Regulation Review and Impact Analysis Report
v. 5.07

as of July 31, 2015

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

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

The purpose of the Regulation Review and Impact Analysis Report (RRIAR) is to identify and summarize key regulations issued by the Centers for Medicare and Medicaid Services (CMS) pertaining to Medicare, Medicaid, CHIP, and health reform[1] that affect (a) American Indians and Alaska Natives and/or (b) Indian Health Service, Indian Tribe and tribal organization, and urban Indian organization providers. Furthermore, the RRIAR includes a summary of the regulatory analyses prepared by the National Indian Health Board (NIHB)[2], if any, and indicates the extent to which the recommendations made by NIHB were incorporated into any subsequent CMS actions.

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

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

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 –

- 52.o. Conditions of Participation for Home Health Agencies (CMS-10539; **comments due 8/3/2015**)
- 7.ddd. ECP Data Collection to Support QHP Certification for PY 2017 (CMS-10561; **comments due 8/4/2015**)
- 50.v. Medical Expenditure Panel Survey--Insurance Component (AHRQ/OMB 0935-0110; **comments due 8/10/2015**)
- 7.k. Agent/Broker Data Collection in Federally-Facilitated Exchanges (CMS-10464; **comments due 8/12/2015**)
- 31.ll. Data Submission for the FFE User Fee Adjustment (CMS-10492; **comments due 8/13/2015**)
- 11.kk. Off-Cycle Submission of Model of Care Changes (CMS-10565; **comments due 8/17/2015**)
- 194.d. 340B CMPs and Ceiling Price Regulations (HRSA/RIN 0906-AA89; **comments due 8/17/2015**)
- 78.k. Hospice Survey and Deficiencies Report Form (CMS-643; **comments due 8/18/2015**)
- 128.f. ACA Internal Claims and Appeals and External Review Procedures (DoL/OMB 1210-0144; **comments due 8/21/2015**)
- 25.aa. State Agency Sheets for Verifying IPPS Exclusions (CMS-437A and CMS-437B; **comments due 8/24/2015**)
- 168. Enrollee Satisfaction Survey Data Collection (CMS-10488; **comments due 8/24/2015**)
- 10.e. Heath Care Payment Learning and Action Network (CMS-10575; **comments due 8/25/2015**)
- 71.n. Changes to ESRD PPS, Quality Incentive Program, and DMEPOS (CMS-1628-P; **comments due 8/25/2015**)
- 12.e. CO-OP Program Guidance Manual (CCIIO/no ref. #; **comments due 8/28/2015**)
- 4.m. Hospital OPPS and ASC Payment System for CY 2016, et al. (CMS-1633-P; **comments due 8/31/2015**)
- 52.p. Home Health PPS Rate Update for CY 2016, et al. (CMS-1625-P; **comments due 9/4/2015**)

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

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

- 2e. Part C--Medicare Advantage and 1876 Cost Plan Expansion (CMS-10237; **comments due 9/8/2015**)
- 2.f. Applications for Medicare Prescription Drug Plan Contracts (CMS-10137; **comments due 9/8/2015**)
- 25.bb. Comprehensive Care for Joint Replacement Payment Model (CMS-5516-P; **comments due 9/8/2015**)
- 70.e. Revisions to PFS and Other Changes to Part B for CY 2016 (CMS-1631-P; **comments due 9/8/2015**)
- 135.e. Reform of Requirements for Long-Term Care Facilities (CMS-3260-P; **comments due 9/14/2015**)
- 72.f. Skilled Nursing Facility PPS and Consolidated Billing (CMS-10837; **comments due 9/21/2015**)
- 148.b. Data for Medicare Part B Drugs and Biologicals (CMS-10110; **comments due 9/21/2015**)
- 172.c. Medicare Beneficiary and Family-Centered Satisfaction Survey (CMS-10393; **comments due 9/21/2015**)

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

- 7.vv. 2016 Letter to Issuers in FFMs (CCIIO/no ref. #; comments submitted 1/12/2015 by TTAG)
- 92.ll. Health Benefit Plan Network Access and Adequacy Model Act (NAIC/no ref. #; comments submitted 1/12/2015 by TTAG)
- 112.e. Tribal Consultation on VA/IHS Reimbursement Agreements (VA/no ref. #; comments submitted 1/14/2015 by TSGAC)
- 112.d. I/T/U Payment for Physician and Non-Hospital-Based Services (IHS/RIN 0917-AA12; comments submitted 2/4/2015)
- 31.pp. Summary of Benefits and Coverage and Uniform Glossary (REG-145878-14, DoL/RIN 1210-AB69, CMS-9938-P; comments submitted 2/28/2015 by TTAG)
- 41.e. New Safe Harbors (OIG-123-N; comments submitted 3/2/2015 by TTAG)
- 112.c. Expanded Access to Non-VA Care Through Veterans Choice (VA/RIN 2900-AP24; comments submitted 3/5/2015)
- 64.c. Tribal Consultation Policy (Treasury/no ref. #; comments submitted 4/2/2015)
- 31.ss. Excise Tax on High Cost Employer Health Coverage (Notice 2015-16; comments submitted 5/15/2015)
- 1.l. EHR Incentive Program--Stage 3 (CMS-3310-P; comments submitted 5/29/2015)
- 7.ccc. Out-of-Pocket Cost Comparison Tool for FFMs (comments submitted 6/29/2015 by TTAG)
- 154.b. Medicaid/CHIP Managed Care (CMS-2390-P; comments submitted 7/27/2015)

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

- 54. ESI Coverage Verification (CMS/RIN 0938-ZB09; approved by OMB 4/26/2012 but not yet published)
- 16.b. Medicaid HCBS Waivers (CMS-2249-F2; approved by OMB 1/14/2014 but not yet published)
- 180. Flu Vaccination Standard for Certain Providers and Suppliers (CMS-3213-F; approved by OMB 4/18/2014 but not yet published)
- 164.b. Medicare Secondary Payer and “Future Medicals” (CMS-6047-P; approved by OMB 10/9/2014 but not yet published)
- 6.i. Pre-Existing Health Insurance Plan Program Updates (CMS-9995-IFC4; sent to OMB 2/3/2015)
- 181.b. Nondiscrimination Under ACA (HHS OCR/RIN 0945-AA02; sent to OMB 4/29/2015)
- 194.e. 340B Program Omnibus Guidelines (HRSA/RIN 0906-AB08; sent to OMB 5/6/2015)
- 25.cc. Revisions to Requirements for Discharge Planning for Hospitals (CMS-3317-P; sent to OMB 7/22/2015)
- 29.y. Medicare PPS for Inpatient Rehab Facilities for FY 2016 (CMS-1624-F; approved by OMB 7/29/2015)
- 72.e. PPS and Consolidated Billing for SNFs for FY 2016, et al. (CMS-1622-F; approved by OMB 7/29/2015)
- 78.j. Hospice Rate Update for FY 2016 (CMS-1629-F; approved by OMB 7/29/2015)
- 25.z. PPS for Acute and Long-Term Care Hospitals for FY 2016, et al. (CMS-1629-F; approved by OMB 7/30/2015)

Recent (final) rules issued –

- 31.mm. 2016 Actuarial Value Calculator (CCIIO/no ref. #; issued 1/16/2015)
- 11.gg. CY 2016 Policy and Technical Changes to Parts C and D (CMS-4159-F2; issued 2/12/2015)
- 7.vv. 2016 Letter to Issuers in FFMs (CCIIO/no ref. #; issued 2/20/2015)
- 39.e. Basic Health Program: Federal Funding Methodology for 2016 (CMS-2391-FN; issued 2/20/2015)

- 111.e. Establishment of Multi-State Plan Program for Exchanges (OPM/RIN 3206-AN12; issued 2/24/2015)
- 145.d. Health Insurance Providers Fee (TD 9711; issued 2/26/2015)
- 89.h. Notice of Benefit and Payment Parameters for 2016 (CMS-9944-F; issued 2/27/2015)
- 157.c. Right of Appeal for Medicare Secondary Payer Determination (CMS-6055-F; issued 2/27/2015)
- 31.oo. Amendments to Excepted Benefits (TD 9714, DoL/RIN 1210-AB70, CMS-9946-F2; issued 3/18/2015)
- 152. Medicare and Medicaid Survey, Certification, and Enforcement (CMS-3255-F; issued 5/22/2015)
- 10.c. Medicare Shared Savings Program: ACOs (CMS-1461-F; issued 6/9/2015)
- 174.f. FEHBP: Rate Setting for Community-Rated Plans (OPM/RIN 3206-AN00; issued 6/10/2015)
- 31.pp. Summary of Benefits and Coverage and Uniform Glossary (TD 9764, DoL/RIN 1210-AB69, CMS-9938-F; issued 6/16/2015)
- 31.dd. Coverage of Certain Preventive Services Under ACA (TD 9726, DoL/RIN 1210-AB67, CMS-9940-F; issued 7/14/2015)

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

National Indian Health Board

TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 7/31/2015

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 70	
			SECTION II: MEDICARE	Beginning on page 10 of 70	
			SECTION III: HEALTH REFORM	Beginning on page 38 of 70	
			SECTION IV: OTHER	Beginning on page 67 of 70	
			SECTION I: MEDICAID (AND DUAL MEDICAID AND MEDICARE)		
1.f.	**Medicare and Medicaid: EHR Incentive Program** **ACTION: Request for Comment** **NOTICE:** Medicare and Medicaid Programs: Electronic Health Record Incentive Program **AGENCY:** CMS	CMS-10336	Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/30/2013; issued extension 4/30/2015 Due Date: 9/30/2013; 6/1/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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

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

National Indian Health Board

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1.l.	**EHR Incentive Program--Stage 3** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 3 **AGENCY:** CMS	CMS-3310-P	Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: 5/29/2015; TTAG also filed comments 5/29/2015 Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:
1.m.	**2015 Edition Health IT Certification Criteria, et al.** **ACTION: Proposed Rule** **NOTICE:** 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications **AGENCY:** HHS ONC	HHS ONC RIN 0991-AB93	Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
1.n.	**EHR Incentive Program--Modifications to Meaningful Use** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Modifications to Meaningful Use in 2015 Through 2017 **AGENCY:** CMS	CMS-3311-P	Issue Date: 4/15/2015 Due Date: 6/15/2015 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:

[green] : regulation review complete — [blue] : regulation currently under review — [yellow] : regulation release pending

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1.o.	**Non-Governmental Test Procedures, etc. for Health IT Certification Program** **ACTION: Notice** **NOTICE:** Acceptance and Approval of Non-Governmental Developed Test Procedures, Test Tools, and Test Data for Use Under the ONC Health IT Certification Program **AGENCY:** HHS ONC	HHS ONC (no reference number)	Issue Date: 6/9/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
8.c.	**ACA Requirements for Section 1115 Projects** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Information and Collection Requirements for Section 1115 Demonstration Projects **AGENCY:** CMS	CMS-10341	Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2015 Due Date: 3/30/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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:

