshold at \$620 (a decrease from the current \$3,017 for 2014), the estimated annual total drug cost for a beneficiary filling two generic prescriptions, based on an analysis of prescription drug event (PDE) data. Regarding Al/ANs and IHS and the current problems with MTM programs, CMS stated: "Another example involves the Indian Health Service, which	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					V of the Indian Health Care Improvement Act. When the majority of American Indians and Alaska Natives live outside reservation land, where most IHS/tribal facilities are located, barriers in access to care are seen in both rural and urban landscapes, where there is limited availability of providers or limited offering of services, respectively. Transportation to IHS/tribal facilities may be a barrier, and the patient-perceived benefit of paying monthly premiums, in light of 100 percent coverage of health care expenses for eligible patients, may also reduce participation in MTM services [T]he Public Health Service Pharmacy program has apprehension about contracting with Part D plans offering MTM programs because limited compensation by Part D plans for MTM services is not cost-effective to implement on a national scale." [79 FR 1952-3] CMS later stated, "This proposed rule may be of interest to, and affect, American Indians/Alaska Natives. Therefore, we plan to consult with Tribes during the comment period and prior to publishing a final rule." [79 FR 1953] Whether CMS consulted with tribes on this provision remains uncertain. However, in the final rule, CMS stated, "We are not finalizing these proposals. We will engage in new notice and comment rulemaking on this issue as warranted in the future." [79 FR 29866] Additional analysis appears in the document embedded below. CMS-4159-F analysis 2014-05-31.docx	
11.v.	MA Chronic Care Improvement Program and QI Reporting Tools	CMS-10209	<u>Issue Date:</u> 1/10/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools; Use: Medicare	
	ACTION: Request for Comment		<u>Due Date:</u> 3/11/2014		Advantage Organizations (MAOs) must have an ongoing quality improvement (QI) program that meets CMS requirements and includes at least one chronic care improvement program (CCIP) and one QI Project. Every MAO must have a QI program	
			NIHB File		that monitors and identifies areas where implementing appropriate interventions would	
	NOTICE: Medicare		Date: None		improve patient outcomes and patient safety. CMS uses the information collected using	
	Advantage Chronic Care		Data of		the CCIP and QIP reporting tools for oversight, monitoring, compliance, and auditing	
	Improvement Program (CCIP) and Quality Improvement		Date of Subsequent		activities necessary to ensure high-quality, value-based health care for Medicare beneficiaries.	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency (QI) Project Reporting Tools AGENCY: CMS	File Code	Issue Date; Due Date & File Date Agency Action, if any: Issued extension 4/2/2014 Due Date: 5/2/2014	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2014-00195.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/2/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-02/pdf/2014-07402.pdf	NIHB Recs.
11.w.	Final Marketing Provisions for Medicare Parts C and D ACTION: Request for Comment NOTICE: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions AGENCY: CMS	CMS-10260	Issue Date: 1/29/2014 Due Date: 2/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions; Use: CMS requires Medicare Advantage (MA) organizations and Part D sponsors to use standardized documents to satisfy disclosure requirements mandated by section 1851(d)(3)(A) of the Social Security Act (Act) for MA organizations and section 1860D-1(c) of the Act for Part D sponsors. MA organizations and Part D sponsors must disclose plan information, including: service area, benefits, access, grievance and appeals procedures, and quality improvement and quality assurance requirements by September 30 of each year. MA organizations and Part D sponsors use this information to comply with the disclosure requirements. CMS will use the approved standardized documents to ensure disclosure of correct information to current and potential enrollees. http://www.gpo.gov/fdsys/pkg/FR-2014-01-29/pdf/2014-01775.pdf SUMMARY OF NIHB ANALYSIS: This PRA request involves a revision to current reporting requirements pertaining to marketing materials used by Medicare Advantage and Part D plans. The plans report on service areas, benefits, etc. No comments recommended.	
11.x.	Medication Therapy Management Program Improvements	CMS-10396	Issue Date: 1/17/2014 Due Date:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medication Therapy Management Program Improvements; Use: Medicare beneficiaries or their authorized representatives, caregivers, and health care providers will use information collected by Part D medication	



Ref.	Short Title/Current Status of Regulation/Title/ 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: Medication Therapy Management Program Improvements AGENCY: CMS		3/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014 Due Date: 5/12/2014		therapy management programs (as required by the standardized format for the comprehensive medication review summary) to improve medication use and achieve better health care outcomes. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00916.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/11/2014 issued an extension of this PRA request. Subsequent to the publication of the 60-day notice published in the 1/17/2014 FR, CMS has made non-substantive changes to this information collection request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf	
11.y.	Notice of Changes to Medicare Parts C and D Payment Policies ACTION: Notice NOTICE: Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter AGENCY: CMS	CMS (no reference number)	Issue Date: 2/21/2014 Due Date: 3/7/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In accordance with section 1853(b)(2) of the Social Security Act (the Act), this notice announces planned changes in the Medicare Advantage (MA) capitation rate methodology and risk adjustment methodology applied under Part C of the Act for calendar year (CY) 2015. This notice also contains the following information: preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2015, changes in payment methodology for CY 2015 for Part D benefits, and annual adjustments for CY 2015 to the Medicare Part D benefit parameters for the defined standard benefit. For 2015, CMS will announce the MA capitation rates on the first Monday in April 2014, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Interested parties can submit comments or questions electronically to the following address: AdvanceNotice2015@cms.hhs.gov. CMS might make comments public, so submitters should not include any confidential or personal information. To receive consideration prior to the April 7, 2014, release of the final Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, interested parties must submit comments by 6 p.m. ET on Friday, March 7, 2014.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2015.pdf A CMS press release on this notice is available at http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-02-21-02.html. A Politico article on this notice is available at http://go.politicoemail.com/?qs=2f3fd5d0ab4340c4e932460059903a0b9bc3096058df55cd2ed6d55887eac92e. SUMMARY OF NIHB ANALYSIS: In relation to "remote access technologies" (e.g., telehealth services) under Medicare Advantage plans, CMS indicated: • Improved Coordination of Care: CMS intends to expand plans' ability to use technologies that enable health care providers to deliver care to beneficiaries in remote locations. The use of remote access technologies as a care delivery option for Medicare Advantage enrollees may improve access to and timeliness of needed care, increase communications between providers and beneficiaries, and enhance care coordination.	
11.z.	Medicare Health Outcomes Survey ACTION: Request for Comment NOTICE: Medicare Health Outcomes Survey (HOS) AGENCY: CMS	CMS-10203	Issue Date: 2/28/2014 Due Date: 4/29/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of currently approved collection; Title: Medicare Health Outcomes Survey (HOS); Use: CMS uses data collected through the Medicare Health Outcomes Survey (HOS) to hold Medicare managed care contracts accountable for the quality of care they deliver to beneficiaries. This reporting requirement allows CMS to obtain the information necessary for proper oversight of the Medicare Advantage program. http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04328.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/16/2014 issued a revision of this PRA request.	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date revision 5/16/2014 Due Date: 6/16/2014	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis http://www.gpo.gov/fdsys/pkg/FR-2014-05-16/pdf/2014-11388.pdf	NIHB Recs.
11.aa.	Predictive Learning Analytics Tracking Outcome Tool ACTION: Request for Comment NOTICE: The Predictive Learning Analytics Tracking Outcome (PLATO) AGENCY: CMS	CMS-10517	Issue Date: 4/25/2014 Due Date: 6/24/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: The Predictive Learning Analytics Tracking Outcome (PLATO); Use: The Predictive Learning Analytics Tracking Outcome (PLATO), a Web-based application tool, will serve as the centerpiece of the advanced analytics initiative with CMS and Health Integrity LLC, the National Benefit Integrity Medicare Integrity Contractor (NBI MEDIC). Developed by Health Integrity and licensed for one of its contracts—the NBI MEDIC—PLATO utilizes a cutting-edge advanced analytics fraud detection process in conjunction with a state-of-the-art, Web-based user interface tool to present fraud and abuse lead information visually to Medicare Part D plan sponsors. PLATO shares summary data, based on National Prescription Drug Event Data and actions from all Medicare Part D plan sponsors, with law enforcement, CMS, NBI MEDIC, and Part D plan sponsors to allow review of historic actions taken against providers enrolled in Part D to assist in detecting and preventing fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2014-04-25/pdf/2014-09505.pdf SUMMARY OF NIHB ANALYSIS:	
11.bb.	Independent Charity Patient Assistance Programs ACTION: Notice NOTICE: Supplemental Special Advisory Bulletin: Independent Charity Patient	HHS OIG (no reference number)	Issue Date: 5/30/2014 Due Date: None NIHB File Date:		SUMMARY OF AGENCY ACTION: This Supplemental Bulletin updates the HHS OIG Special Advisory Bulletin on Patient Assistance Programs (PAPs) for Medicare Part D Enrollees published in the 11/22/2005 FR (70 FR 70623). Patients who cannot afford their cost-sharing obligations for prescription drugs might have the ability to obtain financial assistance through a PAP. PAPs have long provided important safety net assistance to such patients, many of whom have chronic illnesses and high drug costs. Many PAPs also present a risk of fraud, waste, and abuse with respect to Medicare and other Federal health care programs. HHS OIG issued a Special	



Assistance Programs AGENCY: HHS OIG		Date of Subsequent Agency		Advisory Bulletin regarding PAPs in 2005 (the 2005 SAB) in anticipation of questions	
		Action, if any:		likely to arise in connection with the Medicare Part D benefit. In the 2005 SAB, HHS OIG addressed different types of PAPs and stated its belief that lawful avenues exist for pharmaceutical manufacturers and others to help ensure all Part D beneficiaries can afford medically necessary drugs. HHS OIG also noted in the 2005 SAB that it could only speculate on fraud and abuse risk areas because the Part D benefit had not yet begun. HHS OIG issued this Supplemental Bulletin based on experience gained in the intervening years; it does not replace the 2005 SAB, nor does it replace other relevant guidance, such as the 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries. HHS OIG continues to believe that properly structured PAPs can help Federal health care program beneficiaries. This Supplemental Bulletin provides additional guidance regarding PAPs operated by independent charities (Independent Charity PAPs) that provide cost-sharing assistance for prescription drugs. To address some of the specific risks that have come to the attention of HHS OIG in recent years, this Supplemental Bulletin discusses problematic features of PAPs with respect to the anti-kickback statute, section 1128B(b) of the Social Security Act (Act), and the provision of the Civil Monetary Penalties Law prohibiting inducements to Medicare and Medicaid beneficiaries (Beneficiary Inducements CMP), section 1128A(a)(5) of the Act. This Supplemental Bulletin does not address other potential risk areas, including, for example, potential liability under the False Claims Act or other Federal or State laws. http://www.gpo.gov/fdsys/pkg/FR-2014-05-30/pdf/2014-11769.pdf SUMMARY OF NIHB ANALYSIS:	
Business Proposal Forms for QIOs ACTION: Request for Comment NOTICE: Business Proposal	CMS-718- 721	Issue Date: 5/16/2014 Due Date: 7/15/2014 NIHB File		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a previously approved collection; Title: Business Proposal Forms for Quality Improvement Organizations (QIOs); Use: The submission of proposal information by current quality improvement associations (QIOs) and other bidders, on the appropriate forms, will satisfy the need for meaningful, consistent, and verifiable data with which to evaluate contract proposals. CMS uses the data collected on the forms associated with this information collection request to negotiate QIO contracts. CMS will have the ability to	
	for QIOs ACTION: Request for	for QIOs 721 ACTION: Request for Comment NOTICE: Business Proposal	for QIOs 721 5/16/2014 ACTION: Request for Due Date: 7/15/2014 NOTICE: Business Proposal NIHB File	for QIOs 721 5/16/2014 ACTION: Request for Comment Due Date: 7/15/2014 NOTICE: Business Proposal NIHB File	Inducements to Beneficiaries. HHS OIG continues to believe that properly structured PAPs can help Federal health care program beneficiaries. This Supplemental Bulletin provides additional guidance regarding PAPs operated by independent Charities (Independent Charity PAPs) that provide cost-sharing assistance for prescription drugs. To address some of the specific risks that have come to the attention of HHS OIG in recent years, this Supplemental Bulletin discusses problematic features of PAPs with respect to the anti-kickback statute, section 1128B(b) of the Social Security Act (Act), and the provision of the Civil Monetary Penalties Law prohibiting inducements to Medicare and Medicaid beneficiaries (Beneficiary Inducements CMP), section 1128A(a)(5) of the Act. This Supplemental Bulletin does not address other potential risk areas, including, for example, potential liability under the False Claims Act or other Federal or State laws. http://www.gpo.gov/fdsys/pkg/FR-2014-05-30/pdf/2014-11769.pdf SUMMARY OF NIHB ANALYSIS: Summary OF AGENCY ACTION: Type of Information Collection Request: Revision of a previously approved collection: Title: Business Proposal Forms for Quality Improvement Organizations (QIOs); Use: The submission of proposal information by current quality improvement associations (QIOs) and other bidders, on the appropriate forms, will satisfy the need for meaningful, consistent, and verifiable data with which to evaluate contract proposals. CMS uses the data collected on the forms associated with this information collection request to negotiate QIO contracts. CMS will have the ability to



16.b. Mc At Rt NO PI	Improvement Organizations (QIOs) AGENCY: CMS		Date of Subsequent Agency Action, if any:	on the business proposal forms. CMS will base subsequent contract and modification negotiations on historical cost data. The business proposal forms will serve as one element of the historical cost data from which CMS can analyze future proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, CMS can compare proposals among QIOs for reasonableness and appropriateness. http://www.gpo.gov/fdsys/pkg/FR-2014-05-16/pdf/2014-11391.pdf	
AC RI NO PI Ba Pe				SUMMARY OF NIHB ANALYSIS:	
	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: 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 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: None.	No comments filed.



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
16.d.	Elimination of Cost- Sharing for Dual-Eligibles Receiving HCBS ACTION: Request for Comment NOTICE: Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services AGENCY: CMS	CMS-10344	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/20/2013 Due Date: 1/21/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services; Use: This provision eliminates Part D cost-sharing for full benefit dual-eligible beneficiaries who receive home and community based services. To implement this provision, States must identify the affected beneficiaries in their monthly Medicare Modernization Act Phase Down reports. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/20/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf	
16.e.	Community First Choice Option ACTION: Request for Comment NOTICE: Community First Choice Option AGENCY: CMS	CMS-10462	Issue Date: 1/17/2014 Due Date: 3/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/25/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Community First Choice Option; Use: This project will evaluate the implementation and progress of the Community First Choice (CFC) Option. The results of the study will appear in the final Report to Congress delivered by the HHS Secretary in 2015. This project will assist CMS and Congress in their understanding of: State CFC implementation plans, the effectiveness of the CFC Option on individuals receiving home- and community-based attendant care, and State spending on long-term services and supports. Researchers will request data from States approved for CFC via a data form and semi-structured interviews. Information obtained will improve understanding of CFC program design, the targeted patient population, and intended outcomes. At this time, CMS has approved only a California program. To provide comparative information to the HHS Secretary, researchers also will collect data from States that have decided not to pursue the CFC option. Researchers will analyze data and develop them into a report to Congress evaluating the effectiveness of the CFC option, the impact of the program on	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			<u>Due Date:</u> 4/24/2014		the physical and emotional health of participants, and the cost of community-based services versus those provided in institutional settings. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00916.pdf SUMMARY OF NIHB ANALYSIS: California Tribes and tribal health organizations might want to comment on this research and survey to ensure adequate consideration of Al/AN and I/T/U issues. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/25/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-03-25/pdf/2014-06518.pdf Analysis: The Community First Choice Option authorizes an enhanced Federal match to states to provide home and community-based attendant services and supports to Medicaid beneficiaries who require an institutional level of care. To date, only California has an approved program in place. Section 2401 of ACA directs HHS to conduct an evaluation of the CFC Option (section 1915(k) of the Social Security Act). The TTAG Long-term Care and Support Services Committee might want to review the CFC Option and determine any potential benefits of submitting comments for potential inclusion in the report to Congress. A Q&A on the CFC Option appears in the document embedded below.	
23.e.	State Children's Health Insurance Program ACTION: Request for Comment NOTICE: State Children's	CMS-R-308	Issue Date: 10/4/2013 <u>Due Date:</u> 12/3/2013 NIHB File		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: State Children's Health Insurance Program and Supporting Regulations; Use: States must submit title XXI plans and amendments for approval by the HHS Secretary. CMS uses the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Advocacy groups, beneficiaries, applicants, other governmental agencies, provider groups, research organizations, health care corporations, and health care consultants will use the	
	Health Insurance Program and Supporting Regulations		Date: None Date of		information provided in the state plan and state plan amendments. States will use the information collected to assess state plan performance, health outcomes, the amount of substitution of private coverage that occurs as a result of the subsidies, and the effect 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.
	AGENCY: CMS		Subsequent Agency Action, if any: Issued extension 1/23/2014 Due Date: 2/24/2014		the subsidies on access to coverage. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: This PRA request might provide an opportunity to recommend potential changes to better capture I/T/U- and Al/AN-related information. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/23/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-23/pdf/2014-01208.pdf No comments recommended, as CMS has made no changes to the current reporting requirements for states, the District of Columbia, and territories with regard to the CHIP State Plan and amendment processes.	
23.f.	1932(a) State Plan Amendment Template and Requirements ACTION: Request for Comment NOTICE: 1932(a) State Plan Amendment Template, State Plan Requirements, and Supporting Regulations AGENCY: CMS	CMS-10120	Issue Date: 12/6/2013 Due Date: 2/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/14/2014 Due Date: 3/17/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: 1932(a) State Plan Amendment Template, State Plan Requirements, and Supporting Regulations; Use: Section 1932(a)(1)(A) of the Social Security Act (the Act) grants states the authority to enroll Medicaid beneficiaries on a mandatory basis into managed care entitiesmanaged care organizations (MCOs) and primary care case managers (PCCMs). Under this authority, a state can amend its Medicaid state plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without violating provisions of section 1902 of the Act on statewideness, freedom of choice, or comparability. States can use the template to modify their state plans if they choose to implement the provisions of section 1932(a)(1)(A). http://www.gpo.gov/fdsys/pkg/FR-2013-12-06/pdf/2013-29144.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended, as the protection for members of federally recognized tribes is maintained. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/14/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03290.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.	
23.g.	Imposition of Cost Sharing Charges Under Medicaid ACTION: Request for Comment NOTICE: Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations AGENCY: CMS	CMS-R-53 (OMB approval sought under CMS-10398; see 23.a.)	Issue Date: 1/27/2014 Due Date: 2/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued withdrawal 2/7/2014; re- issued revision 2/14/2014 Due Date: 3/17/2014 TTAG File Date: 3/17/2014	TTAG response:	SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations; Use: This information collection seeks to ensure that states impose nominal cost sharing charges upon categorically and medically needy individuals as allowed by law and implementing regulations. States must identify in their state plan the service for which the charge occurs, the amount of the charge, the basis for determining the charge, the basis for determining whether an individual cannot pay the charge and the way in which the individual will get identified to providers, and the procedures for implementing and enforcing the exclusions from cost sharing. CMS has revised the template for this 30-day comment period before submission to OMB for approval under CMS-10398. In addition, CMS seeks to discontinue CMS-R-53 to avoid duplicating requirements and burden. http://www.gpo.gov/fdsys/pkg/FR-2014-01-27/pdf/2014-01465.pdf SUMMARY OF NIHB ANALYSIS: This notice of a revision to a previously approved data collection might provide an opportunity to ensure that states have the procedures in place to ensure Al/ANs receive the cost-sharing protections established in the American Recovery and Reinvestment Act of 2009 (ARRA). ARRA § 5006 eliminates cost-sharing for Al/ANs who receive services from an Indian health care provider or through referral from an Indian health care provider. This notice indicates that "states must identify the procedures for implementing and enforcing the exclusions from cost sharing" for all populations eligible for exclusions from cost-sharing. Although this notice does not reference Al/ANs directly, the ARRA protections for Al/ANs are in effect, and CMS last year published regulations that provide guidance on implementing the ARRA cost-sharing protections for Al/ANs under Medicaid. For Al/ANs to receive the cost-sharing protections, 1) eligible Al/ANs need to be identified as eligible for	See Table C.	



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Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Tribes and tribal organizations might want to consider recommending that TTAG work with CMS and/or a designated state to establish model procedures for 1) identifying Al/ANs eligible for the ARRA protections and 2) communicating this information to providers and MCOs. For example, in previous comments to CMS, tribal representatives recommended that states a) use self-attestation of status for the protections or b) access an electronic database for the identification of Al/ANs who qualify for the ARRA protections. These items could be incorporated into a set of model procedures. TTAG comments on CMS-2334initially published on 1/22/2013 and published in final form on 7/15/2013might provide a guide for tribal comments on CMS-R-53. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/7/2014 issued a notice of withdrawal of this PRA request. According to CMS, it published this PRA request in error. http://www.gpo.gov/fdsys/pkg/FR-2014-02-07/pdf/2014-02660.pdf CMS on 2/14/2014 re-issued this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03297.pdf	
25.b.	Medicare Inpatient Rates ACTION: Proposed-Final Rule NOTICE: Medicare Program; Hospital IPPS for Acute Care Hospitals and the LTCH PPS and FY 2013 Rates; Hospitals' Resident Caps for GME Payment Purposes; Quality Reporting Requirements for Specific Providers and for ASCs AGENCY: CMS	CMS-1588- PF CMS-1588- F2	Issue Date: 4/24/2012 Due Date: 6/25/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 6/11/2012; issued Final Rule 8/31/2012;		SUMMARY OF AGENCY ACTION: This proposed rule would implement American Recovery and Reinvestment Act of 2009 (ARRA) provisions that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. This proposed rule would specify: the initial criteria an EP and eligible hospital must meet to qualify for the incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs and eligible hospitals failing to meaningfully use certified EHR technology; and other program participation requirements. In addition, as required by ARRA, the HHS Office of the National Coordinator for Health Information Technology (ONC) will issue a closely related interim final rule that specifies adoption of an initial set of standards, implementation, specifications, and certification criteria for EHRs. ONC also will issue a notice of proposed rulemaking on the process for organizations to conduct the certification of EHR technology. SUMMARY OF NIHB/TTAG ANALYSIS: TTAG and NIHB would like to comment on 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 correction 10/3/2012; issued correction 10/29/2012; issued correction 3/13/2013; issued correction 3/18/2014		definition of eligible professionals (EPs) and how it might impact Indian health care providers, including those in tribally operated outpatient clinics and urban Indian health centers, in hospital settings. The EHR in the hospital setting differs from that in the hospital-based clinic setting due to the unique and distinct care provided. However, the incentive programs and current definitions of EPs allow for the costs of the hospitals while not considering those of hospital-based clinics. It is not uncommon for one hospital to support 5 individual outpatient clinics. The broad regulatory interpretation of this hospital-based physician definition might inappropriately exclude Indian health care providers practicing in outpatient clinics because they are part of the hospital network. Hundreds of primary care professionals who practice in hospital-based clinics will not qualify for individual provider incentives under this proposed rule, which would exclude individual provider incentives for "hospital based providers," defined as pathologists, emergency room physicians, and anesthesiologists who are employed by the hospital and use hospital inpatient and outpatient location codes for services provided. [See the archived RRIAR v.2.12 dated December 31, 2012, for additional analysis.] SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/18/2014 issued a document (CMS-1588-CN5) to correct technical errors that appeared in this final rule. On page 53602 and 53603 of this final rule, CMS inadvertently included Medicare Advantage (MA) claims in its calculation of the final performance standards that apply to the PSI-90 measure for the FY 2015 and FY 2016 Hospital Value-Based Purchasing Program. http://www.gpo.gov/fdsys/pkg/FR-2014-03-18/pdf/2014-05836.pdf	
25.g.	PPS for Acute and Long- Term Care Hospitals, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Hospital IPPS for Acute Care Hospitals and	CMS-1599- P F CMS-1455-F	Issue Date: 5/10/2013 Due Date: 6/25/2013 NIHB File Date: None		SUMMARY OF AGENCY ACTION: This proposed rule would revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from continuing CMS experience with these systems. Some of the proposed changes would implement certain statutory provisions contained in ACA and other legislation. These proposed changes would apply to discharges occurring on or after 10/1/2013, unless otherwise specified in this proposed rule. This proposed rule also would update the rate-of-increase limits for certain IPPS-excluded hospitals that receive payments on a reasonable cost basis subject to these limits. The proposed updated rate-of-increase limits would apply to cost	



Ref. # Short Title/Current Status of Regulation/Title/ Agency File Code Stile Date & File Date Stile Date Stile Date Stile Date & File Date Stile Date Sti	NIHB Recs.
the Long-Term Care Hospital PPS and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital CoP Action, If any, Issued correction 10/3/2013; Issued correction 10/3/2014; Issued correction 10/3/2015; Issued correction 10/3/2014; Issued correction 10/3/2015; Issued correction 10/3/2016; Issued correction 10/2016; Issued	



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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.
					This final rule also updates the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implements certain statutory changes applied to LTCH PPS by ACA. Generally, these updates and statutory changes will apply to discharges occurring on or after October 1, 2013, unless otherwise specified in this final rule.	
					In addition, this final rule makes a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. This final rule establishes new requirements or revises requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that participate in Medicare.	
					This final rule updates policies relating to the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program. In addition, this final rule revises the conditions of participation (CoPs) for hospitals relating to the administration of vaccines by nursing staff, as well as CoPs for critical access hospitals relating to the provision of acute care inpatient services.	
					This final rule finalizes proposals issued in two separate proposed rules that included payment policies related to patient status: payment of Medicare Part B inpatient services; and admission and medical review criteria for payment of hospital inpatient services under Medicare Part A.	
					http://www.gpo.gov/fdsys/pkg/FR-2013-08-19/pdf/2013-18956.pdf	
					CMS on 10/3/2013 issued a document (CMS-1599 & 1455-CN2) that corrects technical and typographical errors in the final rule that appeared in the 8/19/2013 FR.	
					http://www.gpo.gov/fdsys/pkg/FR-2013-10-03/pdf/2013-24211.pdf	
					CMS on 1/2/2014 issued a document (CMS-1599 & 1455-CN3) that corrects technical errors in the final rules that appeared in the 8/19/2013 FR. This document corrects IPPS Table 2 and Table 3A and LTCH Table 12A in the final rules.	
					http://www.gpo.gov/fdsys/pkg/FR-2014-01-02/pdf/2013-31432.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 1/10/2014 issued a document (CMS-1599-CN4) that corrects technical errors in the correcting document that appeared in the 1/2/2014 FR. On page 61 of the correcting document, CMS inadvertently omitted some CFR part numbers from the heading and inadvertently omitted the applicability date from the DATES section. http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2014-00273.pdf CMS on 3/18/2014 issued a document (CMS-1599-& 1455-CN5) to correct technical errors that appeared in these final rules. On page 50695 of the final rules, in the table titled "Finalized Performance Standards for Certain FY 2016 Hospital VBP Program Outcome Domain Measures," CMS did not make the performance standards for the PSI-90 measure consistent with the FY 2016 performance standards it finalized for that measure. http://www.gpo.gov/fdsys/pkg/FR-2014-03-18/pdf/2014-05837.pdf	
25.m.	Geographic Classification Review Board Procedures ACTION: Request for Comment NOTICE: Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations AGENCY: CMS	CMS-R-138	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 12/13/2013 Due Date: 1/13/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement without change of a currently approved collection; Title: Medicare Geographic Classification Review Board (MGCRB) Procedures and Supporting Regulations; Use: The information submitted by the hospitals serves to determine the validity of the hospital requests and the discretion used by the Medicare Geographic Classification Review Board (MGCRB) in reviewing and making decisions regarding hospital requests for geographic reclassification. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/13/2013 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-12-13/pdf/2013-29726.pdf A Supporting Statement for this PRA request is available at http://www.cms.gov/Regulations-and- Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R- 138.html.	



Ref.	Short Title/Current Status of Regulation/Title/ 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.n.	Inpatient Rehab Facilities Quality Reporting Program Evaluation ACTION: Request for Comment NOTICE: Inpatient Rehabilitation Facilities Quality Reporting Program: Program Evaluation AGENCY: CMS	CMS-10503	Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/10/2014 Due Date: 4/9/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Inpatient Rehabilitation Facilities Quality Reporting Program: Program Evaluation; Use: Section 3004(a) of ACA mandated that CMS establish a quality reporting program for Inpatient Rehabilitation Facilities (IRFs). Specifically, section 3004(a) added section 1886(j)(7) to the Social Security Act (the Act) to establish a quality reporting program for IRFs. This program requires IRFs to submit quality data in a time, form and manner specified by the HHS Secretary. CMS seeks to explore how IRFs respond to the new quality reporting program (QRP) and its measures. CMS believes in the importance of understanding early trends in outcomes, making adjustments as needed to enhance the effectiveness of QRP, seeking opportunities to minimize provider burden, and ensuring the meaningfulness of the program to providers. The methodology employed in the evaluation uses qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, CMS has decided that using a rich, contextual approach to evaluate the process and success of QRP will prove most beneficial at this time. The information collected will help inform CMS about QRP-related experiences, such as program impact related to quality improvement, burden, process-related issues, and education. This information also will inform future measurement development for the IRF QRP, future steps related to data validation, and future monitoring and evaluation. 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 3/10/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-03-10/pdf/2014-05104.pdf	
25.0.	Conditions of Participation for Critical Access Hospitals ACTION: Request for Comment	CMS-10239	<u>Issue Date:</u> 12/20/2013 <u>Due Date:</u> 2/18/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Conditions of Participation for Critical Access Hospitals (CAH) and Supporting Regulations; Use: At the outset of the CAH program, CMS-R-48 addressed all of the information collection requirements for all CAHs. As the CAH program has grown in scope of services and the number of providers, CMS has separated the burden associated with CAHs with distinct part units (DPUs) from the	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB	Brief Summary of Proposed Agency Action	NIHB Recs.
#	Agency	File Code	File Date	Response	and Summary of NIHB Analysis	NIND Recs.
	NOTICE: Conditions of Participation for Critical Access Hospitals (CAH) and Supporting Regulations AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/17/2014 Due Date: 4/16/2014		burden associated with CAHs without DPUs. Section 1820(c)(2)(E)(i) of the Social Security Act provides that a CAH can establish and operate a psychiatric or rehabilitation DPU. Each DPU can maintain as many as 10 beds and must comply with the hospital requirements specified in 42 CFR Subparts A, B, C, and D of part 482. Presently, 105 CAHs have rehabilitation or psychiatric DPUs. The burden associated with CAHs that have DPUs continues to fall under CMS-R-48, along with the burden for all 4,890 accredited and non-accredited hospitals. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30337.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/17/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-03-17/pdf/2014-05785.pdf	
25.p.	Medicare/Medicaid Psychiatric Hospital Survey Data ACTION: Request for Comment NOTICE: Medicare/Medicaid Psychiatric Hospital Survey Data AGENCY: CMS	CMS-724	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/17/2014 Due Date: 4/16/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title: Medicare/Medicaid Psychiatric Hospital Survey Data; Use: CMS-724 form collects data not collected elsewhere and assists CMS in program planning and evaluation and in maintaining an accurate database on providers participating in the psychiatric hospital program. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30994.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/17/2014 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2014-03-17/pdf/2014-05785.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.
25.q.	Hospital Conditions of Participation ACTION: Request for Comment NOTICE: Hospital Conditions of Participation and Supporting Regulations AGENCY: CMS	CMS-R-48	Issue Date: 1/31/2014 Due Date: 4/4/2014 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: Hospital Conditions of Participation and Supporting Regulations; Use: CMS surveyors use the conditions of participation (CoP) and accompanying requirements specified in the supporting regulations as a basis for determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid. The requirements described in this information collection request apply to 4,890 accredited and non-accredited hospitals and an additional 101 critical access hospitals (CAHs) that have distinct part psychiatric or rehabilitation units (DPUs). http://www.gpo.gov/fdsys/pkg/FR-2014-01-31/pdf/2014-02065.pdf SUMMARY OF NIHB ANALYSIS:	
25.r.	Extension of Payment Adjustment for Low- Volume Hospitals ACTION: Interim Final Rule NOTICE: Medicare Program; Extension of the Payment Adjustment for Low-Volume Hospitals and the Medicare- Dependent Hospital (MDH) Program Under the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals for Fiscal Year 2014 AGENCY: CMS	CMS-1599- IFC2	Issue Date: 3/18/2014 Due Date: 5/13/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This interim final rule with comment period implements changes to the payment adjustment for low-volume hospitals and to the Medicare dependent hospital (MDH) program under the hospital inpatient prospective payment systems (IPPS) for FY 2014 (through 3/31/2014) in accordance with sections 1105 and 1106, respectively, of the Pathway for SGR Reform Act of 2013. http://www.gpo.gov/fdsys/pkg/FR-2014-03-18/pdf/2014-05922.pdf SUMMARY OF NIHB ANALYSIS: These payment policies might affect some I/T hospitals. An analysis of the impact of the payment reductions to rural hospital providers appears in the document embedded below (NOTE: Congress might delay these reductions).	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
25.s.	Medicare PPS for Inpatient Rehab Facilities for FY 2015 ACTION: Proposed Rule NOTICE: Medicare Program; Inpatient Rehabilitation Facility PPS for Federal Fiscal Year 2015 AGENCY: CMS	CMS-1608-P	Issue Date: 5/7/2014 Due Date: 6/30/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal FY 2015 (for discharges occurring on or after 10/1/2014, and on or before 9/30/2015) as required by statute. CMS also proposes to collect data on the amount and mode (i.e., Individual, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline, revise the list of impairment group codes that presumptively meet the "60 percent rule" compliance criteria, provide for a new item on the IRF-Patient Assessment Instrument (IRF-PAI) form to indicate compliance with the prior treatment and severity requirements for arthritis cases to presumptively meet the "60 percent rule" compliance criteria, and revise and update quality measures and reporting requirements under the IRF quality reporting program (QRP). In this proposed rule, CMS also address the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), for the IRF prospective payment system (PPS), effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. http://www.gpo.gov/fdsys/pkg/FR-2014-05-07/pdf/2014-10321.pdf SUMMARY OF NIHB ANALYSIS:	
25.t.	Psychiatric Unit Criteria Work Sheet ACTION: Request for Comment NOTICE: Psychiatric Unit Criteria Work Sheet and Supporting Regulations AGENCY: CMS	CMS-437	Issue Date: 4/4/2014 Due Date: 6/3/2014 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: Psychiatric Unit Criteria Work Sheet and Supporting Regulations; Use: CMS proposes to continue the current process of performing initial verifications and annual re-verifications to determine that psychiatric units continue to comply with the regulatory criteria at 42 CFR 412.25 and 42 CFR 412.27 of the Medicare Prospective Payment System (PPS) regulations. These regulations state the criteria that distinct part units must meet for exclusion from PPS. If, as a result of the regular survey process, a State survey agency (SA) certifies a hospital as a psychiatric hospital, then it automatically satisfies the regulatory criteria for exclusion. However, CMS requires some verification to ensure that other types of hospitals and units meet the criteria for exclusion. Consequently, CMS instructed the Fiscal Intermediaries (FIs) and SAs to perform certain verification activities, beginning in October 1983 when PPS took effect. CMS originally developed CMS-437 as an SA	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Worksheet for verifying exclusions from PPS for psychiatric units. Since 4/9/1994, PPS-excluded psychiatric units already excluded from the PPS have met an annual requirement for PPS-exclusion by self-attesting that they remain in compliance with the PPS exclusion criteria. Under the current procedure, SAs survey all psychiatric units applying for first-time exclusion. The SAs also perform surveys to investigate complaint allegations and conduct annual sample re-verification surveys on 5 percent of all psychiatric units. The aforementioned exclusions continue to exist, and CMS thus proposes to continue to use the Criteria Worksheet, CMS-437, for verifying first-time exclusions from the PPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. http://www.gpo.gov/fdsys/pkg/FR-2014-04-04/pdf/2014-07575.pdf SUMMARY OF NIHB ANALYSIS:	
25.u.	Medicare PPS for Inpatient Psychiatric Facilities for FY 2015 ACTION: Proposed Rule NOTICE: Medicare Program; Inpatient Psychiatric Facilities Prospective Payment SystemUpdate for Fiscal Year Beginning October 1, 2014 (FY 2015) AGENCY: CMS	CMS-1606-P	Issue Date: 5/6/2014 Due Date: 6/30/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would update the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs). These changes would apply to IPF discharges occurring during the fiscal year (FY) beginning 10/1/2014 through 9/30/2015. This proposed rule also would address implementation of ICD-10-CM and ICD-10-PCS codes; propose a new methodology for updating the cost of living adjustment (COLA), and propose new quality measures and reporting requirements under the IPF quality reporting program. http://www.gpo.gov/fdsys/pkg/FR-2014-05-06/pdf/2014-10306.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.
25.v.	Acute Care Hospital IPPS and LTCH PPS for FY 2015, et al. ACTION: Proposed Rule NOTICE: Medicare Program; Hospital IPPS for Acute Care Hospitals and the Long-Term Care Hospitals PPS and Proposed FY 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and EHR Incentive Program AGENCY: CMS	CMS-1607-P	Issue Date: 5/15/2014 Due Date: 6/30/2014 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 systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from continuing CMS experience with these systems. Some of the proposed changes would implement certain statutory provisions contained in ACA, the Protecting Access to Medicare Act of 2014, and other legislation. These proposed changes would apply to discharges occurring on or after 10/1/2014 unless otherwise specified in this proposed rule. This proposed rule also would update the rate-of-increase limits for certain hospitals excluded from IPPS that receive payment on a reasonable cost basis subject to these limits. The proposed updated rate-of-increase limits would apply to cost reporting periods beginning on or after 10/1/2014. This proposed rule also 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) and to implement certain statutory changes to the LTCH PPS under ACA, the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013, and the Protecting Access to Medicare Act of 2014. In addition, this proposed rule would revise the interruption of stay policy for LTCHs and retire the "5 percent" payment adjustment for co-located LTCHs. While many of the statutory mandates of the Pathway for SGR Reform Act will apply to discharges occurring on or after 10/1/2014, others will not begin to apply until 2016 and beyond. However, in light of the degree of forthcoming change, this proposed rule discusses changes infra and requests public feedback to inform CMS proposals for FY 2016. Further, this proposed rule would make a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. This proposed rule would establish new requirements or revise requirements for quality reporting by specific providers (acute	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					teaching hospitals excluded from the IPPS; regulatory revisions to broaden the specified uses of risk adjustment data and to specify the conditions for release of risk adjustment data to entities outside of CMS; and changes to the enforcement procedures for organ transplant centers.	
					This proposed rule would align the reporting and submission timelines for clinical quality measures for the Medicare EHR Incentive Program for eligible hospitals and critical access hospitals (CAHs) with the reporting and submission timelines for the Hospital IQR Program. In addition, this proposed rule provides guidance and clarification of certain policies for eligible hospitals and CAHs, such as CMS policy for reporting zero denominators on clinical quality measures and its policy for case threshold exemptions. http://www.gpo.gov/fdsys/pkg/FR-2014-05-15/pdf/2014-10067.pdf	
					SUMMARY OF NIHB ANALYSIS:	
27.c.	Reinsurance, Risk	CMS-10401	Issue Date:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of	
21.6.	Corridors, and Risk	CIVIS-10401	1/25/2013		a currently approved collection; Title: Standards Related to Reinsurance, Risk Corridors,	
	Adjustment Standards		Due Date:		and Risk Adjustment; <i>Use</i> : Section 1341 of ACA provides that each State must establish a transitional reinsurance program to help stabilize premiums for coverage in the	
	ACTION: Request for		3/26/2013		individual market during the first three years of Exchange operation. Section 1342	
	Comment		NIHB File		provides for the establishment of a temporary risk corridors program that will apply to qualified health plans in the individual and small group markets for the first three years of	
	NOTICE: Standards Related		Date:		Exchange operation. Section 1343 provides for a program of risk adjustment for all non-	
	to Reinsurance, Risk Corridors, and Risk		Date of		grandfathered plans in the individual and small group market both inside and outside of the Exchange. These risk-spreading programs seek to mitigate adverse selection and	
	Adjustment		Subsequent		provide stability for health insurance issuers in the individual and small group markets as	
	AGENCY: CMS		Agency Action, if any:		market reforms and Exchanges are implemented. Section 1321(a) also provides broad authority for the HHS Secretary to establish standards and regulations to implement the	
	AGENCI. CIVIS		Issued		statutory requirements related to Exchanges, reinsurance, risk adjustment, and other	
			revision		components of title I of ACA. The data collection and reporting requirements	
			5/24/2013;		described in this information collection request will enable states, HHS, or both	
			issued revision 5/16/2014		states and HHS to implement the aforementioned programs, which will mitigate the impact of adverse selection in the individual and small group markets both inside and	
			0/10/2017		outside the Exchange.	
			Due Date:		http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01570.pdf	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date 6/24/2013; 6/16/2014	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/24/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12465.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/16/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-05-16/pdf/2014-11388.pdf	NIHB Recs.
27.f.	Risk Corridors and Budget Neutrality ACTION: Guidance NOTICE: Risk Corridors and Budget Neutrality AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 4/11/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This guidance answers several frequently asked questions on the risk corridors program, which CMS has said it plans to implement in a budget neutral manner. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/faq-risk-corridors-04-11-2014.pdf SUMMARY OF NIHB ANALYSIS:	
27.g.	Reinsurance Contributions Process ACTION: Guidance NOTICE: Reinsurance Contributions Process	CCIIO (no reference number)	Issue Date: 5/22/2014 Due Date: None NIHB File Date:		SUMMARY OF AGENCY ACTION: This guidance answers the frequently asked question (FAQ) of how a contributing entity will complete the reinsurance contributions process. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Reinsurance-contributions-process-FAQ-5-22-14.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.
	AGENCY: CCIIO		Date of Subsequent Agency Action, if any:			
28.e.	FMAP Notice for FY 2015 ACTION: Notice NOTICE: Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2014, Through September 30, 2015 AGENCY: HHS	HHS (no reference number)	Issue Date: 1/21/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: HHS has calculated the Federal Medical Assistance Percentages (FMAPs), Enhanced Federal Medical Assistance Percentages (eFMAPs), and disaster-recovery FMAP adjustments for FY 2015 pursuant to the Social Security Act (the Act). These percentages will remain effective from October 1, 2014, through September 30, 2015. This notice announces the calculated FMAP and eFMAP rates that HHS will use in determining the amount of federal matching for state medical assistance (Medicaid) and Children's Health Insurance Program (CHIP) expenditures, Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Foster Care Title IV-E Maintenance payments, and Adoption Assistance payments. This notice also announces the disaster-recovery FMAP adjustments that HHS will use in determining the amount of federal matching for state medical assistance (Medicaid) and title IV-E Foster Care and Adoption Assistance and Guardianship Assistance programs for qualifying States for FY 2015. http://www.gpo.gov/fdsys/pkg/FR-2014-01-21/pdf/2014-00931.pdf SUMMARY OF NIHB ANALYSIS:	
29.e.	Information Reporting for Exchanges ACTION: Proposed Final Rule NOTICE: Information Reporting for Affordable Insurance Exchanges	REG- 140789-12 TD 9663	Issue Date: 7/2/2013 Due Date: 9/3/2013 TTAG File Date: 9/3/2013; TSGAC and	TTAG response: TSGAC response: ANTHC response:	SUMMARY OF AGENCY ACTION: This document contains proposed regulations relating to requirements for Affordable Insurance Exchanges (Exchanges) to report information relating to the health insurance premium tax credit enacted by ACA. These proposed regulations affect Exchanges that make qualified health plans available to individuals and employers. http://www.gpo.gov/fdsys/pkg/FR-2013-07-02/pdf/2013-15943.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule provides an option for an additional person to receive the notice(s) from an Exchange. This might prove particularly	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.
	AGENCY: IRS		ANTHC also filed comments 9/3/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 5/7/2014		helpful in instances in which a tribe or tribal organization provides premium sponsorship to an Al/AN through an Exchange. The final rule might require clarification to ensure this option aligns with the authorized representative function with regard to notices. SUMMARY OF SUBSEQUENT AGENCY ACTION: This document contains final regulations relating to requirements for Exchanges to report information relating to the health insurance premium tax credit enacted by ACA. These final regulations apply to Exchanges that make qualified health plans available to individuals. http://www.gpo.gov/fdsys/pkg/FR-2014-05-07/pdf/2014-10419.pdf	
29.g.	Payment Collections Operations Contingency Plan ACTION: Request for Comment NOTICE: Payment Collections Operations Contingency Plan AGENCY: CMS	CMS-10515	Issue Date: 12/27/2013 Due Date: 1/27/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/31/2014 Due Date: 4/4/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Payment Collections Operations Contingency Plan; Use: Under sections 1401, 1411, and 1412 of ACA and 45 CFR part 155 subpart D, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in QHP coverage through the Exchange and seek financial assistance. Using information available at the time of enrollment, the Exchange determines whether the individual meets the income and other requirements for advance payments and the amount of the advance payments available pay premiums. Under section 1412, advance payments occur periodically to the issuer of the QHP in which the individual enrolls. Section 1402 provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 provides for the advance payment of these reductions to issuers. The statute directs issuers to reduce cost sharing for essential health benefits for individuals who have household incomes between 100 and 400 percent of the federal poverty level (FPL), enroll in a silver-level QHP through an individual market Exchange, and qualify for advance payments of the premium tax credit. HHS will use the data collection to make payments or collect charges from issuers under the following programs: advance payments of the premium tax credit, advanced cost-sharing reductions, and Marketplace user fees. HHS will use the template to make payments in January 2014 and for a number of months thereafter. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-31015.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 1/31/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-31/pdf/2014-02065.pdf	
29.h.	Verification of Income for Tax Credits and Cost Sharing ACTION: Guidance NOTICE: Verification of Household Income and Other Qualifications for the Provision of Affordable Care Act Premium Tax Credits and Cost-Sharing Reductions AGENCY: HHS	HHS (no reference number)	Issue Date: 12/31/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This report describes the statutory, regulatory, and policy requirements that both State-based Marketplaces and Federally-facilitated Marketplaces must follow. This report also discusses each verification requirement and describes the operational processes used for each verification. http://www.cms.gov/CCIIO/Resources/Letters/Downloads/verifications-report-12-31-2013.pdf SUMMARY OF NIHB ANALYSIS: This document reviews the verification requirements and processes for each of the data elements HHS will gather through the application process. HHS prepared this report in response to the provision in the recent budget agreement requiring the HHS Secretary to certify the occurrence of income verification.	
29.i.	Victims of Domestic Abuse ACTION: Guidance NOTICE: Victims of Domestic Abuse AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/31/2014 Due Date: None NIHB File Date: Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: The Department of the Treasury recently clarified that a married individual who lives apart from his or her spouse at the time of filing an income tax return for 2014 and cannot file a joint return as a result of domestic abuse can claim a premium tax credit while filing a tax return with a filing status of married filing separately. This guidance provides two options for Marketplaces to ensure immediate implementation of this rule for the purpose of determining eligibility for advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSR). http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/victims-domestic-violence-guidance-3-31-2014.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This guidance provides	