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16.f.	**Annual Report on HCBS Waivers** **ACTION: Request for Comment** **NOTICE:** Annual Report on Home and Community Based Services Waivers and Supporting Regulations **AGENCY:** CMS	CMS-372(S)	Issue Date: 1/16/2015 Due Date: 3/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/22/2015 Due Date: 6/22/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
23.h.	**Administrative Requirements for DRA Section 6071** **ACTION: Request for Comment** **NOTICE:** Administrative Requirements for Section 6071 of the Deficit Reduction Act **AGENCY:** CMS	CMS-10249	Issue Date: 1/9/2015 Due Date: 3/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/25/2015 Due Date: 4/24/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
28.f.	**Medicaid Implementation Advanced Planning Document** **ACTION: Notice** **NOTICE:** Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template **AGENCY:** CMS	CMS-10536	Issue Date: 8/29/2014 Due Date: 10/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/19/2014 Due Date: 1/20/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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28.h.	**Medicaid Eligibility Changes Under ACA** **ACTION: Request for Comment** **NOTICE:** Medicaid Program; Eligibility Changes Under the Affordable Care Act of 2010 **AGENCY:** CMS	CMS-10410	Issue Date: 2/6/2015 Due Date: 4/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/26/2015 Due Date: 7/27/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
28.i.	**Income and Eligibility Verification System Reporting** **ACTION: Request for Comment** **NOTICE:** Income and Eligibility Verification System Reporting **AGENCY:** CMS	CMS-R-74	Issue Date: 2/6/2015 Due Date: 4/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/26/2015 Due Date: 7/27/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
40.	**State Plan Base Plan Pages** **ACTION: Request for Comment** **NOTICE:** State Plan Under Title XIX of the Social Security Act **AGENCY:** CMS	CMS-179	Issue Date: 12/29/2011 Due Date: 2/14/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/23/2012; issued extension 4/20/2015, 6/26/2015 Due Date: 4/23/2012; 6/19/2015; 7/27/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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41.e.	**New Safe Harbors** **ACTION: Notice** **NOTICE:** Solicitation of New Safe Harbors and Special Fraud Alerts **AGENCY:** HHS OIG	OIG-123-N	Issue Date: 12/30/2014 Due Date: 3/2/2015 TTAG File Date: 3/2/2015 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:
62.	**External Quality Review of Medicaid MCOs** **ACTION: Request for Comment** **NOTICE:** External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs) and Supporting Regulations **AGENCY:** CMS	CMS-R-305	Issue Date: 5/31/2012 Due Date: 7/2/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/19/2014, 4/10/2015 Due Date: 2/17/2015; 5/11/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
66.c.	**Additional Requirements for Charitable Hospitals** **ACTION: Final Rule** **NOTICE:** Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return **AGENCY:** IRS	TD 9708 **See also 66.a. and 66.b.**	Issue Date: 12/31/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued corrections 3/11/2015, 5/4/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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83.b.	**Claims Processing and Information Retrieval Systems** **ACTION: Proposed Rule** **NOTICE:** Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems (90/10) **AGENCY:** CMS	CMS-2392-P	Issue Date: 4/16/2015 Due Date: 6/15/2015 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:
135.e.	**Reform of Requirements for Long-Term Care Facilities** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities **AGENCY:** CMS	CMS-3260-P	Issue Date: 7/16/2015 **Due Date: 9/14/2015** 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:
152.	**Medicare and Medicaid Survey, Certification, and Enforcement** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures **AGENCY:** CMS	CMS-3255-~~P~~F	Issue Date: 4/5/2013 Due Date: ~~6/4/2013~~ 7/5/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued notice of due date extension 5/24/2013; issued Final Rule 5/22/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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Updated through 7/31/2015

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154.b.	**Medicaid/CHIP Managed Care** **ACTION: Proposed Rule** **NOTICE:** Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability **AGENCY:** CMS	CMS-2390-P	Issue Date: 6/1/2015 Due Date: 7/27/2015 NIHB File Date: 7/27/2015; TTAG also filed comments 7/27/2015 Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: √ • Subsequent Agency action: • Analysis of Agency action
180.	**Flu Vaccination Standard for Certain Providers and Suppliers** **ACTION: Final Rule** **NOTICE:** Influenza Vaccination Standard for Certain Participating Providers and Suppliers **AGENCY:** CMS	CMS-3213-F	Issue Date: [Approved by OMB on 4/18/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
193.b.	**Executive Summary Form for Research Identifiable Data** **ACTION: Request for Comment** **NOTICE:** Executive Summary Form for Research Identifiable Data **AGENCY:** CMS	CMS-10522	Issue Date: 7/11/2014 Due Date: 9/9/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 11/4/2014; 2/27/2015 Due Date: 12/4/2014; 3/30/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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200.	**Mental Health Parity Rules for Medicaid and CHIP** **ACTION: Proposed Rule** **NOTICE:** Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and ABPs **AGENCY:** CMS	CMS-2333-P	Issue Date: 4/10/2015 Due Date: 6/9/2015 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:
201.	**Use of Restraint and Seclusion in Psychiatric Facilities** **ACTION: Request for Comment** **NOTICE:** Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations **AGENCY:** CMS	CMS-R-306	Issue Date: 1/30/2015 Due Date: 3/31/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/1/2015 Due Date: 6/1/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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203.	**Medicaid Estate Recovery Rules and Protections for AI/ANs** **ACTION: Guidance** **NOTICE:** Medicaid Estate Recovery: Rules and Protections for American Indians and Alaska Natives **AGENCY:** CMS	CMS (no reference number)	Issue Date: May 2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
			SECTION II: MEDICARE		
2.e.	**Part C--Medicare Advantage and 1876 Cost Plan Expansion** **ACTION: Request for Comment** **NOTICE:** Part C--Medicare Advantage and 1876 Cost Plan Expansion Application **AGENCY:** CMS	CMS-10237	Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 10/3/2014, 7/7/2015 **Due Date:** 11/4/2013; 9/9/2014; 11/3/2014; **9/8/2015**	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
2.f.	**Applications for Medicare Prescription Drug Plan Contracts** **ACTION: Request for Comment** **NOTICE:** Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts **AGENCY:** CMS	CMS-10137	Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 9/19/2014, 7/7/2015 **Due Date:** 11/4/2013; 9/9/2014; 10/20/2014; **9/8/2015**	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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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 Due Date: 4/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 9/12/2014, 12/30/2014 Due Date: 11/4/2014; 1/29/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
3.n.	**Expanded Prior Authorization for Power Mobility Devices** **ACTION: Notice** **NOTICE:** Medicare Program; Expanded Medicare Prior Authorization for Power Mobility Devices (PMDs) Demonstration **AGENCY:** CMS	CMS-6057-N CMS-6057-N2	Issue Date: 7/29/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension notice 7/15/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
3.o.	**Certification as a Supplier of Portable X-Ray Form** **ACTION: Request for Comment** **NOTICE:** Certification as a Supplier of Portable X-Ray and Portable X-Ray Survey Report Form and Supporting Regulations **AGENCY:** CMS	CMS-1880 and CMS-1882	Issue Date: 11/17/2014 Due Date: 1/16/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/30/2015 Due Date: 3/2/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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3.p.	**DME Items Requiring Face-to-Face Encounter and Prior Written Order** **ACTION:** Notice **NOTICE:** Medicare Program; Updates to the List of Durable Medical Equipment (DME) Specified Covered Items That Require a Face-to-Face Encounter and a Written Order Prior to Delivery **AGENCY:** CMS	CMS-6062-N	Issue Date: 3/27/2014 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:
4.k.	**Hospital OPPS and ASC 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; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data **AGENCY:** CMS	CMS-1613-~~P~~FC	Issue Date: 7/14/2014 Due Date: 9/2/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 11/10/2014; issued correction 2/24/2015 Due Date: 12/30/2014	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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4.l.	**Ambulatory Surgical Center Quality Reporting Program** **ACTION: Request for Comment** **NOTICE:** Ambulatory Surgical Center Quality Reporting Program **AGENCY:** CMS	CMS-10530	Issue Date: 11/17/2014 Due Date: 1/16/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/30/2015 Due Date: 3/2/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
4.m.	**Hospital OPPS and ASC Payment System for CY 2016, et al.** **ACTION: Proposed Rule** **NOTICE:** Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System **AGENCY:** CMS	CMS-1633-P	Issue Date: 7/8/2015 **Due Date: 8/31/2015** 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

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10.c.	**Medicare Shared Savings Program: ACOs** **ACTION:** **~~Proposed~~ Final Rule** **NOTICE:** Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations **AGENCY:** CMS	CMS-1461-~~PF~~	Issue Date: 12/8/2014 Due Date: 2/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 6/9/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
10.e.	**Heath Care Payment Learning and Action Network** **ACTION: Request for Comment** **NOTICE:** Generic Clearance for the Heath Care Payment Learning and Action Network **AGENCY:** CMS	CMS-10575	Issue Date: 6/26/2015 **Due Date: 8/25/2015** 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.d.	**Bid Pricing Tool** **ACTION: Request for Comment** **NOTICE:** Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs) **AGENCY:** CMS	CMS-10142	Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 10/4/2013, 12/20/2013 9/26/2014, 12/24/2014 Due Date: 2/19/2013; 12/3/2013; 1/21/2014; 11/25/2014; 1/23/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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11.f.	**Plan Benefit Package and Formulary Submission** **ACTION: Request for Comment** **NOTICE:** PBP and Formulary Submission for Medicare Advantage and Prescription Drug Plans **AGENCY:** CMS	CMS-R-262	Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 11/1/2013, 1/17/2014, 9/26/2014, 12/19/2014 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 1/20/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
11.g.	**Medicare Advantage Reporting Requirements** **ACTION: Request for Comment** **NOTICE:** Part C Medicare Advantage Reporting Requirements and Supporting Regulations **AGENCY:** CMS	CMS-10261	Issue Date: 10/26/2012 Due Date: 12/26/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/21/2013, 10/4/2013, 5/1/2015 Due Date: 8/20/2013; 11/4/2013; 6/30/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
11.j.	**Medicare Part D Reporting Requirements** **ACTION: Request for Comment** **NOTICE:** Medicare Part D Reporting Requirements **AGENCY:** CMS	CMS-10185	Issue Date: 3/15/2013 Due Date: 5/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/26/2013, 5/1/2015 Due Date: 8/26/2013; 6/30/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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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, 4/10/2015, 6/19/2015 Due Date: 1/13/2014; 6/9/2015; 7/20/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
11.gg.	**CY 2016 Policy and Technical Changes to Parts C and D** **ACTION: Final Rule** **NOTICE:** Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs **AGENCY:** CMS	CMS-4159-F2 **See also 11.u.**	Issue Date: 2/12/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
11.hh.	**Medicare Part C, Part D, and FFS CAHPS Survey** **ACTION: Request for Comment** **NOTICE:** Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey **AGENCY:** CMS	CMS-R-246	Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/8/2015 Due Date: 6/8/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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11.ii.	**Survey of Retail Community Pharmacy Prices** **ACTION: Request for Comment** **NOTICE:** Survey of Retail Prices: Payment and Utilization Rates and Performance Rankings **AGENCY:** CMS	CMS-10241	Issue Date: 12/19/2014 Due Date: 2/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/25/2015 Due Date: 4/24/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
11.jj.	**Changes to Requirements for Part D Prescribers** **ACTION: Interim Final Rule** **NOTICE:** Medicare Program; Changes to the Requirements for Part D Prescribers **AGENCY:** CMS	CMS-6107-IFC	Issue Date: 5/6/2015 Due Date: 7/6/2015 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.kk.	**Off-Cycle Submission of Model of Care Changes** **ACTION: Request for Comment** **NOTICE:** Off-Cycle Submission of Summaries of Model of Care Changes **AGENCY:** CMS	CMS-10565	Issue Date: 6/17/2015 **Due Date: 8/17/2015** 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

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13.k.	**Appointment of Representative** **ACTION: Request for Comment** **NOTICE:** Appointment of Representative **AGENCY:** CMS	CMS-1696	Issue Date: 2/27/2015 Due Date: 4/28/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/8/2015 Due Date: 6/8/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
25.x.	**Medicare PPS for Inpatient Psychiatric Facilities for FY 2016** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System-Update for Fiscal Year Beginning October 1, 2015 (FY 2016) **AGENCY:** CMS	CMS-1627-P	Issue Date: 5/1/2015 Due Date: 6/23/2015 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.y.	**Medicare PPS for Inpatient Rehab Facilities for FY 2016** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2016 **AGENCY:** CMS	CMS-1624-~~PF~~	Issue Date: 4/27/2015 Due Date: 6/22/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 7/29/2015	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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25.z.	**PPS for Acute and Long-Term Care Hospitals for FY 2016, et al.** **ACTION:** ~~**Proposed**~~ **Final Rule** **NOTICE:** Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program **AGENCY:** CMS	CMS-1632-~~PF~~	<u>Issue Date:</u> 4/30/2015 <u>Due Date:</u> ~~6/29/2015~~ 6/16/2015 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency Action, if any</u>: Issued correction 5/5/2015; Final Rule approved by OMB 7/30/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
25.aa.	**State Agency Sheets for Verifying IPPS Exclusions** **ACTION: Request for Comment** **NOTICE:** State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations **AGENCY:** CMS	CMS-437A and CMS-437B **See also 25.t.**	<u>Issue Date:</u> 5/15/2015 <u>Due Date:</u> 7/14/2015 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency Action, if any</u>: Issued revision 7/24/2015 **<u>Due Date:</u> 8/24/2015**	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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25.bb.	**Comprehensive Care for Joint Replacement Payment Model** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services **AGENCY:** CMS	CMS-5516-P	Issue Date: 7/14/2015 **Due Date: 9/8/2015** 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.cc.	**Revisions to Requirements for Discharge Planning for Hospitals** **ACTION: Proposed Rule** **NOTICE:** Revisions to Requirements for Discharge Planning for Hospitals, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Home Health Agencies, and Critical Access Hospitals **AGENCY:** CMS	CMS-3317-P	Issue Date: [Pending at OMB as of 7/22/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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49.a.	**Reporting and Returns of Medicare Overpayments** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; Reporting and Returning of Overpayments **AGENCY:** CMS	CMS-6037-P	Issue Date: 2/16/2012 Due Date: 4/16/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension notice 2/17/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
52.f.	**OASIS Collection Requirements as Part of the CoPs for HHAs** **ACTION: Request for Comment** **NOTICE:** OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations **AGENCY:** CMS	CMS-R-245	Issue Date: 6/21/2013 Due Date: 8/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 11/8/2013, 8/29/2014; issued extension 11/24/2014, 2/6/2015 Due Date: 12/9/2013; 9/12/2014; 1/23/2015; 3/9/2015	• 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 CMS-6047-N CMS-6059-N2 CMS-6059-N3	Issue Date: 2/4/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension notice 8/1/2014, 2/2/2015, 7/27/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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52.l.	**Home Health Agency Conditions of Participation** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies **AGENCY:** CMS	CMS-3819-P	Issue Date: 10/9/2014 Due Date: ~~12/8/2014~~ 1/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
52.n.	**OASIS-C1/ICD-10** **ACTION: Request for Comment** **NOTICE:** Outcome and Assessment Information Set (OASIS) OASIS-C1/ICD-10 **AGENCY:** CMS	CMS-10545	Issue Date: 1/9/2015 Due Date: 3/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/25/2015 Due Date: 4/24/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
52.o.	**Conditions of Participation for Home Health Agencies** **ACTION: Request for Comment** **NOTICE:** Conditions of Participation for Home Health Agencies (HHAs) **AGENCY:** CMS	CMS-10539	Issue Date: 4/24/2015 Due Date: 6/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 7/2/2015 **Due Date: 8/3/2015**	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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52.p.	**Home Health PPS Rate Update for CY 2016, et al.** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements **AGENCY:** CMS	CMS-1625-P	Issue Date: 7/10/2015 **Due Date: 9/4/2015** 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:
60.k.	**Application for Qualified Entity to Receive Medicare Data** **ACTION: Request for Comment** **NOTICE:** Application to Be a Qualified Entity to Receive Medicare Data for Performance Measurement **AGENCY:** CMS	CMS-10394	Issue Date: 9/8/2014 Due Date: 11/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/20/2015 Due Date: 5/20/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
70.b.	**Medicare Fee-for-Service Prepayment Medical Review** **ACTION: Request for Comment** **NOTICE:** Medicare Fee-for-Service Prepayment Medical Review **AGENCY:** CMS	CMS-10417	Issue Date: 9/21/2012 Due Date: 10/22/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2015, 6/5/2015 Due Date: 4/28/2015; 7/6/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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70.d.	**Revisions to PFS and Other Changes to Part B for CY 2015** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 **AGENCY:** CMS	CMS-1612-~~P~~FC	Issue Date: 7/11/2014 Due Date: 9/2/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 11/13/2014; issued correction 12/31/2014, 3/20/2015 Due Date: 12/30/2014 NIHB File Date: 12/23/2014	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:
70.e.	**Revisions to PFS and Other Changes to Part B for CY 2016** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 **AGENCY:** CMS	CMS-1631-P	Issue Date: 7/15/2015 **Due Date: 9/8/2015** 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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71.m.	**Medicare ESRD PPS, Quality Incentive Program, and DMEPOS** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies **AGENCY:** CMS	CMS-1614-~~PF~~	Issue Date: 7/11/2014 Due Date: 9/2/2014 NIHB File Date: Date of Subsequent Agency Action, if any: Issued Final Rule 11/6/2014; issued correction 3/13/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
71.n.	**Medicare ESRD PPS and Quality Incentive Program** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program **AGENCY:** CMS	CMS-1628-P	Issue Date: 7/1/2015 **Due Date: 8/25/2015** 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

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72.e.	**PPS and Consolidated Billing for SNFs for FY 2016, et al.** **ACTION:** ~~**Proposed**~~ **Final Rule** **NOTICE:** Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection **AGENCY:** CMS	CMS-1622-~~PF~~	Issue Date: 4/20/2015 Due Date: 6/19/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 7/29/2015	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
72.f.	**Skilled Nursing Facility PPS and Consolidated Billing** **ACTION: Request for Comment** **NOTICE:** Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing **AGENCY:** CMS	CMS-10387	Issue Date: 7/21/2015 **Due Date: 9/21/2015** NIHB File Date: 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

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77.d.	**National Provider Identifier Application and Update Form** **ACTION: Request for Comment** **NOTICE:** National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408 **AGENCY:** CMS	CMS-10114	Issue Date: 9/12/2014 Due Date: 11/12/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 11/21/2014, 1/16/2015 Due Date: 12/22/2014; 2/17/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency 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~~ Final 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-~~PF~~	Issue Date: 5/8/2014 Due Date: 7/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 8/22/2014; issued correction 4/30/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
78.i.	**Prior Authorization Form for Beneficiaries Enrolled in Hospice** **ACTION: Request for Comment** **NOTICE:** Prior Authorization Form for Beneficiaries Enrolled in Hospice **AGENCY:** CMS	CMS-10538	Issue Date: 10/3/2014 Due Date: 12/2/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/23/2015 Due Date: 2/23/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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78.j.	**Hospice Rate Update for FY 2016** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Medicare Program; FY 2016 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements **AGENCY:** CMS	CMS-1629-~~PF~~	Issue Date: 5/5/2015 Due Date: 6/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 7/29/2015	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
78.k.	**Hospice Survey and Deficiencies Report Form** **ACTION: Request for Comment** **NOTICE:** Hospice Survey and Deficiencies Report Form and Supporting Regulations **AGENCY:** CMS	CMS-643	Issue Date: 6/19/2015 **Due Date: 8/18/2015** 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:
117.d.	**National Implementation of the Hospital CAHPS Survey** **ACTION: Request for Comment** **NOTICE:** National Implementation of the Hospital CAHPS Survey **AGENCY:** CMS	CMS-10102	Issue Date: 3/13/2015 Due Date: 5/12/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/29/2015 Due Date: 6/29/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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121.i.	**Site Investigation for Diagnostic Testing Facilities** **ACTION: Request for Comment** **NOTICE:** Site Investigation for Independent Diagnostic Testing Facilities (IDTFs) **AGENCY:** CMS	CMS-10221	Issue Date: 1/16/2015 Due Date: 3/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/30/2015 Due Date: 4/29/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
121.j.	**Site Investigation for Suppliers of DMEPOS** **ACTION: Request for Comment** **NOTICE:** Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) **AGENCY:** CMS	CMS-R-263	Issue Date: 1/16/2015 Due Date: 3/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/30/2015 Due Date: 4/29/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
121.k.	**Verification of Clinic Data--Rural Health Clinic Form** **ACTION: Request for Comment** **NOTICE:** Verification of Clinic Data--Rural Health Clinic Form and Supporting Regulations **AGENCY:** CMS	CMS-29	Issue Date: 1/23/2015 Due Date: 3/24/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/30/2015 Due Date: 4/29/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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121.l.	**Medicare Enrollment Application: Reassignment of Benefits** **ACTION: Request for Comment** **NOTICE:** Medicare Enrollment Application: Reassignment of Medicare Benefits **AGENCY:** CMS	CMS-855R	Issue Date: 2/6/2015 Due Date: 4/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 4/20/2015 Due Date: 5/20/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
126.a.	**Medicare Rural Hospital Flexibility Grant Program** **ACTION: Request for Comment** **NOTICE:** Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination **AGENCY:** HRSA	HRSA (OMB 0915-0363)	Issue Date: 12/28/2012 Due Date: 60 days (approx. 3/1/2013) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/26/2013; issued revision 5/27/2015 Due Date: 30 days (approx. 5/28/2013); 7/27/2015	• 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 and Ambulatory Surgery CAHPS Survey** **ACTION: Request for Comment** **NOTICE:** Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) 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; issued revision 1/16/2015, 5/1/2015 Due Date: 1/27/2014; 3/17/2015; 6/1/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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132.g.	**HCAHPS Survey Mode Experiment** **ACTION: Request for Comment** **NOTICE:** Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Mode Experiment **AGENCY:** CMS	CMS-10542	Issue Date: 11/28/2014 Due Date: 1/27/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 2/13/2015 Due Date: 3/16/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
132.h.	**EDPEC Survey Mode Experiment** **ACTION: Request for Comment** **NOTICE:** Emergency Department Patient Experience of Care (EDPEC) Survey Mode Experiment **AGENCY:** CMS	CMS-10543	Issue Date: 11/28/2014 Due Date: 1/27/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 2/13/2015 Due Date: 3/16/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
132.i.	**Hospital National Provider Survey** **ACTION: Request for Comment** **NOTICE:** Hospital National Provider Survey **AGENCY:** CMS	CMS-10550	Issue Date: 3/20/2015 Due Date: 5/19/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/5/2015 Due Date: 7/6/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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132.j.	**Nursing Home National Provider Survey** **ACTION: Request for Comment** **NOTICE:** Nursing Home National Provider Survey **AGENCY:** CMS	CMS-10551	Issue Date: 3/20/2015 Due Date: 5/19/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/5/2015 Due Date: 7/6/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
134.d.	**Hospital and Health Care Complexes (Cost Report)** **ACTION: Request for Comment** **NOTICE:** Hospital and Health Care Complexes and Supporting Regulations **AGENCY:** CMS	CMS-2552-10	Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 7/26/2013, 2/6/2015 Due Date: 8/26/2013; 4/7/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
134.k.	**SNF and SNF Health Care Complex Cost Report** **ACTION: Request for Comment** **NOTICE:** Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report **AGENCY:** CMS	CMS-2540-10	Issue Date: 6/27/2014 Due Date: 8/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 8/29/2014; issued revision 5/1/2015 Due Date: 9/29/2014; 6/30/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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134.l.	**Federally Qualified Health Center Cost Report Form** **ACTION: Request for Comment** **NOTICE:** Federally Qualified Health Center Cost Report Form **AGENCY:** CMS	CMS-224-14	Issue Date: 12/19/2014 Due Date: 2/17/2015 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:
137.c.	**Transcatheter Mitral Valve Repair National Coverage Decision** **ACTION: Request for Comment** **NOTICE:** Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD) **AGENCY:** CMS	CMS-10531	Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/6/2015 Due Date: 4/6/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
148.b.	**Data for Medicare Part B Drugs and Biologicals** **ACTION: Request for Comment** **NOTICE:** Data for Medicare Part B Drugs and Biologicals **AGENCY:** CMS	CMS-10110	Issue Date: 7/21/2015 **Due Date: 9/21/2015** NIHB File Date: 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

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157.c.	**Right of Appeal for Medicare Secondary Payer Determination** **ACTION: ~~Proposed~~ Final 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~~F	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/27/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
164.b.	**Medicare Secondary Payer and "Future Medicals"** **ACTION: Proposed Rule** **NOTICE:** Medicare Secondary Payer and "Future Medicals" **AGENCY:** CMS	CMS-6047-P	Issue Date: [Approved by OMB 10/9/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action

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National Indian Health Board