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Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Action, if any:		two options for Marketplaces to ensure immediate implementation of this rule for the purpose of determining eligibility for advance payments of the premium tax credit (APTC) and cost-sharing reductions (CSR). First, a Marketplace can elect to determine victims of domestic abuse who meet the criteria described above, including attesting to an expected filing status of married, filing separately, eligible for APTC and CSR to the extent that they are otherwise eligible. Alternatively, a Marketplace can elect to permit these individuals to indicate on the application that they are unmarried, without fear of penalty for misreporting marital status, and determine them eligible for APTC and CSR on this basis. The Federally-Facilitated Marketplace (FFM) will take the latter approach. To ensure that eligible individuals who are victims of domestic abuse can enroll in a qualified health plan through the Marketplace with APTC and CSR, CMS is clarifying the availability of a special enrollment period in the FFM ending on 5/30/2014. State-Based Marketplaces similarly can determine these individuals and their dependents eligible for a	
					60-day special enrollment period.	
31.f.	Employer Shared Responsibility	REG- 138006-12 TD 9655	<u>Issue Date:</u> 1/2/2013		SUMMARY OF AGENCY ACTION: This document contains proposed regulations providing guidance under section 4980H of the Internal Revenue Code (Code) with respect to the shared responsibility for employers regarding employee health coverage.	
	ACTION: Proposed Final Rule		<u>Due Date:</u> 3/18/2013		These proposed regulations would affect only employers that meet the definition of "applicable large employer" as described in these proposed regulations. As discussed in section X of this preamble, employers may rely on these proposed regulations for	
	NOTICE: Shared Responsibility for Employers		NIHB File Date: None		guidance pending the issuance of final regulations or other applicable guidance. This document also provides notice of a public hearing on these proposed regulations.	
	Regarding Health Coverage AGENCY: IRS		Date of Subsequent		SUMMARY OF NIHB ANALYSIS: (Edited summary from IRS.)	
			Agency		BASICS OF THE EMPLOYER SHARED RESPONSIBILITY PROVISIONS	
			Action, if any:		1. What are the Employer Shared Responsibility provisions? Starting in 2014, employers employing at least a certain number of employees (generally 50 full-time	
			correction		employees and full-time equivalents, explained more fully below) will be subject to the	
			3/15/2013;		Employer Shared Responsibility provisions under section 4980H of the Internal Revenue	
			issued Final		Code (added to the Code by the Affordable Care Act). Under these provisions, if these	
			Rule		employers do not offer affordable health coverage that provides a minimum level of	
			2/12/2014		coverage to their full-time employees, they may be subject to an Employer Shared	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Responsibility payment if at least one of their full-time employees receives a premium tax credit for purchasing individual coverage on one of the new Affordable Insurance Exchanges.	
					To be subject to these Employer Shared Responsibility provisions, an employer must have at least 50 full-time employees or a combination of full-time and part-time employees that is equivalent to at least 50 full-time employees (for example, 100 half-time employees equals 50 full-time employees). As defined by the statute, a full-time employee is an individual employed on average at least 30 hours per week (so half-time would be 15 hours per week).	
					2. When do the Employer Shared Responsibility provisions go into effect? The Employer Shared Responsibility provisions generally go into effect on January 1, 2014. Employers will use information about the employees they employ during 2013 to determine whether they employ enough employees to be subject to these new provisions in 2014. See question 4 for more information on determining whether an employer is subject to the Employer Shared Responsibility provisions.	
					Which Employers are Subject to the Employer Shared Responsibility provisions apply only to employers employing at least a certain number of employees? How does an employer know whether it employs enough employees to be subject to the provisions? To be subject to the Employer Shared Responsibility provisions, an employer must employ at least 50 full-time employees or a combination of full-time and part-time employees that equals at least 50 (for example, 40 full-time employees employed 30 or more hours per week on average plus 20 half-time employees employed 15 hours per week on average are equivalent to 50 full-time employees). Employers will determine each year, based on their current number of employees, whether they will be considered a large employer for the next year. For example, if an employer has at least 50 full-time employees, (including full-time equivalents) for 2013, it will be considered a large employer for 2014.	
					Employers average their number of employees across the months in the year to see whether they meet the large employer threshold. The averaging can take account of fluctuations that many employers may experience in their work force across the year. For those employers that may be close to the 50 full-time employee (or equivalents) threshold and need to know what to do for 2014, special transition relief is available 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.
					help them count their employees in 2013. See question 19 below for information about this transition relief. The proposed regulations provide additional information about how to determine the average number of employees for a year, including information about how to take account of salaried employees who may not clock their hours and a special rule for seasonal workers.	
					5. If two or more companies have a common owner or are otherwise related, are they combined for purposes of determining whether they employ enough employees to be subject to the Employer Shared Responsibility provisions? Yes, consistent with longstanding standards that apply for other tax and employee benefit purposes, companies that have a common owner or are otherwise related generally are combined together for purposes of determining whether or not they employ at least 50 full-time employees (or an equivalent combination of full-time and part-time employees). If the combined total meets the threshold, then each separate company is subject to the Employer Shared Responsibility provisions, even those companies that individually do not employ enough employees to meet the threshold. (The rules for combining related employers do not apply for purposes of determining whether an employer owes an Employer Shared Responsibility payment or the amount of any payment). The proposed regulations provide information on the rules for determining whether companies are related and how they are applied for purposes of the Employer Shared Responsibility provisions.	
					6. Do the Employer Shared Responsibility provisions apply only to large employers that are for-profit businesses or to other large employers as well? All employers that employ at least 50 full-time employees or an equivalent combination of full-time and part-time employees are subject to the Employer Shared Responsibility provisions, including for-profit, non-profit and government entity employers.	
					7. Which employers are not subject to the Employer Shared Responsibility provisions? Employers who employ fewer than 50 full-time employees (or the equivalent combination of full-time and part-time employees) are not subject to the Employer Shared Responsibility provisions. An employer with at least 50 full-time employees (or equivalents) will not be subject to an Employer Shared Responsibility payment if the employer offers affordable health coverage that provides a minimum level of coverage to its full-time employees.	
					LIABILITY FOR THE EMPLOYER SHARED RESPONSIBILITY PAYMENT	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					10. Under what circumstances will an employer owe an Employer Shared Responsibility payment? In 2014, if an employer meets the 50 full-time employee threshold, the employer generally will be liable for an Employer Shared Responsibility payment only if:	
					(a) The employer does not offer health coverage or offers coverage to less than 95% of its full-time employees, and at least one of the full-time employees receives a premium tax credit to help pay for coverage on an Exchange; [No requirement to offer coverage to dependents in 2014.], or	
					(b) The employer offers health coverage to at least 95% of its full-time employees, but at least one full-time employee receives a premium tax credit to help pay for coverage on an Exchange, which may occur because the employer did not offer coverage to that employee or because the coverage the employer offered that employee was either unaffordable to the employee (see question 11, below) or did not provide minimum value (see question 12, below).	
					After 2014, the rule in paragraph (a) applies to employers that do not offer health coverage or that offer coverage to less than 95% of their full time employees and the dependents of those employees. ["Dependents" do not include spouses.]	
					11. How does an employer know whether the coverage it offers is affordable? If an employee's share of the premium for employer-provided coverage would cost the employee more than 9.5% of that employee's annual household income, the coverage is not considered affordable for that employee. If an employer offers multiple healthcare coverage options, the affordability test applies to the lowest-cost option available to the employee that also meets the minimum value requirement (see question 12, below.) Because employers generally will not know their employees' household incomes, employers can take advantage of one of the affordability safe harbors set forth in the proposed regulations. Under the safe harbors, an employer can avoid a payment if the cost of the coverage to the employee would not exceed 9.5% of the wages the employer pays the employee that year, as reported in Box 1 of Form W-2, or if the coverage satisfies either of two other design-based affordability safe harbors.	
					12. How does an employer know whether the coverage it offers provides minimum value? A minimum value calculator will be made available by the IRS and the Department of Health and Human Services (HHS). The minimum value calculator will	



Ref.	Short Title/Current Status		Issue Date;	NIHB	Brief Summary of Proposed Agency Action	
#	of Regulation/Title/ Agency	File Code	Due Date & File Date	Response	and Summary of NIHB Analysis	NIHB Recs.
					work in a similar fashion to the <u>actuarial value calculator</u> that HHS is making available. Employers can input certain information about the plan, such as deductibles and copays, into the calculator and get a determination as to whether the plan provides minimum value by covering at least 60 percent of the total allowed cost of benefits that are expected to be incurred under the plan.	
					13. If an employer wants to be sure it is offering coverage to all of its full-time employees, how does it know which employees are full-time employees? Does the employer need to offer the coverage to all of its employees because it won't know for certain whether an employee is a full-time employee for a given month until after the month is over and the work has been done? The proposed regulations provide a method to employers for determining in advance whether or not an employee is to be treated as a full-time employee, based on the hours of service credited to the employee during a previous period. Using this look-back method to measure hours of service, the employer will know the employee's status as a full-time employee at the time the employer would offer coverage. The proposed regulations are consistent with IRS notices that have previously been issued and describe approaches that can be used for various circumstances, such as for employees who work variable hour schedules, seasonal employees, and teachers who have time off between school years.	
					CALCULATION OF THE EMPLOYER SHARED RESPONSIBILITY PAYMENT 14. If an employer that does not offer coverage or offers coverage to less than 95% of its employees owes an Employer Shared Responsibility payment, how is the amount of the payment calculated? In 2014, if an employer employs enough employees to be subject to the Employer Shared Responsibility provisions and does not offer coverage during the calendar year to at least 95% of its full-time employees, it owes an Employer Shared Responsibility payment equal to the number of full-time employees the employer employed for the year (minus 30) multiplied by \$2,000, as long as at least one full-time employee receives the premium tax credit. (Note that for purposes of this calculation, a full-time employee does not include a full-time equivalent). For an employer that offers coverage for some months but not others during the calendar year, the payment is computed separately for each month for which coverage was not offered. The amount of the payment for the month equals the number of full-time employees the employer employed for the month (minus up to 30) multiplied by 1/12 of \$2,000. If the employer is related to other employers (see question 5 above), then the 30-employee exclusion is allocated among all the related employers. The payment for the calendar year is the sum of the monthly payments computed for each month for which coverage	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					was not offered. After 2014, these rules apply to employers that do not offer coverage or that offer coverage to less than 95% of their full time employees and the dependents of those employees.	
					15. If an employer offers coverage to at least 95% of its employees, and, nevertheless, owes the Employer Shared Responsibility payment, how is the amount of the payment calculated? For an employer that offers coverage to at least 95% of its full-time employees in 2014, but has one or more full-time employees who receive a premium tax credit, the payment is computed separately for each month. The amount of the payment for the month equals the number of full-time employees who receive a premium tax credit for that month multiplied by 1/12 of \$3,000. The amount of the payment for any calendar month is capped at the number of the employer's full-time employees for the month (minus up to 30) multiplied by 1/12 of \$2,000. (The cap ensures that the payment for an employer that offers coverage can never exceed the payment that employer would owe if it did not offer coverage). After 2014, these rules apply to employers that offer coverage to at least 95% of full time employees and the dependents of those employees.	
					MAKING AN EMPLOYER SHARED RESPONSIBILITY PAYMENT 16. How will an employer know that it owes an Employer Shared Responsibility payment? The IRS will contact employers to inform them of their potential liability and provide them an opportunity to respond before any liability is assessed or notice and demand for payment is made. The contact for a given calendar year will not occur until after employees' individual tax returns are due for that year claiming premium tax credits and after the due date for employers that meet the 50 full-time employee (plus full-time equivalents) threshold to file the information returns identifying their full-time employees and describing the coverage that was offered (if any).	
					17. How will an employer make an Employer Shared Responsibility payment? If it is determined that an employer is liable for an Employer Shared Responsibility payment after the employer has responded to the initial IRS contact, the IRS will send a notice and demand for payment. That notice will instruct the employer on how to make the payment. Employers will not be required to include the Employer Shared Responsibility payment on any tax return that they file.	
					TRANSITION RELIEF 18. I understand that the Employer Shared Responsibility provisions do not go into	



National Indian Health Board Table B: Summary of Notices & Regulations UPDATED THROUGH 5/31/2014

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					effect until 2014. However, the health plan that I offer to my employees runs on a fiscal plan year that starts in 2013 and will run into 2014. Do I need to make sure my plan complies with these new requirements in 2013 when the next fiscal plan year starts? For an employer that as of December 27, 2012, already offers health coverage through a plan that operates on a fiscal year (a fiscal year plan), transition relief is available. First, for any employees who are eligible to participate in the plan under its terms as of December 27, 2012 (whether or not they take the coverage), the employer will not be subject to a potential payment until the first day of the fiscal plan year starting in 2014. Second, if (a) the fiscal year plan (including any other fiscal year plans that have the same plan year) was offered to at least one third of the employer's employees (full-time and part-time) at the most recent open season or (b) the fiscal year plan covered at least one quarter of the employer's employees, then the employer also will not be subject to the Employer Shared Responsibility payment with respect to any of its full-time employees are offered affordable coverage that provides minimum value no later than that first day. So, for example, if during the most recent open season preceding December 27, 2012, an employer offered coverage under a fiscal year plan with a plan year starting on July 1, 2013 to at least one third of its employees (meeting the threshold for the additional relief), the employer could avoid liability for a payment if, by July 1, 2014, it expanded the plan to offer coverage satisfying the Employer Shared Responsibility provisions to the full-time employees who had not been offered coverage. For purposes of determining whether the plan covers at least one quarter of the employer's employees, an employer may look at any day between October 31, 2012 and December 27, 2012. 19. Is transition relief available to help employers that are close to the 50 full-time employees (or an equivalent number of	
					20. When can an employee receive a premium tax credit? Premium tax credits generally are available to help pay for coverage for employees who	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
		File Code			 are between 100% and 400% of the federal poverty level and enroll in coverage through an Affordable Insurance Exchange, are not eligible for coverage through a government-sponsored program like Medicaid or CHIP, and are not eligible for coverage offered by an employer or are eligible only for employer coverage that is unaffordable or that does not provide minimum value. 21. If an employer does not employ enough employees to be subject to the Employer Shared Responsibility provisions, does that affect the employer's employees' eligibility for a premium tax credit? No. The rules for how eligibility for employer-sponsored insurance affects eligibility for the premium tax credit are the same, regardless of whether the employer employs enough employees to be subject to the Employer Shared Responsibility provisions. SUMMARY OF SUBSEQUENT AGENCY ACTION: IRS on 3/15/2013 issued a correction to these proposed regulations. IRS on 2/12/2014 issued a document that contains final regulations providing guidance to employers subject to the shared responsibility provisions regarding employee health coverage under section 4980H of the Internal Revenue Code (Code), enacted by ACA. These regulations affect employers referred to as applicable large employers (generally meaning, for each year, employers that had 50 or more full-time employees, including full-time equivalent employees, during the prior year). Generally, under section 4980H, if an applicable large employer, for a calendar month, fails to offer to its full-time employees health coverage that is affordable and that provides minimum value, it might 	NIHB Recs.
					face an assessable payment if a full-time employee enrolls for that month in a qualified health plan for which the employee receives a premium tax credit. http://www.gpo.gov/fdsys/pkg/FR-2014-02-12/pdf/2014-03082.pdf	
					The final regulations give medium-sized employersthose with between 50 and 99 employeesan extra year, until 2016, before they must offer health insurance to their full-time employees or potentially face an assessable payment	
					A Q&A on employer shared responsibility provisions under ACA is available at http://www.irs.gov/uac/Newsroom/Questions-and-Answers-on-Employer-Shared-	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Responsibility-Provisions-Under-the-Affordable-Care-Act. A Q&A on determining full-time equivalent employees and average annual wages for the small business health care tax credit is available at http://www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-Questions-and-Answers:-Determining-FTEs-and-Average-Annual-Wages . A Q&A on employer health care arrangements is available at http://www.irs.gov/uac/Newsroom/Employer-Health-Care-Arrangements .	
31.0.	Health Insurance Coverage Reporting by Large Employers ACTION: Proposed-Final Rule NOTICE: Information Reporting by Applicable Large Employers on Health Insurance Coverage Offered Under Employer-Sponsored Plans AGENCY: IRS	REG- 136630-12 TD 9661	Issue Date: 9/9/2013 Due Date: 11/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/10/2014		SUMMARY OF AGENCY ACTION: This document contains proposed regulations providing guidance to employers subject to the information reporting requirements under section 6056 of the Internal Revenue Code (Code), enacted by ACA. Section 6056 requires those employers to report to IRS information about their compliance with the employer shared responsibility provisions of section 4980H of the Code and about the health coverage they have offered employees. Section 6056 also requires those employers to furnish to employees related statements they can use to help determine whether, for each month of the calendar year, they can claim on their tax returns a premium tax credit under section 36B of the Code (premium tax credit). In addition, that information will help administer and ensure compliance with the eligibility requirements for the employer shared responsibility provisions and the premium tax credit. The proposed regulations affect applicable large employers (generally meaning employers with 50 or more full-time employees, including full-time equivalent employees, in the prior year), employees, and other individuals. This document also provides notice of a public hearing on these proposed rules. http://www.gpo.gov/fdsys/pkg/FR-2013-09-09/pdf/2013-21791.pdf Related IRS notices: Notice 2013-45Transition Relief for 2014 Under §§ 6055 (§ 6055 Information Reporting), 6056 (§ 6056 Information Reporting) and 4980H (Employer Shared Responsibility Provisions): http://www.irs.gov/pub/irs-drop/n-13-45.pdf Notice 2012-32Request for Comments on Reporting of Health Insurance Coverage: http://www.irs.gov/pub/irs-drop/n-12-32.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.
					 Notice 2012-33 Request for Comments on Reporting by Applicable Large Employers on Health Insurance Coverage Under Employer-Sponsored Plans: http://www.irs.gov/pub/irs-drop/n-12-33.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: This document contains final regulations providing guidance to employers subject to the information reporting requirements under section 6056 of the Internal Revenue Code (Code), enacted by ACA (generally employers with at least 50 full-time employees, including full-time equivalent employees). Section 6056 requires those employers to report to IRS information about the health care coverage, if any, they offered to full-time employees, to administer the employer shared responsibility provisions of section 4980H of the Code. Section 6056 also requires those employers to furnish related statements to employees that employees can use to determine whether, for each month of the calendar year, they can claim on their individual tax returns a premium tax credit under section 36B (premium tax credit). The regulations provide for a general reporting method and alternative reporting methods designed to simplify and reduce the cost of reporting for employers subject to the information reporting requirements under section 6056. The regulations affect those employers, employees, and other individuals. https://www.gpo.gov/fdsys/pkg/FR-2014-03-10/pdf/2014-05050.pdf 	
31.p.	Minimum Essential Coverage Reporting ACTION: Proposed Final Rule NOTICE: Information Reporting of Minimum Essential Coverage AGENCY: IRS	REG- 132455-11 TD 9660	Issue Date: 9/9/2013 Due Date: 11/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This document contains proposed regulations providing guidance to providers of minimum essential health coverage subject to the information reporting requirements of section 6055 of the Internal Revenue Code (Code), enacted by ACA. Health insurance issuers, certain employers, and others that provide minimum essential coverage to individuals must report to IRS information about the type and period of coverage and furnish related statements to covered individuals. These proposed regulations affect health insurance issuers, employers, governments, and other entities that provide minimum essential coverage to individuals. http://www.gpo.gov/fdsys/pkg/FR-2013-09-09/pdf/2013-21783.pdf Related IRS notices:	



Ref. #	Short Title/Current Status of Regulation/Title/ 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 Final Rule 3/10/2014; issued corrections 4/30/2014		 Notice 2013-45—Transition Relief for 2014 Under §§ 6055 (§ 6055 Information Reporting), 6056 (§ 6056 Information Reporting) and 4980H (Employer Shared Responsibility Provisions): http://www.irs.gov/pub/irs-drop/n-13-45.pdf Notice 2012-32—Request for Comments on Reporting of Health Insurance Coverage: http://www.irs.gov/pub/irs-drop/n-12-32.pdf Notice 2012-33—Request for Comments on Reporting by Applicable Large Employers on Health Insurance Coverage Under Employer-Sponsored Plans: http://www.irs.gov/pub/irs-drop/n-12-33.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: This contains final regulations providing guidance to providers of minimum essential health coverage (MEC) subject to the information reporting requirements of section 6055 of the Internal Revenue Code (Code), enacted by ACA. Health insurance issuers, certain employers, and others that provide MEC to individuals must report to IRS information about the type and period of coverage and furnish the information in statements to covered individuals. These final regulations affect health insurance issuers and carriers, employers, governments, and others that provide MEC to individuals. http://www.gpo.gov/fdsys/pkg/FR-2014-03-10/pdf/2014-05051.pdf IRS on 4/30/2014 issued a document that contains corrections to this final rule. As published, this final rule contains errors that might prove misleading and require clarification. Accordingly, this document makes the following correcting amendment to 26 CFR part 1: http://www.gpo.gov/fdsys/pkg/FR-2014-04-30/pdf/2014-09795.pdf 		
31.t.	Amendments to Excepted	REG-	Issue Date:		SUMMARY OF AGENCY ACTION: This proposed rule would amend the regulations		
	Benefits	143172-13	12/24/2013		regarding excepted benefits under ERISA, the Internal Revenue Code, and the Public Health Service Act. Excepted benefits generally do not have to meet the health reform		
	ACTION: Proposed Rule	DoL RIN 1210-	<u>Due Date:</u> 2/24/2014		requirements added to those laws by HIPAA and ACA.		
	NOTICE: Amendments to Excepted Benefits	AB60	NIHB File		http://www.gpo.gov/fdsys/pkg/FR-2013-12-24/pdf/2013-30553.pdf		
	AGENCY: IRS/DoL/CMS	CMS-9946-P	Date: None		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.
	Agency	CCIIO (no reference number) See also 7.dd.				NIHB Recs.
			170/2014		Guidance/Downloads/cancellation-consumer-options-12-19-2013.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/3/2014 issued guidance that includes questions and answers to clarify 12/19/2013 guidance on options available for consumers with cancelled policies. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/cancellation-consumer-options-faq-01-03-2014.pdf This guidance restates instructions for individuals who have canceled policies and seek to purchase catastrophic coverage and/or avoid a tax penalty.	



	Short Title/Current Status		Issue Date;			
Ref.	of Regulation/Title/ Agency	File Code	Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
31.v.	Instructions for the Application for Indian- Specific Exemptions ACTION: Guidance NOTICE: Instructions for the Application for Exemption for American Indians and Alaska Natives and Other Individuals who are Eligible to Receive Services from an Indian Health Care Provider AGENCY: CMS	CMS (no reference number) See also 31.q.	Issue Date: 1/10/2014 Due Date: 1/13/2014 TTAG File Date: 1/13/2014 Date of Subsequent Agency Action, if any:	TTAG response:	SUMMARY OF AGENCY ACTION: On 12/20/2013, CMS forwarded two draft documents that it intends to include with the guidance and instructions to the Application for Exemption from the Shared Responsibility Payment for American Indians and Alaska Natives (Al/ANs). These documents pertain to exemptions available to members of Indian Tribes, which includes members of federally recognized Indian tribes and Alaska Native shareholders in a regional or village corporation established under the Alaska Native Claims Settlement Act (ANCSA), as well as to individuals eligible for services from an Indian health care provider, from the shared responsibility payment established under ACA for failure to obtain minimum essential coverage. On 1/10/2014 (following an ACA policy subcommittee discussion on the issue), CMS sent a request for review of a revised version of these instructions. The revised instructions combined the two previously forwarded documents into one document. SUMMARY OF TTAG ANALYSIS: These instructions are "critical to the basic ability of Exchanges to determine eligibility for and issue certificates of exemption and will also assist Exchanges, HHS, and IRS in ensuring program integrity and quality improvement." In addition, because the Indian-specific exemptions reflect the Federal trust responsibility toward Al/ANs, CMS has an obligation to establish an accurate, user-friendly, and easily understood application process that minimizes the burden on the applicant. These instructions require some revisions to improve the completeness and accuracy of the information provided by applicants for the Indian-specific exemptions.	See Table C.
31.w.	Q&A on Cost-Sharing Reductions for Contract Health Services ACTION: Guidance NOTICE: Question and Answer on Cost-Sharing Reductions for Contract Health Services	CCIIO (no reference number)	Issue Date: 1/8/2014 Due Date: 1/14/2014 NIHB File Date: 1/14/2013 Date of	TTAG response:	SUMMARY OF AGENCY ACTION: On the TTAG conference call on 1/8/2014, CMS asked TTAG to provide comments on draft guidance to QHPs pertaining to cost-sharing protections for members of Indian tribes through Contract Health Services (CHS). The guidance takes the form of a Q&A document. CMS requested that TTAG submit comments by 1/14/2014. SUMMARY OF NIHB ANALYSIS: The language included in the guidance is not consistent with the statutory definition of "contract health service," found at 25 U.S.C. § 1603(5), and there is a need for the addition of some language to the last paragraph to clarify that the referral eliminates any cost-sharing, including at the time of initial service.	See Table C.



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	AGENCY: CCIIO		File Date Subsequent Agency Action, if any: Issued Final Guidance 2/18/2014; sent revised Guidance to TTAG for review 4/2/2014; issued revised Final Guidance 5/9/2014		SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/18/2014 issued final guidance that answers the question of what documentation standards, under the maintenance of records requirements in 45 CFR 156.480, apply for cost-sharing reductions for an item or service furnished through referral from an Indian health program, including an urban Indian program, under contract health services. According to this guidance, "45 CFR 156.420(b)(2) specifies that issuers must provide cost-sharing reductions to eligible enrollees under 45 CFR 155.350(b) on any 'item or service that is an EHB furnished through referral under contract health services.' 45 CFR 156.430 provides for payments to issuers for cost-sharing reductions. To document eligibility for reimbursement for cost-sharing reductions provided to an enrollee on an EHB provided through referral under contract health services, as defined in 25 U.S.C. 1603(5) and any implementing guidance, and to meet the standards set forth at 45 CFR 156.480, the issuer must retain documentation that includes the following information: • Identification of the patient receiving the item or service (e.g. name and date of birth); • The name and address of the provider delivering the item or service; • A description of the item or service furnished through referral under contract health services, including the date(s) the item or service was provided; and • The name of the Indian health program issuing the referral under contract health services, contact information for the program, and the date of the referral. • A copy of the referral. (We note that many of the required elements above may be contained in the referral itself.)" http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/q-and-a-on-contract-health-services-2-18-14.pdf CMS on 4/2/2014 submitted revised guidance to TTAG for review. In the revised guidance, CMS retained the additional bullet requiring "a copy of the referral." In response to TTAG comments, CMS added back a clarification that Indian health 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.
					2nd round-Contract Health Services referi CMS on 5/9/2014 issued revised guidance with the change discussed above. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CSRs and Contract Health Services QA.pdf	
31.x.	MEC and Other Rules on the Shared Responsibility Payment ACTION: Proposed Rule NOTICE: Minimum Essential Coverage and Other Rules Regarding the Shared Responsibility Payment for Individuals AGENCY: IRS	REG- 141036-13	Issue Date: 1/27/2014 Due Date: 4/28/2014 TTAG File Date: 4/28/2014 Date of Subsequent Agency Action, if any: Issued hearing cancellation 5/16/2014	TTAG response:	SUMMARY OF AGENCY ACTION: This document contains proposed regulations relating to the requirement to maintain minimum essential coverage enacted by ACA, as amended by the TRICARE Affirmation Act. These proposed regulations affect individual taxpayers who might have liability for the shared responsibility payment for not maintaining minimum essential coverage. This document also provides notice of a public hearing (scheduled for 5/21/2014 at 10 a.m. ET) on these proposed regulations. IRS must receive outlines of topics for discussed at the public hearing by 4/28/2014. http://www.gpo.gov/fdsys/pkg/FR-2014-01-27/pdf/2014-01439.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule provides a detailed review of MEC requirements, as well as exemptions from the tax penalty for not maintaining MEC. This proposed rule advances the NIHB recommendation on permitting individuals who qualify for services from Indian health care providers to apply for an exemption on a Federal income tax return. The preamble to this proposed rule states (79 FR 4306-7): "Consistent with guidance released by the Secretary of HHS on October, 28, 2013, the proposed regulations provide that an individual who enrolls in a plan through an Exchange during the open enrollment period for coverage for 2014 may claim a hardship exemption for months in 2014 prior to the effective date of the individual's coverage without obtaining a hardship exemption certification from an Exchange [NOTE: The HHS action only involved the release of a notice (Notice 2014-10), not a formal regulation]. If additional situations are identified where an individual should be allowed to claim a hardship exemption without obtaining a hardship exemption certification from an	See Table C.