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168.	**Enrollee Satisfaction Survey Data Collection** **ACTION: Request for Comment** **NOTICE:** Enrollee Satisfaction Survey Data Collection **AGENCY:** CMS	CMS-10488	Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 11/1/2013; issued revision 4/28/2015, 7/24/2015 **Due Date:** 12/2/2013; 6/29/2015; **8/24/2015** NIHB File Date: 12/2/2013; TTAG also filed comments 12/2/2013	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: √ • Subsequent Agency action: √ • Analysis of Agency action: √
172.b.	**Testing and Research for Medicare Beneficiary Survey** **ACTION: Request for Comment** **NOTICE:** Generic Clearance for Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey **AGENCY:** CMS	CMS-10549	Issue Date: 1/30/2015 Due Date: 3/31/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/2/2015 Due Date: 5/4/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
172.c.	**Medicare Beneficiary and Family-Centered Satisfaction Survey** **ACTION: Request for Comment** **NOTICE:** Medicare Beneficiary and Family-Centered Satisfaction Survey **AGENCY:** CMS	CMS-10393	Issue Date: 7/21/2015 **Due Date: 9/21/2015** 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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184.e.	**Fecal Occult Blood Testing Under CLIA** **ACTION: Proposed Rule** **NOTICE:** Clinical Laboratory Improvement Amendments (CLIA); Fecal Occult Blood (FOB) Testing **AGENCY:** CMS	CMS-3271-P	Issue Date: 11/7/2014 Due Date: 1/6/2015 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:
184.f.	**Laboratory Personnel Report** **ACTION: Request for Comment** **NOTICE:** Laboratory Personnel Report (CLIA) and Supporting Regulations **AGENCY:** CMS	CMS-209	Issue Date: 11/28/2014 Due Date: 1/27/2015 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:
184.g.	**Survey Report Form for CLIA** **ACTION: Request for Comment** **NOTICE:** Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations **AGENCY:** CMS	CMS-1557	Issue Date: 12/24/2014 Due Date: 2/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/6/2015 Due Date: 4/6/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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184.h.	**CLIA Exemption for Laboratories in New York** **ACTION:** Notice **NOTICE:** Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit-Holding Laboratories in the State of New York **AGENCY:** CMS	CMS-3308-N	Issue Date: 3/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
184.i.	**Post Clinical Laboratory Survey Questionnaire** **ACTION: Request for Comment** **NOTICE:** Post Clinical Laboratory Survey Questionnaire and Supporting Regulations **AGENCY:** CMS	CMS-668B	Issue Date: 5/22/2015 Due Date: 7/21/2015 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:
196.	**Patient Rights CoPs and Conditions for Coverage** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Program; Revisions to Certain Patient's Rights Conditions of Participation and Conditions for Coverage **AGENCY:** CMS	CMS-3302-P	Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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			SECTION III: HEALTH REFORM		
6.i.	**Pre-Existing Health Insurance Plan Program Updates** **ACTION: Interim Final Rule** **NOTICE:** Pre-Existing Condition Insurance Plan Program Updates **AGENCY:** CMS	CMS-9995-IFC4	Issue Date: [Pending at OMB as of 2/3/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.k.	**Agent/Broker Data Collection in Federally-Facilitated Exchanges** **ACTION: Request for Comment** **NOTICE:** Agent/Broker Data Collection in Federally-Facilitated Health Insurance Exchanges **AGENCY:** CMS	CMS-10464	Issue Date: 2/7/2013 Due Date: 4/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 5/17/2013; issued revision 3/6/2015, 7/13/2015 **Due Date**: 6/17/2013; 5/5/2015; **8/12/2015**	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.l.	**Stand-Alone Dental Plans in Federally-Facilitated Exchanges** **ACTION: Guidance** **NOTICE:** Issuers of Stand-Alone Dental Plans: Intent to Offer in FFE States **AGENCY:** HHS	HHS (no reference number)	Issue Date: 1/28/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 5/6/2014, 2/19/2015	• 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

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7.q.	**Cooperative Agreement to Support Navigators in FFE** **ACTION: Request for Comment** **NOTICE:** Cooperative Agreement to Support Navigators in Federally-Facilitated and State Partnership Exchanges **AGENCY:** CMS	CMS-10463	Issue Date: 4/12/2013 Due Date: 6/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/26/2013; issued revision 4/11/2014, 7/25/2014, 3/30/2015; issued extension 6/26/2015 Due Date: 8/26/2013; 6/10/2014; 8/25/2014; 5/29/2015; 7/27/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.t.	**Cooperative Agreement to Support State Exchanges** **ACTION: Request for Comment** **NOTICE:** Cooperative Agreement to Support Establishment of State-Operated Health Insurance Exchanges **AGENCY:** CMS	CMS-10371	Issue Date: 5/24/2013 Due Date: 7/23/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 8/16/2013; issued emergency review request 9/16/2013, 11/7/2014; issued revision 1/30/2015, 4/20/2015 Due Date: 9/16/2013; 9/23/2013; 11/14/2014; 3/31/2015; 5/20/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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7.v.	**Consumer Assistance Tools and Programs of Exchanges** **ACTION: Request for Comment** **NOTICE:** Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors **AGENCY:** CMS	CMS-10494	Issue Date: 7/17/2013 Due Date: 9/14/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 6/27/2014, 1/30/2015, 4/20/2015 Due Date: 7/28/2014; 3/31/2015; 5/20/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.kk.	**Standards for Navigators and Non-Navigator Personnel** **ACTION: Request for Comment** **NOTICE:** Standards for Navigators and Non-Navigator Assistance Personnel **AGENCY:** CMS	CMS-10472	Issue Date: 6/27/2014 Due Date: 7/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/30/2015, 4/20/2015 Due Date: 3/31/2015; 5/20/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.vv.	**2016 Letter to Issuers in FFMs** **ACTION: Guidance** **NOTICE:** ~~Draft~~ 2016 Letter to Issuers in the Federally-Facilitated Marketplaces **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 12/19/2014 Due Date: 1/12/2015 TTAG File Date: 1/12/2015 Date of Subsequent Agency Action, if any: Issued Final Letter 2/20/2015	• 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

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7.ww.	**Special Protections for AI/ANs** **ACTION: Guidance** **NOTICE:** Health Insurance Marketplace Protections for American Indians and Alaska Natives **AGENCY:** CMS	CMS (no reference number)	Issue Date: 1/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.xx.	**AI/AN Trust Income and MAGI** **ACTION: Guidance** **NOTICE:** American Indian and Alaska Native Trust Income and MAGI **AGENCY:** CMS	CMS (no reference number)	Issue Date: 1/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.yy.	**Special Enrollment Period for Tax Season** **ACTION: Notice** **NOTICE:** CMS Announces Special Enrollment Period for Tax Season **AGENCY:** CMS	CMS (no reference number)	Issue Date: 2/20/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.zz.	**Hardship Exemptions for Persons Meeting Certain Criteria** **ACTION: Guidance** **NOTICE:** Guidance on Hardship Exemptions for Persons Meeting Certain Criteria **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 3/20/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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7.aaa.	**Ending Special Enrollment Periods for Coverage in 2014** **ACTION: Guidance** **NOTICE:** Ending Special Enrollment Periods for Coverage During Calendar Year 2014 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 3/31/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.bbb.	**Key Dates in 2015: QHP Certification in the FFM, et al.** **ACTION: Guidance** **NOTICE:** Ending Special Enrollment Periods for Coverage During Calendar Year 2014 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
7.ccc.	**Out-of-Pocket Cost Comparison Tool for FFMs** **ACTION: Notice** **NOTICE:** CMS Bulletin on Proposed Out-of-Pocket (OOP) Cost Comparison Tool for the Federally-Facilitated Marketplaces (FFMs) **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 5/29/2015 Due Date: 6/29/2015 TTAG File Date: 6/29/2015 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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National Indian Health Board

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7.ddd.	**ECP Data Collection to Support QHP Certification for PY 2017** **ACTION: Request for Comment** **NOTICE:** Essential Community Provider Data Collection to Support QHP Certification for PY 2017 **AGENCY:** CMS	CMS-10561	Issue Date: 6/5/2015 **Due Date: 8/4/2015** NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
12.d.	**Consumer Operated and Oriented Program** **ACTION: Request for Comment** **NOTICE:** Consumer Operated and Oriented (CO-OP) Program **AGENCY:** CMS	CMS-10392	Issue Date: 9/8/2014 Due Date: 11/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 11/21/2014, 1/30/2015, 4/24/2015 Due Date: 12/22/2014; 3/31/2015; 5/26/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
12.e.	**CO-OP Program Guidance Manual** **ACTION: Guidance** **NOTICE:** CO-OP Program Guidance Manual, Version 1 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 7/29/2015 **Due Date: 8/28/2015** 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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27.i.	**Risk Corridors Transitional Policy** **ACTION: Request for Comment** **NOTICE:** Risk Corridors Transitional Policy **AGENCY:** CMS	CMS-10532	Issue Date: 9/8/2014 Due Date: 11/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/5/2015 Due Date: 2/4/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
27.k.	**Transitional Reinsurance Program Collections for 2014** **ACTION: Guidance** **NOTICE:** The Transitional Reinsurance Program's Contribution Collections for the 2014 Benefit Year **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
27.l.	**Transitional Reinsurance Program--Timing of Refunds** **ACTION: Guidance** **NOTICE:** Transitional Reinsurance Program--Timing of Contributions Refund Requests Due to Annual Enrollment Count Misreporting **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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27.m.	**Transitional Adjustment for 2014 Risk Corridors Program** **ACTION: Guidance** **NOTICE:** Transitional Adjustment for 2014 Risk Corridors Program **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/17/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
27.n.	**CSR Amounts in Risk Corridors and MLR Reporting** **ACTION: Guidance** **NOTICE:** Cost-Sharing Reduction Amounts in Risk Corridors and Medical Loss Ratio Reporting **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/19/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
29.q.	**Penalty Relief Related to Advance Payments of PTC** **ACTION: Guidance** **NOTICE:** Penalty Relief Related to Advance Payments of the Premium Tax Credit for 2014 **AGENCY:** IRS	Notice 2015-9	Issue Date: 1/26/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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29.r.	**Victims of Domestic Abuse and Spousal Abandonment** **ACTION:** Guidance **NOTICE:** Updated Guidance on Victims of Domestic Abuse and Spousal Abandonment **AGENCY:** CCIIO	CCIIO (no reference number) **See also 29.i.**	Issue Date: 7/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.dd.	**Coverage of Certain Preventive Services Under ACA** **ACTION:** ~~Proposed~~ Final Rule **NOTICE:** Coverage of Certain Preventive Services Under the Affordable Care Act **AGENCY:** IRS/DoL/CMS	~~REG 129786-14~~ TD 9726 DoL RIN 1210-AB67 CMS-9940-~~PF~~ **See also 31.ee. and 31.ff.**	Issue Date: 8/27/2014 Due Date: 10/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 7/14/2015	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.gg.	**Coverage of Certain Preventive Services Under ACA** **ACTION: Request for Comment** **NOTICE:** Coverage of Certain Preventive Services Under the Affordable Care Act **AGENCY:** DoL	EBSA Form 700 (OMB 1210-0150)	Issue Date: 8/27/2014 Due Date: 10/27/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/11/2014, 2/27/2015 Due Date: 2/9/2015; 3/30/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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31.kk.	**ACA Uniform Explanation of Coverage Documents** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Uniform Explanation of Coverage Documents **AGENCY:** IRS	TD 9575 (OMB 1545-2229)	Issue Date: 9/15/2014 Due Date: 11/14/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/26/2015 Due Date: 3/30/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.ll.	**Data Submission for the FFE User Fee Adjustment** **ACTION: Request for Comment** **NOTICE:** Data Submission for the Federally-Facilitated Exchange User Fee Adjustment **AGENCY:** CMS	CMS-10492 **See also 31.c.**	Issue Date: 9/29/2014 Due Date: 11/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 7/14/2015 **Due Date: 8/13/2015**	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.mm.	**2016 Actuarial Value Calculator** **ACTION: Guidance** **NOTICE:** ~~Draft~~ 2016 Actuarial Value Calculator **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 11/21/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued Final Guidance 1/16/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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31.nn.	**Notification of Objection to Covering Contraceptive Services** **ACTION: Request for Comment** **NOTICE:** Employer Notification to HHS of its Objection to Providing Coverage for Contraceptive Services **AGENCY:** CMS	CMS-10535	Issue Date: 12/8/2014 Due Date: 2/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/6/2915 Due Date: 4/6/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.oo.	**Amendments to Excepted Benefits** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Amendments to Excepted Benefits **AGENCY:** IRS/DoL/CMS	~~REG-132751-14~~ TD 9714 DoL RIN 1210-AB70 CMS-9946-~~P2~~F2	Issue Date: 12/23/2014 Due Date: 1/22/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/18/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.pp.	**Summary of Benefits and Coverage and Uniform Glossary** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Summary of Benefits and Coverage and Uniform Glossary **AGENCY:** IRS/DoL/CMS	~~REG-145878-14~~ TD 9764 DoL RIN 1210-AB69 CMS-9938-~~PF~~	Issue Date: 12/30/2014 Due Date: 3/2/2015 TTAG File Date: 2/28/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 6/16/2015	• 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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31.qq.	**FAQ About Excepted Benefits** **ACTION:** Guidance **NOTICE:** FAQs About Affordable Care Act Implementation: Excepted Benefits **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 2/13/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.rr.	**Minimum Essential Coverage Application Review Process** **ACTION:** Guidance **NOTICE:** Insurance Standards Bulletin Series: CCIIO Sub-Regulatory Guidance: Minimum Essential Coverage Application Review Process **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 2/13/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.ss.	**Excise Tax on High Cost Employer Health Coverage** **ACTION:** Guidance **NOTICE:** Section 4980I--Excise Tax on High Cost Employer-Sponsored Health Coverage **AGENCY:** IRS	Notice 2015-16	Issue Date: 2/23/2015 Due Date: 5/15/2015 NIHB File Date: 5/15/2015 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

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31.tt.	**ACA Section 2715 Summary Disclosures** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Section 2715 Summary Disclosures **AGENCY:** DoL	DoL (OMB 1210-0147)	Issue Date: 2/27/2015 Due Date: 3/30/2015 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.uu.	**ACA Implementation FAQs (SBC)** **ACTION: Guidance** **NOTICE:** Affordable Care Act Implementation FAQs **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 3/30/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.vv.	**EHBs: List of the Largest Three Small Group Products by State** **ACTION: Guidance** **NOTICE:** Essential Health Benefits: List of the Largest Three Small Group Products by State **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/8/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
31.xx.	**ACA Implementation FAQs (Preventive Services)** **ACTION: Guidance** **NOTICE:** FAQs About Affordable Care Act Implementation **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 5/11/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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31.yy.	**ACA Information Returns Reference Guide** **ACTION:** Guidance **NOTICE:** Affordable Care Act (ACA) Information Returns (AIR): AIR Submission Composition and Reference Guide, Version 1.0 **AGENCY:** IRS	IRS (no reference number)	Issue Date: June 2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
39.e.	**Basic Health Program: Federal Funding Methodology for 2016** **ACTION:** ~~Proposed~~ **Final Methodology** **NOTICE:** Basic Health Program; Federal Funding Methodology for Program Year 2016 **AGENCY:** CMS	CMS-2391-~~P~~FN	Issue Date: 10/23/2014 Due Date: 11/24/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Methodology 2/20/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
48.b.	**Medical Loss Ratio Rebate Calculation Report and Notices** **ACTION: Request for Comment** **NOTICE:** Annual MLR and Rebate Calculation Report and MLR Rebate Notices **AGENCY:** CMS	CMS-10418	Issue Date: 12/4/2012 Due Date: 2/4/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/22/2013, 11/22/2013, 1/31/2014, 1/30/2015, 4/24/2015 Due Date: 3/25/2013; 1/21/2014; 3/5/2014; 3/31/2015; 5/26/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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48.h.	**Q&A on MLR Reporting and Rebate Requirements** **ACTION: Guidance** **NOTICE:** CCIIO Technical Guidance: Questions and Answers Regarding the MLR Reporting and Rebate Requirements **AGENCY:** CCIIO	CCIIO 2015-0001	Issue Date: 5/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
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, 2/10/2014, 7/30/2014; issued extension 2/11/2015, 4/28/2015 Due Date: 12/31/2013; 3/12/2014; 8/27/2014; 4/13/2015; 5/28/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
50.v.	**Medical Expenditure Panel Survey--Insurance Component** **ACTION: Request for Comment** **NOTICE:** Medical Expenditure Panel Survey--Insurance 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, 2/18/2015, 5/7/2015; issued extension 6/11/2015 **Due Date:** 4/30/2014; 4/20/2015; 6/8/2015; **8/10/2015**	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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50.aa.	**SHOP Effective Date and Termination Notice Requirements** **ACTION: Request for Comment** **NOTICE:** Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements **AGENCY:** CMS	CMS-10555	Issue Date: 3/9/2015 Due Date: 5/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
50.bb.	**FAQs on Flexibilities for State-Based SHOP Direct Enrollment** **ACTION: Guidance** **NOTICE:** Flexibilities for State-Based SHOP Direct Enrollment--Frequently Asked Questions (FAQs) **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/1/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
50.cc.	**FAQs on SBM Options for Shared Responsibility Exemptions** **ACTION: Guidance** **NOTICE:** Frequently Asked Questions on State-Based Marketplace Options for Implementing Exemptions from the Shared Responsibility Payment **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 7/28/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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54.	**ESI Coverage Verification** **ACTION: Notice** **NOTICE:** Employer-Sponsored Coverage Verification: Preliminary Informational Statement **AGENCY:** CMS	CMS RIN 0938-ZB09	Issue Date: [Approved by OMB 4/26/2012] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
64.c.	**Tribal Consultation Policy** **ACTION: Notice** **NOTICE:** Tribal Consultation Policy **AGENCY:** Treasury	Treasury (no reference number)	Issue Date: 12/3/2014 Due Date: 4/2/2015 NIHB File Date: 4/2/2015 Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:
67.g.	**FAQs on Use of 1311 Funds for Establishment Activities** **ACTION: Guidance** **NOTICE:** FAQs on the Clarification of the Use of 1311 Funds for Establishment Activities **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/8/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
77.e.	**Requirements for the Health Plan Identifier** **ACTION: Request for Information** **NOTICE:** Request for Information Regarding the Requirements for the Health Plan Identifier **AGENCY:** CMS	CMS-0026-NC	Issue Date: 5/29/2015 Due Date: 7/28/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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89.h.	**Notice of Benefit and Payment Parameters for 2016** **ACTION:** ~~Proposed~~ Final Rule **NOTICE:** Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 **AGENCY:** CMS	CMS-9944-~~PF~~	Issue Date: 11/26/2014 Due Date: 12/22/2014 TTAG File Date: 12/22/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 2/27/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• TTAG recommendations included: √ • Subsequent Agency action: √ • Analysis of Agency action: √
89.i.	**Information Collection for Machine-Readable Data for QHPs** **ACTION: Request for Comment** **NOTICE:** Information Collection for Machine-Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs **AGENCY:** CMS	CMS-10558	Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/26/2015 Due Date: 7/27/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
89.j.	**ACA Implementation FAQs (Cost-Sharing Limitations)** **ACTION: Guidance** **NOTICE:** FAQs About Affordable Care Act Implementation **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 5/26/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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89.k.	**Eligibility Determinations for Indian-Specific CSVs** **ACTION: Letter to CCIIO** **NOTICE:** Request for Confirmation that Eligibility Determinations for Indian-Specific Cost-Sharing Protections Are Being Made Consistent with ACA and Implementing Regulations **AGENCY:** TTAG	TTAG (no reference number)	Issue Date: 6/26/2015 Due Date: None NIHB File Date: 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:
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: Issued revised Guidance 1/15/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
92.hh.	**Annual Eligibility Redetermination Notices, et al.** **ACTION: Request for Comment** **NOTICE:** Annual Eligibility Redetermination, Product Discontinuation, and Renewal Notices **AGENCY:** CMS	CMS-10527	Issue Date: 11/4/2014 Due Date: 1/5/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/23/2015 Due Date: 2/23/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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92.kk.	**Summary of Benefits and Coverage and Uniform Glossary** **ACTION: Request for Comment** **NOTICE:** Summary of Benefits and Coverage and Uniform Glossary **AGENCY:** CMS	CMS-10407	Issue Date: 11/24/2014 Due Date: 1/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/24/2015 Due Date: 3/26/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
92.ll.	**Health Benefit Plan Network Access and Adequacy Model Act** **ACTION: Request for Comment** **NOTICE:** Health Benefit Plan Network Access and Adequacy Model Act (Draft) **AGENCY:** NAIC	NAIC (no reference number)	Issue Date: 11/12/2014 Due Date: 1/12/2015 TTAG File Date: 1/12/2015 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:
92.mm.	**Rate Review Requirements** **ACTION: Guidance** **NOTICE:** Insurance Standards Bulletin Series: Questions and Answers Regarding Rate Review Requirements **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 3/31/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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92.nn.	**Rate Filing Justifications for Single Risk Pool Coverage** **ACTION:** Guidance **NOTICE:** Insurance Standards Bulletin Series: CCIIO Sub-Regulatory Guidance: Timing of Submission and Posting of Rate Filing Justifications for the 2015 Filing Year for Single Risk Pool Compliant Coverage Effective on or after January 1, 2016 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
92.oo.	**Eligibility Redeterminations for Marketplace Coverage** **ACTION:** Guidance **NOTICE:** Guidance on Annual Eligibility Redeterminations and Re-Enrollments for Marketplace Coverage for 2016 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/22/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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92.pp.	**ACA Reporting Requirements for Health Coverage Providers** **ACTION:** Guidance **NOTICE:** ACA: Responsibilities for Health Coverage Providers--Understanding Reporting Requirements of the Health Care Law **AGENCY:** IRS	Publication 5215	Issue Date: 4/22/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
92.qq.	**Evaluation of EDGE Data Submissions** **ACTION:** Guidance **NOTICE:** EDGE Server Data Bulletin--Evaluation of EDGE Data Submissions **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/24/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
92.rr.	**EDGE Data Submission Grace Period** **ACTION:** Guidance **NOTICE:** EDGE Server Data Bulletin--EDGE Data Submission Grace Period **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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92.ss.	**Rate Review Requirements in States with SBMs** **ACTION: Guidance** **NOTICE:** Insurance Standards Bulletin Series: Questions and Answers Regarding Rate Review Requirements **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 5/13/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
92.tt.	**QIS Implementation Plan and Progress Report** **ACTION: Request for Comment** **NOTICE:** Quality Improvement Strategy Implementation Plan and Progress Report **AGENCY:** CMS	CMS-10540	Issue Date: 6/19/2015 Due Date: 7/20/2015 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.uu.	**Information Distribution on PTCs and CSRs for FFM Coverage** **ACTION: Guidance** **NOTICE:** Distribution of Information Regarding Advance Payments of the Premium Tax Credit (APTC) and Cost-Sharing Reductions (CSRs) in Federal Standard Notices for Coverage Offered Through the Federally-Facilitated Marketplaces **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/12/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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92.vv.	**FAQs on Uniform Modification and Plan/Product Withdrawal** **ACTION:** Guidance **NOTICE:** Uniform Modification and Plan/Product Withdrawal FAQ **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/15/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
92.ww.	**Standard Notices of Product Discontinuation and Renewal** **ACTION:** Guidance **NOTICE:** Guidance on Federal Standard Notices of Product Discontinuation and Renewal in Connection with the Open Enrollment Period for the 2016 Coverage Year **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 7/7/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
99.d.	**FAQs About ACA Implementation (Wellness Programs)** **ACTION:** Guidance **NOTICE:** FAQs About Affordable Care Act Implementation **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/16/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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99.e.	**FAQs on Market Reforms and Wellness Programs** **ACTION:** Guidance **NOTICE:** Frequently Asked Questions on Health Insurance Market Reforms and Wellness Programs **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/16/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
111.e.	**Establishment of Multi-State Plan Program for Exchanges** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges **AGENCY:** OPM	OPM RIN 3206-AN12	Issue Date: 11/24/2014 Due Date: 12/24/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/24/2015; issued correction 3/30/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
112.c.	**Expanded Access to Non-VA Care Through Veterans Choice** **ACTION: Interim Final Rule** **NOTICE:** Expanded Access to Non-VA Care Through Veterans Choice Program **AGENCY:** VA	VA RIN 2900-AP24	Issue Date: 11/5/2014 Due Date: 3/5/2015 NIHB File Date: 3/5/2015 Date of Subsequent Agency Action, if any: Issued start date notice 11/21/2014, issued interim final rule (amendment) 4/24/2015 Due Date: 5/26/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:

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112.d.	**I/T/U Payment for Physician and Non-Hospital-Based Services** **ACTION: Proposed Rule** **NOTICE:** Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated with Non-Hospital-Based Care **AGENCY:** IHS	IHS RIN 0917-AA12	Issue Date: 12/5/2014 Due Date: ~~1/20/2015~~ 2/4/2015 NIHB File Date: 2/4/2015 Date of Subsequent Agency Action, if any: Issued due date extension 1/14/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:
112.e.	**Tribal Consultation on VA/IHS Reimbursement Agreements** **ACTION: Notice** **NOTICE:** Section 102(c) of the Veterans Access, Choice, and Accountability Act of 2014 **AGENCY:** VA	VA (no reference number)	Issue Date: 12/30/2014 Due Date: 1/14/2015 TSGAC File Date: 1/14/2015 Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• TSGAC recommendations included: √ • Subsequent Agency action: • Analysis of Agency action:
112.f.	**IHS Reimbursement Rates for CY 2015** **ACTION: Notice** **NOTICE:** Reimbursement Rates for Calendar Year 2015 **AGENCY:** IHS	IHS (no reference number)	Issue Date: 4/2/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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112.g.	**Receipt of Non-VA Care Under Veterans Choice Program** **ACTION: Request for Comment** **NOTICE:** Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program **AGENCY:** VA	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015 Due Date: 6/15/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
112.h.	**Health Care Plan Information for Veterans Choice Program** **ACTION: Request for Comment** **NOTICE:** Health Care Plan Information for the Veterans Choice Program **AGENCY:** VA	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015 Due Date: 6/15/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
112.i.	**Submission of Medical Records Under Veterans Choice Program** **ACTION: Request for Comment** **NOTICE:** Submission of Medical Record Information under the Veterans Choice Program **AGENCY:** VA	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015 Due Date: 6/15/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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National Indian Health Board

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112.j.	**Submission of Credentials by Eligible Entities or Providers** **ACTION: Request for Comment** **NOTICE:** Submission of Information on Credentials and Licenses by Eligible Entities or Providers **AGENCY:** VA	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015 Due Date: 6/15/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
128.e.	**Electing a Federal External Review Process** **ACTION: Guidance** **NOTICE:** Instructions for Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage on How to Elect a Federal External Review Process **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/15/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
128.f.	**ACA Internal Claims and Appeals and External Review Procedures** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-Grandfathered Plans **AGENCY:** DoL	DoL (OMB 1210-0144)	Issue Date: 10/15/2014 Due Date: 12/15/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/23/2015 **Due Date: 8/21/2015**	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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

National Indian Health Board

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145.c.	**Health Insurance Providers Fee** **ACTION: Proposed Rule** **NOTICE:** Health Insurance Providers Fee **AGENCY:** IRS	REG-143416-14 **See also 145.b.**	Issue Date: 2/26/2015 Due Date: 5/27/2015 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:
145.d.	**Health Insurance Providers Fee** **ACTION: Final/Temporary Rule** **NOTICE:** Health Insurance Providers Fee **AGENCY:** IRS	TD 9711 **See also 145.a.**	Issue Date: 2/26/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
174.f.	**FEHBP: Rate Setting for Community-Rated Plans** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Federal Employees Health Benefits Program; Rate Setting for Community-Rated Plans **AGENCY:** OPM	OPM (RIN 3206-AN00)	Issue Date: 1/17/2015 Due Date: 3/9/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 6/10/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
198.c.	**Branded Prescription Drug Fee** **ACTION: Request for Comment** **NOTICE:** Branded Prescription Drug Fee **AGENCY:** IRS	REG-112805-10 (OMB 1545-2209)	Issue Date: 3/17/2015 Due Date: 5/18/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/29/2015 Due Date: 6/29/2015	• Summary of Agency action: √ • NIHB analysis of action: √ • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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			SECTION IV: OTHER		
109.d.	**COBRA Coverage Requirements for Group Health Plans** **ACTION: Request for Comment** **NOTICE:** Continuation Coverage Requirements Application to Group Health Plans **AGENCY:** IRS	REG-209485-86/TD 8812 (OMB 1545-1581)	Issue Date: 10/8/2014 Due Date: 12/8/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/30/2014 Due Date: 1/29/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
125.	**Interest Rate on Overdue Debts** **ACTION: Notice** **NOTICE:** Notice of Interest Rate on Overdue Debts **AGENCY:** HHS	HHS (no reference number)	Issue Date: 12/28/2012 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revisions 3/5/2013, 4/23/2013, 7/23/2013, 11/12/2013, 9/2/2014, 10/27/2014, 1/27/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
181.b.	**Nondiscrimination Under ACA** **ACTION: Proposed Rule** **NOTICE:** Nondiscrimination Under the Patient Protection and Affordable Care Act **AGENCY:** HHS OCR	HHS OCR RIN 0945-AA02	Issue Date: [Pending at OMB as of 4/29/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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185.g.	**Safe Harbor for FQHC Arrangements** **ACTION: Request for Comment** **NOTICE:** Safe Harbor for Federally Qualified Health Centers Arrangements **AGENCY:** HHS OIG	HHS-OS-0990-0322-60D HHS-OS-0990-0322-30D	Issue Date: 10/1/2014 Due Date: 12/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 1/23/2015 Due Date: 2/23/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
189.b.	**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: 1/22/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
194.c.	**Enrollment and Re-Certification of Entities in the 340B Program** **ACTION: Request for Comment** **NOTICE:** Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations **AGENCY:** HRSA	HRSA (OMB 0915-0327)	Issue Date: 9/30/2014 Due Date: 12/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 4/21/2015 Due Date: 5/21/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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194.d.	**340B Ceiling Price and CMPs Regulation** **ACTION: Proposed Rule** **NOTICE:** 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation **AGENCY:** HRSA	HRSA RIN 0906-AA89	Issue Date: 6/17/2015 **Due Date: 8/17/2015** NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: √ • NIHB analysis of action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
194.e.	**340B Program Omnibus Guidelines** **ACTION: Proposed Rule** **NOTICE:** 340B Program Omnibus Guidelines **AGENCY:** HRSA	HRSA RIN 0906-AB08	Issue Date: [Pending at OMB as of 5/6/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	• Summary of Agency action: • NIHB analysis of action:	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
199.a.	**National CLAS Standards in Health and Health Care** **ACTION: Request for Comment** **NOTICE:** National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care: Evaluation of Awareness, Adoption, and Implementation **AGENCY:** HHS	HHS-OS-0990-New-60D HHS-OS-0990-New-30D	Issue Date: 9/26/2014 Due Date: 11/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/19/2014 Due Date: 1/20/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:

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199.b.	**CLAS County Data** **ACTION: Guidance** **NOTICE:** CLAS County Data **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 12/12/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 1/7/2015, 2/9/2015	• Summary of Agency action: √ • NIHB analysis of action: • Summary of subsequent Agency action: √	• NIHB recommendations included: • Subsequent Agency action: • Analysis of Agency action:
202.	**Health Needs of the AI/AN LGBT Community** **ACTION: Request for Information** **NOTICE:** Notice of Request for Information **AGENCY:** IHS	IHS (no reference number)	Issue Date: 6/5/2015 Due Date: 7/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued meeting notice 7/22/2015	• 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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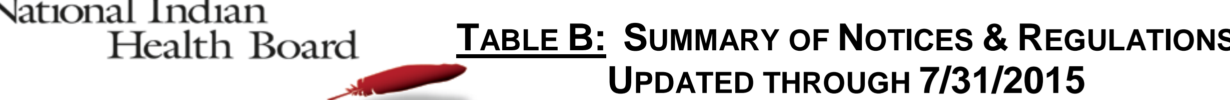