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB	Brief Summary of Proposed Agency Action	NIHB Recs.
#	Agency		File Date	Response	Exchange, the Secretary of HHS and the Secretary of the Treasury will continue to coordinate guidance. To facilitate issuing guidance in this situation, the proposed regulations provide that a taxpayer may claim a hardship exemption on a return if the Secretary of HHS issues published guidance of general applicability describing the hardship and indicating that the hardship can be claimed on a Federal income tax return pursuant to guidance published by the Secretary of the Treasury, and the Secretary of the Treasury issues published guidance of general applicability allowing an individual to claim such hardship exemption on a Federal income tax return without obtaining a hardship exemption from an Exchange." Clarification is needed on what additional action Treasury will need to take to permit an individual to apply for any additional exemption for which HHS might stipulate individuals can apply through a Federal income tax return. Or specifically, when (hopefully) HHS indicates that individuals eligible for services from an Indian health care provider can apply for the exemption on a Federal income tax return, what additional action will Treasury need to take before the individuals can apply. NIHB and/or TTAG and others should submit comments to support the IRS action to which the above analysis refers. SUMMARY OF SUBSEQUENT AGENCY ACTION: IRS on 5/16/2014 issued a document to cancel a public hearing, scheduled on 5/21/2014, on this proposed rule. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics they sought to address. As of 5/12/2014, no one had requested to speak. http://www.gpo.gov/fdsys/pkg/FR-2014-05-16/pdf/2014-11414.pdf	
32.c.	Bundled Payments for Care Improvement 2014 Winter Period ACTION: Notice NOTICE: Medicare	CMS-5504- N4	<u>Issue Date:</u> 2/14/2014 <u>Due Date:</u> 4/18/2014 <u>NIHB File</u>		SUMMARY OF AGENCY ACTION: This notice announces an open period for additional organizations to apply for consideration for participation in Models 2, 3, and 4 of the Bundled Payments for Care Improvement initiative. Interested organizations must submit Models 2, 3, and 4 Open Period intake forms by April 18, 2014, in a searchable word or PDF format via email at BundledPayments@cms.hhs.gov . http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03311.pdf	

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Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Program; Bundled Payments for Care Improvement Models 2, 3, and 4 2014 Winter Open Period AGENCY: CMS		Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF NIHB ANALYSIS: Some I/T/Us may find it beneficial to participate in this bundled payment demonstration.	
39.b.	Basic Health Program ACTION: Proposed-Final Rule NOTICE: Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity AGENCY: CMS	CMS-2380- PF	Issue Date: 9/25/2013 Due Date: 11/25/2013 NIHB File Date: None NIHB File Date: 11/22/2013; ANTHC, TSGAC, and TTAG also filed comments 11/22/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 3/12/2014	NIHB response: ANTHC response: TSGAC response: TTAG response:	SUMMARY OF AGENCY ACTION: This proposed rule would establish the Basic Health Program, as required by section 1331 of ACA. The Basic Health Program provides states with the flexibility to establish a health benefits coverage program for low-income individuals who would otherwise qualify to purchase coverage through the Affordable Insurance Exchange (Exchange, or Health Insurance Marketplace). The Basic Health Program would complement and coordinate with enrollment in a QHP through the Exchange, as well as with enrollment in Medicaid and CHIP. This proposed rule sets forth a framework for Basic Health Program eligibility and enrollment, benefits, delivery of health care services, transfer of funds to participating states, and federal oversight. In addition, this proposed rule would amend other rules issued by the HHS Secretary to clarify the applicability of those rules to the Basic Health Program. http://www.gpo.gov/fdsys/pkg/FR-2013-09-25/pdf/2013-23292.pdf A CMS fact sheet on this proposed rule is available at http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2013-Fact-Sheets-Items/2013-09-20.html. SUMMARY OF NIHB ANALYSIS: The Basic Health Program applies to individuals between the Medicaid eligibility level in the State (or 138% FPL, whichever is higher) in States that choose to adopt the Basic Health Program option. The proposed rule maintains the protections for Al/ANs provided under an Exchange to Al/ANs who might enroll under a Basic Health Plan option. These protections appear in proposed 45 CFR 600.160, including a) special monthly enrollment periods, b) permitting tribal sponsorship, c) no cost-sharing, and d) I/T/U as payer of last resort. In addition, tribal consultation requirements appear in 45 CFR 600.155. The definition of Indian under the ACA applies under the Basic Health 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.
					Section 1331 of ACA establishing the Basic Health Program provides that, with regard to premiums, "the amount of the monthly premium an eligible individual is required to pay for coverage under the standard health plan for the individual and the individual's dependents does not exceed the amount of the monthly premium that the eligible individual would have been required to pay (in the rating area in which the individual resides) if the individual had enrolled in the applicable second lowest cost silver plan." No reference appears to the ability of Al/ANs to enroll in a bronze plan and maintain the cost-sharing protections. As such, Al/ANs might have to pay a premium based on the premium of the second-lowest-cost silver plan in the area, rather than the premium of a lower-cost bronze plan. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule establishes the Basic Health Program (BHP), as required by section 1331 of ACA. BHP provides states the flexibility to establish a health benefits coverage program for low-income individuals who would otherwise qualify to purchase coverage through the Affordable Insurance Exchange (Exchange, also called Health Insurance Marketplace). BHP complements and coordinates with enrollment in a QHP through the Exchange, as well as with enrollment in Medicaid and the CHIP. This final rule also sets forth a framework for BHP eligibility and enrollment, benefits, delivery of health care services, transfer of funds to participating states, and federal oversight. Additionally, this final rule amends another rule issued by the HHS Secretary to clarify the applicability of that rule to BHP. http://www.gpo.gov/fdsys/pkg/FR-2014-03-12/pdf/2014-05299.pdf	
39.c.	Basic Health Program: Federal Funding Methodology for 2015 ACTION: Proposed Final Methodology NOTICE: Basic Health Program: Proposed Federal Funding Methodology for Program Year 2015	CMS-2380- PFN	Issue Date: 12/23/2013 Due Date: 1/22/2014 TTAG File Date: 1/22/2014; TSGAC also filed comments	TTAG response: TSGAC response:	SUMMARY OF AGENCY ACTION: This document provides the methodology and data sources necessary to determine federal payment amounts made to states that elect to establish a Basic Health Program certified by the HHS Secretary under section 1331 of ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges. http://www.gpo.gov/fdsys/pkg/FR-2013-12-23/pdf/2013-30435.pdf SUMMARY OF NIHB ANALYSIS: In discussions with CMS, staff indicated that the ACA does not provide for <i>mandating</i> that States that exercise the Basic Health Program option charge Al/AN no more than the equivalent of the cost of a bronze plan (as requested by Tribal representatives). The proposed funding methodology indicated below, though,	See Table C (see also 39.b.).



Ref.	Short Title/Current Status of Regulation/Title/ 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		Date of Subsequent Agency Action, if any: Issued Final Methodology 3/12/2014		provides funding adjustments that account for Al/AN choosing bronze plans and the higher cost to the Federal government for the cost-sharing reductions for Al/AN that result. These higher Federal subsidy costs would be factored into the calculation of the payment level from the Federal government to states electing the Basic Health Program option. Although the final rule for CMS-2380-P has not yet been published, the proposed funding methodology outlined below could support a policy whereby the Federal government, if not requiring, encourages States to limit premium contributions for Al/AN to the bronze-plan equivalent. This may be accomplished by CMS making available to states that elect to limit premiums for Al/AN the higher Federal payments. For states that do not elect to limit premiums for Al/AN to the equivalent of the bronze plan premium, CMS could withhold payment of the higher amounts. The following are excerpts from the published notice 77402 Federal Register / Vol. 78, No. 246 / Monday, December 23, 2013 / Proposed Rules "We further propose a separate calculation that includes different adjustments for American Indian/Alaska Native BHP enrollees, as described in section E." Federal Register / Vol. 78, No. 246 / Monday, December 23, 2013 / Proposed Rules 77405 "For American Indian/Alaska Native BHP enrollees, we propose to use the lowest cost bronze plan as the basis for the reference premium as described further in section E." Federal Register / Vol. 78, No. 246 / Monday, December 23, 2013 / Proposed Rules 77409 "E. Adjustments for American Indians and Alaska Natives There are several exceptions made for American Indians and Alaska Natives enrolled in QHPs through an Exchange to calculate the PTC and CSRs. Thus, we propose adjustments to the payment methodology described above to be consistent with the Exchange rules.	



We propose that the adjusted reference premium for use in the CSR portion of the rate would use the lowest cost bronze plan instead of the second lowest cost sliver plan, with the same adjustments for the premium trend factor and population health factor. American Indians and Alaska Natives are eligible for CSRs with any metal level plan, and thus we believe that eligible persons would be more likely to select a bronze level plan instead of a sliver level plan. (It is important to note that this would not change the PTC, as that is the maximum possible PTC payment, which is always based on the second lowest cost sliver plan.) We invite comments as to whether other assumptions are warranted about the distribution arong bronze plans charging various premiums, of American Indian and Alaska Native BHP-eligible Individuals. 2. We propose that the actuarial value for use in the CSR portion of the rate would be 0.60 instead of 0.70, which is consistent with the actuarial value of a bronze level plan. 3. We propose that the induced utilization factor for use in the CSR portion of the rate would be 1.15, which is consistent with the proposed HHS Notice of Benefit and Payment Parameters for 2015 induced utilization factor for calculating advance CSR payments for persons enrolled in bronze level plans and eligible for CSRs up to 100 percent of actuarial value. 4. We propose that the change in the actuarial value for use in the CSR portion of the rate would be 0.40. This reflects the increase from 60 percent actuarial value of the bronze plan to 100 percent actuarial value. SUMMARY OF SUBSEQUENT AGENCY ACTION: This document provides the methodology and data sources to determine the federal payment amounts made to states in program year 2015 that elect to establish a Basic Health Program certified by the HHS Secretary under section 1331 of ACA to ofter health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges.	Ref.	Short Title/Current Status of Regulation/Title/ 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. We propose that the adjusted reference premium for use in the CSR portion of the rate would use the lowest cost bronze plan instead of the second lowest cost silver plan, with the same adjustments for the premium trend factor and population health factor. American Indians and Alaska Natives are eligible for CSRs with any metal level plan, and thus we believe that eligible persons would be more likely to select a bronze level plan instead of a silver level plan. (It is important to note that this would not change the PTC, as that is the maximum possible PTC payment, which is always based on the second lowest cost silver plan.) We invite comments as to whether other assumptions are warranted about the distribution, among bronze plans charging various premiums, of American Indian and Alaska Native BHP-eligible individuals. 2. We propose that the actuarial value for use in the CSR portion of the rate would be 0.60 instead of 0.70, which is consistent with the actuarial value of a bronze level plan. 3. We propose that the induced utilization factor for use in the CSR portion of the rate would be 1.15, which is consistent with the proposed HHS Notice of Benefit and Payment Parameters for 2015 induced utilization factor for calculating advance CSR payments for persons enrolled in bronze level plans and eligible for CSRs up to 100 percent of actuarial value. 4. We propose that the change in the actuarial value for use in the CSR portion of the rate would be 0.40. This reflects the increase from 60 percent actuarial value of the bronze plan to 100 percent actuarial value, as American Indians and Alaska Natives are eligible to receive CSRs up to 100 percent of actuarial value." SUMMARY OF SUBSEQUENT AGENCY ACTION: This document provides the methodology and data sources to determine the federal payment amounts made to states in program year 2015 that elect to establish a Basic Health Program certified by the HHS Secretary under section 1331 of ACA to offer health benefits coverage to lowincome individuals otherwi	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
39.d.	Basic Health Program Report for Exchange Premium ACTION: Request for Comment NOTICE: Basic Health Program Report for Health Insurance Exchange Premium AGENCY: CMS	CMS-10510	Issue Date: 12/23/2013 Due Date: 1/2/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 12/27/2013; issued extension 4/18/2014 Due Date: 6/17/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Basic Health Program Report for Health Insurance Exchange Premium; Use: In accordance with section 1331 of ACA, the Basic Health Program (BHP) receives federal funding by determining the amount of payments that the federal government would have made through premium tax credits (PTCs) and cost-sharing reductions (CSRs) for individuals enrolled in BHP had they instead enrolled in an Exchange. To calculate these amounts for each state, CMS needs the reference premiums for the second-lowest-cost silver plans (SLCSPs) in each geographic area in a state, as SLCSPs serve as a basic unit in the calculation of PTCs and CSRs under the Exchanges. In addition, the reference premiums for these SLCSPs serve as critical components in the BHP payment methodology to estimate what PTCs and CSRs would have received in payments. Similarly, CMS needs to collect reference premiums for the lowest-cost bronze plans to appropriately account for CSR calculations for Al/ANs. Reference premiums serve as foundational inputs into the BHP payment methodology. CMS has the necessary information to determine these reference premiums for states with Exchanges operated by the Federally Facilitated Exchange (FFE) or in Partnership with FFE. Therefore, this collection pertains to only the 17 states operating State-Based Exchanges. http://www.gpo.gov/fdsys/pkg/FR-2013-12-23/pdf/2013-30434.pdf CMS-10510 and a Supporting Statement for this PRA request are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10510.html. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/27/2013 issued a document that corrects a date in the 12/23/2013 FR notice titled "Basic Health Program Report for Health Insurance Exchange Premium." On page 77469, in the third column, in the third paragraph, the first sentence should read, "We are requesting OMB review and approval of this collection by January 6, 2014, with a 180	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis "December 23, 2013." http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30989.pdf CMS on 4/18/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-18/pdf/2014-08898.pdf No comments recommended. This PRA request notes the need for information on the lowest-cost bronze plan to calculate correctly the amount of CSR due to a state for Al/AN enrollees. This statement comports with the final BHP regulations related to this provision.	NIHB Recs.
41.d.	New Safe Harbors ACTION: Notice NOTICE: Solicitation of New Safe Harbors and Special Fraud Alerts AGENCY: HHS OIG	OIG-122-N	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In accordance with section 205 of HIPAA, this annual notice 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. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30429.pdf SUMMARY OF NIHB ANALYSIS:	
44.e.	Multi-Payer Advanced Primary Care Practice Demonstration ACTION: Request for Comment NOTICE: Evaluation of the	CMS-10485	Issue Date: 7/12/2013 Due Date: 9/10/2013 NIHB File Date: None		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Evaluation of the Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration: Provider Survey; Use: On 9/16/2009, HHS announced the establishment of the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration, under which Medicare joined Medicaid and private insurers as a payer participant in state-sponsored patient-centered medical home (PCMH) initiatives. CMS selected eight states to participate in this demonstration: Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan, and Minnesota.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration: Provider Survey AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued new request 1/29/2014 Due Date: 2/28/2014		CMS proposes to conduct this provider survey to understand how participating practice structures and functions vary, particularly with respect to their adoption of different components of the PCMH model of care. Researchers evaluating the MAPCP Demonstration plan to combine these survey data with claims data to conduct statistical analyses that identify which particular medical home care processes relate to the largest gains in health care quality and reductions in health care cost trends. http://www.gpo.gov/fdsys/pkg/FR-2013-07-12/pdf/2013-16740.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/29/2014 issued a new version of this PRA request. Subsequent to the publication of the 60-day notice in the 7/12/2013 FR (78 FR 41931), CMS has revised the survey. CMS also has made a slight increase in the annual burden hours.	
46.d.	Preliminary DSH Allotments for FY 2014 ACTION: Request for Comment NOTICE: Medicaid Program; Preliminary Disproportionate Share Hospital (DSH) Allotments for Fiscal Year (FY) 2014 and the Preliminary Institutions for Mental Diseases Disproportionate Share Hospital Limits for FY 2014 AGENCY: CMS	CMS-2389-N	Issue Date: 2/28/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This notice announces the preliminary federal share disproportionate share hospital (DSH) allotments for FY 2014 and the preliminary federal share FY 2014 limits on aggregate DSH payments that states can make to institutions for mental diseases (IMDs) and other mental health facilities. This notice also includes additional information regarding the calculation of the FY 2014 DSH allotments and FY 2014 IMD DSH limits. http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04032.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.
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; issued revision 11/22/2013; issued revision 1/31/2014 Due Date: 3/25/2013; 1/21/2014; 3/5/2014		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 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 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.goo.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 instruct	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					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 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	
48.e.	Computation of MLR ACTION: Proposed Rule NOTICE: Computation of, and Rules Relating to, Medical Loss Ratio AGENCY: IRS	REG- 126633-12 TD 9651	Issue Date: 5/13/2013 Due Date: 8/12/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 1/7/2014		SUMMARY OF AGENCY ACTION: This document contains proposed regulations that provide guidance to Blue Cross and Blue Shield organizations, and certain other health care organizations, on computing and applying the medical loss ratio added to the Internal Revenue Code by ACA. This document also contains a request for comments and provides notice of a public hearing on these proposed regulations. http://www.gpo.gov/fdsys/pkg/FR-2013-05-13/pdf/2013-11297.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This document indicates that certain insurers, including Blue Cross/Blue Shield (BC/BS) plans, will lose tax preferences if they fail to meet MLR standards. This document takes a position contrary to the regulation issued by CCIIO (in implementing PHSA § 2718) on costs allowed in the numerator of the MLR calculation. For plans covered under section 833 of the Internal Revenue Code (such as BC/BS plans), the numerator of the MLR calculation cannot include "activities that improve health care quality."	



Ref.	Short Title/Current Status of Regulation/Title/ 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: This document contains final regulations that provide guidance to Blue Cross and Blue Shield organizations, and certain other qualifying health care organizations, on computing and applying the medical loss ratio added to the Internal Revenue Code by ACA. http://www.gpo.gov/fdsys/pkg/FR-2014-01-07/pdf/2014-00092.pdf	
50.e.	Initial Plan Data Collection to Support QHP Certification ACTION: Request for Comment NOTICE: Initial Plan Data Collection to Support Qualified Health Plan Certification and Other Financial Management and Exchange Operations AGENCY: CMS	CMS-10433	Issue Date: 11/21/2012 Due Date: 12/21/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 11/1/2013; issued revision 2/10/2014 Due Date: 12/31/2013; 3/12/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection: New collection; Title: Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; Use: To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as Qualified Health Plans (QHPs) by the Exchange. The Exchange must collect data and validate that QHPs meet these minimum requirements and other requirements, and this information collection will facilitate this process. On 7/6/2012, CMS began a 60-day comment period on this information collection, and in response to comments received, the agency has worked to address concerns about duplicate data collection and clarify the data elements in this collection. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/1/2013 issued a revision of this PRA request. According to CMS, in addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs, outlined by ACA and established by CMS-9975-F, have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs, including CMS-9964-F and CMS-9957-F2/CMS-9964-F3, provide further reporting requirements. Based on experience with the first year of data collection, CMS proposes revisions to the data elements collected and the burden estimates for years two and three. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26083.pdf CMS on 2/10/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-10/pdf/2014-02787.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.
					A number of documents related to CMS-10433 (listed below) are available at http://www.cms.gov/Regulations-and-guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10433.html . Appendix A.1: Administrative Data v3.22 Appendix A.2: Essential Community Providers v3.2 Appendix A.3.1: NCQA Template v1.6 Appendix A.3.1: URAC Template v1.4 Appendix A.4: Network Template v1.71 Appendix B.1: Plans and Benefits Template Appendix B.2: Prescription Drug Formulary Template Appendix B.3: Service Area v2.91 Appendix C.1: Rates Table Template Appendix C.2: Business Rules Template Appendix D: Transitional Reinsurance Program, Risk Adjustment Program, and Payment Operations Data Requirements Supporting Statement Comments warranted on this PRA request, particularly regarding Appendix A.2.	
50.o.	State Health Insurance Exchange Incident Report ACTION: Request for Comment NOTICE: State Health Insurance Exchange Incident Report AGENCY: CMS	CMS-10496	Issue Date: 8/21/2013 Due Date: 9/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: State Health Insurance Exchange Incident Report; Use: CMS has implemented a Computer Matching Agreement (CMA) with State-based Administering Entities (AEs). This agreement establishes the terms, conditions, safeguards, and procedures under which CMS will disclose certain information to the AEs in accordance with ACA, amendments to the Social Security Act made by ACA, and implementing regulations. AEs, state entities administering Insurance Affordability Programs, will use the data, accessed through the CMS Data Services Hub (Hub), to make eligibility determinations for insurance affordability programs and certificates of exemption. AEs shall report suspected or confirmed incidents affecting loss or suspected loss of PII within one hour of discovery to their designated CCIIO State Officer, who will then notify the affected Federal agency data sources, i.e., IRS, Department of Defense,	



Ref.	Short Title/Current Status of Regulation/Title/ 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 12/20/2013; issued extension 2/28/2014 Due Date: 2/18/2014; 3/31/2014		Department of Homeland Security, Social Security Administration, Peace Corps, OPM, and VA. Additionally, AEs shall contact the office of the appropriate Special Agent-in-Charge, Treasury Inspector General for Tax Administration (TIGTA), and the IRS Office of Safeguards within 24 hours of discovery of any potential breach, loss, or misuse of return Information. http://www.gpo.gov/fdsys/pkg/FR-2013-08-21/pdf/2013-20396.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/20/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30337.pdf CMS on 2/28/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04327.pdf	
50.q.	Third Party Payments of Premiums for QHPs ACTION: Guidance NOTICE: FAQ: Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces AGENCY: CCIIO	CCIIO (no reference number) See also 50.r.	Issue Date: 11/4/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued clarification 2/7/2014		SUMMARY OF AGENCY ACTION: This guidance answers the question of whether third party payors can make premium payments to health insurance issuers for qualified health plans on behalf of enrolled individuals. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf SUMMARY OF NIHB ANALYSIS: This guidance might raise questions about premium sponsorship programs operated by Tribes and Tribal organizations. Providing a memo to Tribes and HHS highlighting past statements made by, and regulations issued by, the department on premium sponsorship by Tribes might prove useful. HHS appears to have issued this guidance after it clarified that it will not consider QHPs, FFMs, etc. "Federal Health Care Programs" and that, as a result, anti-kickback statutes will not apply to them (see HHS letter to Rep. Jim McDermott below). Having eliminated the concern of providers about anti-kickback statutes, HHS clarified that it does not want providers sponsoring patients when this might cause adverse selection against QHPs. http://mcdermott.house.gov/images/The%20Honorable%20Jim%20McDermott.pdf	



National Indian Health Board Table B: Summary of Notices & Regulations UPDATED THROUGH 5/31/2014

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					The following appeared in an explanation of these interacting actions by the law firm McDermott, Will, and Emory: Provider payments of QHP premiums. Although the announcement appeared to remove a major hurdle for providers that may consider payment of premiums to enroll individuals	
					in QHPs, or to keep them enrolled during a grace period, HHS subsequently released a guidance document on Nov. 4, 2013, indicating that the agency "has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel field in the Marketplaces." HHS will monitor this practice and "encourages issuers to reject such third party payments." Other hurdles may continue to apply in addition to HHS's guidance. For example, in order to prevent adverse selection, coverage in the individual market can only be purchased during an annual open enrollment period, or a special enrollment period in a number of limited circumstances. Moreover, coverage	
					purchased during the annual open enrollment periods will not be effective immediately. Finally, state anti-kickback, insurance and other laws will continue to apply." http://www.mwe.com/HHS-Clarifies-that-ACA-Qualified-Health-Plans-are-Not-Subject-to-Federal-Anti-Kickback-Statute-11-05-2013/ SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/7/2014 issued a	
					clarification to address questions that have arisen about whether this guidance applies to payments of premiums and cost sharing made on behalf of QHP enrollees by certain types of third party payors, including Indian tribes , tribal organizations , and urban Indian organizations (I/T/Us).	
					According to this clarification: "The November 4, 2013, FAQ does not apply to payments for premiums and cost sharing made on behalf of QHP enrollees by Indian tribes, tribal organizations, urban Indian organizations QHP issuers and Marketplaces are encouraged to accept such payments.	
					As CMS stated in its 2015 Draft Letter to Issuers on Federally-facilitated and State Partnership Exchanges, pursuant to section 1312 of the Affordable Care Act, section 402 of the Indian Health Care Improvement Act, and 45 CFR 155.240(b), a Marketplace may permit Indian tribes, tribal organizations, and urban Indian organizations to pay QHP premiums on behalf of members who are qualified individuals, subject to terms and conditions determined by the Marketplace. Indeed, Federal law specifically provides for this approach."	



Ref.	Short Title/Current Status of Regulation/Title/ 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.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf	
50.r.	Implementation of Section 402 of IHCIA ACTION: Guidance NOTICE: Tribal Leader Letter: Implementation of Section 402 of the Indian Health Care Improvement Act AGENCY: IHS	IHS (no reference number) See also 50.q.	Issue Date: 10/24/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This Tribal Leader Letter addresses implementation of section 402 of the Indian Health Care Improvement Act. In part, this letter states: "In summary, a Tribe, Tribal Organization, or Urban Indian organization (T/TO/U) may use funds awarded under the ISDEAA or Title V of the IHCIA to buy health benefits coverage for IHS beneficiaries. To the extent that a T/TO/U seeks to purchase health benefits coverage for IHS beneficiaries, its contract or compact should reflect that activity." This letter also cautions or clarifies that: "In implementing health benefits coverage, a T/TO/U that wishes to limit the number of beneficiaries covered should be aware that financial need is the only factor permitted by statute upon which to base coverage decisions" [emphasis added]. SUMMARY OF NIHB ANALYSIS: TSGAC on 4/15/2014 sent a letter to the IHS Director on section 402 and the agency interpretation. The letter appears below. TSGAC Response to IHS DTLL section 402	
50.s.	State-Based Marketplace Annual Report ACTION: Request for Comment NOTICE: State-Based Marketplace Annual Report (SMAR)	CMS-10507	<u>Issue Date:</u> 11/15/2013 <u>Due Date:</u> 1/14/2014 <u>NIHB File</u> <u>Date</u> : None		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: State-Based Marketplace Annual Report (SMAR); Use: The annual report serves as the primary vehicle to ensure comprehensive compliance with all reporting requirements contained in ACA. Section 1313(a)(1) of ACA requires a State-based Marketplace (SBM) to keep an accurate accounting of all activities, receipts, and expenditures and to submit a report annually to the HHS Secretary concerning such accounting. CMS will use the information collected from states to assist in determining if a state has maintained a compliant operational Exchange. It also will provide a mechanism to collect innovative approaches to meeting challenges encountered 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.
	AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued new request 1/31/2014 Due Date: 3/5/2014		SBMs during the preceding year. Additionally, it will provide information to CMS regarding potential changes in priorities and approaches for the upcoming year. http://www.gpo.gov/fdsys/pkg/FR-2013-11-15/pdf/2013-27305.pdf CMS-10507 and a Supporting Statement are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10507.html. SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/31/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-31/pdf/2014-02061.pdf	
50.t.	QHP Quality Rating System Measures and Methodology ACTION: Request for Comment NOTICE: Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS), Framework Measures and Methodology AGENCY: CMS	CMS-3288- NC	Issue Date: 11/22/2013 Due Date: 1/21/2014 TTAG File Date: 1/21/2014 Date of Subsequent Agency Action, if any:	TTAG response:	SUMMARY OF AGENCY ACTION: This notice with comment describes the overall Quality Rating System (QRS) framework for rating Qualified Health Plans (QHPs) offered through an Exchange. This notice seeks comments on the list of proposed QRS quality measures that QHP issuers would have to collect and report, the hierarchical structure of the measure sets and the elements of the QRS rating methodology. In addition, this notice solicits comments on ways to ensure the integrity of QRS ratings, and on priority areas for future QRS measure enhancement and development. http://www.gpo.gov/fdsys/pkg/FR-2013-11-19/pdf/2013-27649.pdf SUMMARY OF NIHB ANALYSIS: A review of the QRS framework described in this notice might provide an opportunity to highlight issues of particular concern to Al/ANs and I/T/Us.	See Table C.
50.v.	Medical Expenditure Panel SurveyInsurance Component	AHRQ (OMB 0935-0110)	<u>Issue Date:</u> 1/10/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medical Expenditure Panel SurveyInsurance Component; Use: The Medical Expenditure Panel SurveyInsurance Component	



Ref.	Short Title/Current Status of Regulation/Title/ 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: Medical Expenditure Panel Survey-Insurance Component AGENCY: AHRQ		Due Date: 3/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/31/2014 Due Date: 4/30/2014		(MEPS-IC) measures the extent, cost, and coverage of employer-sponsored health insurance on an annual basis. To ensure that MEPS-IC can capture important changes in the employer-sponsored health insurance market resulting from the implementation of ACA, AHRQ researched and proposed additions to the 2014 survey questionnaires based on the provisions of the law. Many of these proposed additions involve the implementation of the Small Business Health Options Program (SHOP), through which small employers can purchase health insurance beginning in 2014. In addition to new questions recommended for 2014, AHRQ proposes to delete several questions in the 2013 survey to minimize the burden on survey respondents. These questions have less analytic value than others, have poor response rates, or no longer apply due to changes made under ACA. A list of the proposed additions and deletions appears in this notice. All of the supporting documents for the current MEPS-IC are available on the OMB Web site at http://www.reginfo.gov/public/do/PRAViewDocument?ref nbr=201310-0935-001. http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31480.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: AHRQ on 3/31/2014 issued a revision of this PRA request. AHRQ received one comment in response to the 60-day notice published in the 1/10/2014 FR. http://www.gpo.gov/fdsys/pkg/FR-2014-03-31/pdf/2014-07110.pdf	
50.w.	Retroactive Advance Payments of PTCs and CSRs Due to Exceptional Circumstances ACTION: Request for Comment	CCIIO (no reference number)	Issue Date: 2/27/2014 Due Date: None NIHB File Date:		SUMMARY OF AGENCY ACTION: This guidance applies to Marketplaces that, due to technical issues in establishing automated eligibility and enrollment functionality, have had difficulty in providing timely eligibility determinations to applicants and enrolling qualified individuals in Qualified Health Plans (QHPs) through the Marketplace during the initial open enrollment period for the 2014 coverage year. Such a circumstance might qualify as an exceptional circumstance for individuals who could not enroll in a QHP through the Marketplace due to these issues. In this guidance, CMS discusses the availability of advance payments of the premium tax credit (APTC) and advance	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
Ref. #		File Code		NIHB Response	Payments of cost-sharing reductions (CSRs) on a retroactive basis to an issuer once the Marketplace has provided a qualified individual with an appropriate eligibility determination and has determined that the individual qualifies for such assistance and that the individual has enrolled in a QHP through the Marketplace. CMS also clarifies the attendant responsibilities of the QHP issuer in this circumstance. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/retroactive-advance-payments-ptc-csrs-02-27-14.pdf SUMMARY OF NIHB ANALYSIS: An analysis of this guidance appears below. • General requirement: "In order for the Marketplace to perform a determination of eligibility for coverage offered through the Marketplace, an individual must have submitted an application for coverage to the Marketplace using an HHS-approved single, streamlined application during the open enrollment period." • With regard to Indian-specific provisions, Q #5 addresses the ability of a qualified Al/AN who enrolled in a plan outside a Marketplace to qualify for retroactive APTC and CSRs even if not enrolled in a silver-level plan. • In Q #5, CCIIO indicates, "For Indians, 45 CFR 156.420(b) requires a QHP issuer to submit a zero cost sharing plan and limited cost sharing plan variation for each of its health plans (at each level of coverage) an issuer offers, or intends to offer in the individual market on a Marketplace." This guidance goes on to indicate in a footnote: "The 2014 HHS Notice of Benefit and Payment Parameters clarifies that a Marketplace is adequately enforcing this requirement if, within a set of standard plans offered by an issuer that differ only by the cost-sharing or premium, it allows an issuer to submit one zero cost sharing plan variation for only the standard plan	NIHB Recs.
					with the lowest premium within the set. (78 FR 15511)" (Emphasis added.) [At 78 FR 15511 (March 11, 2013), the preamble to the final rule indicates, "In paragraph (b), we further establish that a QHP issuer must, for each of its health plans at any metal level of coverage, submit a zero cost sharing plan variation and a limited cost sharing plan variation of each health plan offered or proposed to be offered in the individual market on the Exchange. However, in this final rule, we clarify that an Exchange is adequately enforcing this requirement if, within a set of standard plans offered by an issuer that differ only by the cost sharing or premium, it allows an issuer to submit one zero cost sharing plan variation for only the standard plan with the lowest premium within the set. Although this approach will likely reduce	



Ref.	Short Title/Current Status of Regulation/Title/ 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 burden on issuers and Exchanges, it is unclear how many Exchanges will adopt this approach, and as a result, we have not adjusted our burden estimates below. We estimate that 1,200 issuers will participate in an Exchange nationally, and that each issuer will offer one QHP per metal level with four zero cost sharing plan variations and four limited cost sharing plan variations (one per metal level QHP) and three plan variations for low-income populations, for a total of four standard plans and eleven plan variations."] SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/14/2014 issued a clarification that includes Frequently Asked Questions (FAQs) and answers on the 2/27/2014 bulletin. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/retroactive-advance-payments-ptc-csrs-03-14-14.pdf	
50.x.	Third Party Payment of QHP Premiums ACTION: Interim Final Rule NOTICE: Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums AGENCY: CMS	CMS-9943- IFC	Issue Date: 3/19/2014 Due Date: 5/13/2014 TTAG File Date: 5/13/2014 Date of Subsequent Agency Action, if any:	TTAG response:	SUMMARY OF AGENCY ACTION: This interim final rule requires issuers of qualified health plans (QHPs), including stand-alone dental plans (SADPs), to accept premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program; other Federal and State government programs that provide premium and cost sharing support for specific individuals; and I/T/Us. http://www.gpo.gov/fdsys/pkg/FR-2014-03-19/pdf/2014-06031.pdf SUMMARY OF NIHB ANALYSIS: In the preamble to this interim final rule, CMS noted the Federal policy in favor of (premium and cost-sharing) sponsorship by a limited set of entities: "In a FAQ issued on November 4, 2013 (the November FAQ), CMS encouraged QHP issuers not to accept third-party payments from hospitals, other healthcare providers, and other commercial entities due to concerns that such practices could skew the insurance risk pool and create an unlevel field in the Exchanges. On February 7, 2014, CMS issued additional FAQs (the February FAQs) clarifying that the November FAQ was not intended to discourage QHP issuers from accepting third party premium and cost-sharing payments made by Indian tribes, tribal organizations, and urban Indian organizations, as well as by state and federal government programs (such as the Ryan White HIV/AIDS Program). CMS affirmatively encouraged QHP issuers to accept such payments given that federal or state law or policy specifically envisions third	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.
	<u>=</u>	File Code			party payment of premium and cost-sharing amounts by these entities." [79 FR 15241] The interim final rule continued with a discussion of I/T/U-related sponsorship, noting: "In addition, section 1312 of the Affordable Care Act, section 402 of the Indian Health Care Improvement Act, and 45 CFR 155.240(b) provides that Exchanges may permit Indian tribes, tribal organizations, and urban Indian organizations to pay aggregated QHP premiums on behalf of qualified individuals, subject to terms and conditions determined by the Exchange. In the past, a number of tribes have provided premium assistance to tribal members eligible to enroll in the Medicare Part D program. These arrangements have resulted in an increase in the number of tribal members enrolled in Medicare Part D. Building from that experience, these same arrangements are being replicated by tribes and tribal organizations in providing premium assistance to qualified individuals for QHPs in the Exchanges. Under these arrangements tribes aggregate premium payments to issuers and reduce their administrative costs." [79 Fed Reg 15242] Due to reports that some QHPs had not accepted premium sponsorship from organizations when sponsors used Ryan White funding (and possible problems experienced by the other identified potential sponsors: I/T/Us and other State and Federal government programs), CMS added: "[W]e are including within the new requirement that QHPs and SADPs must accept third party premium and cost-sharing payments from the following other entities in addition to the Ryan White HIV/AIDS Program: Indian tribes, tribal organizations, and urban Indian organizations; and state and federal government programs. This standard applies to all individual market QHPs and SADPs, regardless of whether they are offered through an FFE, an SBE, or outside of the Exchanges." [79 FR 15242] The added requirement on QHPs in 45 CFR § 156.1250 reads as follows: § 156.1250 Acceptance of certain third party payments. Issuers offering individual market QHPs, including stand-	NIHB Recs.
					In § 156.805, CMS strengthened the enforcement provisions for this and other QHP requirements, noting: "Accordingly, failure to comply with the requirement to accept	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.	
					third party payments in accordance with § 156.1250 could constitute a violation of §156.805(a)(1) as 'substantial noncompliance with [an] Exchange standard.' Depending upon the circumstances, a QHP or SADP [Stand Alone Drug Plan] issuer's failure to comply with § 156.1250 could also fall under §156.805(a)(4) as a 'practice that would reasonably be expected to have the effect of denying or discouraging enrollment into a QHP offered by the issuer (except as permitted by this part) by qualified individuals whose medical condition or history indicates the potential for a future need for significant medical services or items." [79 FR 15242] CMS also noted (at 79 FR 15243) that it remains open to additional regulatory changes: "We continue to consider making additional regulatory changes: "We continue to consider making additional regulatory changes to QHP and SADP issuer responsibilities to ensure that QHPs and SADPs accept third party premium and cost-sharing payments from the Ryan White HIV/AIDS Program, other state and federal government programs that support premium and cost sharing, and Indian tribes, tribal organizations, and urban Indian organizations." [79 FR 15242] A Federally-Facilitated Exchange (FFE) special enrollment period might apply to individuals who qualify for the premium sponsorship but who cannot obtain sponsorship because of QHP actions: "CMS will issue additional guidance in the near future clarifying the specific criteria for obtaining the SEP or hardship exemption." [79 FR 15243] In this interim final rule, CMS makes the policy effective immediately (as of 3/14/2014), commenting: "In this case, given the short timeframe under which this change must be implemented, delaying the promulgation and effectiveness of this rule would mean that some people who are eligible to enroll in a QHP but rely on the Ryan White HIV/AIDs Program, tribes and tribal organizations, or other state or federal programs to contribute to the cost of the premium, either in whole or in part, would not be able to effe		



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
50.y.	Tax Treatment of Retirement Plan Payment of Premiums ACTION: Final Rule NOTICE: Tax Treatment of Qualified Retirement Plan Payment of Accident or Health Insurance Premiums AGENCY: IRS	TD 9665	Issue Date: 5/12/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This document contains final regulations clarifying the rules regarding the tax treatment of payments by qualified retirement plans for accident or health insurance. These final regulations set forth the general rule under section 402(a) that amounts held in a qualified plan used to pay accident or health insurance premiums are taxable distributions unless described in certain statutory exceptions. These final regulations do not extend this result to arrangements under which amounts are used to pay premiums for disability insurance that replaces retirement plan contributions in the event of a disability. These regulations affect sponsors, administrators, participants, and beneficiaries of qualified retirement plans. http://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10849.pdf SUMMARY OF NIHB ANALYSIS:	
52.i.	Home Health PPS Rate Update: Physician Narrative Requirement ACTION: Request for Comment NOTICE: Medicare Program- Home Health Prospective Payment System Rate Update for CY 2010: Physician Narrative Requirement and Supporting Regulation AGENCY: CMS	CMS-10311	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/20/2013 Due Date: 1/21/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare ProgramHome Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation; Use: Federal or state surveyors use the conditions of participation and accompanying requirements specified in the regulations as a basis for determining whether a home health agency qualifies for approval or re-approval under Medicare. Contractors and CMS use the physician certification and recertification of the need of the patient for skilled care services and homebound status, clinical justification for skilled nursing management, and evaluation of the care plan specified in the regulations at 42 CFR 424.22 when reviewing the patient medical record as a basis for determining whether the patient qualifies for the Medicare home health benefit and whether the medical record meets the criteria for coverage and Medicare payment. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/20/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf	