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
1.f.	**Medicare and Medicaid: EHR Incentive Program** **ACTION: Request for Comment** **NOTICE:** Medicare and Medicaid Programs: Electronic Health Record Incentive Program **AGENCY:** CMS	CMS-10336	Issue Date: 6/7/2013 Due Date: 8/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 8/30/2013; issued extension 4/30/2015 Due Date: 9/30/2013; 6/1/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Reinstatement with change of a previously approved collection; *Title*: Medicare and Medicaid Programs: Electronic Health Record Incentive Program; Use: Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Recovery Act) amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health record (EHR) technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, constitute the "Health Information Technology for Economic and Clinical Health Act" or "HITECH Act." The HITECH Act creates incentive programs for EPs and eligible hospitals, including CAHs, in the Medicare Fee-for-Service (FFS), MA, and Medicaid programs that successfully demonstrate meaningful use of certified EHR technology. In their first payment year, Medicaid EPs and eligible hospitals can adopt, implement, or upgrade to certified EHR technology. The HITECH Act also provides for payment adjustments in the Medicare FFS and MA programs, starting in FY 2015, for EPs and eligible hospitals participating in Medicare not considered meaningful users of certified EHR technology. These payment adjustments do not pertain to Medicaid providers. This information collection serves to implement the HITECH Act. To avoid duplicate payments, all EPs are enumerated through their National Provider Identifier (NPI), and all eligible hospitals and CAHs are enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider tax identification number and NPI or CCN combination to make payments; validate payment eligibility; and detect and prevent duplicate payments for EPs, eligible hospitals, and CAHs. http://www.gpo.gov/fdsys/pkg/FR-2013-06-07/pdf/2013-13578.pdf **SUMMARY OF NIHB ANALYSIS:** This PRA request might provide an opportunity to comment on incentive payment implementation, if concerns exist. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 8/30/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-08-30/pdf/2013-21257.pdf	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					CMS on 4/30/2015 issued an extension/reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10197.pdf No comments recommended.	
1.l.	**EHR Incentive Program--Stage 3** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 3 **AGENCY:** CMS	CMS-3310-P	Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: 5/29/2015; TTAG also filed comments 5/29/2015 Date of Subsequent Agency Action, if any:	NIHB response: TTAG response:	**SUMMARY OF AGENCY ACTION:** This Stage 3 proposed rule would specify the meaningful use criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under Medicare for Stage 3 of the EHR Incentive Programs. It would continue to encourage electronic submission of clinical quality measure (CQM) data for all providers where feasible in 2017, propose to require the electronic submission of CQMs where feasible in 2018, and establish requirements to transition the program to a single stage for meaningful use. Finally, this Stage 3 proposed rule would change the EHR reporting period so that all providers would report under a full calendar year timeline with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time. These changes together support broader CMS efforts to increase simplicity and flexibility in the program while driving interoperability and a focus on patient outcomes in the meaningful use program. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-06685.pdf **SUMMARY OF NIHB ANALYSIS:** The proposed rule includes a number of provisions supported by tribal organizations, particularly those that help simplify and align reporting periods (calendar year for EPs and eligible hospitals), as well as those that allow for a 90-day reporting period. In addition, tribal organizations support the exceptions for the lack of availability of Internet access or barriers to obtain IT infrastructure.	See Table C.
1.m.	**2015 Edition Health IT Certification Criteria, et al.** **ACTION: Proposed Rule**	HHS ONC RIN 0991-AB93	Issue Date: 3/30/2015 Due Date: 5/29/2015		**SUMMARY OF AGENCY ACTION:** This notice of proposed rulemaking introduces a new edition of certification criteria (the 2015 Edition health IT certification criteria or "2015 Edition"), proposes a new 2015 Edition Base Electronic Health Record (EHR) definition, and proposes to modify the HHS ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care 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.
	NOTICE: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications		NIHB File Date: None Date of Subsequent Agency Action, if any:		practice settings. The 2015 Edition also would establish the capabilities and specify the related standards and implementation specifications that Certified EHR Technology (CEHRT) would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) when these programs require the use of such edition. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-06612.pdf **SUMMARY OF NIHB ANALYSIS:**	
1.n.	**EHR Incentive Program--Modifications to Meaningful Use** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Modifications to Meaningful Use in 2015 Through 2017 **AGENCY:** CMS	CMS-3311-P	Issue Date: 4/15/2015 Due Date: 6/15/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would change the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program EHR reporting period in 2015 to a 90-day period aligned with the calendar year and would align the EHR reporting period in 2016 with the calendar year. In addition, this proposed rule would modify the patient action measures in the Stage 2 objectives related to patient engagement. Finally, it would streamline the program by removing reporting requirements on measures that have become redundant, duplicative, or topped out through advancements in EHR function and provider performance for Stage 1 and Stage 2 of the Medicare and Medicaid EHR Incentive Programs. http://www.gpo.gov/fdsys/pkg/FR-2015-04-15/pdf/2015-08514.pdf **SUMMARY OF NIHB ANALYSIS:** A summary of this proposed rule is embedded below. Summary of CMS proposed rule on Stag	
1.o.	**Non-Governmental Test Procedures, etc. for Health IT Certification Program**	HHS ONC (no reference number)	Issue Date: 6/9/2015 Due Date:		**SUMMARY OF AGENCY ACTION:** This document further informs the public of the HHS ONC policy that permits any individual or entity to submit test procedures, test tools, and test data for approval and use under the ONC Health IT Certification Program.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Notice **NOTICE:** Acceptance and Approval of Non-Governmental Developed Test Procedures, Test Tools, and Test Data for Use Under the ONC Health IT Certification Program **AGENCY:** HHS ONC		None NIHB File Date: Date of Subsequent Agency Action, if any:		http://www.gpo.gov/fdsys/pkg/FR-2015-06-09/pdf/2015-13510.pdf **SUMMARY OF NIHB ANALYSIS:**	
2.e.	**Part C--Medicare Advantage and 1876 Cost Plan Expansion** **ACTION: Request for Comment** **NOTICE:** Part C--Medicare Advantage and 1876 Cost Plan Expansion Application **AGENCY:** CMS	CMS-10237	Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 10/3/2014, 7/7/2015 **Due Date:** 11/4/2013; 9/9/2014;		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Part C--Medicare Advantage and 1876 Cost Plan Expansion Application; *Use*: Organizations wishing to provide healthcare services under Medicare Advantage (MA) and/or MA organizations that offer integrated prescription drug and health care products must complete an application, file a bid, and receive final approval from CMS. Existing MA plans can request to expand their contracted service area by completing the Service Area Expansion application. Any current 1876 Cost Plan Contractor that wants to expand its Medicare cost-based contract with CMS can complete the application. CMS collects information to ensure applicant compliance with requirements and gather data to support its determination of contract awards. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 7/11/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-16076.pdf This PRA request includes no reference to the Indian Addendum. No comments	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			11/3/2014; **9/8/2015**		recommended. CMS on 10/3/2014 issued a revision of this PRA request. CMS has revised this PRA request subsequent to the publication of the 30-day notice in 7/11/2014 FR (79 FR 40105). http://www.gpo.gov/fdsys/pkg/FR-2014-10-03/pdf/2014-23614.pdf CMS on 7/7/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-07/pdf/2015-16608.pdf No comments recommended.	
2.f.	**Applications for Medicare Prescription Drug Plan Contracts** **ACTION: Request for Comment** **NOTICE:** Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts **AGENCY:** CMS	CMS-10137	Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 10/4/2013, 7/11/2014, 9/19/2014, 7/7/2015 **Due Date:** 11/4/2013; 9/9/2014;		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts; Use: CMS will collect the information under the solicitation of proposals from prescription drug plans, Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage, Cost Plans, PACE, and EGWP applicants. CMS will use the information collected to ensure that applicants meet requirements and to support the determination of contract awards. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf **SUMMARY OF NIHB ANALYSIS:** This PRA request provides a potential opportunity to comment on language used to communicate the requirement to offer contracts, using an Indian Addendum, to I/T/U facilities. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 7/11/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-16076.pdf This PRA request includes no reference to the Indian Addendum. No comments recommended.	

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			10/20/2014; **9/8/2015**		CMS on 9/19/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22379.pdf CMS on 7/7/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-07/pdf/2015-16608.pdf No comments recommended.	
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 Due Date: 4/18/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 9/12/2014, 12/30/2014 Due Date: 11/4/2014; 1/29/2015		**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 a prior authorization program for Power Mobility Device (PMD) claims in certain States. 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	

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					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.** http://www.gpo.gov/fdsys/pkg/FR-2014-04-04/pdf/2014-07577.pdf SUMMARY OF NIHB ANALYSIS: **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 9/12/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-12/pdf/2014-21798.pdf CMS on 12/30/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-12-30/pdf/2014-30468.pdf	
3.n.	**Expanded Prior Authorization for Power Mobility Devices** **ACTION: Notice**	CMS-6057-N CMS-6057-N2	Issue Date: 7/29/2014 Due Date: None		**SUMMARY OF AGENCY ACTION:** This notice announces the expansion of the Medicare Prior Authorization for Power Mobility Devices (PMDs) Demonstration to 12 additional states (Pennsylvania, Ohio, Louisiana, Missouri, Washington, New Jersey, Maryland, Indiana, Kentucky, Georgia, Tennessee, and Arizona) that have high expenditures and improper payments for PMDs based on 2012 billing data. The 19 states selected for the demonstration, which include the 7 current (California, Florida,	