Ref.	Short Title/Current Status of Regulation/Title/ 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.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	Issue Date: 2/4/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		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:	
52.k.	Application for Participation in the IVIG Demonstration ACTION: Request for Comment NOTICE: Application for Participation in the Intravenous Immune Globulin Demonstration AGENCY: CMS	CMS-10518	Issue Date: 3/7/2014 Due Date: 5/6/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration; Use: Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for individuals with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer the drug for non-homebound individuals who do not otherwise receive services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their physician office or in an outpatient hospital setting. The Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 authorizes a 3-year demonstration under Part B of Title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the in-home administration of IVIG for the treatment of PIDD. The statute limited the demonstration to 4,000 beneficiaries and \$45 million, including administrative expenses for implementation and evaluation, as well as benefit costs. The statute also required an evaluation of the demonstration. Under the demonstration,	



Ref.	Short Title/Current Status of Regulation/Title/ 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.I.	Home Health Agency Conditions of Participation ACTION: Request for Comment NOTICE: Home Health Agency Conditions of Participation AGENCY: CMS	CMS-3819-P	Issue Date: [Pending at OMB as of 5/22/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		Medicare will issue under Part B a bundled payment for all medically necessary supplies and services to administer IVIG in the home to non-homebound beneficiaries who do not otherwise receive home health care benefits. This collection of information includes the application to participate in the demonstration. Participation remains voluntary, and beneficiaries can leave the demonstration at any time. Beneficiaries who do not participate will continue to qualify for all of the regular Medicare Part B benefits that they could receive in the absence of the demonstration. http://www.gpo.gov/fdsys/pkg/FR-2014-03-07/pdf/2014-04998.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: This proposed rule would revise the existing Conditions of Participation (CoPs) that home health agencies (HHAs) must meet to participate in the Medicare program. The new requirements will focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. SUMMARY OF NIHB ANALYSIS:	
54.	ESI Coverage Verification ACTION: Notice NOTICE: Employer- Sponsored Coverage Verification: Preliminary	CMS RIN 0938- ZB09	Issue Date: [Approved by OMB 4/26/2012 but not yet published]		SUMMARY OF AGENCY ACTION: To be entered. 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.
	Informational Statement AGENCY: CMS		Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:			
58.	Medicare Hospital Conditions of Participation ACTION: Final Rule NOTICE: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation AGENCY: CMS	CMS-3244-F	Issue Date: 5/16/2012 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued correcting amendment 2/25/2014		SUMMARY OF AGENCY ACTION: This final rule revises the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These changes serve as an integral part of efforts to reduce procedural burdens on providers. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/25/2014 issued a document (CMS-3244-F2) that corrects a technical error in this final rule. On page 29075 of this final rule, in the amendatory instructions for 42 CFR 482.42, CMS revised the introductory text of paragraph (a) to include the provisions of paragraph (a)(1) but inadvertently neglected to omit paragraph (a)(1) from the regulations text. In addition, CMS proposed to remove the burdensome requirement for an infection log at paragraph (a)(2) but inadvertently neglected to omit paragraph (a)(2) from the regulations text. http://www.gpo.gov/fdsys/pkg/FR-2014-02-25/pdf/2014-04024.pdf	
63.c.	Certification of Compliance for Health Plans ACTION: Proposed Rule NOTICE: Administrative	CMS-0037-P	<u>Issue Date:</u> 1/2/2014 <u>Due Date:</u> 3/3/2014 4/3/2014		SUMMARY OF AGENCY ACTION: This proposed rule would require a controlling health plan (CHP) to submit information and documentation demonstrating its compliance with certain standards and operating rules adopted by the HHS Secretary under HIPAA. This proposed rule also would establish penalty fees for a CHP that fails to comply with the certification of compliance requirements. http://www.gpo.gov/fdsys/pkg/FR-2014-01-02/pdf/2013-31318.pdf	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Simplification: Certification of Compliance for Health Plans AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 3/5/2014		SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/5/2014 issued a document (CMS-0037-N) that extends the comment period for this proposed rule from 3/3/2014 to 4/3/2014. http://www.gpo.gov/fdsys/pkg/FR-2014-03-05/pdf/2014-04828.pdf	
65.	Health Care Reform Insurance Web Portal Requirements ACTION: Request for Comment NOTICE: Health Care Reform Insurance Web Portal Requirements AGENCY: CMS	CMS-10320	Issue Date: 8/15/2012 Due Date: 9/13/2012 TTAG File Date: 9/13/2012; ANTHC also filed comments 9/13/2012 Date of Subsequent Agency Action, if any: Issued revision 2/3/2014; issued revision 4/11/2014	TTAG response:	SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Health Care Reform Insurance Web Portal Requirements 45 CFR Part 159; Use: Sections 1103 and 10102 of ACA mandate this information collection. Once collected from insurance issuers of major medical health insurance (issuers) and other affected parties, the data will appear on the Web site http://www.healthcare.gov . Issuers must provide information quarterly, and healthcare.gov will update on a periodic schedule during each quarter. The information provided will help the general public make educated decisions about organizations providing private health insurance. In accordance with ACA, HHS created healthcare.gov to meet the requirements of sections 1103 and 10102 and other provisions of the law, with data collection conducted for six months based upon an emergency information collection request. The interim final rule published on 5/5/2010 served as the emergency Federal Register notice for the prior information collection request. CMS has begun updating a system (Web portal) where state Departments of Insurance and issuers can log in using a custom user ID and password validation. States might have to provide information on issuers in their state and various Web sites maintained for consumers. Issuers will have to provide information on their major medical insurance products and plans. They ultimately will have the choice to download a basic information template, enter their data into the template, and upload them into the Web portal; to enter their data manually within the Web portal; or to submit .xml files containing their data. Once the states and issuers submit their data, they will receive an email notifying them of any errors and indicating receipt of their submission. CMS requires issuers to verify and update their information on a quarterly basis and asks	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: 4/1/2014; 5/12/2014 TTAG File Date: 5/12/2014		States to verify their information on an annual basis. In the event that an issuer enhances its existing plans, proposes new plans, or deactivates plans, it would have to update the information in the Web portal. Changes occurring during the three-month quarterly periods can occur by utilizing effective dates for both the plans and rates associated with the plans. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/3/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-03/pdf/2014-02124.pdf Several documents related to CMS-10320 (listed below) are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10320.html. Appendix A: Supporting Statement Appendix B: Section 1103 (of ACA) Appendix C: Insurance Issuer and Product Level Data Appendix C: Insurance Issuer and Product Level Data Appendix E: State Requirements Appendix F: High Risk Pool Market Requirements Plans and issuers must provide a Summary of Benefits and Coverage (SBC) for the base QHP offerings (but not each cost-sharing variation) and the uniform glossary of medical and insurance terms. Plans and issuers must provide information about covered services, cost sharing, limitations and exceptions on coverage, coverage examples, and other disclosures in the SBC. These documents outline the timing and formatting required for providing this information. 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	



Ref.	Short Title/Current Status of Regulation/Title/ 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.d.	Use of 1311 Funds and No Cost Extensions ACTION: Guidance NOTICE: FAQs on the Use of 1311 Funds and No Cost Extensions AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/14/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This guidance includes several frequently asked questions (FAQs) and answers on use of 1311 funds and no cost extensions. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/no-cost-extension-faqs-3-14-14.pdf SUMMARY OF NIHB ANALYSIS:	
70.b.	Revisions to Medicare Payment Policies Under PFS, et al. ACTION: Proposed Final Rule NOTICE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014 AGENCY: CMS	CMS-1600- PFC	Issue Date: 7/19/2013 Due Date: 9/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 12/10/2013 Due Date: 1/27/2014		SUMMARY OF AGENCY ACTION: This major proposed rule 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. http://www.gpo.gov/fdsys/pkg/FR-2013-07-19/pdf/2013-16547.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This major final rule with comment period addresses changes to the physician fee schedule, clinical laboratory 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. This final rule with comment period also includes a discussion in the Supplementary Information regarding various programs. http://www.gpo.gov/fdsys/pkg/FR-2013-12-10/pdf/2013-28696.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.
70.c.	Policy on FOA Disclosure of Payments to Medicare Physicians ACTION: Notice NOTICE: Modified Policy on Freedom of Information Act Disclosure of Amounts Paid to Individual Physicians Under the Medicare Program AGENCY: CMS	CMS-0041-N	Issue Date: 1/17/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This notice sets forth a new policy regarding requests made under the Freedom of Information Act for information on amounts paid to individual physicians under the Medicare program in which CMS will make case-by-case determinations as to whether exemption 6 of the Freedom of Information Act applies to a given request for such information. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00808.pdf SUMMARY OF NIHB ANALYSIS:	
71.c.	ESRD Care Model ACTION: Notice NOTICE: Medicare Comprehensive End-Stage Renal Disease Care Model Announcement AGENCY: CMS	CMS-5506-N	Issue Date: 2/6/2013 Due Date: 5/1/2013 7/19/2013 8/30/2013 6/23/2014 NIHB File Date: Date of Subsequent Agency Action, if any: Issued deadline extension 7/17/2013,		SUMMARY OF AGENCY ACTION: This notice announces a request for applications from organizations to participate in the testing of the Comprehensive End-Stage Renal Disease (ESRD) Care Model, a new initiative from the Center for Medicare and Medicaid Innovation (Innovation Center), for a period beginning in 2013 and ending in 2016, with a possible extension into subsequent years. http://www.gpo.gov/fdsys/pkg/FR-2013-02-06/pdf/2013-02194.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBEQUENT AGENCY ACTION: CMS on 7/17/2014 issued a notice (CMS-5506-N2) that reopens the Comprehensive ESRD Care Initiative letter of intent submission period, with a submission deadline of 7/19/2013, and extends the deadline for the application to 8/1/2013. http://www.gpo.gov/fdsys/pkg/FR-2013-07-17/pdf/2013-17131.pdf CMS on 8/9/2013 issued a notice (CMS-5506-N3) that reopens the Comprehensive ESRD Care Initiative letter of intent submission period and extends the submission deadlines for the letter of intent and the application to 8/30/2013.	



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.
			8/9/2013, 4/17/2014		http://www.gpo.gov/fdsys/pkg/FR-2013-08-09/pdf/2013-19351.pdf CMS on 4/17/2014 issued a notice (CMS-5506-N4) that reopens the Comprehensive ESRD Care Initiative application submission period and provides information on new submission deadlines for the letter of intent and application. This notice extends the letter of intent submission deadline for End-stage Renal Disease Seamless Care Organizations (ESCOs) that include a dialysis facility from a large dialysis organization (LDO) to 6/23/2014 and the deadline for the LDO application to 6/23/2014. In addition, this notice extends the letter of intent submission deadline for ESCOs that include a non-LDO facility to 9/15/2014 and the deadline for the non-LDO application to 9/15/2014. http://www.gpo.gov/fdsys/pkg/FR-2014-04-17/pdf/2014-08758.pdf	
71.m.	Changes to ESRD PPS and QI Program for 2015 ACTION: Proposed Rule NOTICE: CY 2015 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program AGENCY: CMS	CMS-1614-P	Issue Date: [Pending at OMB as of 5/15/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This annual proposed rule would update the bundled payment system for ESRD facilities by 1/1/2015. This proposed rule also would update the quality incentives in the ESRD program. SUMMARY OF NIHB ANALYSIS:	
72.b.	Medicare PPS and Consolidated Billing for SNFs for FY 2014 ACTION: Proposed Final	CMS-1446- PF	Issue Date: 5/6/2013 Due Date: 7/1/2013		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 fiscal year (FY) 2014, revise and rebase the SNF market basket, and make certain technical and conforming revisions in the regulations text. This proposed rule also includes a proposed policy for reporting the SNF market basket forecast error correction	



Ref. # Short Title/Current Status of Regulation/Title/ Agency File Code File Date Status Due Date & File Date Response Respons	f Summary of Proposed Agency Action and Summary of NIHB Analysis NIHB Recs.
Rule NOTICE: Medicare Program; PPS and Consolidated Billing for Skilled Nursing Facilities for FY 2014 AGENCY: CMS AGENCY: CMS Subsequent Rule 8/6/2013; issued correction 10/3/2013; issued correction 11/2/2014; issued that appeared in the final Based Statistical Area (C data of a certain hospital; Table A accordingly. CMS on 11/2/2014 issued that appeared in the final Based Statistical Area (C data of a certain hospital; Table A accordingly. http://www.gpo.gov/fdsys CMS on 1/10/2014 issued that cappeared in the final Based Statistical Area (C data of a certain hospital; Table A accordingly.	JENT AGENCY ACTION: This final rule updates the payment spective payment system for skilled nursing facilities (SNFs) for exises and rebases the SNF market basket, revises and updates and makes certain technical and conforming revisions in the all rule also includes a policy for reporting the SNF market basket mitted circumstances and adds a new item to the Minimum Data for reporting the number of distinct therapy days. Finally, this e to the diagnosis code used to determine which residents will payment, effective for services provided on or after the n date for conversion to ICD-10-CM. Sypkg/FR-2013-08-06/pdf/2013-18776.pdf d a document (CMS-1446-CN) that corrects technical errors 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.
72.d.	Medicare PPS and Consolidated Billing for SNFs for FY 2015 ACTION: Proposed Rule NOTICE: Medicare Program; PPS and Consolidated Billing for Skilled Nursing Facilities for FY 2015 AGENCY: CMS	CMS-1605-P	Issue Date: 5/6/2014 Due Date: 6/30/2014 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 2015. In addition, it includes a proposal to adopt the most recent OMB statistical area delineations to identify the urban or rural status of a facility for the purpose of determining which set of rate tables would apply to the facility and determining the SNF PPS wage index including a proposed one-year transition with a blended wage index for all providers for FY 2015. It also includes a discussion of the SNF therapy payment research currently underway within CMS. Further, this proposed rule would revise policies related to the Change of Therapy (COT) Other Medicare Required Assessment (OMRA). This proposed rule includes a discussion of a provision related to ACA involving Civil Money Penalties. Finally, this proposed rule includes a discussion of observed trends related to therapy utilization among SNF providers and a discussion of accelerating health information exchange in SNFs. http://www.gpo.gov/fdsys/pkg/FR-2014-05-06/pdf/2014-10319.pdf SUMMARY OF NIHB ANALYSIS:	
78.c.	Hospice Request for Certification ACTION: Request for Comment NOTICE: Hospice Request for Certification and Supporting Regulations AGENCY: CMS	CMS-417	Issue Date: 11/1/2013 Due Date: 12/31/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/29/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Hospice Request for Certification and Supporting Regulations; Use: The Hospice Request for Certification serves as the identification and screening form used to initiate the certification process and determine if the provider has sufficient personnel to participate in the Medicare program. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26083.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 1/29/2014 issued a revision of this PRA request. Subsequent to the publication of the 60-day notice in the 11/1/2013 FR (78 FR 65656), CMS has made minor changes to the form. http://www.gpo.gov/fdsys/pkg/FR-2014-01-29/pdf/2014-01775.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.
	of Regulation/Title/	File Code CMS-10504	Due Date &		No comments recommended. SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Hospice Quality Reporting Program: Program Evaluation; Use: Section 3004(c) of ACA mandated that CMS establish a quality reporting program for hospices. Specifically, section 3004(c) added section 1814(i)(5) to the Social Security Act (the Act) to establish a quality reporting program for hospices. This program requires hospices to submit quality data in a time, form and manner specified by the HHS Secretary. CMS seeks to explore how hospices respond to the new quality reporting program (QRP) and its measures. CMS believes in the importance of understanding early trends in outcomes, making adjustments as needed to enhance the effectiveness of QRP, seeking opportunities to minimize provider burden, and ensuring the meaningfulness of the program to providers. The methodology employed in the evaluation uses qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, CMS has decided that using a rich, contextual approach to evaluate the process and success of QRP will prove most beneficial at this time.	NIHB Recs.
			<u>Due Date</u> : 4/9/2014		The information collected will help inform CMS about QRP-related experiences, such as program impact related to quality improvement, burden, process-related issues, and education. This information also will inform future measurement development for the hospice QRP, future steps related to data validation, and future monitoring and evaluation. http://www.gpo.gov/fdsys/pkg/FR-2013-11-22/pdf/2013-28049.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 3/10/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-03-10/pdf/2014-05104.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.
78.e.	Hospice Conditions of Participation ACTION: Request for Comment NOTICE: Hospice Conditions of Participation AGENCY: CMS	CMS-10277	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/29/2014 Due Date: 2/28/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Hospice Conditions of Participation and Supporting Regulations; Use: Federal or State surveyors use the Conditions of Participation and accompanying requirements as a basis for determining whether a hospice qualifies for approval or re-approval under Medicare. CMS believes that the availability to the hospice of the type of records and general content of records ensures the well-being and safety of patients and professional treatment accountability. This information collection request includes no program changes or new requirements, but CMS plans to adjust the numbers of respondents and responses. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28537.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: CMS on 1/29/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-29/pdf/2014-01775.pdf	
78.f.	Request for Applications for the Medicare Care Choices Model ACTION: Notice NOTICE: Medicare Program; Request for Applications for the Medicare Care Choices Model AGENCY: CMS	CMS-5512-N	Issue Date: 3/21/2014 Due Date: 6/19/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This notice informs interested parties of an opportunity to apply for participation in the Medicare Care Choices Model. The Medicare Care Choices Model will test whether beneficiaries who meet Medicare hospice eligibility requirements would elect hospice if they could continue to seek curative services. http://www.gpo.gov/fdsys/pkg/FR-2014-03-21/pdf/2014-06158.pdf SUMMARY OF NIHB ANALYSIS: The Medicare Care Choices Model, funded by the CMS Center for Medicare and Medicaid Innovation (Innovation Center), seeks to test whether traditional Medicare beneficiaries with certain types of advanced cancers, congestive heart failure (CHF), human immunodeficiency virus (HIV), and chronic obstructive pulmonary disease (COPD) who meet Medicare hospice eligibility requirements under either the Medicare or Medicaid Hospice Benefit would elect to receive hospice supportive services earlier in their disease trajectories if they could continue to seek curative services. The Model will evaluate whether this practice	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					produces any associated improvements in patient care, patient and family or caregiver satisfaction with care, and quality of life at the end-of-life. Participating hospices will use care coordination services both within the hospice and between the hospice and other providers and suppliers to effectively manage hospice-eligible Medicare beneficiaries and report process and outcome measures on their results. The Medicare Care Choices Model participating hospices will receive a \$400 per beneficiary per month fee for certain hospice support services furnished to traditional fee-for-service Medicare beneficiaries who are hospice eligible and meet the criteria stated in the Request for Application (RFA). In selecting hospices to participate in the program, CMS seeks eligible beneficiaries from a mix of rural and urban areas representing Medicare hospices of all sizes.	
78.g.	Report of New System of Records (Hospice Item Set) ACTION: Notice NOTICE: Privacy Act of 1974, Report of New System of Records AGENCY: CMS	CMS (no reference number)	Issue Date: 4/8/2014 Due Date: 30 days (approx. 5/8/2014) NIHB File Date: None Date of Subsequent Agency Action, if any		SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, CMS plans to establish a new system of records (SOR) titled, "Hospice Item Set (HIS) System," System No. 09-70-0548. The new system will support the collection of data required for the Hospice Quality Reporting Program (HQRP) pursuant to Section 3004(c) of ACA, which amended the Social Security Act (the Act). HISa standardized, patient-level data collection vehicleconsists of data elements confirming that hospitals made appropriate assessments and addressed inquiries or concerns for each patient at the time of admission for the following domains of care: (1) Pain; (2) Respiratory Status; (3) Medications; (4) Patient Preferences; and (5) Beliefs Values. http://www.gpo.gov/fdsys/pkg/FR-2014-04-08/pdf/2014-07552.pdf SUMMARY OF NIHB ANALYSIS:	
78.h.	Wage Index and Payment Rates for Hospices for FY 2015, et al. ACTION: Proposed Rule	CMS-1609-P	<u>Issue Date</u> : 5/8/2014 <u>Due Date</u> : 7/1/2014		SUMMARY OF AGENCY ACTION: This proposed rule would update the hospice payment rates and the wage index for FY 2015 and continue the phase out of the wage index budget neutrality adjustment factor (BNAF). This proposed rule provides an update on hospice payment reform analyses and solicits comments on "terminal illness" and "related conditions" definitions, as well as on a process and appeals for Part D payment	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice AGENCY: CMS		NIHB File Date: Date of Subsequent Agency Action, if any		for drugs, while beneficiaries receiving care under a hospice election. Also, this rule proposes timeframes for filing the notice of election and the notice of termination/revocation; the addition of the attending physician to the hospice election form; a requirement that hospices complete their hospice inpatient and aggregate cap determinations within 5 months after the cap year ends and remit any overpayments; and updates for the hospice quality reporting program. In addition, this proposed rule would provide guidance on determining hospice eligibility, information on the delay in the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), and further clarification on reporting diagnoses on hospice claims. Finally, this rule proposes to make a technical regulatory text change. http://www.gpo.gov/fdsys/pkg/FR-2014-05-08/pdf/2014-10505.pdf SUMMARY OF NIHB ANALYSIS:	
81.	Efficiency, Transparency, and Burden Reduction ACTION: Proposed-Final Rule NOTICE: Medicare and Medicaid Programs; Part II-Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction AGENCY: CMS	CMS-3267- PF	Issue Date: 2/7/2013 Due Date: 4/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 5/12/2014		SUMMARY OF AGENCY ACTION: This proposed rule would reform Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This proposed rule would increase the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources from providing high quality patient care. http://www.gpo.gov/fdsys/pkg/FR-2013-02-07/pdf/2013-02421.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule reforms Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This final rule also increases the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					divert resources away from providing high-quality patient care. CMS has issued this final rule to achieve regulatory reforms under Executive Order 13563 on improving regulation and regulatory review and the HHS plan for retrospective review of existing rules. http://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf The details of this final rule might pose an interest for THOs. The below document, prepared by Sam Ennis, provides a summary of the proposed rule. 2013-04-02 Summary of CMS-326	
82.e.	CLIA Program and HIPAA Privacy Rule ACTION: Final Rule NOTICE: CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports AGENCY: CMS	CMS-2319-F	Issue Date: 2/5/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This final rule amends Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon the request of a patient (or his or her personal representative), laboratories subject to CLIA can provide the patient, his or her personal representative, or an individual designated by the patient, as applicable, with copies of completed test reports identifiable as belonging to the patient using the authentication process of the laboratory. Subject to conforming amendments, this final rule retains the existing provisions that require release of test reports only to authorized individuals and, if applicable, to the individuals responsible for using the test reports and to the laboratory initially requesting the test. In addition, this final rule amends the HIPAA Privacy Rule to provide individuals (or their personal representatives) with the right to access test reports directly from laboratories subject to HIPAA (and to direct the transmission of copies of those test reports to individuals or entities designated by them) by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information. These changes to the CLIA regulations and the HIPAA Privacy Rule provide individuals with a greater ability to access their health information, empowering them to take a more active role in managing their health and health care. http://www.gpo.gov/fdsys/pkg/FR-2014-02-06/pdf/2014-02280.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.
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 Due Date: 3/5/2014		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	
82.i.	HIPAA Covered Entity and Associate Pre-Audit Survey ACTION: Request for Comment NOTICE: HIPAA Covered Entity and Business Associate Pre-Audit Survey AGENCY: HHS OCR	HHS-OS- 21435-60D HHS-OS- 0945-New- 30D	Issue Date: 2/24/2014 Due Date: 4/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: HIPAA Covered Entity and Business Associate Pre-Audit Survey; Use: This information collection consists of a survey of as many as 1200 HIPAA covered entities (health plans, health care clearinghouses, and certain health care providers) and business associates (entities that provide certain services to a HIPAA covered entity) to determine suitability for the HHS Office for Civil Rights (OCR) HIPAA Audit Program. The survey will gather information about respondents to enable OCR to assess the size, complexity, and fitness of a respondent for an audit. Information collected includes, among other things, recent data about the number of patient visits or insured lives, use of electronic information, revenue, and business locations. http://www.gpo.gov/fdsys/pkg/FR-2014-02-24/pdf/2014-03830.pdf	



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	- gy		request 5/12/2014 <u>Due Date</u> : 6/11/2014		SUMMARY OF SUBSEQUENT AGENCY ACTION: HHS OCR on 5/12/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10829.pdf	
85.c.	Medicaid and CHIP Access to Preventive Services State Survey ACTION: Request for Comment NOTICE: Improving Quality of Care in Medicaid and CHIP through Increased Access to Preventive Services State Survey AGENCY: CMS	CMS-10521	Issue Date: 4/14/2014 Due Date: 6/10/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Improving Quality of Care in Medicaid and CHIP through Increased Access to Preventive Services State Survey; Use: CMS will use this survey to gain a better understanding of state efforts to increase utilization of preventive services and to develop resources (including educational and outreach resources) to help states increase utilization of preventive services. The results will provide a baseline on regarding coverage of preventive services and will help CMS identify ways to assist states with materials focusing on prevention and technical assistance. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf SUMMARY OF NIHB ANALYSIS:	
89.e.	Notice of Benefit and Payment Parameters for 2015 ACTION: Proposed-Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015	CMS-9954- PF	Issue Date: 12/2/2013 Due Date: 12/26/2013 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule sets forth payment parameters and oversight 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 (FFEs). It also proposes additional standards with respect to composite rating, privacy and security of personally identifiable information, the annual open enrollment period for 2015, the actuarial value calculator, the annual limitation in cost sharing for stand-alone dental plans, the meaningful difference standard for qualified health plans offered through an FFE, patient safety standards for issuers of qualified health plans, and the Small Business Health Options Program. http://www.gpo.gov/fdsys/pkg/FR-2013-12-02/pdf/2013-28610.pdf The Proposed 2015 Actuarial Value Calculator 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.
	AGENCY: ČMS		Issued Final Rule 3/11/2014		http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/proposed-2015-av-calculator.xls. The Proposed 2015 Actuarial Value Calculator Methodology is available at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/proposed-2015-av-calc-methodology.pdf. A Draft User Guide to the Proposed 2015 Actuarial Value Calculator is available at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/proposed-2015-av-calc-user-guide.pdf. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule sets forth payment parameters and oversight 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 (FFEs). It also provides additional standards with respect to composite premiums, privacy and security of personally identifiable information, the annual open enrollment period for 2015, the actuarial value calculator, the annual ilmitation in cost sharing for stand-alone dental plans, the meaningful difference standard for qualified health plans (QHPs) offered through FFEs, patient safety standards for issuers of QHPs, and the Small Business Health Options Program. http://www.gpo.gov/fdsys/pkg/FR-2014-03-11/pdf/2014-05052.pdf The 2015 Actuarial Value Calculator is available at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-av-calculator-final.xlsm. The 2015 Actuarial Value Calculator Methodology is available at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-av-calculator-methodology.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.
91.b.	Waiting Period Limitation and Coverage Requirements ACTION: Proposed-Final Rule NOTICE: Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under ACA AGENCY: IRS/DoL/CMS	REG- 122706-12 DoL (RIN 1210-AB56) CMS-9952- PF	Issue Date: 3/21/2013 Due Date: 5/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/24/2014		SUMMARY OF AGENCY ACTION: This proposed rule would implement the 90-day waiting period limitation under section 2708 of the Public Health Service Act, as added by ACA, as amended and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. This rule also proposes amendments to regulations to conform to ACA provisions currently in effect, as well as those that will become effective beginning in 2014. The proposed conforming amendments would make changes to existing requirements, such as preexisting condition limitations and other portability provisions added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and implementing regulations because they have become moot or need amendment as a result of new market reform protections under ACA. http://www.gpo.gov/fdsys/pkg/FR-2013-03-21/pdf/2013-06454.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: These final regulations implement the 90-day waiting period limitation under section 2708 of the Public Health Service Act, as added by ACA, as amended, and incorporated into ERISA and the Internal Revenue Code. These regulations also finalize amendments to existing regulations to conform to ACA provisions. Specifically, these rules amend regulations implementing existing provisions, such as some of the portability provisions added by HIPAA, because those provisions of the HIPAA regulations have become superseded or require amendment as a result of the market reform protections added by ACA. http://www.gpo.gov/fdsys/pkg/FR-2014-02-24/pdf/2014-03809.pdf	
91.c.	Waiting Period Limitation ACTION: Proposed Rule NOTICE: Ninety-Day Waiting Period Limitation AGENCY: IRS/DoL/CMS	DoL (RIN 1210-AB60)	REG-122706- 12 DoL (RIN 1210-AB61) CMS-9952-P2		SUMMARY OF AGENCY ACTION: These proposed regulations would clarify the maximum allowed length of any reasonable and bona fide employment-based orientation period, consistent with the 90-day waiting period limitation set forth in section 2708 of the Public Health Service Act, as added by ACA, as amended, and incorporated into ERISA and the Internal Revenue Code. http://www.gpo.gov/fdsys/pkg/FR-2014-02-24/pdf/2014-03811.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. Roughly, an employer can impose a "bona fide employment-based orientation period" that has the effect of adding an additional month to the waiting period.	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
92.h.	Disclosure and Recordkeeping for Grandfathered Health Plans ACTION: Request for Comment NOTICE: Affordable Care Act Grandfathered Health Plan Disclosure, Recordkeeping Requirement, and Change in Carrier Disclosure AGENCY: DoL	DoL (OMB 1210-0140)	Issue Date: 5/22/2013 Due Date: 7/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 11/29/2013 Due Date: 1/2/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Affordable Care Act Grandfathered Health Plan Disclosure, Recordkeeping Requirement, and Change in Carrier Disclosure; Use: Section 1251 of ACA provides that certain plans and health insurance in existence as of 3/23/2010, known as grandfathered health plans, do not have to comply with certain statutory provisions in the law. To maintain its status as a grandfathered health plan, the interim final regulations require the plan to maintain records documenting the terms of the plan in effect on 3/23/2010, and any other documents necessary to verify, explain, or clarify status as a grandfathered health plan. The plan must make such records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official. The interim final regulations also require a grandfathered health plan to include a statement in any plan material provided to participants or beneficiaries describing the benefits provided under the plan or health insurance; indicating the plan believes it is a grandfathered health plan within the meaning of section 1251 of ACA; indicating, as a grandfathered health plan within the meaning of section 1251 of ACA; indicating, as a grandfathered health plan information for participants to direct questions regarding which protections apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status and to file complaints. http://www.gpo.gov/fdsys/pkg/FR-2013-05-22/pdf/2013-12191.pdf Model language for the disclosure requirement is available at http://www.dol.gov/ebsa/grandfatherregmodelnotice.doc. A Supporting Statement for this PRA request is available at http://www.dol.gov/ebsa/grandfatherregmodelnotice.doc. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/29/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28557	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
92.i.	ACA Notice of Rescission ACTION: Request for Comment NOTICE: Affordable Care Act Notice of Rescission AGENCY: Treasury	TD 9491 (OMB 1545- 2180)	Issue Date: 6/27/2013 Due Date: 8/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2014 Due Date: 3/31/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Affordable Care Act Notice of Rescission; Use: Section 2712 of the Public Health Service Act (PHS Act), incorporated into section 9815 of the Internal Revenue Code by section 1563(f) of ACA, prohibits group health plans and health insurance issuers from rescinding coverage of an individual unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. The temporary Treasury regulations provide that a group health plan or a health insurance issuer offering group health insurance coverage must provide at least 30 days advance notice to an individual before it can rescind coverage. This notice meets the third-party disclosure requirement under section 2712 of the PHS Act. Individuals about to have their coverage rescinded might need to arrange for other coverage, or make decisions about whether they wish to appeal the decision to rescind their coverage, or make arrangements to defer the receipt of medical care that is optional or not needed immediately. Individuals who receive the disclosure can make an informed decision on these matters. http://www.gpo.gov/fdsys/pkg/FR-2013-06-27/pdf/2013-15361.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: Treasury on 2/27/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04298.pdf No comments recommended.	
92.k.	ACA Notice of Patient Protection ACTION: Request for Comment NOTICE: Affordable Care	REG- 120399-10 (OMB 1545- 2181)	<u>Issue Date:</u> 9/4/2013 <u>Due Date:</u> 11/4/2013 NIHB File		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Affordable Care Act Notice of Patient Protection; Use: Section 2719A of the Public Health Service Act (PHS Act), incorporated into Internal Revenue Code section 9815 by section 1563(f) of ACA, directs a group health plan or a health insurance issuer requiring or allowing for the designation of a primary care provider to notify participants of the right to designate a primary care provider (including a pediatrician for a child) and of the right to obtain access to obstetrical or gynecological	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Act Notice of Patient Protection AGENCY: IRS		Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2014 Due Date: 3/31/2014		services without referral from a primary care provider. This PRA request includes no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-09-04/pdf/2013-21400.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: IRS on 2/27/2014 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2014-02-27/pdf/2014-04298.pdf	
92.n.	Rules for Group Health Plans Related to Grandfather Status ACTION: Request for Comment NOTICE: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act AGENCY: IRS	REG- 118412-10 (OMB 1545- 2178)	Issue Date: 10/29/2013 Due Date: 12/30/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/27/2014 Due Date: 3/31/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Use: Section 1251 of ACA provides that certain plans and health insurance coverage in existence as of 3/23/2010, known as grandfathered health plans, do not have to comply with certain statutory provisions in the law. Treas. Reg. §54.9815-1215T requires a grandfathered health plan to include a statement in any plan material provided to participants or beneficiaries stating its intent to exist as a grandfathered health plan within the meaning of §1251 of ACA. To maintain status as a grandfathered health plan, the plan or issuer must maintain records documenting the terms of the plan or health insurance coverage in effect on 3/23/2010 and any other documents necessary to verify, explain, or clarify status as a grandfathered health plan. The plan or issuer must make such records available for examination. http://www.gpo.gov/fdsys/pkg/FR-2013-10-29/pdf/2013-25581.pdf A Supporting Statement for this PRA request is available at http://www.reginfo.gov/public/do/DownloadDocument?documentID=212859&version=1. This information collection does not have any associated forms. SUMMARY OF NIHB ANALYSIS:	



92.q. ACA Advance Notice of Rescission ACTION: Request for Comment NOTICE: Affordable Care Act Advance Notice of Rescission Date of Rescission Date of Rescission Notice of Rescission Date of Rescission Date of Rescission SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Affordable Care Act Advance Notice of Rescission; Use: Section 2712 of the Public Health Service (PHS) Act, as added by ACA, and DoL interim final regulations provide rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and the interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, generally must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market or self-insured coverage. The rules also apply regardless 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.
Rescission ACTION: Request for Comment NOTICE: Affordable Care Act Advance Notice of Rescission; Due Date: 1/28/2014 NOTICE: Affordable Care Act Advance Notice of Rescission; Use: Section 2712 of the Public Health Service (PHS) Act, as added by ACA, and DoL interim final regulations provide rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and the interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, generally must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market or self-insured coverage. The rules also apply regardless of						of this PRA request.	
AGENCY: DoL Agency Action, if any: Issued extension 2/19/2014 Extensi	92.q.	Rescission ACTION: Request for Comment NOTICE: Affordable Care Act Advance Notice of		Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/19/2014 Due Date:		a currently approved collection; <i>Title</i> : Affordable Care Act Advance Notice of Rescission; <i>Use</i> : Section 2712 of the Public Health Service (PHS) Act, as added by ACA, and DoL interim final regulations provide rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and the interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, generally must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market or self-insured coverage. The rules also apply regardless of any contestability period of the plan or issuer. PHS Act section 2712 adds a new advance notice requirement when health plans or health insurance issuers rescind coverage where still permissible. Specifically, the second sentence in section 2712 provides that plans or issuers cannot cancel coverage unless they provide prior notice, and then only as permitted under PHS Act sections 2702(c) and 2742(b). Under the interim final regulations, even if plans or issuers provide prior notice, rescission can occur only in cases of fraud or an intentional misrepresentation of a material fact as permitted under the cited provisions. The interim final regulations require health plans or health insurance issuers to provide at least 30 days advance notice to an individual before they can rescind coverage may be rescinded, regardless of whether the rescission involves group or individual coverage; whether, in the case of group coverage, the rescission involves insured or self-insured coverage; or whether the rescission applies to an entire group or only to an individual within the group. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28568.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 SUBSEQUENT AGENCY ACTION: IRS on 2/19/2014 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2014-02-19/pdf/2014-03541.pdf	
92.r.	ACA Patient Protection Notice ACTION: Request for Comment NOTICE: Affordable Care Act Patient Protection Notice AGENCY: DoL	DoL (OMB 1210-0142)	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/28/2014 Due Date: 3/31/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Affordable Care Act Patient Protection Notice; Use: Section 2719A of the Public Health Service (PHS) Act, as added by ACA and the DoL interim final regulations, states that, if a group health plan or a health insurance issuer offering group or individual health insurance coverage requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider to accept the participant, beneficiary, or enrollee. When applicable, individuals enrolled in a plan or health insurance coverage must know their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, paragraph (a)(4) of the interim final regulations requires such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. The interim final regulations provide model language. Plans and insurers must provide the notice whenever they provide a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage or, in the individual market, provide a primary subscriber with a policy, certificate, or contract of health insurance. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28568.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: DoL on 2/28/2014 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.
					http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04397.pdf A Model Notice is available at http://www.dol.gov/ebsa/patientprotectionmodelnotice.doc. A Supporting Statement for this PRA request is available at http://www.reginfo.gov/public/do/DownloadDocument?documentID=448661&version=0 This notice indicates that an enrollee has the right to select a primary care or OB/GYN provider in the plan network but also indicates that the health plan or health insurance issuer might impose prior authorization requirements on these providers.	
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: 2/25/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 4/2/2014 Due Date: 5/2/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved information collection; Title: Rate Increase Disclosure and Review Reporting Requirements; Use: Section 1003 of ACA adds a new section 2794 of the Public Health Service Act (PHS Act) directing the HHS Secretary, in conjunction with states, to establish a process for the annual review of "unreasonable increases in premiums for health insurance coverage." The statute provides that health insurance issuers must submit to the HHS Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 also specifies that, beginning with plan years starting in 2014, the HHS Secretary, in conjunction with states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. Section 2794 directs the HHS Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. The regulation therefore develops a process to ensure the public disclosure of all such information and justification. Section 2794 requires that health insurance issuers submit justification for an unreasonable rate increase to both CMS and the relevant state prior to its implementation. Additionally, section 2794 requires the HHS Secretary, in conjunction with states, to monitor rate increases effective in 2014 (submitted for review in 2013). To those ends, the regulation establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined unreasonable by a state or CMS, and a notification requirement for unreasonable rate increases that the issuer will not	



Ref. # Short Title/Current Status of Regulation/Title/ Agency File Code Sisue Date; Due Date & File Date NIHB Response NIHB Response Signature Signature NiHB Analysis NIHB Analysis NIHB Analysis NIHB Recs. NIHB Analysis NIHB Analysis NIHB Recs. NIHB Analysis NIHB Analysis		_			
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	of Regulation/Title/	File Code	Due Date &	and Summary of NIHB Analysis	NIHB Recs.
(market rating Jules, 2702 (guaranteed availability), 2704 (pronibition on health satus discrimination), and 2707 (requirements of essential health benefits). In addition, because the single risk pool (1311(e)) depends on all of the aforementioned sections (2701, 2702, 2704, 2705, and 2707), the transitional plans remain exempt from the single risk pool. CMS designed the Unified Rate Review Template and system exclusively for use with the single risk pool plan, and any attempt to include non-single risk pool plans in the Unified Rate Review template or system will create errors, inaccuracies, and limitations that would prevent the effectiveness of reviews of both sets of non-grandfathered plans (single risk pool and transitional). For these many reasons, CMS requires issuers with transitional plans experiencing rate increases unject 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.				On 11/14/ 2013, CMS issued a letter to State Insurance Commissioners outlining transitional policy for non-grandfathered coverage in the small group and individual health insurance markets. If permitted by applicable state authorities, health insurance issuers can continue coverage that would otherwise get terminated or cancelled, and affected individuals and small businesses can re-enroll in such coverage. Under this transitional policy, non-grandfathered health insurance coverage in the individual or small group market renewed for a policy year starting between 1/1/2014 and 10/1/2014 will remain in compliance with certain market reforms if it meets certain specific conditions. These transitional plans remain subject to the requirements of section 2794 but not 2701 (market rating rules), 2702 (guaranteed availability), 2704 (prohibition on health status rating), 2705 (prohibition on health status discrimination), and 2707 (requirements of essential health benefits). In addition, because the single risk pool (1311(e)) depends on all of the aforementioned sections (2701, 2702, 2704, 2705, and 2707), the transitional plans remain exempt from the single risk pool. CMS designed the Unified Rate Review Template and system exclusively for use with the single risk pool plan, and any attempt to include non-single risk pool plans in the Unified Rate Review template or system will create errors, inaccuracies, and limitations that would prevent the effectiveness of reviews of both sets of non-grandfathered plans (single risk pool and transitional). For these many reasons, CMS requires issuers with transitional plans experiencing rate increases subject to review to use the Rate Review Justification system and templates required and utilized prior to 4/1/2013. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30994.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/2/2014 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2014-04-0	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
92.t.	ACA Implementation: Market Reform and Mental Health Parity ACTION: Guidance NOTICE: Affordable Care Act Implementation FAQs: Market Reform Provisions and Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/9/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This guidance includes additional Frequently Asked Questions (FAQs) and answers regarding implementation of the market reform provisions of ACA, as well as FAQs regarding implementation of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by ACA. HHS and the Departments of Labor and the Treasury prepared these FAQs. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html SUMMARY OF NIHB ANALYSIS:	
92.u.	Exchange and Insurance Market Standards for 2015 and Beyond ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond AGENCY: CMS	CMS-9949- PF	Issue Date: 3/21/2014 Due Date: 4/21/2014 NIHB File Date: 4/21/2014; TTAG also filed comments 4/21/2014 Date of Subsequent Agency	NIHB response: TTAG response:	SUMMARY OF AGENCY ACTION: This proposed rule would address various requirements applicable to health insurance issuers, Affordable Insurance Exchanges (Exchanges), Navigators, non-Navigator assistance personnel, and other entities under ACA. Specifically, this rule proposes standards related to product discontinuation and renewal, quality reporting, non-discrimination standards, minimum certification standards and responsibilities of QHP issuers, the Small Business Health Options Program, and enforcement remedies in Federally-facilitated Exchanges. It also proposes: a modification of HHS allocation of reinsurance contributions collected if those contributions do not meet projections; certain changes to the ceiling on allowable administrative expenses in the risk corridors calculation; modifications to the way HHS calculates certain cost-sharing parameters to round those parameters down to the nearest \$50 increment; certain approaches HHS has considered to index the required contribution used to determine eligibility for an exemption from the shared responsibility payment under section 5000A of the Internal Revenue Code; grounds for imposing civil money penalties on individuals who provide false or fraudulent information to the Exchange and on individuals who improperly use or disclose information; updated standards for the consumer assistance programs; standards related to the opt-out	See Table C.



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Ref.	of Regulation/Title/	File Code	Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		Action, if any: Issued Final Rule 5/27/2014		provisions for self-funded, non-Federal governmental plans and the individual market provisions under HIPAA; standards for recognition of certain types of foreign group health coverage as minimum essential coverage; amendments to Exchange appeals standards and coverage enrollment and termination standards; and time-limited adjustments to the standards relating to the medical loss ratio program. http://www.gpo.gov/fdsys/pkg/FR-2014-03-21/pdf/2014-06134.pdf	
					A CCIIO fact sheet on this proposed rule is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/marketstandards-3-14-2014.html .	
					A CCIIO fact sheet on enforcement of ACA provisions is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/compliance-3-15-2013.html .	
					SUMMARY OF NIHB ANALYSIS: This proposed rule includes several Al/AN-related provisions on which tribal representatives might want to comment:	
					Exception to Non-Discrimination Provision for Certified Application Counselors: This proposed rule would create a limited exception to existing non-discrimination regulations. Under this exception, an organization that receives Federal funds to provide services to a defined population under the terms of Federal legal authorities (e.g., an Indian health provider) and that participates in the certified application counselor program can limit its provision of certified application counselor services to the same defined population without violating existing nondiscrimination provisions. According to CMS, this exception would "allow such organizations to provide certified application counselor services and assist their defined populations in enrolling in health coverage offered through the Exchanges consistent with the Federal legal authorities under which such organizations operate." [79 FR 15822] **Tribal representatives might want to indicate in comments support for this**	
					provision.	
					CMPs for Providing False or Fraudulent Information: This proposed rule specifies the circumstances in which HHS can impose CMPs on individuals if it	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					determines that they have provided false or fraudulent information or improperly used or disclosed information in violation of section 1411 of ACA. Under this proposed rule, HHS can impose CMPs for three specific types of actions related to the provision of false or fraudulent information and the improper use of information. The first of these actions applies to individuals who apply for enrollment in a QHP offered through an Exchange in the individual market; for premium tax credits or cost sharing reductions; or for an exemption from the individual shared responsibility payment based on their status as a member of an exempt religious sect or division, as an Indian, or as an individual eligible for a hardship exemption or based on their lack of affordable coverage or their status as a taxpayer with household income less than 100 percent of the federal poverty level. If these individuals fail to make a reasonable attempt to provide accurate, complete, and comprehensive information (as required by section 1411 of ACA) and, as a result, provide incorrect information in their applications, they might face CMPs under this proposed rule. One consideration in reviewing the establishment of CMPs for individuals applying for the Indian-specific exemptions from the tax penalty is whether this is warranted at this time (and might discourage eligible individuals), particularly given the experiences in states (such as California) where families appear to get grouped together by the online application system as "members of an Indian tribe," even when only some of the families indicate they meet this eligibility category.	
					 Requirements for QHPs Offering to Contract with Indian Health Care Providers: This proposed rule does not include provisions mentioned by CCIIO in the "2015 Letter to Issuers in the Federally-Facilitated Marketplaces" pertaining to QHPs offering to contract with Indian health care providers. In the introduction to the letter, CCIIO stated: "Additional proposed requirements are included in a regulation titled 'Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond,' CMS-9949-P that is being released simultaneously with this letter." Specifically, in Chapter 2, Section 4 (pp. 20-21 of the draft version of the letter), CMS announced plans to propose a rule that would 1) require QHP applications to "list the offers that [issuers have] extended to all available Indian health providers in each county in the service area," 2) include an expectation that "issuers be able to provide verification of such offers if CMS chooses to verify the offers," and 3) 	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					consider offers "in good faith" if they include "terms that a willing, similarly- situated, non-ECP provider would accept or has accepted." These additional requirements do not appear in this proposed rule.	
					Tribal representatives might want to recommend that CMS include the provisions referenced in the CCIIO 2015 Letter in the final rule.	
					This proposed rule also does not include provider directory requirements outlined by CCIIO in the 2015 Issue Letter, and as a result, whether these requirements remain in effect appears unclear. The provider directory provision in the letter reads: "CMS, as administrator of the FFMs, will require QHPs to make their provider directories available to the Marketplace for publication online by providing the URL link to their network directory. CMS expects the URL link to direct consumers to an up-to-date provider directory where the consumer can view the provider network that is specific to a given QHP. The URL provided to the Marketplace as part of the QHP Application should link directly to the directory, such that consumers do not have to log on, enter a policy number, or otherwise navigate the issuer's website before locating the directory. If an issuer has multiple provider directories, it should be clear to consumers which directory applies to which QHP(s). Further, CMS expects the directory to include location, contact information, specialty, and medical group, any institutional affiliations for each provider, and whether the provider is accepting new patients. CMS encourages issuers to include languages spoken, provider credentials, and whether the provider is an Indian health provider. Directory information for Indian health providers should describe the service population served by each provider, as some Indian health providers may limit services to Indian beneficiaries, while others may choose to serve the general public." Tribal representatives might want to seek clarification on this issue.	
					Press reports indicate that CMS might not impose this requirement on QHPs, citing technological issues. Tribal representatives, among other items, might want to recommend that CMS identify simplified approaches that are technologically feasible.	
					SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule addresses various requirements applicable to health insurance issuers, Affordable Insurance Exchanges (Exchanges), Navigators, non-Navigator assistance personnel, and other entities under ACA. Specifically, this final rule establishes standards related to product discontinuation and renewal, quality reporting, non-discrimination standards, minimum certification standards and responsibilities of qualified health plan (QHP) issuers, the Small Business	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Health Options Program, and enforcement remedies in Federally-facilitated Exchanges. It also finalizes: • A modification of HHS allocation of reinsurance collections if those collections do not meet its projections; • Certain changes to allowable administrative expenses in the risk corridors calculation; • Modifications to the way HHS calculates the annual limit on cost sharing so that it rounds this parameter down to the nearest \$50 increment; • An approach to index the required contribution used to determine eligibility for an exemption from the shared responsibility payment under section 5000A of the Internal Revenue Code; • Grounds for imposing civil money penalties on individuals who provide false or fraudulent information to the Exchange and on individuals who improperly use or disclose information; • Updated standards for the consumer assistance programs; • Standards related to the opt-out provisions for self-funded, non-Federal governmental plans and related to the individual market provisions under HIPAA, including excepted benefits; • Standards regarding how enrollees can request access to non-formulary drugs under exigent circumstances; • Armendments to Exchange appeals standards and coverage enrollment and termination standards; and • Time-limited adjustments to the standards relating to the medical loss ratio (MLR) program. http://www.gpo.gov/fdsys/pkg/FR-2014-05-27/pdf/2014-11657.pdf A CCIIO fact sheet on this final rule is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/marketstandards-5-16-2014.html. Analysis: CMS finalized the majority of the provisions in this final rule as originally drafted in the proposed rule. In addition, in the final rule, CMS opted not to address requests from tribal organizations to codify or clarify certain provisions included in the CCIIO 2015 Letter to Issuers in the Federally-Facilitated Marketplaces (see 7.ee.) but	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis which did not appear in the proposed rulei.e., requirements for QHPs to offer to contract with Indian health providers, etc. (see Table C). Additional analysis appears in the document embedded below.	NIHB Recs.
					CMS-9949-F analysis 2014-05-31.docx	
92.v.	Q&A on Outreach by Medicaid MCOs to Former Enrollees ACTION: Guidance NOTICE: Question and Answer on Outreach by Medicaid Managed Care Contractors and Health Insurance Issuers to Former Enrollees AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/21/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Medicaid managed care organizations (MCOs), which provide coverage to beneficiaries on a risk basis, have existed since before the enactment of ACA. Many individuals once enrolled in a Medicaid managed care plan might no longer qualify for Medicaid as determined by States. Many issuers that contract with States as MCOs have become involved in offering Qualified Health Plans (QHPs) on the Federally-Facilitated Marketplace or in State-Based Marketplaces, providing coverage to previously uninsured individuals. This guidance answers the question of whether an issuer with a Medicaid MCO contract can reach out to former enrollees who States disenrolled because of a loss of Medicaid eligibility to assist them in enrolling in health coverage offered by the issuer through the Marketplace. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/medicaid-mco-enrollee-outreach-faq-2-21-14.pdf SUMMARY OF NIHB ANALYSIS:	
92.w.	Provider Non- Discrimination ACTION: Request for Information NOTICE: Request for Information Regarding	CMS-9942- NC	Issue Date: 3/12/2014 Due Date: 6/10/2014 NIHB File Date:		SUMMARY OF AGENCY ACTION: This document contains a request for information regarding provider non-discrimination. HHS, DoL, and the Department of the Treasury (collectively, the Departments) invite public comments via this request for information. A Senate Committee on Appropriations report dated 7/11/2013 states: section 2706 of the Public Health Service (PHS) Act "prohibits certain types of health plans and issuers from discriminating against any healthcare provider who is acting within the scope of that provider's license or certification under applicable State law, when determining networks	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
***	Agency Provider Non-Discrimination AGENCY: CMS/IRS/DoL		Date of Subsequent Agency Action, if any:	Response	of care eligible for reimbursement. The goal of this provision is to ensure that patients have the right to access covered health services from the full range of providers licensed and certified in their State. The Committee is therefore concerned that the FAQ document issued by HHS, DoL, and the Department of Treasury on April 29, 2013, advises insurers that this nondiscrimination provision allows them to exclude from participation whole categories of providers operating under a State license or certification. In addition, the FAQ advises insurers that section 2706 allows discrimination in the reimbursement rates based on broad 'market considerations' rather than the more limited exception cited in the law for performance and quality measures. Section 2706 was intended to prohibit exactly these types of discrimination. The Committee believes that insurers should be made aware of their obligation under section 2706 before their health plans begin operating in 2014. The Committee directs HHS to work [with] DoL and the Department of Treasury to correct the FAQ to reflect the law and congressional intent within 30 days of enactment of this act." Pursuant to this report, the Departments request comments on all aspects of the interpretation of section 2706(a) of the PHS Act. This includes but is not limited to comments on access, costs, other federal and state laws, and feasibility. The FAQ is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html . A similar FAQ issued by DoL is available at http://www.dol.gov/ebsa/faqs/faq-aca15.html . The Senate Committee on Appropriations report is available at http://www.goo.gov/fdsys/pkg/CRPT-113srpt71/pdf/CRPT-113srpt71.pdf SUMMARY OF NIHB ANALYSIS: This request for information provides an opp	
92.x.	Extension of Transitional	CCIIO (no	Issue Date:		SUMMARY OF AGENCY ACTION: On 11/14/2013, CMS issued a letter to 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.
	Policy for Non-Grandfathered Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin Series Extension of Transitional Policy through October 1, 2016: Extended Transition to ACA-Compliant Policies AGENCY: CCIIO	reference number)	3/5/2014 <u>Due Date:</u> None <u>NIHB File</u> <u>Date:</u> <u>Date of</u> <u>Subsequent</u> <u>Agency</u> <u>Action, if any:</u>		Insurance Commissioners outlining a transitional policy for non-grandfathered coverage in the small group and individual health insurance markets. In the letter, CMS announced that, if permitted by applicable State authorities, health insurance issuers can choose to continue certain coverage that would otherwise get canceled, and affected individuals and small businesses can choose to re-enroll in such coverage. The letter further stated that, under the transitional policy, if certain specific conditions are met, CMS will not consider this coverage—non-grandfathered 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. In the 11/14/2013 letter, CMS indicated that it would consider the impact of the transitional policy in assessing whether to extend it beyond the specified timeframe. This guidance announces that CMS has considered the impact of the transitional policy and will extend it for two years—to policy years beginning on or before 10/1/2016 in the small group and individual markets. CMS will consider the impact of the two-year extension of the transitional policy in assessing the appropriateness of an additional one-year extension. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/transition-to-compliant-policies-03-06-2015.pdf SUMMARY OF NIHB ANALYSIS:	
92.y.	Draft Notices When Discontinuing or Renewing a Product ACTION: Guidance NOTICE: Insurance Standards Bulletin Series: Draft Notices When Discontinuing or Renewing a Product in the Group or Individual Market	CCIIO (no reference number)	Issue Date: 3/14/2014 Due Date: 4/18/2014 NIHB File Date: None Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: Contemporaneously with the issuance of this bulletin, CMS has released a proposed rule, titled "Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond" (see 92.u.). This bulletin provides draft notices that this rule would require to if finalized. Interested parties can submit comments on the draft notices as described in section III of this bulletin. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-discontinuance-renewal-notices-03-14-14.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.
	AGENCY: CCIIO		Action, if any:			
92.z.	Coverage of Same-Sex Spouses ACTION: Guidance NOTICE: Frequently Asked Question on Coverage of Same-Sex Spouses AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 3/14/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: On 2/27/2013, CMS published final regulations implementing section 2702 of the Public Health Service Act (PHS Act). Section 2702 of the PHS Act requires health insurance issuers offering non-grandfathered health insurance coverage in the group or individual markets (including qualified health plans offered through Affordable Insurance Exchanges or Exchanges) to guarantee the availability of coverage unless one or more exceptions applies. The preamble to this final rule (78 FR 13417) indicates that discriminatory marketing practices or benefit designs represent a failure by health insurance issuers to comply with the guaranteed availability requirements, and the final regulations at 45 CFR 147.104(e) establish certain marketing and nondiscrimination standards in the regulation text. This guidance serves to clarify the meaning of the terms used in 45 CFR 147.104(e) for the purposes of describing the requirements health insurance issuers must meet to ensure guaranteed availability of coverage. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/frequently-asked-questions-on-coverage-of-same-sex-spouses.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This guidance requires issuers to offer cover to a same-sex spouse if they offer coverage to an opposite-sex spouse, and to do so on equivalent terms. The requirement applies to non-grandfathered health plans in the group or individual markets. The requirement will take effect as of 1/1/2015.	
92.aa.	Health Insurance Market Reforms and Marketplace Standards ACTION: Guidance NOTICE: Frequently Asked	CCIIO (no reference number)	Issue Date: 5/16/2014 Due Date: None NIHB File		SUMMARY OF AGENCY ACTION: This document includes Frequently Asked Questions (FAQs) and answers regarding implementation of certain health insurance market reforms and Marketplace standards established in ACA. Specifically, this document includes guidance on the implementation of the essential health benefits (EHB) and actuarial value (AV), guaranteed availability, minimum essential coverage (MEC), and transitional policy extensions.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Questions on Health Insurance Market Reforms and Marketplace Standards AGENCY: CCIIO		Date: Date of Subsequent Agency Action, if any:		http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Final-Master-FAQs-5-16-14.pdf SUMMARY OF NIHB ANALYSIS:	
92.bb.	Employer Health Care Arrangements (Q&A) ACTION: Guidance NOTICE: Employer Health Care Arrangements AGENCY: IRS	IRS (no reference number) See also 92.I.	Issue Date: 5/13/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This guidance explains the consequences to an employer if the employer does not establish a health insurance plan for its own employees but reimburses those employees for premiums they pay for health insurance (either through a qualified health plan in the Marketplace or outside the Marketplace). IRS previously informed employers in Notice 2013-54 (see 92.I.) that they cannot give their workers a tax-free lump sum to cover their health insurance costs outside of employer-provided coverage. According to this guidance: "Under IRS Notice 2013-54, such arrangements are described as employer payment plans. An employer payment plan, as the term is used in this notice, generally does not include an arrangement under which an employee may have an after-tax amount applied toward health coverage or take that amount in cash compensation. As explained in Notice 2013-54, these employer payment plans are considered to be group health plans subject to the market reforms, including the prohibition on annual limits for essential health benefits and the requirement to provide certain preventive care without cost sharing. Notice 2013-54 clarifies that such arrangements cannot be integrated with individual policies to satisfy the market reforms. Consequently, such an arrangement fails to satisfy the market reforms and may be subject to a \$100/day excise tax per applicable employee (which is \$36,500 per year, per employee) under section 4980D of the Internal Revenue Code." http://www.irs.gov/uac/Newsroom/Employer-Health-Care-Arrangements A New York Times article on this guidance is available at http://www.nytimes.com/2014/05/26/us/irs-bars-employers-from-dumping-workers-into-	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					health-exchanges.html?wpisrc=nl_wonk. SUMMARY OF NIHB ANALYSIS:	
94.	Methodology for Designation of Frontier and Remote Areas ACTION: Notice NOTICE: Methodology for Designation of Frontier and Remote Areas AGENCY: HRSA	HRSA (no reference number)	Issue Date: 11/5/2012 Due Date: 1/4/2013 NIHB File Date: 1/4/2013 Date of Subsequent Agency Action, if any: Issued Final Notice 5/5/2014	NIHB response:	SUMMARY OF AGENCY ACTION: This notice announces a request for public comment on a methodology derived from the Frontier and Remote (FAR) system for designating U.S. frontier areas. This methodology was developed in a collaborative project between the HRSA Office of Rural Health Policy (ORHP); and the USDA Economic Research Service (ERS). While other HHS agencies and ERS might in the future choose to use the FAR methodology to demarcate the frontier areas of the U.S., there is no requirement that they do so, and they may choose other, alternate methodologies and definitions that best suit their program requirements. SUMMARY OF NIHB ANALYSIS: A need exists to define "frontier and remote" areas, but the proposed methodology, as drafted, poses significant procedural and substantive concerns. As HRSA notes, the increased per capita costs of providing servicessuch as health care, as well as schools, police and fire protection, public utilities, and transportationrepresents one of the fundamental and defining challenges facing frontier communities. A very significant percentage of Tribes face these challenges every day. SUMMARY OF SUBSEQUENT AGENCY ACTION: HRSA ORHP published a 60-day public notice in the 11/5/2012 FR (77 FR 66471-6) describing a methodology for designating U.S. frontier areas. ORHP developed the FAR Codes methodology in a collaborative project with USDA ERS. This notice responds to the comments received during this 60-day public notice. http://www.gpo.gov/fdsys/pkg/FR-2014-05-05/pdf/2014-10193.pdf	See Table C.
99.c.	Evaluation of Wellness and Prevention Programs ACTION: Request for Comment	CMS-10509	Issue Date: 11/22/2013 Due Date: 1/21/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Prospective Evaluation of Evidence-Based Community Wellness and Prevention Programs; Use: Section 4202(b) of ACA mandated that CMS conduct an evidence review and independent evaluation of wellness programs focusing on the following six intervention areas: chronic disease self-management, increasing physical activity, reducing obesity, improving diet and nutrition, reducing falls, and mental 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.
	NOTICE: Prospective Evaluation of Evidence- Based Community Wellness and Prevention Programs AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/18/2014 Due Date: 5/19/2014		management. In response, CMS adopted a three-phase approach to evaluate the impact of wellness programs on Medicare beneficiary health, utilization, and costs to determine whether broader participation in wellness programs could lower future growth in program spending. Phase I consisted of a comprehensive literature review and environmental scan to identify a list of wellness programs for further evaluation. Phase II involved a retrospective evaluation of 10 wellness programs in the targeted intervention areas mentioned above. This evaluation sought to use Medicare claims data to assess the impact of 10 wellness programs on beneficiary outcomes, including health service utilization and medical costs. The findings in Phase II indicated that several wellness programs demonstrated the potential to reduce medical costs among participating beneficiaries. In Phase III, CMS will conduct an evaluation to round out its understanding of how wellness programs affect Medicare beneficiaries and what cost saving opportunities exist for the program. This evaluation will (1) describe the overall distribution of readiness to engage with wellness programs in the Medicare population, (2) better adjust for selection biases of individual programs and interventions using beneficiary level survey data, (3) evaluate program impacts on health behaviors, self-reported health outcomes, and claims-based measures of utilization and costs, and (4) better describe program implementation, operations, and cost in relation to the expected benefits. The results of these analyses will inform wellness and prevention activities in the future. To achieve the goals of this project, CMS will conduct a nationally representative survey of Medicare beneficiaries to assess their readiness to participate in community-based wellness programs. CMS will generate national estimates of Medicare beneficiary demand for wellness services and benefits from this survey. In addition, CMS will partner with evidence-based wellness programs for the purposes of enroll	
					version of this PRA request. CMS received no comments on the 60-day notice	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					published in the 11/22/2013 FR (78 FR 70059). During recent discussions with potential wellness programs, CMS determined that it underestimated the earlier projected response rate. Thus, CMS has increased the projected response rate and the total number of completed baseline surveys. CMS also has increased the total estimated burden associated with completing the Participant survey. In addition, results from the cognitive testing with less than 9 Medicare beneficiaries suggested the need for clarification for several items, and in response, CMS has added and deleted questions from the surveys. CMS has made these clarifications throughout the surveys in response to this feedback and documented the changes in Part A, Attachment 5. http://www.gpo.gov/fdsys/pkg/FR-2014-04-18/pdf/2014-08897.pdf	
100.b.	Marketplace Quality Standards ACTION: Request for Comment NOTICE: Marketplace Quality Standards AGENCY: CMS	CMS-10520	Issue Date: 5/23/2014 Due Date: 6/23/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Marketplace Quality Standards; Use: Section 1311(c)(3) of ACA directs the HHS Secretary to develop a rating system for qualified health plans (QHPs) on the relative basis of quality and price and requires Marketplaces to display this quality rating information on their Web sites. Section 1311(c)(4) requires the HHS Secretary to develop an enrollee satisfaction survey system (ESS) that assesses consumer experience with QHPs (with more than 500 enrollees in the previous year) offered through a Marketplace and requires Marketplaces to display enrollee satisfaction information to allow individuals to compare enrollee satisfaction levels between comparable plans. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards beginning 1/1/2015. The collection of information from QHP issuers is necessary to implement these quality standards and to provide adequate and timely health care quality information to consumers, regulators, and Marketplaces. Specifically, for implementation and reporting for the Federal Quality Rating System (QRS) and for ESS, the collection, validation and submission of validated data is required as outlined in § 156.1120 and § 156.1125. In addition, QHP issuers must demonstrate compliance with the patient safety standards outlined in § 156.1110, which involves associated information collection, recordkeeping, and disclosure requirements. It is also necessary to collect information per § 156.1105 to appropriately monitor and provide a process for survey vendors to appeal an HHS decision to not approve ESS vendor applications. http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11948.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		The Date		SUMMARY OF NIHB ANALYSIS: In this PRA Notice, CMS seeks OMB approval to collect information associated with the following quality standards: • Implementation and reporting for QRS; • Implementation and reporting for ESS; • Monitoring and appeals process for survey vendors; and • Patient safety reporting standards for QHP issuers. On 1/21/2014, TTAG filed comments on CMS-3288-NC, "Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS), Framework Measures and Methodology," a Paperwork Reduction Actrelated notice. These comments addressed concerns about information on access to I/T/U providers, information on Al/AN member experience, and other Al/AN specific measures. In addition, on December 2, 2013, NIHB and TTAG filed comments on CMS-10488, "Enrollee Satisfaction Survey Data Collection," another Paperwork Reduction Act-related notice. These comments addressed concerns about questions specific to Al/ANs in Marketplace and QHP surveys, questions regarding race, and Al/AN survey response rates (see below for more detailed information). CMS has not responded to either set of comments as of May 31, 2014. In addition to the Marketplace enrollee satisfaction information, this PRA Notice includes information collection associated with patient safety reporting standards for QHP issuers. Under §156.1110, QHP issuers must collect and maintain CMS Certification Numbers for each hospital certified as having more than 50 beds with which they contract. An Exchange can request this information and use it as demonstration of compliance by QHP issuers with patient safety reporting standards outlined in §155.1110. Additional analysis appears in the document 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.
109.c.	Health Care Continuation Coverage ACTION: Proposed Rule NOTICE: Health Care Continuation Coverage AGENCY: DoL	DoL RIN 1210- AB65	Issue Date: 5/7/2014 Due Date: 7/7/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: These proposed regulations contain amendments to notice requirements of the health care continuation coverage (COBRA) provisions of Part 6 of title I of ERISA to better align the provision of guidance under the COBRA notice requirements with ACA provisions already in effect, as well as any provisions of federal law that will become applicable in the future. These proposed regulations would eliminate the current version of the model general notice contained in the appendix of § 2590.606-1 and the model election notice contained in the appendix of § 2590.606-4, as these model notices are outdated. In addition, these proposed regulations would make technical changes to the instruction language pointing to the model notices in the appendices in paragraph (g) of § 2590.606-1 and paragraph (g) of § 2590.606-4. These changes would permit DoL to amend the model notices as necessary and provide the most current versions of the model notices on its Web site. The updated model notices are available in modifiable, electronic form on the DOL Web site at http://www.dol.gov/ebsa/cobra.html. http://www.gpo.gov/fdsys/pkg/FR-2014-05-07/pdf/2014-10416.pdf SUMMARY OF NIHB ANALYSIS:	
110.f.	Requirements for Open Payments ACTION: Request for Comment NOTICE: Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments	CMS-10495	Issue Date: 7/22/2013 Due Date: 9/20/2013 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments; Use: Section 6002 of ACA added section 1128G to the Social Security Act (Act), which requires applicable manufacturers and applicable group purchasing organizations (GPOs) of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals, as well as certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs. Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies must submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made 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.
	AGENCY: CMS		Issued new request 11/8/2013; issued revision 5/5/2014 Due Date: 12/9/2013; 6/2/2014		physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS the required information about physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs could face civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. The statute requires CMS to publish the reported data on a public Web site in a downloadable, easily searchable, and aggregated format. In addition, CMS must submit annual reports to the Congress and each state summarizing the data reported. Finally, section 1128G of the Act generally preempts state laws that require disclosure of the same type of information by manufacturers. To implement this program, CMS in 2013 published a final rule (see 110.a.) that included several information collections subject to the Paperwork Reduction Act. This information collection request informs the public about data collected for registration, attestation, dispute resolution and corrections, record retention, and submitting an assumptions document within Open Payments. http://www.gpo.gov/fdsys/pkg/FR-2013-07-22/pdf/2013-17476.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/8/2013 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-11-08/pdf/2013-26822.pdf CMS on 5/5/2014 issued a revision of this 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 would occur and resubmitted a revised ICR for OMB review and approval. Although CMS	NIHB Recs.
					resubmitted the entire ICR, the agency specifically seeks comments on the dispute resolution and comment process. http://www.gpo.gov/fdsys/pkg/FR-2014-05-05/pdf/2014-10228.pdf	
110.g.	Procedures for Advisory Opinions on Physician Referrals ACTION: Request for Comment NOTICE: Procedures for Advisory Opinions Concerning Physicians' Referrals and Supporting Regulations AGENCY: CMS	CMS-R-216	Issue Date: 11/8/2013 Due Date: 1/7/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/17/2014 Due Date: 2/18/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Procedures for Advisory Opinions Concerning Physicians' Referrals and Supporting Regulations; Use: The information collection requirements contained in 42 CFR 411.372 and 411.373 allow CMS to consider requests for advisory opinions and provide accurate and useful opinions. CMS reads and analyzes the information to develop and issue an advisory opinion to the individual or entity that submitted the information. The Center for Medicare, which issues of advisory opinions, serves as the primary office using the information. http://www.gpo.gov/fdsys/pkg/FR-2013-11-08/pdf/2013-26829.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/17/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00915.pdf	
110.h.	Hospital Disclosures Regarding Physician Ownership ACTION: Request for Comment NOTICE: Disclosures Required of Certain	CMS-10225	<u>Issue Date</u> : 12/13/2013 <u>Due Date</u> : 2/11/2014 <u>NIHB File</u> <u>Date</u> : None		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership; Use: Medicare does not prohibit physician investment in a hospital or critical access hospital (CAH). In addition, Medicare does not require a hospital or CAH to have a physician on-site at all times, although the program does require a hospital or CAH to have the ability to provide basic elements of emergency care to its patients. However, patients might consider an ownership interest by their referring physician, the	



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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.
	Hospitals and Critical Access Hospitals Regarding Physician Ownership AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued revision 3/10/2014 Due Date: 4/9/2014		presence of a physician on-site, or both important factors in their decisions about where to seek hospital care. Accordingly, patients should know about the physician ownership of a hospital, whether a physician remains in the hospital at all times, and hospital plans to address patient emergency medical conditions in the absence of a physician. The disclosures seek to increase the transparency of hospital ownership and operations to patients as they make decisions about receiving hospital care. http://www.gpo.gov/fdsys/pkg/FR-2013-12-13/pdf/2013-29725.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/10/2014 issued a revision of this PRA request. CMS has revised this information collection request subsequent to the publication of the 60-day notice in the 12/13/2013 FR (78 FR 75925). http://www.gpo.gov/fdsys/pkg/FR-2014-03-10/pdf/2014-05104.pdf	
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 Due Date:		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 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	



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			6/2/2014		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	
110.j.	Disclosure for the In-Office Ancillary Services Exception ACTION: Request for Comment NOTICE: Disclosure for the In-Office Ancillary Services Exception AGENCY: CMS	CMS-10332	Issue Date: 4/4/2014 Due Date: 6/3/2014 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: Disclosure for the In-Office Ancillary Services Exception; Use: Physicians who provide certain imaging services (magnetic resonance imaging, computed tomography, and positron emission tomography) under the in-office ancillary services exception to the physician self-referral prohibition must create the disclosure notice, as well as the list of other imaging suppliers the patient will use. The patient can use the disclosure notice and list of suppliers in making an informed decision about his or her course of care for the imaging service. The physician must maintain a record of the disclosure in patient medical records. If CMS investigates the referrals of a physician providing advanced imaging services under the in-office ancillary services exception, it would review the written disclosure to determine whether the physician satisfied the requirement. http://www.gpo.gov/fdsys/pkg/FR-2014-04-04/pdf/2014-07575.pdf SUMMARY OF NIHB ANALYSIS:	
112.b.	IHS Reimbursement Rates for CY 2014 ACTION: Notice NOTICE: Reimbursement Rates for Calendar Year 2014 AGENCY: IHS	IHS RIN 0917- ZA28	Issue Date: 3/31/2014 Due Date: None NIHB File Date: Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: This notice announces that the Director of the Indian Health Service (IHS), 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 Calendar Year 2014 for beneficiaries of Medicare, Medicaid, and other Federal programs and for recoveries under the Federal Medical Care Recovery Act. This notice excludes the Medicare Part A inpatient reimbursement rates, which are based on the prospective payment system. Since the inpatient rates set forth in this notice do not include all physician services and practitioner services, IHS will make additional payment available to the extent that those services are provided. CY 2014 Rates	



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			Action, if any:		Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services) • Lower 48 States: \$2,413 • Alaska: \$2,675 Outpatient Per Visit Rate (Excluding Medicare) • Lower 48 States: \$342 • Alaska: \$564 Outpatient Per Visit Rate (Medicare) • Lower 48 States: \$297 • Alaska: \$516 Medicare Part B Inpatient Ancillary Per Diem Rate • Lower 48 States: \$502 • Alaska: \$862 Outpatient Surgery Rate (Medicare): Established Medicare rates for freestanding Ambulatory Surgery Centers. Effective Date for CY 2014 Rates Consistent with previous annual rate revisions, the CY 2014 rates will take effect for services provided on/after 1/1/2014 to the extent consistent with payment authorities, including the applicable Medicaid State plan. SUMMARY OF NIHB ANALYSIS: A table comparing CY 2014 and CY 2013 IHS reimbursement rates is embedded below.	
113.	Additional Medicare Tax ACTION: Proposed Final Rule	REG- 130074-11 TD 9645	<u>Issue Date</u> : 12/5/2012 <u>Due Date</u> :		SUMMARY OF AGENCY ACTION: This document contains proposed regulations relating to Additional Hospital Insurance Tax on income above threshold amounts ("Additional Medicare Tax"), as added by the Affordable Care Act. Specifically, these proposed regulations provide guidance for employers and individuals relating 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.
	NOTICE: Rules Relating to Additional Medicare Tax AGENCY: IRS		3/5/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 1/30/2013; issued Final Rule 11/29/2013		implementation of Additional Medicare Tax. This document also contains proposed regulations relating to the requirement to file a return reporting Additional Medicare Tax, the employer process for making adjustments of underpayments and overpayments of Additional Medicare Tax, and the employer and employee processes for filing a claim for refund for an overpayment of Additional Medicare Tax. This document also provides notice of a public hearing on these proposed rules. http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29237.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSQENT AGENCY ACTION: This correction makes the following change to the proposed rule that appeared on in the December 5, 2012, FR (77 FR 72268): http://www.gpo.gov/fdsys/pkg/FR-2013-01-30/pdf/C1-2012-29237.pdf This correction makes the following changes to the proposed rule that appeared on in the December 5, 2012, FR (77 FR 72268): http://www.gpo.gov/fdsys/pkg/FR-2013-01-30/pdf/2013-01885.pdf IRS on 11/29/2013 issued a document that contains final regulations relating to Additional Hospital Insurance Tax on income above threshold amounts ("Additional Medicare Tax"), as added by ACA. Specifically, these final regulations provide guidance for employers and individuals relating to the implementation of Additional Medicare Tax, including the requirement to file a return reporting Additional Medicare Tax, the employer process for adjusting underpayments and overpayments of Additional Medicare Tax, and the employer and individual processes for filing a claim for refund for an overpayment of Additional Medicare Tax. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28411.pdf IRS on 1/22/2014 issued a document that contains corrections to final regulations (TD 9645) published in the 11/29/2013 FR (78 FR 71468). The final regulations address the Additional Hospital Insurance Tax on income higher than threshold amounts, as added by ACA. http://www.gpo.gov/fdsys/pkg/FR-2014-01-29/pdf/2014-01619.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.
121.g.	Health Insurance Benefit Agreement ACTION: Request for Comment NOTICE: Health Insurance Benefit Agreement AGENCY: CMS	CMS-1561	Issue Date: 11/1/2013 Due Date: 12/31/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/17/2014 Due Date: 2/18/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Health Insurance Benefit Agreement; Use: Applicants to the Medicare program must agree to provide services in accordance with Federal requirements. CMS-1561 allows CMS to ensure that applicants comply with the requirements. Applicants must sign the completed form and provide operational information to CMS to assure that they continue to meet the requirements after approval. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26083.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/17/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00915.pdf	
121.h.	Medicare Enrollment Application: Part A Institutional Providers ACTION: Request for Comment NOTICE: Medicare Enrollment Application: Part A Institutional Providers AGENCY: CMS	CMS-855A	Issue Date: 11/15/2013 Due Date: 1/14/2014 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: Medicare Enrollment Application: Medicare Part A Institutional Providers; Use: CMS has revised the CMS-855 Medicare Enrollment Applications information collection request to remove the CMS-855I, CMS-855B and CMS-855R applications from its collection. CMS has found that the regulations governing the enrollment requirements for health care facilities occur at intervals separate from the other provider and supplier types reimbursed by Medicare. Consequently, CMS might need to revise and submit the CMS-855A enrollment application for OMB approval at intervals separate from the other enrollment applications, which include the CMS-855B, CMS-855I, and CMS-855R enrollment applications. CMS plans to maintain the continuity of the CMS-855 enrollment applications by using the same formats and layout of the current CMS-855 enrollment applications, regardless of the separation of the CMS 855A from the collective enrollment application package.	



Ref.	Short Title/Current Status of Regulation/Title/ 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 has made editorial and clerical corrections to CMS-855A to simplify and clarify the current data collection and to remove obsolete requirements. CMS also has re-numbered and re-sequenced the sections and sub-sections within the form to create a more logical flow of the data collection. In addition, CMS has added a data collection for an address to mail the periodic request for the revalidation of enrollment information (only if it differs from other addresses currently collected). CMS-855A also will collect more specific information regarding types of Home Health Agency sub-units. Other than the information above, new data collected in this revision package includes information on, if applicable, where the supplier stores its patient records electronically. http://www.gpo.gov/fdsys/pkg/FR-2013-11-15/pdf/2013-27305.pdf	
					SUMMARY OF NIHB ANALYSIS:	
126.b.	Evaluation of the Rural Community Hospital Demo	CMS-10508	Issue Date: 11/15/2013		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Evaluation of the Rural Community Hospital Demonstration (RCHD); Use: Section 10313 of ACA extended and expanded the Rural Community Hospital	
	ACTION: Request for Comment		<u>Due Date</u> : 1/14/2014		Demonstration (RCHD). Originally authorized under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), RCHD provides enhanced reimbursement for inpatient services to small rural hospitals that do not qualify as critical	
	NOTICE: Evaluation of the Rural Community Hospital Demonstration		NIHB File Date: None		access hospitals (CAHs). RCHD seeks to increase the capability of these hospitals to meet the health care needs of rural beneficiaries in their service areas. As a demonstration, RCHD aims to provide information to assess the feasibility and	
	AGENCY: CMS		Date of Subsequent		advisability of establishing a new category of rural community hospitals for reimbursement policy.	
			Agency Action, if any: Issued new		For the original demonstration, MMA required a Report to Congress six months after the end of the demonstration, a requirement unchanged by ACA. An initial evaluation,	
			request 1/23/2014		conducted between 2007 and 2011 in preparation for a Report to Congress, focused on the 17 hospitals that had participated at some point between October 2004 and March 2011. CMS received findings from this evaluation in the Interim Evaluation Report of the	
			<u>Due Date:</u> 2/24/2014		Rural Community Hospital Demonstration (an unpublished report).	
			, ,_ ,_ ,_ ,		The current five-year evaluation of RCHD will extend and build on the prior evaluation and produce the Report to Congress required by the MMA. It will assess the impact 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.
					the RCHD in meeting its goals: to enable hospitals to achieve community benefits, such as improved services for their communities (especially Medicare beneficiaries); meet their individual strategic goals; and improve the financial solvency and viability of the participating hospitals. In addition, the evaluation will determine the feasibility and advisability of creating a new payment category of rural hospitals. To achieve this objective, the evaluation will examine how RCHD hospitals responded to payment options and assess how the costs to Medicare under RCHD compare to existing alternative payment options. The evaluation also will summarize the characteristics of the markets served by RCHD hospitals, including beneficiary proximity to inpatient providers and competition among providers in the area. CMS will use the information to assess the implications of expanding the RCHD payment system to hospitals in various market environments. In addition, the evaluation will examine the potential costs of expanding the RCHD payment methodology, accounting for alternative approaches to targeting rural hospitals. http://www.gpo.gov/fdsys/pkg/FR-2013-11-15/pdf/2013-27305.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/23/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-23/pdf/2014-01208.pdf This demonstration provides enhanced reimbursement rates for inpatient services to small rural hospitals that do not qualify as critical access hospitals (CAHs). Tribal health organizations (THOs) participating in the demo (or interested in participating in the demo) might want to review and comment on this PRA request.	
132.e.	Outpatient/Ambulatory Surgery Experience of Care Survey	CMS-10500	Issue Date: 10/4/2013 Due Date:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Outpatient and Ambulatory Surgery Experience of Care Survey; Use: CMS will use the information collected through the field test to inform the development of a larger national survey effort, including development of the final survey instrument and	
	ACTION: Request for Comment		12/3/2013 NIHB File		data collection procedures. CMS will use the data collected in this survey effort to conduct a rigorous psychometric analysis of the survey content. Such an analysis seeks to assess the measurement properties of the proposed instrument and sub-domain	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
134.f.	NOTICE: Outpatient and Ambulatory Surgery Experience of Care Survey AGENCY: CMS	CMS-2088- 92	Date: None Date of Subsequent Agency Action, if any: Issued new request 12/27/2013 Due Date: 1/27/2014 Issue Date: 10/23/2013 Due Date: 12/23/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 1/2/2014 Due Date: 2/3/2014		composites created from item subsets to assure the definition of information reported from any future administrations of the survey. This field test also will serve to refine data collection procedures. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/27/2013 issued a new version of this PRA request. CMS has revised this PRA request since the publication of the 60-day notice in the 10/4/2013 FR (78 FR 61848). http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-31015.pdf SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Outpatient Rehabilitation Facility, Community Mental Health Center Cost Report and Supporting Regulations; Use: Outpatient rehabilitation facilities and community mental health centers must file the cost report with their Medicare Administrative Contractor (MAC). MACs use the cost report to calculate provider cost-to-charge ratios, which help in computing outlier payments and determining a final cost settlement for providers by comparing interim payments received to the reasonable cost for the fiscal period covered by the cost report. In addition, CMS uses data collected in the cost report to support program operations and payment refinement activities and to make Medicare Trust Fund projections. CMS and other stakeholders also use this date to analyze a myriad of health care measures on a national level. Stakeholders include OMB, CBO, the Medicare Payment Advisory Commission, Congress, researchers, universities, and other interested parties. http://www.gpo.gov/fdsys/pkg/FR-2013-10-23/pdf/2013-24854.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/2/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-02/pdf/2013-31390.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.
134.g.	Organ Procurement Organization Laboratory Cost Report ACTION: Request for Comment NOTICE: Organ Procurement Organization/Histocompatibil ity Laboratory Cost Report AGENCY: CMS	CMS-216-94	Issue Date: 3/25/2014 Due Date: 5/23/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Organ Procurement Organization/Histocompatibility Laboratory Cost Report; Use: Freestanding organ procurement organizations (OPOs) and histocompatibility laboratory providers participating in the Medicare program file form CMS 216-94 annually to determine the reasonable costs incurred to furnish treatment for renal transplant patients. http://www.gpo.gov/fdsys/pkg/FR-2014-03-25/pdf/2014-06516.pdf SUMMARY OF NIHB ANALYSIS:	
134.h.	Home Office Cost Statement ACTION: Request for Comment NOTICE: Home Office Cost Statement Form AGENCY: CMS	CMS-287-05	Issue Date: 4/18/2014 Due Date: 6/17/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Home Office Cost Statement Form; Use: Providers of services participating in the Medicare program must, under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act, submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.17, 413.20, and 413.24 require adequate cost data and cost reports from providers on an annual basis. Chain organizations file the home office cost statement form annually to report costs directly related to services furnished to individual providers that involve patient care plus an appropriate share of indirect costs. http://www.gpo.gov/fdsys/pkg/FR-2014-04-18/pdf/2014-08898.pdf SUMMARY OF NIHB ANALYSIS:	
134.i.	Rural Health Clinic/Freestanding FQHC Cost Report	CMS-222-92	<u>Issue Date</u> : 5/16/2014 <u>Due Date</u> :		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Independent Rural Health Clinic/Freestanding Federally Qualified Health Center Cost Report; Use: Providers of services participating in the Medicare program, under sections 1815(a) and 1861(v)(1)(A) of the Social Security	



Ref.	Short Title/Current Status of Regulation/Title/ 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: Independent Rural Health Clinic/Freestanding Federally Qualified Health Center Cost Report AGENCY: CMS		7/15/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		Act, must submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. CMS needs the form CMS-222-92 cost report to determine the reasonable costs incurred by the provider in furnishing medical services to Medicare beneficiaries and reimbursement due to or due from the provider. http://www.gpo.gov/fdsys/pkg/FR-2014-05-16/pdf/2014-11391.pdf SUMMARY OF NIHB ANALYSIS:	
135.d.	LTCH Quality Reporting Program Evaluation ACTION: Request for Comment NOTICE: Long Term Care Hospital Quality Reporting Program: Program Evaluation AGENCY: CMS	CMS-10502	Issue Date: 11/22/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/10/2014 Due Date: 4/9/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Long Term Care Hospital Quality Reporting Program: Program Evaluation; Use: Section 3004(a) of ACA mandated that CMS establish a quality reporting program for Long Term Care Hospitals (LTCHs). Specifically, section 3004(a) added section 1886(m)(5) to the Social Security Act (the Act) to establish a quality reporting program for LTCHs. This program requires LTCHs to submit quality data in a time, form and manner specified by the HHS Secretary. CMS seeks to explore how LTCHs respond to the new quality reporting program (QRP) and its measures. CMS believes in the importance of understanding early trends in outcomes, making adjustments as needed to enhance the effectiveness of QRP, seeking opportunities to minimize provider burden, and ensuring the meaningfulness of the program to providers. The methodology employed in the evaluation uses qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, CMS has decided that using a rich, contextual approach to evaluate the process and success of QRP will prove most beneficial at this time. The information collected will help inform CMS about QRP-related experiences, such as program impact related to quality improvement, burden, process-related issues, and education. This information also will inform future measurement development for the LTCH QRP, future steps related to data validation, and future monitoring and evaluation. http://www.gpo.gov/fdsys/pkg/FR-2013-11-22/pdf/2013-28049.pdf	



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	* **				SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/10/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-03-10/pdf/2014-05104.pdf	
136.c.	PQRS and the eRx Incentive Program Data Assessment ACTION: Request for Comment NOTICE: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support AGENCY: CMS	CMS-10519	Issue Date: 3/17/2014 Due Date: 5/16/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		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.	
145.a.	Health Insurance Providers Fee ACTION: Proposed Final Rule	REG- 118315-12 TD 9643	<u>Issue Date:</u> 3/4/2013 <u>Due Date:</u> 6/3/2013		SUMMARY OF AGENCY ACTION: This document contains proposed regulations that provide guidance on the annual fee imposed on covered entities engaged in the business of providing health insurance for U.S. health risks. This fee is imposed by section 9010 of ACA. The regulations affect persons engaged in the business of providing health insurance for U.S. health risks.	



Ref.	Short Title/Current Status of Regulation/Title/ 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: Health Insurance Providers Fee AGENCY: IRS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 3/22/2013; issued Final Rule 11/29/2013; issued correction 1/22/2014		http://www.gpo.gov/fdsys/pkg/FR-2013-03-04/pdf/2013-04836.pdf SUMMARY OF NIHB ANALYSIS: The fee seeks to raise revenues to fund the ACA. In 2014, IRS expects to collect \$8 billion, increasing to \$14 billion per year. In the proposed regulations, a number of entities providing health insurance are excluded from the fee. Excluded entities include employer self-insured plans and governments. The regulations specifically exclude Indian tribal governments from the fee. No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: This document contains a correction to a notice of proposed rulemaking and notice of public hearing (REG-118315-12) published in the Federal Register on 3/4/2013 (78 FR 14034). This document makes the following correction: \$ 57.1 [Corrected]: On page 14042, column 1, line 17 of paragraph (b), the language "section 9010 of the ACA, as amended." is corrected to read "section 9010 of the ACA." http://www.gpo.gov/fdsys/pkg/FR-2013-03-22/pdf/2013-06701.pdf IRS on 11/29/2013 issued a document that contains final regulations relating to the annual fee imposed on covered entities engaged in the business of providing health insurance for U.S. health risks by section 9010 of ACA, as amended. These final regulations affect persons engaged in the business of providing health insurance for U.S. health risks. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28412.pdf IRS on 1/22/2014 issued a document to correct an error that appeared in the final regulations published in the 11/29/2013 FR. On page 71481 of the final regulations, in the second column, in the first full paragraph, in the last line, "§ 1.414(c)-(5)" should read "§ 1.414(c)-5)". http://www.gpo.gov/fdsys/pkg/FR-2014-01-22/pdf/C1-2013-28412.pdf	



# Agency File Date Response and Summary of NIHB Analysis 145.b. Report of Health Insurance Provider Information Form 8963 Issue Date: 11/21/2013 SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New Collection; Title: Report of Health Insurance Provider Information; Use: Section 9010 of ACA, as amended, imposes an annual fee on health insurance providers that provide health insurance for U.S. health risks (a covered entity). In REG-118315-12 (see 145.a.),						
Provider Information 11/21/2013 Collection; Title: Report of Health Insurance Provider Information; Use: Section 9010 of ACA, as amended, imposes an annual fee on health insurance providers that provide health insurance for U.S. health risks (a covered entity). In REG-118315-12 (see 145.a.),		of Regulation/Title/	File Code	Due Date &		NIHB Recs.
NOTICE: Report of Health Insurance Provider Information AGENCY: IRS AGENCY: IRS	145.b.	Provider Information ACTION: Request for Comment NOTICE: Report of Health Insurance Provider Information	Form 8963	11/21/2013 Due Date: 1/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/29/2014 Due Date:	collection; <i>Title</i> : Report of Health Insurance Provider Information; <i>Use</i> : Section 9010 of ACA, as amended, imposes an annual fee on health insurance providers that provide health insurance for U.S. health risks (a covered entity). In REG-118315-12 (see 145.a.), IRS described how it will administer this fee. This regulation treats members of a controlled group as a single covered entity. This regulation generally allows members of a controlled group to designate a single entity to report on their behalf. The information collection covered under this request will address the recordkeeping requirements prescribed in §57.2(e)(2) of REG-118315-12, under which each member of a controlled group must maintain records of consent to the selection of the designated entity. This information collection also will address the reporting requirements prescribed in §57.3. IRS will use the collected data for compliance purposes. In a situation where the designated entity reports information for another controlled group member covered entity, IRS might need to verify that the member covered entity gave the designated entity consent to report on its behalf. http://www.gpo.gov/fdsys/pkg/FR-2013-11-21/pdf/2013-27893.pdf A Supporting Statement for this PRA request is available at http://www.reginfo.gov/public/do/DownloadDocument?documentID=401859&version=2. SUMMARY OF SUBSEQUENT AGENCY ACTION: IRS on 1/29/2014 issued a revision of this PRA request. This PRA request clarifies reporting requirements for the members/participants in a "controlled group," including a record of giving consent to the designated (lead) entity. Excluded entities include employer self-insured plans and governments, with the regulations specifically excluding tribal governments.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
147.a.	Statement of Expenditure for Medical Assistance ACTION: Request for Comment NOTICE: Quarterly Statement of Expenditure for Medical Assistance AGENCY: CMS	CMS-64	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 10/4/2013; issued extension 4/11/2014 Due Date: 6/24/2013; 12/3/2013; 5/12/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Quarterly Medicaid Statement of Expenditure for the Medical Assistance; Use: Since January 1980, state Medicaid agencies have used form CMS-64 to report their actual program benefit costs and administrative expenses. CMS uses this information to compute the federal financial participation for state Medicaid program costs. States use certain schedules of form CMS-64 to report budget, expenditure, and related statistical information required for implementation of the Medicaid portion of the State Children's Health Insurance Programs, Title XXI of the Social Security Act, established by the Balanced Budget Act of 1997. 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. http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12465.pdf 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 4/11/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf	
147.b.	Statement of Budget for Medical Assistance ACTION: Request for Comment NOTICE: Quarterly Statement of Budget for	CMS-37	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Quarterly Statement of Budget for Medical Assistance; Use: CMS requires that each State Medicaid agency quarterlyNovember 15, February 15, May 15, and August 15 of each fiscal yearsubmit form CMS-37 via the Web-based Medicaid and CHIP Program Budget and Expenditure System (MBES/CBES). All submissions represent equally important components of the grant award cycle, but the May and November submissions have particular significance for budget formulation. The November submission introduces a new fiscal year to the budget	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.			
	Medical Assistance AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued extension 4/11/2014 Due Date: 5/12/2014		cycle and serves as the basis for the formulation of the Medicaid portion of the budget presented by the president to Congress in January. The February and August submissions primarily serve in budget execution by providing interim updates to the CMS Office of Financial Management, HHS, OMB, and Congress, depending on the scheduling of the national budget review process in a given fiscal year. These submissions provide CMS with base information necessary to track current year obligations and expenditures in relation to the current year appropriation and to notify senior managers of any impending surpluses or deficits. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/11/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf				
147.c.	Quarterly CHIP Statement of Expenditures and Budget Report ACTION: Request for Comment NOTICE: Quarterly Children's Health Insurance Program (CHIP) Statement of Expenditures for the Title XXI Program (CMS-21) and State Children's Health Insurance Program Budget Report for the Title XXI Program State Plan Expenditures (CMS-21B)	CMS-21 and CMS 21B	Issue Date: 2/14/2014 Due Date: 4/15/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/25/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Quarterly Children's Health Insurance Program (CHIP) Statement of Expenditures for the Title XXI Program (CMS-21) and State Children's Health Insurance Program Budget Report for the Title XXI Program State Plan Expenditures (CMS-21B); Use: Forms CMS-21 and CMS-21B provide CMS with the information necessary to issue quarterly grant awards, monitor current-year expenditure levels, determine the allowability of state claims for reimbursement, develop CHIP financial management information, provide for state reporting of waiver expenditures, and ensure states do not exceed their federally established allotment. Further, CMS needs these forms for the redistribution and reallocation of unspent funds over the federally mandated timeframes. http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03293.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/25/2014 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.
	AGENCY: CMS		<u>Due Date:</u> 5/27/2014		extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-02/pdf/2014-07405.pdf	
151.a.	Request for Employment Information ACTION: Request for Comment NOTICE: Request for Employment Information AGENCY: CMS	CMS-R-297	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/26/2013; issued revision 1/2/2014 Due Date: 8/26/2013; 2/3/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Request for Employment Information; Use: The Social Security Administration uses this form to obtain information from employers regarding whether Medicare beneficiary coverage under a group health plan is based on current employment status. http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07800.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 7/26/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf No comments recommended as this PRA request pertains to an existing form used solely for Medicare purposes. CMS on 1/2/2014 issued a revision of this PRA request. Use: Section 1837(i) of the Social Security Act provides for a special enrollment period for individuals who delay enrolling in Medicare Part B because they receive coverage through a group health plan based on their own current employment status or that of their spouse. Disabled individuals with Medicare also might delay enrollment because they have large group health plan coverage based on their own current employment status or that of a family member. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. http://www.gpo.gov/fdsys/pkg/FR-2014-01-02/pdf/2013-31390.pdf	
153.j.	CMS/VA Computer Matching Program	CMS (no reference number)	<u>Issue Date</u> : 12/5/2013		SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the renewal of a computer matching program (CMP) that CMS plans to conduct with the Purchased Care at the Health	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency ACTION: Notice NOTICE: Privacy Act of 1974: CMS Computer Matching Program Match No. 2013-01; HHS Computer Matching Program Match No. 1312 AGENCY: CMS	File Code	Issue Date; Due Date & File Date Due Date: 30 days (approx. 1/6/2014) NIHB File Date: None Date of Subsequent Action, if any:	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis Administration Center (PC@HAC) of VA. CMS has provided background information about the proposed matching program in the "Supplementary Information" section of this notice. Although the Privacy Act requires only that CMS provide an opportunity for interested individuals to comment on the proposed CMP, the agency invites comments on all portions of this notice. http://www.gpo.gov/fdsys/pkg/FR-2013-12-05/pdf/2013-29066.pdf SUMMARY OF NIHB ANALYSIS:	NIHB Recs.
153.k.	CMS/SSA/IRS Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974, CMS Computer Match No. 2013-03, HHS Computer Match No. 1314, SSA Computer Match No. 1048, IRS Project No. 241 AGENCY: CMS	CMS (no reference number)	Issue Date: 1/28/2014 Due Date: 30 days (approx. 2/27/2014) 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 (CMP) that CMS plans to conduct with the Social Security Administration and IRS. This CMP seeks to establish the conditions under which: (1) IRS agrees to disclose return information relating to taxpayer identity to SSA and (2) SSA agrees to disclose return information relating to beneficiary and employer identity, commingled with information disclosed by the IRS, to CMS. These disclosures will provide CMS with information to determine the extent to which any Medicare beneficiary has coverage under any group health plan. http://www.gpo.gov/fdsys/pkg/FR-2014-01-28/pdf/2014-01566.pdf SUMMARY OF NIHB ANALYSIS:	
157.b.	Medicare Secondary Payer and Certain Civil Money Penalties ACTION: Advanced Notice of Proposed Rule Making NOTICE: Medicare	CMS-6061- ANPRM	<u>Issue Date:</u> 12/11/2013 <u>Due Date:</u> 2/10/2014 <u>NIHB File</u> <u>Date</u> : None		SUMMARY OF AGENCY ACTION: This advance notice of proposed rulemaking (ANPRM) solicits public comment on specific practices for which CMS might impose civil money penalties (CMPs) for failure to comply with Medicare Secondary Payer reporting requirements for certain group health plan and non-group health plan arrangements. http://www.gpo.gov/fdsys/pkg/FR-2013-12-11/pdf/2013-29473.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.
	Program; Medicare Secondary Payer and Certain Civil Money Penalties AGENCY: CMS		Date of Subsequent Agency Action, if any:			
159.b.	Medicare PPS for Federally Qualified Health Centers, et al. ACTION: Proposed-Final Rule NOTICE: Medicare Program; PPS for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral AGENCY: CMS	CMS-1443- PFC	Issue Date: 9/23/2013 Due Date: 11/18/2013 ANTHC File Date: 11/18/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 5/2/2014 Due Date: 7/1/2013	ANTHC response:	SUMMARY OF AGENCY ACTION: This proposed rule would establish methodology and payment rates for a prospective payment system (PPS) for federally qualified health center (FQHC) services under Medicare Part B, beginning 10/1/2014, in compliance with the statutory requirement of ACA. This proposed rule also would establish a policy allowing rural health clinics (RHCs) to contract with nonphysician practitioners when they meet the statutory requirements for employment of nurse practitioners and physician assistants and would make other technical and conforming changes to the RHC and FQHC regulations. Finally, this proposed rule would make changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing referral. http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/pdf/2013-22934.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule with comment period implements methodology and payment rates for a prospective payment system (PPS) for federally qualified health center (FQHC) services under Medicare Part B beginning on 10/1/2014 in compliance with the statutory requirement of ACA. In addition, it establishes a policy which allows rural health clinics (RHCs) to contract with non-physician practitioners when they meet statutory requirements for employment of nurse practitioners and physician assistants and makes other technical and conforming changes to RHC and FQHC regulations. Finally, this final rule with comment period implements changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing (PT) referrals. CMS will consider comments on the subjects indicated in sections II.B.1. (FQHC PPS/Policy Considerations/Multiple Visits on the Same Day), E.2. (FQHC PPS/Implementation/Medicare Claims Payment), and E.4. (FQHC	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.
					PPS/Implementation/Waiving Coinsurance for Preventive Services) of this final rule with comment period. Analysis: TTAG filed comments on the proposed rule on 11/18/2013. A comparison of CMS-1443-FC and the TTAG recommendations appears in the document below. A limited number of provisions in CMS-1443-FC are open for comment (see below). The majority of the regulation is finalized. Tribal organizations should comment (favorably) on at least one provision open for comment: a new exception to the per diem PPS payment for subsequent injury or illness and for mental health services furnished on the same day as a medical visit. TTAG recommended a version of this change in comments on the proposed rule. Tribal organizations might want to comment on the proposal to establish Healthcare Common Procedure Coding System (HCPCS) G-codes for FQHCs billing codes, as well as on the proposed method for calculating coinsurance. CMS-1443-FC analysis 2014-05-03b	
159.c.	CoPs for Community Mental Health Centers ACTION: Request for Comment NOTICE: Conditions of Participation for Community Mental Health Centers and Supporting Regulations in 42 CFR 485 AGENCY: CMS	CMS-10506	Issue Date: 3/10/2014 Due Date: 4/9/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Conditions of Participation for Community Mental Health Centers and Supporting Regulations in 42 CFR 485; Use: On 6/17/2011, CMS proposed for the first time new conditions of participation (CoPs) for community mental health centers (CMHCs), and it finalized them in a rule published in the 10/29/2013 FR (78 FR 64604). These CoPs, based on criteria prescribed in law, seek to ensure that each facility has properly trained staff to provide the appropriate safe physical environment for patients. State agency surveyors, CMS, and CMHCs will use this information collection for the purpose of ensuring compliance with Medicare CoPs, as well as ensuring the quality of care provided by CMHCs to patients. http://www.gpo.gov/fdsys/pkg/FR-2014-03-10/pdf/2014-05104.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.
164.b.	Medicare Secondary Payer and "Future Medicals" ACTION: Proposed Rule NOTICE: Medicare Secondary Payer and "Future Medicals" AGENCY: CMS	CMS-6047	Issue Date: [Pending at OMB as of 8/1/2013 Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would announce the intention of CMS regarding means beneficiaries or their representatives can use to protect the 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:	
165.c.	Application for Medicare Part B Enrollment ACTION: Request for Comment NOTICE: Application for Enrollment in Medicare the Medical Insurance Program AGENCY: CMS	CMS-40B	Issue Date: 10/23/2013 Due Date: 12/23/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/2/2014 Due Date: 2/3/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Application for Enrollment in Medicare the Medical Insurance Program; Use: Form CMS-40B establishes entitlement to and enrollment in supplementary medical insurance for beneficiaries who have Part A but not Part B. This form solicits information used to determine enrollment for individuals who meet the requirements in section 1836 of the Social Security Act, as well as the entitlement of the applicant or a spouse regarding a benefit or annuity paid by the Social Security Administration (SSA) or OPM for premium deduction purposes. SSA will use the collected information to establish Part B enrollment. http://www.gpo.gov/fdsys/pkg/FR-2013-10-23/pdf/2013-24854.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/2/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-02/pdf/2013-31390.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.
165.d.	Application for Hospital Insurance ACTION: Request for Comment NOTICE: Application for Hospital Insurance and Supporting Regulations AGENCY: CMS	CMS-18F5	Issue Date: 12/6/2013 Due Date: 2/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/14/2014 Due Date: 3/17/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Application for Hospital Insurance and Supporting Regulations; Use: Regulations at 42 CFR 406.6 specify the individuals who must file an application for Medicare Hospital Insurance (Part A) and those who need not file an application for Part A. Section 406.7 lists CMS-18F5 as the application form. This form elicits information that the Social Security Administration and CMS need to determine entitlement to Part A and Supplementary Medical Insurance (Part B). http://www.gpo.gov/fdsys/pkg/FR-2013-12-06/pdf/2013-29144.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/14/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03290.pdf	
171.	Medicaid Emergency Psychiatric Demonstration Evaluation ACTION: Request for Comment NOTICE: Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation AGENCY: CMS	CMS-10487	Issue Date: 7/26/2013 Due Date: 9/24/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/6/2013		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation; Use: Since the inception of Medicaid, inpatient care provided to adults ages 21 to 64 in institutions for mental disease (IMDs) has not drawn federal matching funds. The Emergency Medical Treatment and Active Labor Act (EMTALA), however, requires IMDs that participate in Medicare to provide treatment for psychiatric emergency medical conditions (EMCs), even for Medicaid patients. Section 2707 of ACA directs the HHS Secretary to conduct and evaluate a demonstration project to determine the impact of providing payment under Medicaid for inpatient services delivered by private IMDs to individuals with emergency psychiatric conditions between the ages of 21 and 64. CMS will use the data to evaluate the Medicaid Emergency Psychiatric Demonstration (MEPD) in accordance with the ACA mandates. Congress will use this evaluation to determine whether to continue or expand the demonstration. If the demonstration expands, the data collected will help inform both CMS and its stakeholders about possible effects of contextual factors and important procedural issues to consider in the expansion, as well as the likelihood of various outcomes.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			<u>Due Date:</u> 1/6/2014		http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-17985.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/6/2013 issued a new version of this PRA request. Subsequent to publication of the 60-day notice in the 7/26/2013 FR (78 FR 45205), CMS has increased the burden estimate to reflect an increase in time assessed for reviewing medical records and the need to obtain additional informed consents for beneficiary interviews. CMS also has made changes to the "Key Informant Interview Questions" for clarification purposes. http://www.gpo.gov/fdsys/pkg/FR-2013-12-06/pdf/2013-29143.pdf	
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 Due Date: 5/12/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Medicaid Drug Program Monthly and Quarterly Drug Reporting Format; Use: Labelers transmit drug data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) for each National Drug Code and distributes the URA to all state Medicaid agencies. States use the URA to invoice the labeler for rebates. CMS uses the monthly data to calculate Federal Upper Limit prices for applicable drugs, and states can use this data to establish their pharmacy reimbursement methodology. http://www.gpo.gov/fdsys/pkg/FR-2013-08-09/pdf/2013-19379.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/11/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf	



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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.		
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 Due Date: 4/16/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicaid Drug Use Review 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 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 su			
					<u>Analysis</u>			



Ref. #	Short Title/Current Status of Regulation/Title/ 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 survey included in this PRA request includes no Al/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.			
175.c.	Submitting Drug Identifying Information to Medicaid Programs ACTION: Request for Comment NOTICE: Medicaid Payment for Prescription Drugs Physicians and Hospital Outpatient Departments	CMS-10215	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicaid Payment for Prescription DrugsPhysicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs; Use: In accordance with the Deficit Reduction Act of 2005, states must provide for the collection and submission of utilization data for certain physician-administered drugs to receive federal financial participation for these drugs. Physicians, serving as respondents to states, submit National Drug Code numbers and utilization information for "J" code physician-administered drugs to provide states with sufficient information to collect drug rebate dollars. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-31016.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.	
	Collecting and Submitting Drug Identifying Information to State Medicaid Programs AGENCY: CMS		Agency Action, if any: Issued reinstatement 3/7/2014 Due Date: 4/7/2014		SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/7/2014 issued a reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2014-03-07/pdf/2014-05000.pdf		
175.d.	Reconciliation of State Invoice and Prior Quarter Adjustment ACTION: Request for Comment NOTICE: Reconciliation of State Invoice and Prior Quarter Adjustment Statement AGENCY: CMS	CMS-304 and CMS- 304a	Issue Date: 5/2/2014 Due Date: 7/1/2014 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: Reconciliation of State Invoice and Prior Quarter Adjustment Statement; Use: Manufacturers use form CMS-304 (Reconciliation of State Invoice) to respond to the state rebate invoice for current quarter utilization. Manufacturers must use form CMS-304a (Prior Quarter Adjustment Statement) only in those instances where they need to change to the original rebate data submittal. http://www.gpo.gov/fdsys/pkg/FR-2014-05-02/pdf/2014-10128.pdf SUMMARY OF NIHB ANALYSIS:		
175.e.	Medicaid Drug Rebate Program Forms ACTION: Request for Comment NOTICE: Medicaid Drug Rebate Program Forms AGENCY: CMS	CMS-368 and CMS-R- 144	Issue Date: 5/2/2014 Due Date: 7/1/2014 NIHB File Date: Date of Subsequent		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicaid Drug Rebate Program Forms; Use: CMS develops the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to CMS the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount. States must submit this report within 60 days of the end of each calendar quarter. The information in the report comes from claims paid by the state Medicaid agency during a calendar quarter. States must submit CMS-R-144 (Quarterly Report Data) quarterly to report utilization for any drugs paid for during that quarter. States must use form CMS-368 (Administrative Data) only in those instances where they need 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.
			Agency Action, if any:		change to the original data submittal. http://www.gpo.gov/fdsys/pkg/FR-2014-05-02/pdf/2014-10128.pdf SUMMARY OF NIHB ANALYSIS:	
176.	EPSDT Participation Report ACTION: Request for Comment NOTICE: Annual Early and Periodic Screening, Diagnostic, and Treatment Participation Report AGENCY: CMS	CMS-416	Issue Date: 8/9/2013 Due Date: 10/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/6/2013 Due Date: 1/6/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report; Use: CMS uses the baseline data collected to assess the effectiveness of state early and periodic screening, diagnostic, and treatment (EPSDT) programs in reaching eligible children, by age group and basis of Medicaid eligibility, who receive initial and periodic child health screening services, obtain referral for corrective treatment, and receiving dental, hearing, and vision services. CMS couples this assessment with state results in attaining the set participation goals. The information gathered from this report permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. http://www.gpo.gov/fdsys/pkg/FR-2013-08-09/pdf/2013-19321.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/6/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-06/pdf/2013-29143.pdf	
180.	Flu Vaccination Standard for Certain Providers and Suppliers ACTION: Request for Comment NOTICE: Influenza	CMS-3213-F	Issue Date: [Approved by OMB on 4/18/2014] Due Date: NIHB File		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.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.			
	Vaccination Standard for Certain Participating Providers and Suppliers AGENCY: CMS		Date: Date of Subsequent Agency Action, if any:		SUMMARY OF NIHB ANALYSIS:				
181.	Nondiscrimination Provisions ACTION: Proposed Rule NOTICE: Nondiscrimination Provisions AGENCY: OPM	OPM RIN 3206- AM77	Issue Date: 9/4/2013 Due Date: 11/4/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 5/8/2014		SUMMARY OF AGENCY ACTION: This proposed rule would update various nondiscrimination provisions appearing in title 5, Code of Federal Regulations, to provide greater consistency and reflect current law. http://www.gpo.gov/fdsys/pkg/FR-2013-09-04/pdf/2013-21486.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.				
184.a.	Clinical Laboratory Improvement Amendments Regulations ACTION: Request for Comment NOTICE: Clinical Laboratory Improvement Amendments (CLIA) Regulations	CMS-R-26	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent	ANTHC response:	SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Clinical Laboratory Improvement Amendments (CLIA) Regulations; Use: The information serves to determine entity compliance with the congressionally mandated program with respect to the regulation of laboratory testing. In addition, laboratories participating in the Medicare program must comply with CLIA requirements as mandated by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.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.
	AGENCY: CMS		Agency Action, if any: Issued extension 12/6/2013 Due Date: 1/6/2014 ANTHC File Date: 1/6/2014		SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/6/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-06/pdf/2013-29143.pdf The unique financial and geographical challenges of IHS facilities and tribal health programs greatly impact their ability to satisfy CLIA-related disclosure requirements pertaining to specimen integrity, communication, and personnel competency assessment. These special circumstances necessitate an increase in the estimated burden for fulfilling these requirements. In addition, the need exists for a rulemaking process that would allow CMS to make more substantive amendments to the CLIA reporting process.	
184.b.	Clinical Laboratory Improvement Amendments Application Form ACTION: Request for Comment NOTICE: Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations AGENCY: CMS	CMS-116	Issue Date: 12/13/2013 Due Date: 2/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/24/2014 Due Date: 3/26/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Entities performing laboratory testing specimens for diagnostic or treatment purposes must complete the application. This information serves as a vital part of the certification process. http://www.gpo.gov/fdsys/pkg/FR-2013-12-13/pdf/2013-29725.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/24/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-02-24/pdf/2014-03877.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.
184.c.	CLIA Budget Workload Reports ACTION: Request for Comment NOTICE: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations AGENCY: CMS	CMS-102 and CMS- 105	Issue Date: 1/10/2014 Due Date: 3/11/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/11/2014 Due Date: 5/12/2014		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations; Use: CMS will use the collected information to determine the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation, and budget approval. Form CMS-102, a multipurpose form, captures and records all budget and expenditure data. Form CMS-105 captures the annual projected CLIA workload that the State survey agency will accomplish. CMS regional offices also use the information to approve the annual projected CLIA workload. The section 1864 agreement with the State requires the information. http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2014-00195.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/11/2014 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf	
185.a.	Healthcare Fraud Prevention Partnership: Data Sharing ACTION: Request for Comment NOTICE: Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange AGENCY: CMS	CMS-10501	Issue Date: 10/23/2013 Due Date: 12/23/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange; Use: Section 1128C(a)(2) of the Social Security Act (Act) authorizes the HHS Secretary and the Attorney General to consult with, and arrange for the sharing of data with, representatives of health plans to establish a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Act. The Healthcare Fraud Prevention Partnership (HFPP), officially established by a Charter in fall 2012 by HHS and the Department of Justice, seeks to detect and prevent the prevalence of health care fraud through data and information sharing and applying analytic capabilities by the public and private sectors. HFPP seeks to identify the optimal way to coordinate nationwide sharing of health care claims information, including aggregating claims and payment information from large public health care programs and private insurance payers. In addition to sharing data and information, HFPP focuses on advancing analytics, training, outreach, and education to support anti-fraud efforts 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.
			1/10/2014 <u>Due Date</u> : 2/10/2014		achieving its objectives, primarily through goal-oriented, well-designed fraud studies. http://www.gpo.gov/fdsys/pkg/FR-2013-10-23/pdf/2013-24854.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/10/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2014-00188.pdf	
185.b.	Revisions to HHS OIG Civil Monetary Penalty Rules ACTION: Request for Comment NOTICE: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules AGENCY: HHS OIG	HHS OIG RIN 0936- AA04	Issue Date: 5/12/2014 Due Date: 7/11/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would amend the civil monetary penalty (CMP or penalty) rules of the HHS Office of Inspector General (OIG) to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on CMPs, assessments, and exclusions to improve readability and clarity. ACA provides for CMPs, assessments, and exclusions for: • Failure to grant OIG timely access to records; • Ordering or prescribing while excluded; • Making false statements, omissions, or misrepresentations in an enrollment application; • Failure to report and return an overpayment; and • Making or using a false record or statement material to a false or fraudulent claim. This proposed rule reflects these statutory changes. In addition, this rule proposes an alternate methodology for calculating penalties and assessments for employing excluded individuals in positions in which the individuals do not directly bill Federal health care programs for furnishing items or services. This proposed rule also would clarify the liability guidelines under OIG authorities, including the Civil Monetary Penalties Law (CMPL); the Emergency Medical Treatment and Labor Act (EMTALA); section 1140 of the Social Security Act (Act) for conduct involving electronic mail, Internet, and telemarketing solicitations; and section 1927 of the Act for late or incomplete reporting of drug-pricing information. http://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10394.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.
185.c.	Revisions to HHS OIG Exclusion Authorities ACTION: Request for Comment NOTICE: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities AGENCY: HHS OIG	HHS OIG RIN 0936- AA05	Issue Date: 5/9/2014 Due Date: 7/8/2014 NIHB File Date: Date of Subsequent Agency Action:		SUMMARY OF AGENCY ACTION: This proposed rule would amend the regulations relating to exclusion authorities under the authority of the HHS Office of Inspector General (OIG). This proposed rule would incorporate statutory changes, propose early reinstatement procedures, and clarify existing regulatory provisions. http://www.gpo.gov/fdsys/pkg/FR-2014-05-09/pdf/2014-10390.pdf SUMMARY OF NIHB ANALYSIS:	
185.d.	Revisions to Safe Harbors Under the Anti-Kickback Statute, et al. ACTION: Request for Comment NOTICE: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti- Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing AGENCY: HHS OIG	HHS OIG RIN 0936- AA06	Issue Date: [Pending at OMB as of 5/15/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would amend the safe harbors to the anti-kickback statute and the civil monetary penalty rules under the authority of the HHS Office of Inspector General (OIG). This proposed rule would add new safe harbors, some of which codify statutory changes set forth in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) and ACA, all of which would protect certain payment practices and business arrangements from criminal prosecution and civil sanctions under the anti-kickback provisions of the statute. This proposed rule also would codify the ACA-revised definition of "remuneration" and add a gain-sharing civil monetary penalty (CMP or penalty) provision in 42 CFR part 1003. 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.
186.	DSW Resource Center Core Competencies Survey ACTION: Request for Comment NOTICE: Direct Service Workforce (DSW) Resource Center (RC) Core Competencies (CC) Survey Instrument AGENCY: CMS	CMS-10512	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection: Title: Direct Service Workforce (DSW) Resource Center (RC) Core Competencies (CC) Survey Instrument; Use: This survey comprises part of Phase IIIB of the Direct Service Workforce Resource Center Road Map of Core Competencies for the Direct Service Workforce, a multi-phased research project implemented to identify a common set of core competencies across community-based long-term services and supports (LTSS) population sectors: aging, behavioral health (including mental health and substance use), intellectual and developmental disabilities, and physical disabilities. Phase IIIB includes (1) field testing and a national study to validate the core competency set among the workforce; (2) establishing the core competency set in the public domain; and (3) providing technical assistance to promote the development of specializations within each sector. The survey serves as item 1 of Phase IIIB. The DSW RC, states, direct service agencies, and other partners interested in implementing the core competencies will use the data collected in the survey. The target populations for the surveys include DSW professionals, front line supervisors and managers, agency administrators and directors, participants and families/guardians, and self-advocates. This survey seeks to confirm and validate the relevance and applicability of the DSW RC set of core competencies to actual direct service workers, their employers, and their participants. Information gained from the survey will lend credibility to the set of core competencies. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28537.pdf	
188.a.	Emergency Preparedness Requirements ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs;	CMS-3178-P	<u>Issue Date:</u> 12/27/2013 <u>Due Date:</u> 2/25/2014 3/31/2014	TTAG response:	SUMMARY OF AGENCY ACTION: This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and manmade disasters and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It also would ensure that these providers and suppliers adequately prepare to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.	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.	
	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS		TTAG File Date: 3/31/2014 Date of Subsequent Agency Action, if any: Issued due date extension 2/21/2014		CMS proposes emergency preparedness requirements that 17 provider and supplier types must meet to participate in the Medicare and Medicaid programs. Since existing Medicare and Medicaid requirements vary across the types of providers and suppliers, CMS also proposes variations in these requirements. CMS has based these variations on existing statutory and regulatory policies and differing needs of each provider or supplier type and the individuals to whom they provide health care services. Despite these variations, this proposed rule would provide generally consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30724.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule, which seeks to ensure the availability of health care during emergencies, would impose substantial new emergency and disaster preparedness requirements on various Medicare and Medicaid providers and suppliers in an effort to safeguard human resources, ensure business continuity, and protect physical resources. Of note, this proposed rule directs providers to "comply with all applicable Federal and State emergency preparedness requirements" and requires a communications plan that complies with federal and state law, provisions potentially imposing additional emergency preparedness 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		



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					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 Facilities ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities AGENCY: CMS	CMS-3277-P	Issue Date: 4/16/2014 Due Date: 6/16/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would amend the fire safety standards for Medicare and Medicaid participating hospitals, critical access hospitals (CAHs), long-term care facilities, intermediate care facilities for individuals with intellectual disabilities (ICF-IID), ambulatory surgery centers (ASCs), hospices that provide inpatient services, religious non-medical health care institutions (RNHCls), 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.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
189.	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: 1/22/2014 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 in the last calendar year as measured by the Consumer Price Index. http://www.gpo.gov/fdsys/pkg/FR-2014-01-22/pdf/2014-01303.pdf SUMMARY OF NIHB ANALYSIS: Beginning January 22, 2014, the 2014 Federal Poverty Guidelines (referred to as "Federal Poverty Level" or "FPL") are to be used when determining Medicaid program eligibility. For the Marketplace, the 2013 FPL will continue to be used for all of the 2014 coverage year. Tribal Self-Governance Advisory Committee handout: TSGAC FPL Handout - Medicaid and Market	
190.	Frontier Community Health Integration Project Demo ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Solicitation for Proposals for the Frontier Community Health Integration Project Demonstration AGENCY: CMS	CMS-5511-N	Issue Date: 2/4/2014 Due Date: 5/5/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This notice provides eligible entities with the information necessary to apply for participation in the Frontier Community Health Integration Project (FCHIP) demonstration. The demonstration seeks to better integrate the delivery of acute care, extended care, and other health care services, as well as improve access to care for Medicare and Medicaid beneficiaries residing in very sparsely populated areas. CMS will use a competitive application process to select eligible entities for participation in this demonstration, which will last as long as 3 years. Interested and eligible parties can obtain complete solicitation and supporting information on the CMS Web site at http://innovation.cms.gov/initiatives/index.html . http://www.gpo.gov/fdsys/pkg/FR-2014-02-04/pdf/2014-02062.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.
191.a.		CMS-10224	Issue Date: 3/25/2014 Due Date: 5/23/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Healthcare Common Procedure Coding System (HCPCS)Level II Code Modification Request Process; Use: The Healthcare Common Procedure Coding System (HCPCS) Level II Code Set serves as a standardized code set used in claims processing. Level II of HCPCS, also referred to as alpha-numeric codes, serves as a standardized code set used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulatory services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used in the home or outpatient setting. CMS has maintained the HCPCS code set via modifications of codes, modifiers, and descriptions based on data received from applicants. HCPCS code set maintenance requires continual collection of information from applicants on an annual basis. As new technology evolves and new devices, drugs, and supplies reach the market, applicants submit applications to CMS requesting modifications to the HCPCS Level II code set. http://www.gpo.gov/fdsys/pkg/FR-2014-03-25/pdf/2014-06516.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
191.b.	New Clinical Diagnostic Lab Test Codes for CY 2015 ACTION: Notice NOTICE: Medicare Program; Public Meeting on July 14, 2014 Regarding New Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2015 AGENCY: CMS	CMS-1610-N	Issue Date: 3/25/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This notice announces a public meeting to receive comments and recommendations (including accompanying data) from the public on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System (HCPCS) codes under consideration for Medicare payment through the clinical laboratory fee schedule (CLFS) for calendar year (CY) 2015. This meeting also provides a forum for those who submitted certain reconsideration requests regarding final determinations made last year on new test codes and for the public to provide comment on the requests. http://www.gpo.gov/fdsys/pkg/FR-2014-03-25/pdf/2014-06515.pdf SUMMARY OF NIHB ANALYSIS: This notice might hold some interest for I/Ts.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
192.	Blue Button Connector ACTION: Request for Comment NOTICE: The Blue Button Connector AGENCY: HHS	HHS-OS- 0990-New- 60D	Issue Date: 4/2/2014 Due Date: 6/2/2014 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: The Blue Button Connector; Use: The Blue Button Connector, a Web site, helps consumers and patients find their own health information online from the entities that collect their information (i.e., hospitals, physicians, labs, immunization registries, state health information exchanges, etc.). The Web site also helps developers build tools that respond to the readiness of the market. In addition, the Web site will provide for consumers links to apps and tools that use structured electronic health data. This information collection will allow health care organizations to sign up to appear on the Connector and update their profile pages on an ongoing basis as they improve their offerings and features to patients. HHS would like for this capability to exist for no more than 3 years. http://www.gpo.gov/fdsys/pkg/FR-2014-04-02/pdf/2014-07350.pdf A link to the Blue Button Connector is available at http://bluebuttonconnector.healthit.gov/. From HHS ONC: The Blue Button Connector allows millions of U.S. residents to obtain easy, secure online access to their health records, storing them in many places, such as physician offices, hospitals, drug stores, and health insurers. Blue Button permits individuals to access their health records online to allow them to: • Share them with their physician, family members, or caregivers; • Check their health information for accuracy and completeness; • Track vaccinations for children; • Have their medical history available in case of emergency or when traveling, seeking a second opinion, or switching health insurers; and • Input their health information into apps and tools that help them set and reach personalized health goals. Although Blue Button remains in its early stages, it has begun expanding rapidly. Individuals should ask their health care providers or health insurers if they offer you the ability to view online, download, and share their health records via Blue Button. An FAQ about	



TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2014

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					SUMMARY OF NIHB ANALYSIS: The Blue Button Connector is an interesting initiative that might have potential benefit for/use by I/T/Us.	
193.	Utilization and Payment Data: Physician and Other Supplier ACTION: Notice NOTICE: Medicare Provider Utilization and Payment Data: Physician and Other Supplier AGENCY: CMS	CMS (no reference number)	Issue Date: 4/9/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: As part of efforts to make the health care system more transparent, affordable, and accountable, CMS has prepared a public data set, the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (Physician and Other Supplier PUF), with information on services and procedures provided to Medicare beneficiaries by physicians and other health care professionals. The Physician and Other Supplier PUF contains information on utilization, payment (allowed amount and Medicare payment), and submitted charges organized by National Provider Identifier (NPI), Healthcare Common Procedure Coding System (HCPCS) code, and place of service. This PUF is based on information from the CMS National Claims History Standard Analytic Files. The data in the Physician and Other Supplier PUF covers calendar year 2012 and contains 100 percent final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service population. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html A CMS letter to AMA on this data set is available at http://downloads.cms.gov/files/Madara_Final_Signed.pdf. A Politico article on physician opposition to the release of this data set is available at http://www.politico.com/politicopulse/0414/politicopulse13499.html. SUMMARY OF NIHB ANALYSIS:	



TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 5/31/2014

194. 340B Drug Pricing Program Regulations ACTION: Proposed Rule NOTICE: 340B Drug Pricing Program Regulations AGENCY: HRSA AGENCY: HRSA BRIN 0906- AB04 HRSA RIN 0906- AB04 HRSA RIN 0906- AB04 Brile Date: Date of Subsequent Agency Action, if any:	Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	194.	Program Regulations ACTION: Proposed Rule NOTICE: 340B Drug Pricing Program Regulations	RIN 0906-	[Pending at OMB as of 4/9/2014] Due Date: NIHB File Date: Date of Subsequent Agency		340B Drug Pricing Program requirements for participating covered entities and manufacturers. SUMMARY OF NIHB ANALYSIS: This proposed rule might contain important changes	



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.b.	Establishment of Exchange Rules ACTION: Proposed Final/Interim Final Rule NOTICE: Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers AGENCY: CMS	CMS-9989-PF Issue Date: 7/15/2011 Due Date: 9/28/2011 NIHB File Date: 10/31/2011 Date of Subsequent Action, if any: Issued Final/Interim Final Rule 3/27/2012 Due Date: 5/11/2012 NIHB File Date: None.	[For a complete list of recommendations and analysis of the subsequent Final/Interim Final Rule, see the archived RRIAR v.2.12 dated December 31, 2012.] CMS should facilitate Indian Tribes and tribal organizations in becoming financial sponsors for Al/ANs by requiring each Exchange to permit I/T/Us to pay the unsubsidized portion of health plan premiums on behalf of Exchange enrollees they designate, through an aggregated payment process.	CMS on 3/19/2014 issued CMS-9943-IFC (see 50.x.), which contains regulations on third-party premium and cost-sharing payments. Accepted in part. CMS-9943-IFC requires issuers of QHPs, including stand-alone dental plans (SADPs), to accept premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program; other Federal and State government programs that provide premium and cost sharing support for specific individuals; and I/T/Us (previously, CMS had encouraged, but not required, QHP issuers to accept these payments). This standard applies to all individual market QHPs and SADPs, regardless of whether they are offered through a Federally-facilitated Exchange or a State-based Exchange or outside of the Exchanges. [79 FR 15242] CMS-9943-IFC does not require QHPs to accept aggregate third-party premium and cost-sharing payments (or issue aggregate billings).



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.ee.	2015 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft-2015 Letter to Issuers in the Federally- Facilitated Marketplaces AGENCY: CCIIO	CCIIO (no reference number) Issue Date: 2/4/2014 Due Date: 2/25/2014 TTAG File Date: 2/25/2014; NIHB and TSGAC also filed comments 2/15/2014 Date of Subsequent Agency Action, if any: Issued Final Letter 3/14/2014	 Chapter 2QHP and Stand-Alone Dental Plan Certification Standards, Section 2Service Area: a. State Flexibility: The opening sentence of Chapter 2, Section 2 (p. 17) reads, "States performing plan management functions in an FFM may use a similar approach [to that CMS will use]"; CMS should require close Federal oversight of all requirements associated expressly with Indian Health Providers (IHPs) to ensure full compliance by states performing plan management functions. b. Counties in Service Areas: The requirement that QHPs serve areas generally no smaller than counties, or a group of counties defined by the Marketplace, should help prevent issuers from avoiding areas with large concentrations of Al/ANs, who tend to have poorer health than other individuals; CMS also should take steps to have Marketplaces encourage QHP applicants to serve areas large enough to encompass an entire reservation when a reservation spans more than one county and consider this factor when assessing whether applicants can choose to serve only part of a county. Chapter 2, Section 4Essential Community Providers (ECPs), Subsection iEvaluation of Network Adequacy with respect to ECP: 	In the 3/14/2014 Final Letter 1. Chapter 2QHP and Stand-Alone Dental Plan Certification Standards, Section 2Service Area: • a. State Flexibility: Not accepted. CMS approved this section as proposed. • b. Counties in Service Areas: Not accepted. CMS approved this section as proposed. 2. Chapter 2, Section 4Essential Community Providers (ECPs), Subsection iEvaluation of Network Adequacy with respect to ECP:



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
			a. Proposed Rule: In Chapter 2, Section 4 (p. 20-21), CMS announces plans to propose a rule that would 1) require QHP applications to "list the offers that [issuers have] extended to all available Indian health providers in each county in the service area," 2) include an expectation that "issuers be able to provide verification of such offers if CMS chooses to verify the offers," and 3) consider offers "in good faith" if they include "terms that a willing, similarly-situated, non-ECP provider would accept or has accepted."	 a. Proposed Rule: In the introduction to the Final Letter, CCIIO noted: "Additional proposed requirements are included in a regulation titled 'Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond,' CMS-9949-P, that is being released simultaneously with this letter." CMS-9949-P does not contain these requirements. As of 3/19/2014, CMS has proposed no regulations to codify these requirements. However, in the Final Letter, CCIIO included: "As part of the issuer's QHP application, we expect that the issuer list the contract offers that it has extended to all available Indian health providers and at least one ECP in each ECP category in each county in the service area. To be offered in good faith, a contract should offer terms that a willing, similarly-situated, non-ECP provider would accept or has accepted. We would expect issuers to be able to provide verification of such offers if CMS chooses to verify the offers."
			Regarding this section of the letter and the proposed rule, CMS should:	
			 b. Revise the definition of IHPs to reference the full range of providers operating under the health programs of I/T/Us; 	 b. Accepted. In its definition of IHP, CMS added the phrase "to include the Indian Health Service, Indian Tribes, Tribal



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. Expressly state that any issuer relying on narrative justification to obtain approval for a QHP not meeting the 30 percent ECP standard for 2015 must comply with the requirement to offer to contract with all IHPs in the service area;	organizations, and urban Indian organizations." • c. Accepted. CMS added the following requirement for narrative justification: "Attestation that the issuer has satisfied the 'good faith' contracting requirement with respect to offering contracts to all available Indian health providers, and one ECP in each major ECP category per county, where an ECP in that category is available."
			 d. Clarify that a contract offered "in good faith" to an IHP must include payment rates at least equal to the generally applicable rates of the issuer for network providers; and e. Expressly state its intention to review each QHP application for compliance with the provision of Section 4 regarding contract offers to IHPs and to validate all offers to IHPs listed on applications. f. Alternate ECP Standard of 45 CFR § 156.235(a)(2) 	 d. Not accepted. e. Not accepted. f. Alternate ECP Standard of 45 CFR §
			and (b): In Chapter 2, Section 4, CMS interprets the requirements to satisfy the alternate ECP standard, and this interpretation does not explicitly include the requirement to make good faith contract offers to all IHPs in the service area or in the areas located in, or contiguous to, Health Professional Shortage Areas (HPSA) and areas in which more than 30 percent of the population falls below 200 percent of the federal poverty level; CMS should expressly state that this requirement	156.235(a)(2) and (b): Not accepted. CMS did not expressly make this statement and approved the referenced paragraph (almost exactly) as proposed. [NOTE: Because the offer to contract with I/T/Us is a separate requirement than the "30 percent ECP guideline," it is a reasonable read of the guidance that



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
			applies.	the requirement to offer contracts to I/T/Us continues under the "Alternate ECP Standard."]
			3. Chapter 2, Section 4Essential Community Providers (ECPs), Subsection iiRequirement for Payment of Federally Qualified Health Centers (FQHCs): In Chapter 2, Section 4, CMS should include a subsection iii that states the requirements in Section 206 of the Indian Health Care Improvement Act regarding payments to IHPs.	3. Chapter 2, Section 4Essential Community Providers (ECPs), Subsection iiRequirement for Payment of Federally Qualified Health Centers (FQHCs): Not accepted.
			4. Chapter 3Qualified Health Plan and SADP Design, Section 7Coverage of Primary Care: 2015 Approach: CMS should require issuers (through a rule) to make available plans allowing three primary care office visits	4. Chapter 3Qualified Health Plan and SADP Design, Section 7Coverage of Primary Care: 2015 Approach: N/A.
			before the patient must meet any deductible.	CMS removed this section and did not discuss this issue in the Final Letter (CMS stated, generally: "Some policies with operational implications in the Draft 2015 Letter to Issuers are not being finalized in this Final 2015 Letter to Issuers, with the intent to continue work to accomplish them.").
			5. Chapter 6Consumer Support and Related Issues, Section 1Provider Directory: Regarding provider directories, CMS encourages issuers to identify the language spoken by providers and whether providers are IHPs; CMS	 Chapter 6Consumer Support and Related Issues, Section 1Provider Directory: Not accepted. CMS approved this section as proposed.
			should require issuers to identify whether providers are IHPs. 6. Chapter 6, Section 2Complaints Tracking and Resolution and Section 3Coverage Appeals: In each of these sections, CMS should require issuers to track complaints and appeals filed by individuals identified as Al/ANs, as well as the subject of these complaints and their resolutions.	6. Chapter 6, Section 2Complaints Tracking and Resolution and Section 3Coverage Appeals: Not accepted.



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
			 Chapter 7Tribal Relations and Support, Section 1Model Contract Addendum for Issuers Working with Indian Health Providers: Chapter 7, Section 1 (p. 51) states that "CMS is continuing to recommend the use of the Model QHP Addendum (Addendum) as described in the 2014 Letter to Issuers"; CMS should revise this section to correspond with Chapter 2, Section 4, which indicates that it plans to propose a rule requiring the inclusion of the Addendum in all contracts offered to IHPs. Chapter 7, Section 2Tribal Sponsorship of Premiums: CMS should require issuers to facilitate and accept aggregation premiums paid by tribal sponsors. 	 Chapter 7Tribal Relations and Support, Section 1Model Contract Addendum for Issuers Working with Indian Health Providers: Accepted. CMS changed the language in this section to read, "CMS expects issuers to offer contracts to Indian health care providers and use the recommended Model QHP Addendum (Addendum) as described in the 2014 Letter to Issuers." Chapter 7, Section 2Tribal Sponsorship of Premiums: Not accepted. CMS approved this section as proposed.
23.g.	Imposition of Cost Sharing Charges Under Medicaid ACTION: Request for Comment NOTICE: Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations AGENCY: CMS	CMS-R-53 (OMB approval sought under CMS-10398; see 23.a.) Issue Date: 1/27/2014 Due Date: 2/26/2014 NIHB File Date: None	To facilitate the successful development of procedures that would effectively implement and enforce the exclusions from cost sharing for certain AI/ANs found in current regulations, CMS should: 1. Template: Develop a template (or templates) of procedures to implement and enforce the Indian-specific exclusions from cost sharing and allow states to adopt this template or develop alternative approaches, a policy that likely would expedite implementation of approaches effective in providing protections to AI/ANs and minimize the burden placed on states, providers, health plans, and enrollees. 2. Self-Attestation: Incorporate into the template an option for	No subsequent Agency action taken (as of 5/31/2014).



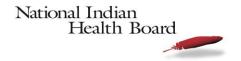
Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
	Date of Subsequent Agency Action, if any: Issued withdrawal 2/7/2014; re- issued request 2/14/2014 Due Date: 3/17/2014 TTAG File Date: 3/17/2014	self-attestation of eligibility as an American Indian or Alaska Native, a policy that would streamline the process for eligibility determinations and eliminate the likelihood that paperwork requirements would impede individuals from accessing the protections for which they qualify. 3. Indian Identifier: Continue and complete ongoing efforts to modify state Medicaid Statistical Information Systems to capture an identifier for individuals determined to qualify for the Indian-specific cost-sharing protections, including assisting states with adoption of the new functionality. 4. Electronic Data Matching: Include in the template a mechanism for electronic data matching (potentially through the IHS National Data Warehouse) to proactively identify individuals eligible for Indian-specific cost-sharing protections, a policy that would increase the number of eligible individuals who receive these protections, given their lack of familiarity among Al/AN enrollees (and possibly state Medicaid agency caseworkers).	
Information Reporting for Exchanges ACTION: Proposed Final Rule NOTICE: Information Reporting for	REG-140789- 12 TD 9663 Issue Date: 7/2/2013 Due Date: 9/3/2013	1. Designation of Authorized Representative: IRS should indicate in regulations that the designation by the taxpayer or responsible adult (i.e., applicant or enrollee) of an authorized representative for Exchange purposes (pursuant to 45 CFR § 155.227) also serves as the designation of an authorized representative for purposes of receiving 26 CFR §1.36B statements, requiring an Exchange to send §1.36B statements to the authorized representative if requested by	In the 5/7/2014 Final Rule 1. Designation of Authorized Representative : Not accepted. IRS approved this provision as proposed. According to IRS, "The final regulations do not prohibit Exchanges from providing statements to third parties if permitted under other law. However, section 36B(f)(3) does not authorize the IRS to require Exchanges to do so. In addition, the IRS is not able to provide statements to third parties based on
	Title/Current Status of Regulation/ Title/Agency Information Reporting for Exchanges ACTION: Proposed Final Rule NOTICE: Information	Title/Current Status of Regulation/Title/Agency Date of Subsequent Agency Action, if any: Issued withdrawal 2/7/2014; resissued request 2/14/2014 Due Date: 3/17/2014 TTAG File Date: 3/17/2014 Information Reporting for Exchanges ACTION: Proposed Final Rule NOTICE: Information Reporting for Exchanges NOTICE: Information Reporting for Pinal Rule Due Date: 7/2/2013 Due Date: 9/3/2013	Title/Current Status of Regulation/ Title/Agency Date of Subsequent Agency Action, if any: Issued withdrawal 277/2014; resisued request 2/14/2014 Dae Date: 3/17/2014 TTAG File Date: 3/17/2014 Date: 3/17/2014 TTAG File Date: 3/17/2014 Date: 3/17/2014 TTAG File Date: 4/27/2013 TTAG File Date: 5/12/2013 TTAG File Date: 7/2/2013 TTAG File Date: 7/2/2013



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
	Insurance Exchanges AGENCY: IRS	Date: 9/3/2013; TSGAC and ANTHC also filed comments 9/3/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 5/7/2014	 individual from having additional authorized representatives, such as CPAs or other individuals who assist in tax filing, receive information from IRS. Receipt of Statements: IRS should allow the taxpayer or responsible adult and the authorized representative to receive statements through paper form, electronic delivery, or both as requested. 	authorization to an Exchange because information obtained pursuant to section 36B(f)(3) is return information and, under section 6103, return information may be disclosed only under express authority of the Code." [79 FR 26116] 2. Receipt of Statements: Not accepted. IRS stated, "The final regulations do not prohibit an Exchange from sending both paper and electronic statements to an individual. However, the final regulations retain the electronic statement procedures in the proposed regulations, which provide for affirmative consent to receive statements electronically, and clarify that the consent requirement is not satisfied if the recipient withdraws the consent. These procedures are the same as long-standing procedures that also apply in other information reporting contexts. The procedures are intended to ensure that all individuals, including those who do not have access to or are not fully comfortable with electronic technology, are able to access information necessary to prepare their tax returns." [79 FR 26116]
31.v.	Instructions for the Application for Indian-Specific Exemptions ACTION: Guidance NOTICE: Instructions	CMS (no reference number) See also 31.q. Issue Date: 1/10/2014	TTAG recommendations (see attachment below for specific line edits) 1. Page 1, first bullet and Step 2, Item 7: CMS should add language to the instructions for these items to clarify that "member of an Indian tribe" includes Alaska Native village members and Alaska Native Claims Settlement Act (ANCSA) shareholders.	No subsequent Agency action taken (as of 5/31/2014).



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
	for the Application for Exemption for American Indians and Alaska Natives and Other Individuals who are Eligible to Receive Services from an Indian Health Care Provider AGENCY: CMS	Due Date: 1/13/2014 TTAG File Date: 1/13/2014 Date of Subsequent Agency Action, if any:	 3. 5. 6. 	Tables, Second Paragraph: For clarification purposes, CMS should change all instances of "you're" to "you are" in the instructions for these items. Introduction to Tables, Second Paragraph: CMS should add the word "only" to the second sentence in this paragraph to emphasize that applicants who can supply the documents listed in Table 1 do not have to supply the documents listed in Table 2; in addition, in the introduction to Table 1, CMS should avoid emphasis on the "Federally recognized tribe" language to prevent confusion about which exemption applies to ANCSA shareholders.	



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
			the categories of Indians entitled to health care services provided by IHS under the Indian Health Care Improvement Act. Instructions for AIAN Exemption App-Tribal	
31.w.	Q&A on Cost-Sharing Reductions for Contract Health Services ACTION: Guidance NOTICE: Question and Answer on Cost-Sharing Reductions for Contract Health Services AGENCY: CCIIO	CCIIO (no reference number) Issue Date: 1/8/2014 Due Date: 1/14/2014 TTAG File Date: 1/14/2014 Date of Subsequent Agency Action, if any: Issued Final Guidance 2/18/2014; sent	TTAG recommendations (see attachment below for specific line edits) 1. "Contract Health Service" Language: CMS should make the language of this guidance consistent with the statutory definition of "contract health service" found at 25 USC § 1603(5); this definition includes both services for which an Indian health program might pay and those for which it might not pay. 2. Cost-Sharing Language: CMS should add language to the last paragraph of this guidance to clarify that the Indian health program referral eliminates any cost sharing, including at the time of initial service. TTAG Response to CMS on CMS guidance	In the 2/18/2014 Final Guidance [and the 5/9/2014 revised Final Guidance] 1. "Contract Health Service" Language: Accepted. In reference to the term "contract health service," CMS added the phrase "as defined in 25 U.S.C. 1603(5) and any implementing guidance." [Retained in the revised Final Guidance.] 2. Cost-Sharing Language: Not accepted. CMS did not add this language and deleted the last paragraph entirely. [Not added in the revised Final Guidance.] The attachment below compares the last draft and the Final Guidance. The addition of the following bullet marked the most significant change:



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
		revised Guidance to TTAG for review 4/2/2014; issued revised Final Guidance 5/9/2014		A copy of the referral. (We note that many of the required elements above may be contained in the referral itself.) [In the revised Final Guidance, CMS modified this bullet to read, "A copy of the referral. (We note that many of the required elements above may be contained in the referral itself, and recognize that often the referral will be obtained after the service has been provided.").] The last draft included the statement, "To document eligibility for reimbursement the issuer must retain documentation that includes the following information," and listed four elements, but it did not explicitly state that the issuer must retain a copy of the referral (as did the Final Guidance). Comparison- CCIIO CHS cost sharing guid
31.x.	MEC and Other Rules on the Shared Responsibility Payment ACTION: Proposed	REG-141036- 13 <u>Issue Date:</u> 1/27/2014 Due Date:	TTAG recommendations The recommendations generally address the avenues available to apply for and claim the exemption from the shared responsibility payment for individuals eligible for services from an Indian Health Care Provider (the IHCP-eligible exemption) and the exemption for individuals who are members of an Indian tribe	No subsequent Agency action taken (as of 5/31/2014).



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: Minimum Essential Coverage and Other Rules Regarding the Shared Responsibility Payment for Individuals AGENCY: IRS	4/28/2014 TTAG File Date: 4/28/2014 Date of Subsequent Agency Action, if any: Issued hearing cancellation 5/16/2014	 (the Indian exemption). At present, individuals must claim the IHCP-eligible exemption through a Marketplace but can claim the Indian exemption either through a Marketplace or through the Federal tax-filing process. To mitigate confusion, minimize expenditures, maximize resources, and ensure accurate processing of Al/AN exemptions, IRS and HHS should establish parallel processes that would allow individuals to claim the two Indian-specific exemptions through either a Marketplace or the Federal tax-filing process. In regard to the proposed rule, specific recommendations appear below. Streamlined Process to Establish Avenue for Claiming Additional Hardship Exemptions: The proposed rule includes a provision that would establish a streamlined regulatory process in § 1.5000A-3 of the Internal Revenue Code under which IRS could accept a delegation of authority from HHS to allow an individual to claim an additional type of hardship exemption through the Federal tax-filing process without first obtaining a hardship exemption through a Marketplace; IRS should: a. Retain this provision in the final rule; and b. In the preamble to the final rule, cite as a potential example of the use of this streamlined process the expedited establishment of authority for individuals to apply for and claim the IHCP-eligible exemption through the Federal tax-filing process. 	



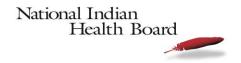
RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
39.b.	Basic Health Program ACTION: Proposed Final Rule NOTICE: Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity AGENCY: CMS	CMS-2380-PF Issue Date: 9/25/2013 Due Date: 11/25/2013 NIHB File Date: 11/22/2013; ANTHC, TSGAC, and TTAG also filed comments 11/22/2013 Date of Subsequent Agency Action, if any: Issued Final Rule 3/12/2014	 NIHB/ANTHC/TSGAC/TTAG recommendations We concur with the inclusion of these provisions in the BHP and recommend each provision be retained in the final rule. a. In § 600.160(a), we propose to apply the same special enrollment status for enrollment in standard health plans as established in 45 CFR 155.420, which permits Indians to enroll in QHPs or change QHPs once per month. b. We propose at § 600.160(b) that a state permit Tribal organizations to pay premiums on behalf of enrolled individuals as is permitted in the Exchange at 45 CFR 155.240. 	 Items TTAG concurred with a. Accepted/retained. b. Accepted/retained and expanded. The final rule extended the ability for third parties to sponsor premiums to also include cost-sharing. Also, the provision is not limited to Al/AN enrollees (but all BHP enrollees). And, the revised provision is not limited to I/T/U sponsors (but includes the governmental entities and governmental funding listed below). The final rule reads, at § 600.520(d): "(d) Acceptance of certain third party payments. States must ensure that standard health plans must accept premium and cost-sharing payments from the following third party entities on behalf of plan enrollees: (1) Ryan White HIV/AIDS Programs under title XXVI of the Public Health Service Act; (2) Indian tribes, tribal organizations or urban



RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
			 c. At § 600.160(c), we propose that cost-sharing may not be imposed on Indians to further align the Exchange's cost-sharing protections for Indians with household incomes at BHP levels. d. We also propose that BHP standard health plans must pay primary to Indian health programs for covered services; in other words, Indian health programs shall be the "payers of last resort" for services received through such programs that are covered by a standard health plan (with respect to the standard health plan). Premium Payments: To ensure that the BHP does not disadvantage Al/ANs, CMS should 	Indian organizations; and (3) State and federal government programs. [79 FR 14149] • c. Accepted/retained. • d. Accepted/retained.
			a. Modify § 600.505 to protect them from paying more in premiums than they would have paid for the applicable lowest-cost bronze plan (in the rating area in which they reside) or	We appreciate and understand the commenters' point regarding the premium levels for the American Indian and Alaska Native population. However, the statute does not support requiring the bronze plan premiums as a minimum standard, nor does such a premium protection exist in the Exchange." CMS adds that "states have the flexibility to use BHP trust funds (or state funds) to lower premiums for individuals eligible for BHP" and that it encourages commenters to work with their respective states on this issue. [79]



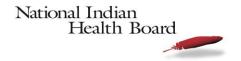
RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
			b. Adopt a provision allowing Al/ANs to decline enrollment through the program and enroll in the individual market through an Exchange.	CMS further responded: "One commenter requested clarification that BHP trust funds are available to reduce premiums for American Indians and Alaska Natives. Response: Yes. The state has the option to further reduce premiums for eligible BHP enrollees that are American Indian and Alaska Natives with its trust funds. This is a permissible expenditure." [79 FR 14133] • b. Not accepted. In regard to the recommendation Al/ANs should have the ability to opt out of BHP, CMS states that, "if individuals opt out of BHP, they would not be eligible to receive federal subsidies to purchase coverage in the Exchange, adding that the "statute specifies that individuals eligible for BHP are ineligible to receive the premium tax credit and cost-sharing reductions." [79 FR 14128]
			3. Payments to Providers : CMS should modify the proposed rule to incorporate the protections for Indian Health Care Providers contained in 45 CFR § 156.430(g).	3. Payments to Providers: Accepted. CMS agrees that, "if the cost of protecting Indians from cost sharing was placed on providers, it would have the result of reducing access to care and would frustrate the purpose of the cost-sharing protection" and therefore has added this protection to §600.160 as a new paragraph (c). [79 FR 14117]



RRIAR Ref. #	Status of	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
			4. Tribal Consultation : The proposed rule, at 45 CFR § 600.155, would require a state to "consult with Indian tribes located in the State on the development and execution of the BHP Blueprint using the State or Federal tribal consultation policy approved by the applicable State or Federal Exchange"; CMS should eliminate the phrase "or Federal" from this provision. CMS should also use the Washington State Exchange Tribal Consultation Policy as the standard as it reviews BHP blueprints submitted by states.	"(c) Payments to providers. Equal to the protection extended to Indian health providers providing services to Indians enrolled in a QHP in the individual market through an Exchange at 45 CFR 156.430(g), BHP offerors may not reduce the payment for services to Indian health providers by the amount of any cost-sharing that would be due from the Indian but for the prohibition in paragraph (b) of this section." [79 FR 14144] 4. Tribal Consultation: Accepted in part. CMS agrees that "it is not necessary to identify in this rule whether the state exchange was established by the state or federal government, or whether the tribal consultation policy was based on a state or federal policy," only to "make clear that the BHP should comply with the state Exchange's tribal consultation policy." As a result, CMS has removed "State or Federal" as descriptors of the tribal consultation policy. Although CMS appreciates the reference to the Washington State Exchange tribal consultation policy, "because each state has a different tribal makeup and relationship, it is important to maintain state flexibility in determining an appropriate consultation policy," and therefore this final rule does not specify adoption of the policy of any specific state. [79 FR 14117]



RRIAR Ref. #	Status of	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
39.c.	Basic Health Program: Federal Funding Methodology for 2015 ACTION: Proposed Final Methodology NOTICE: Basic Health Program: Proposed-Federal Funding Methodology for Program Year 2015 AGENCY: CMS	CMS-2380-PFN Issue Date: 12/23/2013 Due Date: 1/22/2014 TTAG File Date: 1/22/2014; TSGAC also filed comments 1/22/2014 Date of Subsequent Agency Action, if any: Issued Final Methodology 3/12/2014	 CSR Calculation: With one exception discussed below under "Reference Premium for CSR Calculation," CMS should retain the proposed payment methodology to account for the cost-sharing reductions (CSRs) in the premium tax credit (PTC) calculation particular to Al/ANs, as it appears that this methodology will result in an equivalent (or 95 percent) amount of resources available to a state for this purpose. a. CSR calculation assumes Al/AN will enroll in a plan with a 60% actuarial value (bonze plan) that will result in the CSR amount being greater (40% rather than 30% if in a silver level plan) b. CSR calculation applies a utilization factor that assumes utilization will increase as a result of zero cost-sharing. Each provision will increase the amount of CSR payments a state will receive for Al/AN enrollees. Reference Premium for CSR Calculation: CMS should modify the proposed methodology for determining federal payments to states for the Basic Health Program (BHP) to account for the likelihood that Al/ANs will elect to enroll in a bronze-level qualified health plan (QHP) that consumes the entire premium tax credit (PTC) available to them or their family. This means Al/AN will enroll in a bronze plan but one 	2. Reference Premium for CSR Calculation: Not accepted. CMS commented: "With regard to the comments that American Indians and Alaska Natives who would enroll through the Exchange may select other bronze level QHPs than the lowest cost plan, we acknowledge the likelihood of the selection of different bronze level QHPs, but we believe it is not possible to project how these enrollees would



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
			that has a higher premium than the lowest cost bronze plan. Making this adjustment will more accurately reflect what AI/AN actions would have been through an Exchange and will have the effect of increasing the amount of the CSR payment made to a state for AI/AN enrollees (as the 40% CSR calculation will be multiplied against a higher premium amount.) Doing so will result in the PTC amount being properly calculated, which will also ensure the full value of the CSR amounts are calculated, and provided to states, on behalf of AI/AN enrollees. 3. Premium Tax Credit Adjustment: For any AI/AN-specific adjustment in the formula for PTC payments to states, CMS should ensure it accounts for the likelihood that AI/ANs who enroll in a QHP through an Exchange will expend the full value of the PTC available to them.	select different plans for 2015 (similar to the limitations regarding the assumption of how enrollees would select plans other than the second lowest cost silver plan). In addition, while there may be instances where the value of PTC would exceed the value of some bronze QHP premiums, this may vary by age, household size, household income, and other factors; we believe this further limits the ability to project how enrollees would select different plans. Thus, we have selected what we believe to be an assumption that is reasonable and results in the correct level of funding for BHP." [79 FR 18392] 3. Premium Tax Credit Adjustment: Accepted. CMS clarified that the methodology as proposed assumes Al/ANs who enroll through the Exchange would choose a QHP with a premium at least equal to the value of the PTC. CMS stated: "Comment: Several commenters requested that, when calculating the CSR component of the federal BHP payment, CMS account for the likelihood that American Indians and Alaska Natives will elect to enroll in a bronze-level QHP that would utilize the entire PTC that would have otherwise been available to the enrollees rather than assuming the enrollees will select the lowest cost bronze level QHP. The commenter noted that while American Indians and Alaska Natives purchasing coverage in the Exchange will likely select a bronze level QHP, they may not always select the lowest cost bronze plan.



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			4. Application of Al/AN-Specific Protections under BHP: CMS should condition the receipt by a state of the payment adjustment for Al/AN-specific benefits and protections on its agreement to ensure that, in its implementation of BHP, Al/ANs will receive protections equivalent to those they would have received by enrolling in a QHP through an Exchange.	Response: We appreciate the commenters' concerns about the level of funding related to American Indians and Alaska Natives enrolled in BHP. With regard to comments that the methodology assume that American Indians and Alaska Natives who enroll through the Exchange would choose a QHP with a premium that is at least equal to the value of the PTC, the payment methodology is consistent with this assumption Thus, we have selected what we believe to be an assumption that is reasonable and results in the correct level of funding for BHP." [i.e., calculation assumes full expenditure of PTC that would have been available to Al/ANs in an Exchange.] [79 FR 18392] 4. Application of Al/AN-Specific Protections under BHP: Accepted, in part. According to CMS, this comment falls outside the scope of CMS-2380-FN. [79 FR 13895] However, in CMS-2380-F, CMS mandated that states apply full cost-sharing protections for Al/ANs if a state implements BHP. Under § 600.160(b), "Cost sharing: No cost sharing may be imposed on Indians under the standard health plan." As such, states that elect to implement BHP are required to provide full cost-sharing protections for Al/ANs. It is worthwhile to note that the cost-sharing protections are not contingent on an Al/AN receiving a referral from an I/T/U for services at non-I/T/U providers. With regard to mandating premium contribution protections



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				for Al/ANs under BHP that require the payment of premiums that are no higher than an Al/AN would experience through an Exchange if an Al/AN were to select the lowest cost bronze level plan, in CMS-2380-F, CMS stated that CMS lacks the authority to require a state to provide this protection to Al/ANs as there is not a requirement under an Exchange to limit premium contributions for Al/ANs to no more than the lowest-premium amount for a bronze-level plan.
50.t.	QHP Quality Rating System Measures and Methodology ACTION: Request for Comment NOTICE: Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS), Framework Measures and Methodology	CMS-3288-NC Issue Date: 11/22/2013 Due Date: 1/21/2014 TTAG File Date: 1/21/2014 Date of Subsequent Agency Action, if any:	 Information on Access to I/T/U Providers: To address the need for timely and accurate information on the inclusion of I/T/U providers in qualified health plan (QHP) networks, CMS should add the following individual QRS measures: Number of I/T/U providers in the geographic area served by the QHP; Number of I/T/U providers in the geographic area served by the QHP considered in-network providers; and Percentage of I/T/U providers in the geographic area served by the QHP considered in-network providers. Information on Al/AN Member Experience: To ensure that QHPs help Al/ANs understand and obtain the many Al/ANspecific protections provided by ACA, TTAG, in comments 	No subsequent Agency action taken (as of 5/31/2014).



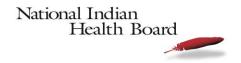
RRIAR Ref. #	Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
	AGENCY: CMS		 Enrollee Survey an Al/AN-specific section with a number of topics, and by adopting these recommendations, CMS will have the information necessary to add the following individual QRS measures: Percentage of Al/AN members who are aware of the availability of I/T/Us as in-network providers in the QHP; Percentage of claims denied by the QHP, in full or in part, for services provided at an I/T/U; Percentage of Al/AN members who have ever had cost sharing in any circumstances in which ACA exempts them; Percentage of Al/AN members who have entered disputes with the QHP over cost sharing, as well as the percentage of resolved disputes; and Percentage of Al/AN members who positively rate their experience with QHP personnel. 3. Al/AN-Specific CAHPS Measures: QRS, as proposed, includes 13 Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey measures, but these measures might not reflect the special circumstances and needs of Al/ANs; the American Indian Survey—which CAHPS developed in 2004-2005 to help establish benchmarks for Al/AN patient experiences, whether at I/T/U or non-I/T/U facilities—produces a number of Al/AN-specific measures, and CMS should add these measures as individual QRS measures. 	



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
50.x.	Third Party Payment of QHP Premiums ACTION: Interim Final Rule NOTICE: Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums AGENCY: CMS	CMS-9943-IFC Issue Date: 3/19/2014 Due Date: 5/13/2014 TTAG File Date: 5/13/2014 Date of Subsequent Agency Action, if any:	This Interim Final Rule ensures that I/T/Us will not face continued problems by requiring QHPs to accept aggregated premium payments and imposing civil penalties if the QHPs reject these payments; specifically, TTAG indicated strong support for the following provisions: 1. The added requirement on QHPs in 45 CFR § 156.1250, which reads: "§ 156.1250 Acceptance of certain third party payments. Issuers offering individual market QHPs, including standalone dental plans, must accept premium and cost sharing payments from the following third-party entities on behalf of plan enrollees: (a) Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act; (b) Indian tribes, tribal organizations or urban Indian organizations; and (c) State and Federal Government programs." 2. The strengthened enforcement provision in § 156.805, which now includes that failure to comply with the requirement to accept third party payments in accordance with § 156.1250 could constitute a violation of § 156.805(a)(1) as "substantial noncompliance with [an] Exchange standard[]."	No subsequent Agency action taken (as of 5/31/2014).



RRIAR Ref. #	Status of	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
65.	Health Care Reform Insurance Web Portal Requirements ACTION: Request for Comments NOTICE: Health Care Reform Insurance Web Portal Requirements AGENCY: CMS	Issue Date: 8/15/2012 Due Date: 9/13/2012 TTAG File Date: 9/13/2012; ANTHC also filed comments 9/13/2012 Date of Subsequent Agency Action, if any: Issued revision 2/3/2014; issued revision 4/11/2014 Due Date: 4/1/2014; 5/12/2014 TTAG File Date: 5/12/2014	TTAG recommendations (9/13/2012, additional subsequent recommendations appear below) The collection and dissemination of information on health plans will provide information that is necessary for individuals to make educated decisions about plan options, but two areas exist where additional information specific to Al/ANs would improve the quality and utility of the information collected, resulting in a decrease in the information collection burden Al/ANs experience when securing health insurance and accessing health care services: 1. Use of the Health Care Reform Insurance Web Portal to Facilitate Tribal Sponsorship: One critical element to consider when selecting a plan is the net premium and cost-sharing amounts an applicant will be responsible for paying, after any available premium assistance. For Al/ANs, premium assistance might include "Tribal Sponsorship." Tribal Sponsorship models envision interested tribes and tribal organizations paying all or part of an Al/AN applicant's share of the premium for a health insurance plan secured through a Health Insurance Exchange (Exchange). Although not currently designed to do so, the Health Care Reform Insurance Web Portal could provide an opportunity to collect, and then disseminate, information on potential Tribal Sponsorship options for Al/AN applicants. CMS should consider establishing such a mechanism to gather and disseminate information on Tribal Sponsorship options.	 Use of the Health Care Reform Insurance Web Portal to Facilitate Tribal Sponsorship: Not accepted. None of the documents associated with this information collection request discuss the issue of tribal sponsorship or a related Web portal. In the draft 2014 Letter to Issuers in the Federally-Facilitated Marketplace, issued on 3/1/2013, CCIIO made no mention of premium sponsorship. In the final version of the letter, issued on 4/5/2013, CCIIO included the following: "SECTION 2. TRIBAL SPONSORSHIP OF PREMIUMS 45 C.F.R. § 155.240(b) provides Exchanges with flexibility to permit Indian tribes, tribal organizations, and urban Indian organizations to pay QHP premiums—including aggregated payment—on behalf of members who are



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			Sponsorship that mirrors the functionality of that described in this Request for Comment. The Web portal would provide tribes and tribal organizations with a password protected mechanism to submit and update information on Tribal Sponsorship to HHS, including providing contact information for specific tribes offering Tribal Sponsorship and/or contact information for a tribal organization that may coordinate Tribal Sponsorship for multiple tribes. The information would be made available to Exchange enrollment staff, applicant assisters (such as Navigators and in-person assisters), as well as through healthcare.gov to help Al/ANs make educated decisions about their insurance options, including the availability of assistance with premiums that may be available through Tribal Sponsorship. At a minimum, HHS should develop a tribal Web portal capacity that enables some static information to be made available by tribes to the Exchange/call center staff so that the information could then be made available to Al/AN applicants during the Exchange application process.	qualified individuals, subject to terms and conditions determined by the Exchange. During consultations with tribal governments, tribal leaders indicated the importance of tribes having the ability to pay premiums on behalf of their members. Over the course of several months, CMS assessed its various systems to determine how the FFEs could establish a process to facilitate Tribal Premium Sponsorship or the ability of Indian tribes, tribal organizations, and urban Indian organizations to pay premiums on behalf of Al/ANs. Because the FFEs will not collect premiums directly from individuals, CMS concluded that the FFEs will not be able to establish a process that would facilitate premium sponsorship, including Tribal Premium Sponsorship, for October 1, 2013. CMS recognizes that aggregating premium payments can be an effective mechanism for increasing the enrollment of Al/ANs in QHPs and will continue to work on this option for future years. It should be noted that tribes are able to work with issuers or tribal members directly to pay premiums. Additionally, this determination does not preclude Statebased Exchanges from developing and implementing a process for Tribal Premium Sponsorship. CMS encourages tribes to continue to work closely with State-based Exchanges, including the option to explore tribal premium sponsorship." It is not evident that the inclusion of the discussion on tribal sponsorship in the 2014 Letter to Issuers was at all related to the comments on premium sponsorship in response to CMS-10320. In fact, CCIIO released the draft 2014 Letter to Issuers (which contained no mention of premium



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			2. Inclusion of Indian Health Care Providers in Posted Information on Plan Provider Networks: Many Al/ANs receive a majority of their health services through I/T/Us. As Al/ANs use the Web site to select a plan, it is critical that they know whether or not their usual Indian Health Care Provider is in the plan's network of providers. Rather than look for the name of a specific doctor, Al/ANs might look for the name of the I/T/U facility where they are most likely to seek care. Health plans should supply this information to HHS, and the department (and Exchanges) should post this information. Although Federal law allows I/T/U providers to bill health plans for services provided to the plan's enrollees whether or not the I/T/U provider is in the plan's network, it is preferable that the I/T/U be part of a plan's network to facilitate coordination of care, minimize duplication of services, and provide greater certainty to the I/T/U providers in the timeliness and amount of payments.	sponsorship) after the comments were submitted on CMS- 10320 (which recommended inclusion of language on tribal premium sponsorship). Note: The formal TTAG comments on the CCIIO draft 2014 Letter to Issuers (submitted on 3/15/2013) did not contain a recommendation to include provisions on tribal premium sponsorship. It appears, as stated above, that "[d]uring consultations with tribal governments" CCIIO became aware of the issue for the first time, or at least became aware of the intensity of the tribal interest in tribal premium sponsorship. 2. Inclusion of Indian Health Care Providers in Posted Information on Plan Provider Networks: Not accepted. In Appendix CInsurance Issuer and Product Level Data, CMS states that health insurance issuers must indicate whether their product utilizes a specific network of providers and, if available, provide a URL link to a listing of exclusive or preferred providers. Appendix C does not discuss Indian health care providers. In the draft 2014 Letter to Issuers, CCIIO stated: "Pursuant to 45 C.F.R. § 156.230, CMS will require QHPs to make their provider directories available to the Exchange for publication online by providing the URL link to their network directory. CMS expects the directory to include location, contact information, specialty and medical group, and any institutional affiliations for each provider. CMS



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				encourages issuers to include information such as whether the provider is accepting new patients, languages spoken, provider credentials, and whether the provider is an Indian provider." In the 2015 Letter to Issuers in the Federally-Facilitated Marketplaces (see 7.ee.) issued on 3/14/2014, CMS stated it "will require QHPs to make their provider directories available to the Marketplace for publication online by providing the URL link to their network directory. CMS expects the URL link to direct consumers to an up-to-date provider directory where the consumer can view the provider network that is specific to a given QHPFurther, CMS expects the directory to include location, contact information, specialty, and medical group, any institutional affiliations for each provider, and whether the provider is accepting new patients."
				With regard to the directives to plans on Indian health care provider (IHCP) specific information, CMS provided somewhat conflicting information. CMS stated, "CMS encourages issuers to include languages spoken, provider credentials, and whether the provider is an Indian health provider" (emphasis added). CMS continued in the next sentence, "Directory information for Indian health providers should describe the service population served by each provider, as some Indian health providers may limit services to Indian beneficiaries, while others may choose to serve the general public." So while it is optional to indicate whether a provider is an IHCP, it is required (i.e., "[d]irectory information for [IHCPs] should describe") that



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	Title/Agency		TTAG recommendations (5/12/2014) 1. Information Availability: Requiring health insurance issuers to provide information on the QHP offerings available to Al/ANs through the Marketplace Web portal, as well as requiring both issuers and Marketplaces to post or link to this information on their respective Web sites, would help address a significant barrier to Al/AN enrollment in the QHPs; in setting the parameters for the information issuers	issuers indicate for each IHCP the population served by each." The requirement to indicate what population is served by each IHCP does not seem to be limited to only those instances where the issuer noted that a provider is an IHCP. In CMS-9949-P (see 92.u.), a related proposed rule issued on 3/21/2014 and identified as, in part, codifying the CCIIO 2015 Letter to Issuers, CMS did not discuss provider directories in general nor Indian health care providers in particular. In the TTAG comments on CMS-9949-P (submitted on 4/21/2014), TTAG requested that CMS clarify the intent of the 2015 Letter to Issuers, hopefully to indicate that issuers "should" indicate which providers are IHCPs and which populations each serves. No subsequent Agency action as of May 31, 2014.
			must submit to the Web portal and the subsequent dissemination of this information, CMS should: • a. Require issuers to submit to the Marketplaces an explanation that Al/ANs can enroll in all QHPs offered	



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			and that each of these QHPs has a zero cost-sharing plan variation and a limited cost-sharing plan variation specifically for Al/ANs, with the distinctions between these plans indicated; • b. Require Marketplaces to create a template Summary of Benefits and Coverage (SBC) for the zero cost-sharing plan variation and the limited cost-sharing plan variation to identify the cost-sharing protections and how they generally apply to covered services; • c. Create a template for use by QHP issuers and require them to populate it template with information on each zero and limited cost-sharing plan variation and provide access to the SBC to potential QHP enrollees by making the cost-sharing variation-specific SBC accessible on their Web sites that display the QHP options without requiring the use of passwords or other barriers (and require Marketplaces to list this information on their Web sites); and • d. Require issuers to provide proactively the cost-sharing-specific SBC to enrollees within seven days of receiving an application from a potential enrollee.	



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92.u.	Exchange and Insurance Market Standards for 2015 and Beyond ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond AGENCY: CMS	Issue Date: 3/21/2014 Due Date: 4/21/2014 NIHB File Date: 4/21/2014; TTAG also filed comments 4/21/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 5/27/2014	 Requirement to Offer Contracts "in Good Faith" to Indian Health Providers (IHPs): a. The 2015 Letter to Issuers in the Federally-Facilitated Marketplaces includes a requirement that QHPs offer contracts "in good faith" to IHPs; CMS should codify this requirement in the Final Rule b. Clarify that a contract offered in good faith to an IHP must include payment rates at least equal to the generally applicable rates of the QHP issuer for innetwork providers, as the current standard would allow an issuer to identify the lowest contract rate (and most issuer-friendly terms) it has ever obtained and take the position that at least one "willing, similarly situated non-ECP provider" "has accepted" this rate. Limited Non-Discrimination Exception for IHPs Serving as Certified Application Counselors: The Proposed Rule includes an exception that would allow "an organization receiving Federal funds to provide services to a defined population under the terms of Federal legal authorities (for example an Indian health provider) that participates in the certified application counselor program" to "limit its provision of certified application counselor services to the same defined population"; CMS should retain this exception in the Final Rule. 	 In the 5/27/2014 Final Rule Requirement to Offer Contracts "in Good Faith" to Indian Health Providers (IHPs): Not accepted. a. CMS did not address this issue in the final rule. b. CMS did not address this issue in the final rule. Limited Non-Discrimination Exception for IHPs Serving as Certified Application Counselors: Accepted. Note: CMS revised paragraph (c)(2) of §155.120 to clarify that organizations limiting their provision of certified application counselor services to a defined population under this exception still must comply with the non-discrimination provisions in paragraph (c)(1) with respect to the provision of these services to that defined population. CMS also made technical revisions to §155.120(c) to highlight to organizations their obligations under other laws. Consistent with this technical revision, CMS made a change to the text of §155.120(c) to clarify that the exception to the non-discrimination requirement at §155.120(c) only applies to the non-discrimination



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				provisions created under this rule and not to other laws. [79 FR 30261-2]
			3. Requirement to Publish Online Provider Directories:	3. Requirement to Publish Online Provider Directories:
			 a. Availability: The 2015 Letter to Issuers included a requirement that QHPs make provider directories 	a. Availability: Not accepted.
			available online and provide a URL directory link as part of their application; CMS should codify this requirement in the Final Rule.	CMS did not address this issue in the final rule.
			b. Identification of IHPs: In the 2015 Letter to Issuers, CMS stated, "CMS encourages issuers to include languages spoken, provider credentials, and whether the provider is an Indian health provider, adding, "Directory information for Indian health providers should describe the service population served by each provider, as some Indian health providers may limit services to Indian beneficiaries, while others may choose to serve the general public" (emphasis added); in the Final Rule, CMS should clarify that the provider directory must indicate which providers are IHPs and, if an IHP has provided the information, whether it also serves non-IHS-eligible populations.	b. Identification of IHPs: Not accepted. CMS did not address this issue in the final rule.
			4. Civil Money Penalties (CMPs) for Providing False or Fraudulent Information: Under the Proposed Rule, if any individual "fails to provide correct information under section 1411(b) of the Affordable Care Act and such failure is attributable to negligence or disregard of any regulations of	4. Civil Money Penalties (CMPs) for Providing False or Fraudulent Information: Not accepted. CMS finalized this provision as proposed. According to CMS, the "proposed definition of 'negligence' is modeled.



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			the Secretary, the person may be subject to a CMP," with negligence defined as "any failure to make a reasonable attempt to provide accurate, complete, and comprehensive information," but a number of factors could lead Al/ANs acting in good faith to fail to provide "accurate, complete, and comprehensive information"; CMS should clarify and broadly define the term "reasonable attempt" as it applies to Al/ANs, as the current negligence standard might penalize Al/ANs acting in good faith or might dissuade them from applying for health insurance through the Marketplaces over concerns that the information they provide could lead to a financial punishment.	on section 6662 of the Internal Revenue Code and was incorporated based on the similarities between providing information on tax filing forms and completing an application for Exchange coverage." CMS added that it believes this definition "is appropriate because it holds actions that are made through honest mistake and error (which are protected by the reasonable cause provision in §155.285(b)(3)) not culpable for a violation." [79 FR 30291]
94.	Methodology for	HRSA (no	NIHB recommendations	In the 5/5/2014 Final Notice
V			Time recommendations	
	Designation of	reference		
	Designation of Frontier and	reference number)	Tribal Consultation: HRSA did not engage in Tribal	Tribal Consultation: Not accepted.
		number)	consultation regarding the proposed methodology; HRSA	'
	Frontier and Remote Areas	number) Issue Date:	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to	HRSA stated that it sponsored five regional stakeholder
	Frontier and	number)	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to Al/ANs, who are highly represented in frontier and remote	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input
	Frontier and Remote Areas ACTION: Notice	number) Issue Date: 11/5/2012	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input through the comment process, adding that it "welcomes
	Frontier and Remote Areas ACTION: Notice NOTICE:	number) Issue Date:	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to Al/ANs, who are highly represented in frontier and remote	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input through the comment process, adding that it "welcomes further input in future revisions of the FAR codes from tribal
	Frontier and Remote Areas ACTION: Notice NOTICE: Methodology for Designation of	number) Issue Date: 11/5/2012 Due Date: 1/4/2013	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to Al/ANs, who are highly represented in frontier and remote areas.	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input through the comment process, adding that it "welcomes further input in future revisions of the FAR codes from tribal organizations and others." [79 FR 25602]
	Frontier and Remote Areas ACTION: Notice NOTICE: Methodology for Designation of Frontier and	number) Issue Date: 11/5/2012 Due Date: 1/4/2013 NIHB File Date:	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to Al/ANs, who are highly represented in frontier and remote areas. 2. Uniformity of Application: The proposed methodology	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input through the comment process, adding that it "welcomes further input in future revisions of the FAR codes from tribal
	Frontier and Remote Areas ACTION: Notice NOTICE: Methodology for Designation of	number) Issue Date: 11/5/2012 Due Date: 1/4/2013	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to Al/ANs, who are highly represented in frontier and remote areas. 2. Uniformity of Application: The proposed methodology appears to lack uniformity of application; HRSA needs to	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input through the comment process, adding that it "welcomes further input in future revisions of the FAR codes from tribal organizations and others." [79 FR 25602] 2. Uniformity of Application: Not accepted.
	Frontier and Remote Areas ACTION: Notice NOTICE: Methodology for Designation of Frontier and Remote Areas	number) Issue Date: 11/5/2012 Due Date: 1/4/2013 NIHB File Date: 1/4/2013	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to Al/ANs, who are highly represented in frontier and remote areas. 2. Uniformity of Application: The proposed methodology appears to lack uniformity of application; HRSA needs to address this issue to allow confidence in, and meaningful	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input through the comment process, adding that it "welcomes further input in future revisions of the FAR codes from tribal organizations and others." [79 FR 25602]
	Frontier and Remote Areas ACTION: Notice NOTICE: Methodology for Designation of Frontier and	number) Issue Date: 11/5/2012 Due Date: 1/4/2013 NIHB File Date:	consultation regarding the proposed methodology; HRSA should address this issue to meet trust obligations owed to Al/ANs, who are highly represented in frontier and remote areas. 2. Uniformity of Application: The proposed methodology appears to lack uniformity of application; HRSA needs to	HRSA stated that it sponsored five regional stakeholder meetings across the United States and sought input through the comment process, adding that it "welcomes further input in future revisions of the FAR codes from tribal organizations and others." [79 FR 25602] 2. Uniformity of Application: Not accepted.



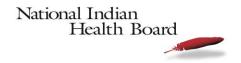
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		if any: Issued Final Notice 5/5/2014	population of 50,000 as the central place from which to measure, but population size does not necessarily serve as a reliable measure of the goods and services available within a community; HRSA should use other metrics for a central place from which to measure.	HRSA noted that the population threshold of 50,000 also forms the core for both the Urbanized Areas of the Census Bureau and Metropolitan Areas as defined by OMB, adding that it "believes urban areas of 50,000 or more have a sufficient population base to support necessary services, including advanced medical services, and that there is no need to change the threshold." [79 FR 25599-600]
			4. Use of 60 Minutes Travel Time from the Central Place: The proposed methodology would measure travel time by calculating a one-way trip by the fastest paved road route with one-hour travel time added for locations only accessible by air, but this measure fails in a number of ways; HRSA should develop a metric based on added cost in all cases in which transportation by some means other than a personal vehicle is required.	4. Use of 60 Minutes Travel Time from the Central Place: Accepted in part. HRSA recognized that the 60-minute travel time "represents different distances depending on circumstances, such as available roads or highways, and depending on the mode of transportation used, such as cars, boats, or aircraft," but concluded that the "current model addresses concerns stated in regards to remote areas with limited road infrastructure or that are reliant on non-road transport." HRSA also noted that, although weather might affect travel time, "there is no data source we know of that will allow the FAR codes to be adjusted for weather conditions." [79 FR 25600] HRSA, however, did indicate plans to examine the possibility of creating another level of designation for extremely remote Frontier Areas "that will be 2 or more hours travel time from the nearest Urbanized Area in future versions of the FAR Codes." [79 FR 25600]



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			5.	Four Standard Levels: The proposed methodology asks for comment on whether the "50 percent population threshold for assigning frontier status to a ZIP code/census tract is the appropriate level for the four standard provided levels," but the use of ZIP code/census tract methodology would fail to adequately represent the most remote and isolated populations in our country; HRSA should not use the 50 percent population threshold or establish only four standard levels, which would fail to capture the differences among locations that are not urban but much different than very remote tribal areas.	5.	Four Standard Levels: Accepted in part. HRSA "believes that the 50 percent threshold is a reasonable criterion for designating ZIP code areas or Census Tracts as FAR regions," adding, "When the data analysis with Census 2010 is completed, users will have access to variables that show, for each ZIP code, the percentage of the population that is designated frontier, and therefore can set their own thresholds if the need arises to use some level other than 50 percent." [79 FR 25600-1]
			6.	1 1 37 7 1	6.	HRSA did recognize that, "when attempting to compare populations with geographic boundaries that do not match, inaccurate classifications are inevitable" and stated that future Web access to FAR data "not based on ZIP code areas but using the grid cells will allow greater specificity in analysis." [79 FR 25602] Applicability of FAR to Island Populations: Accepted in
				the degree of isolation of all communities.		HRSA stated that "travel time on any island would be treated the same way as travel time on the mainland and would produce similar results," adding that islands "with small populations would be classified as remote, while islands with large populations could have areas that are classified as FAR depending on their distance from the population center." [79 FR 25601]



RRIAR Title Ref. # Re	Short e/Current atus of gulation/ e/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
			 Need for Census Tract and County Version: The proposed methodology would begin at the 1x1 kilometer grid level; HRSA should organize grid data in a database that allows aggregation at a variety of levels (including each town, county, Indian reservation, school district, county, census block, census tract, etc.), with a clear definition of their development. Potential Metrics: Some possibilities for metrics that HRSA should consider for the proposed methodology include: 	 HRSA did concede that island populations and residents of isolated areas, such as the Alaskan bush, have legitimate concerns and indicated that an update of the FAR codes based on 2010 Census data should clarify the status of island populations. [79 FR 25601] Need for Census Tract and County Version: Accepted in part. HRSA acknowledged the limitations of the use of the 1x1 kilometer grid, stating, "In the revision of the FAR methodology, the use of a 1 x 1 kilometer grid will be replaced with a 1/2 x 1/2 kilometer grid, which will increase accuracy, and further functionality will be added to the Web site allowing users to drill down and examine small areas." HRSA added that "this level of analysis obviates the need to overlay other sources of data, while still allowing users to include other data appropriate to their use of the FAR codes." [79 FR 25601] In regard to concerns about distances between population centers in Alaska, HRSA said that it plans to examine the issue, "when data from Alaska are added to the FAR codes through use of the Census 2010 data, to determine whether the use of the grid layer will allow an accurate representation of the Frontier status of the communities that make up the Bethel Census area." [79 FR 25601] Potential Metrics: Accepted in part.



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			 Population density using the 1x1 grids with the ability to roll up to various political and geographic units; 	 HRSA indicated plans to examine making different levels of aggregation based on geographic units available in the future on the FAR Codes Web site [79 FR 25602];
			 Distance by paved road to locations of a certain population with adjustment factors for other forms of required transportation, as well as interference with the means of transportation due to weather and other conditions, using standardized measurements generally available, including cost; 	HRSA discussed this issue in part (see response to #4 above).
			Distance from certain goods and services, including a hospital that can perform certain procedures (including the level of trauma center available and the ability to provide other health services), a broad array of grocery items (including fresh vegetables and fruit), police and other emergency services, the nearest elementary and	HRSA did not address this issue;
			secondary school, and the nearest public pool; • Availability of public safe water and sanitation; and • Cost of fuel measured against the cost in the largest community in the State.	 HRSA did not address this issue; HRSA did not address this issue.
159.b.	Medicare PPS for	CMS-1443-	ANTHC recommendations	In the 5/2/2014 Final Rule
	Federally Qualified Health Centers, et al. ACTION: Proposed	PFC <u>Issue Date:</u> 9/23/2013	Federal Qualified Health Center (FQHC) Prospective Payment System (PPS): The proposed rule would establish a new FQHC payment methodologywhich would consist of a single encounter rate, adjusted for geographic location and	Federal Qualified Health Center (FQHC) Prospective Payment System (PPS):
	Final Rule	<u>Due Date:</u>	patient typeand to prevent potential related issues arising	



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: Medicare Program; PPS for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral AGENCY: CMS	ANTHC File Date: 11/18/2013 Date of Subsequent Agency Action. if any: Issued Final Rule 5/2/2014 Due Date: 7/1/2013	 from the inequities and complexities of the Indian health system, CMS should: a. Include low-volume upward adjustments, a population density adjustment, and a service mix adjustment in the new FQHC PPS, as severe underfunding of the Indian health system can result in low service volumes or the absence of certain types of services, limiting the allowable costs included in facility cost reports used to calculate reimbursement rates. b. Continue to permit FQHCs to bill multiple visits for different treatment modalities on the same day, as Al/AN elderly and disabled patients often must travel great distances to receive care and have economic and 	 a. Not accepted. In the final rule, CMS acknowledged the challenges that tribal FQHCs face in furnishing services, especially in rural and isolated areas, and the significant health disparities that remain for Al/AN populations. CMS also acknowledged that providers in isolated and rural areas, including tribal FQHCs, might have fewer patients than providers in more densely populated areas, and might lack the ability to offer as full of a range or level of complexity in their services as other providers, or benefit from the economies of scale that providers with higher volume or in more densely populated areas might have. Although CMS said it considered various possible adjustments, including a low-volume adjustment, in developing the PPS, the agency stated that it "did not propose to include a low-volume adjustment, because we believe that the PPS rate, along with adjustments for new and initial visits and AWV, will provide appropriate reimbursement for the costs of services provided." [79 FR 25453] b. Accepted in part. In the final rule, CMS modified its proposal to permit
			transportation constraints;	an exception to the per diem PPS payment: a) for



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			c. Not exclude outlier health centers and outlier visits from total allowable costs in computing the PPS rate, as these limitations do not comport with statute, which requires the agency to base the aggregate amount of PPS rates on "100 percent of the estimated amount of reasonable costs," without the application of caps and screens; and	 subsequent injury or illness and b) for mental health services furnished on the same day as a medical visit and requested public comments on this change. However, CMS adopted as final its proposal not to allow an exception to the per diem PPS payment for diabetes self-management training/medical nutrition therapy (DSMT/MNT) or initial preventive physical examination (IPPE) when such a visit occurs on the same day. [79 FR 25447] c. Not accepted. Of the approximately 69 tribal FQHCs furnishing services at approximately 114 separate sites, CMS noted that only 8 tribal FQHCs had costs considered statistical outliers, adding, "Although tribal FQHCs have a higher rate of statistical outliers than non-tribal FQHCs, the number of tribal FQHCs whose costs were more than three standard deviations from the geometric mean is still quite low." CMS also stated that the statute "does not require the rate to reflect actual costs for each individual FQHC" and that the "per diem rate that is established reflects the national average cost of a FQHC visit." [79 FR 25443]
			 d. Allow FQHCs to transition to the PPS before the effective date of October 1, 2014, and provide assistance to facilitate this process, as waiting until the effective date would result in almost a yearlong wait for the transition for many facilities. 	 d. Not accepted. According to CMS, a "change in cost reporting periods that is made primarily to maximize payment would not be acceptable under established cost reporting policy,"



RRIAR Ref. #	Ctatus of	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
			2. Sanctions for Proficiency Testing (PT) Referrals: The proposed rule would specify three categories for the imposition of sanctions for PT referral violations to provide CMS, under certain circumstances, with more latitude in assigning less severe sanctions than those currently applied; CMS should include some exception(s) for violations classified as "category one"which involves the most severe sanctionsspecifically in cases in which violations occurred inadvertently and/or were self-reported by the laboratory director or owner, as imposing category one sanctions in these instances would have a dire impact on rural and critical access laboratories within the Indian health system.	a principle that "has been applied uniformly to the implementation of all new prospective payment systems in Medicare." CMS added that Medicare Administrative Contractors do not have the discretion to transition an FQHC at a time other than their cost reporting period except when an FQHC has a change of ownership resulting in a different cost reporting period, or otherwise has good cause, which "is not met if it is determined that the reason is to maximize reimbursement." [79 FR 25455-6] 2. Sanctions for Proficiency Testing (PT) Referrals: Accepted in part. Although CMS did not appear to address this issue specifically with regard to laboratories in the Indian health system, the agency did add an exception to the ban imposed on owners of laboratories that commit violations classified as "category one." In the final rule, CMS included a provision to "limit the reach of the owner ban for certain laboratories under the same ownership as the revoked laboratory if we find, after review of relevant facts and circumstances, that patients would not be at risk if the laboratory were exempted from the ban, and that there is no evidence that a laboratory to be exempted from the ban participated or was complicit in the PT referral, except that any laboratory of the owner that received a PT sample from another laboratory, and failed to timely report such receipt to CMS or to a CMS-approved accrediting organization, may not be exempted from the owner ban." [79 FR 25466]



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184.a.	Clinical Laboratory Improvement Amendments Regulations ACTION: Request for Comment NOTICE: Clinical Laboratory Improvement Amendments (CLIA) Regulations AGENCY: CMS	CMS-R-26 Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/6/2013 Due Date: 1/6/2014 ANTHC File Date: 1/6/2014	 ANTHC recommendations Burden EstimatesCMS should: a. Increase the burden estimates assigned to enrollment and successful participation in proficiency testing (PT) to reflect practical experience and to recognize special circumstances (e.g. limited federal funding, remote lab sites, and transient employees) affecting IHS and tribal health programs; and b. Clarify the burden estimate for each step in the PT process (i.e. receipt and handling, testing, reporting, and director review/analysis) to facilitate the accuracy of information collection pertaining to PT, as without these changes, the Agency will continue to underestimate the difficulty and time required for laboratories (particularly IHS and tribal facilities) to comply with reporting requirements. 2. CLIA Reporting ProcessCMS should initiate a formal rulemaking procedure with an associated Notice and Comment period to substantively amend and streamline the CLIA reporting process; through this procedure, to lessen the burden of IHS and tribal facilities in meeting competency assessment requirements and increase the relevance of these requirements to evaluate competency of all testing personnel, the Agency should: a. Develop an alternate option for competency assessment, similar to the recent alternate quality 	No subsequent Agency action taken (as of 5/31/2014).



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			 control option allowed by 42 CFR § 493.1250; and Include exceptions for actions falling under § 493.1840(b) or its amendments to allow lesser penalties that will not impact the CLIA certificate(s) of the laboratory director. 	
188.a.	Emergency Preparedness Requirements ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS	CMS-3178-P 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	 Impact on Tribes and Indian Health ProgramsTo acknowledge the challenges that this proposed rule will pose for Tribes and Indian health programs, CMS should: a. Perhaps collaboratively with other federal agencies, provide training for Tribes and Indian health programs regarding current emergency preparedness laws and directives and their roles in satisfying these laws and directives; b. Perhaps collaboratively with other federal agencies, offer on- site technical assistance and other support to Indian health programs that need help obtaining the necessary collaboration of non-Indian health providers and state and local of governments; and c. Schedule consultation with Indian health programs, in conjunction with TTAG, about how the new requirements will affect various provider types and adopt provisions for delayed implementation of the requirements in Indian health care facilities until adequate consultation and training occur. Alternative Approaches to ImplementationCMS should: 	No subsequent Agency action taken (as of 5/31/2014).



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			 a. Allow providers to obtain waivers of the deadlines and of specific requirements, if the provider has a minimal plan for compliance within its proposed timeline, because one year might not provide adequate time for some providers to become familiar with all of the new requirements and to implement them. b. Allow providers to establish their own training exercise schedule based on local conditions, because with the large variation in the types of facilities and the conditions under which they operate, "one-size-fits-all" training will not necessarily achieve the best outcome. c. When the same owner administers multiple facility types (a common practice among Indian health programs), allow the facilities to obtain waivers of specific requirements or have a single, multi-facility plan approved, if they can collectively adopt a functionally equivalent strategy based on the requirements that might apply to one of their other facility typesas proposed, this rule would require each of these facility types to meet certain specific requirements, a policy that might lead to duplicative, and ultimately confusing, emergency protocols; and d. Offer facilities an opportunity to review their existing policies and procedures and seek approval for continuing to rely on them instead of implementing the new requirements, if the facility can demonstrate that this would achieve a substantially similar outcome, with deadlines for compliance with any new requirements applied only after a review of the continuation plan. 	