Ref. #	Short Title/Current Status of Regulation/Title/ 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; Expanded Medicare Prior Authorization for Power Mobility Devices (PMDs) Demonstration **AGENCY:** CMS		NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension notice 7/15/2015		Illinois, Michigan, New York, North Carolina, and Texas) and 12 additional states, account for 71 percent of expenditures for PMDs in 2012. The remaining states and territories serve in the control group for the demonstration. http://www.gpo.gov/fdsys/pkg/FR-2014-07-29/pdf/2014-17805.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/15/2015 issued a notice (CMS-6057-N2) to announce an extension of the Medicare Prior Authorization for Power Mobility Devices (PMDs) demonstration. Under the extension, this demonstration will end on August 31, 2018. http://www.gpo.gov/fdsys/pkg/FR-2015-07-15/pdf/2015-17365.pdf	
3.o.	**Certification as a Supplier of Portable X-Ray Form** **ACTION: Request for Comment** **NOTICE:** Certification as a Supplier of Portable X-Ray and Portable X-Ray Survey Report Form and Supporting Regulations **AGENCY:** CMS	CMS-1880 and CMS-1882	Issue Date: 11/17/2014 Due Date: 1/16/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/30/2015 Due Date: 3/2/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension without change of a currently approved collection; *Title*: Certification as a Supplier of Portable X-Ray and Portable X-Ray Survey Report Form and Supporting Regulations; *Use*: Suppliers of portable X-ray services expressing an interest in and requesting participation in the Medicare program initially complete CMS-1880. This form initiates the process of obtaining a decision as to whether they meet the conditions of coverage as a portable X-ray supplier. It also promotes data reduction or introduction to, and retrieval from, the Certification and Survey Provider Enhanced Reporting (CASPER) by the CMS Regional Offices (ROs). The State survey agency uses CMS-1882 to provide data collected during an onsite survey of a supplier of portable X-ray services to determine compliance with the applicable conditions of participation and to report this information to the Federal Government. The form primarily serves as a coding worksheet designed to facilitate data reduction and retrieval into the ASPEN system at the CMS Regional Offices. The form includes basic information on compliance (i.e., met, not met, explanatory statements) and does not require any descriptive information regarding the survey activity itself. CMS has the responsibility and authority for certification decisions based on supplier compliance with the applicable conditions of participation. CMS has access to the information needed to make these decisions only through the use of information abstracted from the survey report form.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					SUMMARY OF NIHB ANALYSIS: No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 1/30/2015 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01777.pdf	
3.p.	**DME Items Requiring Face-to-Face Encounter and Prior Written Order** **ACTION: Notice** **NOTICE:** Medicare Program; Updates to the List of Durable Medical Equipment (DME) Specified Covered Items That Require a Face-to-Face Encounter and a Written Order Prior to Delivery **AGENCY:** CMS	CMS-6062-N	Issue Date: 3/27/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This notice updates the Healthcare Common Procedure Coding System (HCPCS) codes on the Durable Medical Equipment (DME) List of Specified Covered Items that require a face-to-face encounter and a written order prior to delivery. http://www.gpo.gov/fdsys/pkg/FR-2015-03-27/pdf/2015-07108.pdf **SUMMARY OF NIHB ANALYSIS:**	
4.k.	**Hospital OPPS and ASC Payment System, et al.** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Medicare and Medicaid Programs: Hospital	CMS-1613-~~P~~FC	Issue Date: 7/14/2014 Due Date: 9/2/2014 NIHB File Date: None		**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 2015 to implement applicable statutory requirements and changes arising from continuing CMS experience with these systems. In this proposed rule, CMS describes the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data **AGENCY:** CMS		Date of Subsequent Agency Action, if any: Issued Final Rule 11/10/2014; issued correction 2/24/2015 Due Date: 12/30/2014		the ASC Quality Reporting (ASCQR) Program. In this document, CMS also proposes changes to the data sources used for expansion requests for physician-owned hospitals under the physician self-referral regulations; changes to the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and changes to establish a three-level appeals process for Medicare Advantage (MA) organizations and Part D sponsors that would apply to CMS-identified overpayments associated with data submitted by these organizations and sponsors. http://www.gpo.gov/fdsys/pkg/FR-2014-07-14/pdf/2014-15939.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2015 to implement applicable statutory 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 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 and the ASC Quality Reporting (ASCQR) Program. In this document, CMS also makes changes to the data sources permitted for expansion requests for physician-owned hospitals under the physician self-referral regulations; changes to the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and changes to establish a formal process, including a three-level appeals process, to recoup overpayments that result from the submission of erroneous payment data by Medicare Advantage (MA) organizations and Part D sponsors in the limited circumstances in which the organization or sponsor fails to correct these data. http://www.gpo.gov/fdsys/pkg/FR-2014-11-10/pdf/2014-26146.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 2/24/2014 issued a document (CMS-1613-CN) to correct technical errors that appeared in the final rule with comment period published in the in 11/10/2014 FR (79 FR 66770) and titled "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data." The provisions in this notice apply to payments for services furnished on or after January 1, 2015, as if they had appeared in the final rule. http://www.gpo.gov/fdsys/pkg/FR-2015-02-24/pdf/2015-03760.pdf	
4.I.	**Ambulatory Surgical Center Quality Reporting Program** **ACTION: Request for Comment** **NOTICE:** Ambulatory Surgical Center Quality Reporting Program **AGENCY:** CMS	CMS-10530	Issue Date: 11/17/2014 Due Date: 1/16/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/30/2015 Due Date: 3/2/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Ambulatory Surgical Center Quality Reporting Program; *Use*: CMS quality reporting programs promote higher quality, more efficient health care for Medicare beneficiaries. CMS has implemented quality measure reporting programs for multiple settings, including for ambulatory surgical centers (ASCs). Section 109(b) of the Tax Relief and Health Care Act of 2006 (TRHCA) amended section 1833(i) of the Social Security Act (the Act) by re-designating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the HHS Secretary to implement the revised ASC payment system "in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7)." Section 1833(i)(7)(A) of the Act states that the HHS Secretary can provide that any ASC failing to submit quality measures in accordance with paragraph (7) will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. Sections 1833(t)(17)(C)(i) and (ii) of the Act require the HHS Secretary to develop measures appropriate for the measurement of the quality of care furnished in outpatient settings. Section 3014 of ACA modified section 1890(b) of the Act to require CMS to develop quality and efficiency measures through a "consensus-based entity." To fulfill this requirement, CMS formed the Measure Applications Partnership (MAP) to review measures consistent with these requirements. In implementing this and other quality	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					reporting programs, CMS seeks to support National Quality Strategy goals of health for individuals, better health for populations, and lower costs for health care. CMS uses this information to direct contractors, including Quality Improvement Organizations (QIOs), to focus on particular areas of improvement and to develop quality improvement initiatives. CMS makes this information available to ASCs for their use in internal quality improvement initiatives. Most importantly, Medicare beneficiaries, as well as to the general public, can use this information to assist them in making decisions about their health care. http://www.gpo.gov/fdsys/pkg/FR-2014-11-17/pdf/2014-27137.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 1/30/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01777.pdf	
4.m.	**Hospital OPPS and ASC Payment System for CY 2016, et al.** **ACTION: Proposed Rule** **NOTICE:** Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the	CMS-1633-P	Issue Date: 7/8/2015 **Due Date: 8/31/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**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 2016 to implement applicable statutory requirements and changes arising from continuing CMS experience with these systems. In this proposed rule, CMS describes the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under 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 and the ASC Quality Reporting (ASCQR) Program.** Further, this proposed rule includes certain proposals relating to the hospital inpatient prospective payment system: proposed changes to the 2-midnight rule under the short inpatient hospital stay policy, as well as a discussion of the related -0.2 percent payment adjustment; and a proposed transition for Medicare-dependent, small rural hospitals located in all-urban states. http://www.gpo.gov/fdsys/pkg/FR-2015-07-08/pdf/2015-16577.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.
	Hospital Inpatient Prospective Payment System **AGENCY:** CMS				**SUMMARY OF NIHB ANALYSIS:** This proposed rule would implement additional payment reforms.	
6.i.	**Pre-Existing Health Insurance Plan Program Updates** **ACTION: Interim Final Rule** **NOTICE:** Pre-Existing Condition Insurance Plan Program Updates **AGENCY:** CMS	CMS-9995-IFC4	Issue Date: [Pending at OMB as of 2/3/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** **SUMMARY OF NIHB ANALYSIS:**	
7.k.	**Agent/Broker Data Collection in Federally-Facilitated Exchanges** **ACTION: Request for Comment** **NOTICE:** Agent/Broker Data Collection in Federally-Facilitated Health Insurance Exchanges **AGENCY:** CMS	CMS-10464	Issue Date: 2/7/2013 Due Date: 4/8/2013 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New Collection; *Title*: Agent/Broker Data Collection in Federally-Facilitated Health Insurance Exchanges; *Use*: CMS will collect data, including licensure and personally identifiable information, from agents/brokers to register them with the Federally-Facilitated Exchange (FFE) through the Exchange Portal. A key component of the registration process requiring data collection involves verifying agent/broker licensure status, as well as any issuer appointments. Agents/brokers will enter basic identifying information on the Exchange Portal during the initial registration phase. After completing registration successfully completed, agents/brokers will move to CMS LMS to access and complete required training and exams. CMS will use the user names and zip codes that agents/brokers provide during training to record their training history through CMS LMS and communicate training results with the Exchange Portal. As accompanying modules demonstrate, the training and exams will ensure agents/brokers possess the basic	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Issued new request 5/17/2013; issued revision 3/6/2015, 7/13/2015 Due Date: 6/17/2013; 5/5/2015; **8/12/2015**		knowledge required to enroll individuals and small business health options plan (SHOP) employers/employees through the Exchange. In addition, CMS will use the collected data for oversight and monitoring of agents/brokers and to ensure compliance with ACA provisions under 45 CFR 155.220. If CMS detects anomalies, CMS will follow up to resolve issues, as necessary. http://www.gpo.gov/fdsys/pkg/FR-2013-02-07/pdf/2013-02714.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. This PRA request solely reviews the technical process for a broker to 1) register and 2) provide an online attestation to calculate the burden of complying with the broker paperwork requirements. A related CCIIO guidance document (**see 7.r.**) reviews the involvement of brokers in Exchange activities. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/17/2013 issued a new version of this PRA request. CMS received three relevant comments in response to the 60-day FR notice published on 2/7/2013 (78 FR 9056). Specifically, one commenter requested a process that would allow Web-brokers to enroll individuals without reporting individual issuer appointments, and CMS made this revision to the registration process. CMS also received some questions about how the training process will work. CMS confirmed that agents and brokers will need to register for the FFE only once and that the agency will host the training program, as opposed to individual issuers. As a result of the comments, CMS modified both the registration process and simplified how agents and brokers will participate in the Exchanges to make them align more closely with how issuers, agents, and Web-brokers currently conduct business. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 3/6/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-06/pdf/2015-05166.pdf No comments recommended. CMS on 7/13/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-13/pdf/2015-17037.pdf No comments recommended.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
7.l.	**Stand-Alone Dental Plans in Federally-Facilitated Exchanges** **ACTION: Guidance** **NOTICE:** Issuers of Stand-Alone Dental Plans: Intent to Offer in FFE States **AGENCY:** HHS	HHS (no reference number)	Issue Date: 1/28/2013 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 5/6/2014, 2/19/2015		**SUMMARY OF AGENCY ACTION:** This document includes attached tables that list the number of issuers planning to offer stand-alone dental plans (SADPs) in states expected to have a Federally-facilitated Exchange (FFE), including State Partnership Exchanges, based on the current Exchange Blueprint Approvals. ACA permits an SADP to participate in an Exchange if the plan provides the pediatric dental benefits that the Secretary has defined as part of the essential health benefits (EHB). ACA also permits a health plan that does not provide the pediatric dental EHB to obtain certification as a qualified health plan (QHP) eligible for Exchange participation, provided that the Exchange offers at least one SADP. http://cciio.cms.gov/resources/files/voluntary-dental-reporting-list-1-28-13.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/26/2013 issued a revision of this document. This document includes a table listing the number of issuers that intend to offer SADPs in states expected to have an FFE, including State Partnership Exchanges, based on the current Exchange Blueprint Approvals. This information is current as of 4/15/2014. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/voluntary-reporting-guidance.pdf CMS on 2/19/2015 issued guidance listing the number of issuers that intend to offer SADPs in states expected to have an FFM, including State Partnership Marketplaces, based on the current Marketplace Blueprint Approvals. This information, current as of 2/10/2015, applies to the 2016 plan year. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Voluntary-SADP-Reporting-Guidance-02182015.pdf	
7.q.	**Cooperative Agreement to Support Navigators in FFE** **ACTION: Request for**	CMS-10463	Issue Date: 4/12/2013 Due Date:		**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	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Comment **NOTICE:** Cooperative Agreement to Support Navigators in Federally-Facilitated and State Partnership Exchanges **AGENCY:** CMS		6/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 7/26/2013; issued revision 4/11/2014, 7/25/2014, 3/30/2015; issued extension 6/26/2015 Due Date: 8/26/2013; 6/10/2014; 8/25/2014; 5/29/2015; 7/27/2015		and facilitating selection of qualified health plans (QHPs) within Exchanges, as well as other required duties. Section 1311(i) requires that an Exchange operating as of 1/12014 must establish a Navigator Program under which it awards grants to eligible individuals or entities that satisfy the requirements to serve as Exchange Navigators. For Federally-Facilitated Exchanges (FFE) and State Partnership Exchanges (SPEs), CMS will award these grants. Navigator awardees must provide quarterly, biannual, and annual progress reports to CMS on the activities performed during the grant period and any sub-awardees receiving funds. **SUMMARY OF NIHB ANALYSIS:** This PRA request relates to CCIIO CA-NAV-13-001 (**see 7.p.**). No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/26/2013 issued a reinstatement of this PRA request with changes. In response to a 60-day notice on this information collection published in the 4/12/2013 FR (78 FR 21957), several commenters suggested changes to the reporting requirements, and CMS incorporated them where appropriate. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf CMS on 4/11/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-04-11/pdf/2014-08209.pdf CMS on 7/25/2014 issued a revision of this PRA request. CMS has modified the data collection requirements for the weekly, monthly, quarterly, and annual reports provided in the 60-day notice in the 4/11/2014 FR. http://www.gpo.gov/fdsys/pkg/FR-2014-07-25/pdf/2014-17555.pdf CMS on 3/30/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-07089.pdf No comments recommended. CMS on 6/26/2015 issued an extension of this PRA request. CMS has modified the data collection requirements for the weekly, monthly, quarterly, and annual reports provided in the 60-day notice in the 5/30/2015 FR (80 FR 16687). http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/pdf/2015-15770.pdf	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					No comments recommended.	
7.t.	**Cooperative Agreement to Support State Exchanges** **ACTION: Request for Comment** **NOTICE:** Cooperative Agreement to Support Establishment of State-Operated Health Insurance Exchanges **AGENCY:** CMS	CMS-10371	Issue Date: 5/24/2013 Due Date: 7/23/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 8/16/2013; issued emergency review request 9/16/2013, 11/7/2014; issued revision, 4/20/2015 Due Date: 9/16/2013; 9/23/2013; 11/14/2014; 3/31/2015; 5/20/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Cooperative Agreement to Support Establishment of State-Operated Health Insurance Exchanges; *Use*: All states (which include the 50 states, consortia of states, territories, and the District of Columbia) that received a State Planning and Establishment Grant for Exchanges under ACA qualify for the Cooperative Agreement to Support Establishment of State Operated Insurance Exchanges. Section 1311 of ACA offers the opportunity for each state to establish an Exchange (or Marketplace) and provides for grants to states for the planning and establishment of these Exchanges. To provide appropriate and timely guidance and technical assistance, the HHS Secretary must have access to timely, periodic information regarding state progress. Consequently, the information collection associated with these grants serves to facilitate reasonable and appropriate federal monitoring of funds, providing statutorily-mandated assistance to states to implement Exchanges in accordance with federal requirements, and to ensure states have all necessary information required to proceed, minimizing retrospective corrective action. http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12469.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 8/16/2013 issued a revision of this PRA request. **The submitted revision adds sets of Outcomes and Operational Metrics to state data collection requirements**; CMS will use the resulting data to evaluate Marketplace performance and overall effectiveness of ACA. Key areas of measurement include the effectiveness of eligibility determination and enrollment processes, the impact on affordability for consumers, and the effect of Marketplace participation on health insurances markets. Furthermore, these metrics facilitate actionable feedback and technical assistance to states for quality improvement efforts during the critical early period of operations. http://www.gpo.gov/fdsys/pkg/FR-2013-08-16/pdf/2013-20023.pdf No comments recommended.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					This information collection requires reporting on a number of measures. Performance standards are not quantified and included in the materials. These materials do not mention the need to report on exemptions from tax penalty requested, processed, etc. CMS on 9/16/2013 issued a request for an emergency OMB review of this information collection, with comments due 9/23/2013. According to CMS, an emergency review is needed because the approval of the data collection tools for outcomes and operational metrics is essential to ensuring that State-based Marketplaces provide substantive operational and monitoring data to the agency in a uniform format from the beginning of the enrollment period, 10/1/2013. http://www.gpo.gov/fdsys/pkg/FR-2013-09-16/pdf/2013-22517.pdf CMS on 11/7/2014 issued a request for an emergency OMB review of this information collection, with comments due 11/14/2014. http://www.gpo.gov/fdsys/pkg/FR-2014-11-07/pdf/2014-26584.pdf CMS on 1/30/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf CMS on 4/20/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-20/pdf/2015-09009.pdf No comments recommended.	
7.v.	**Consumer Assistance Tools and Programs of Exchanges** **ACTION: Request for Comment** **NOTICE:** Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance	CMS-10494	Issue Date: 7/17/2013 Due Date: 9/14/2013 NIHB File Date: None Date of Subsequent Agency Action,		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors; *Use*: Section 1413 of ACA directs the HHS Secretary to establish, subject to minimum requirements, a streamlined enrollment system for qualified health plans offered through the Exchange and insurance affordability programs. In addition, section 1321(a)(1) of ACA directs and authorizes the HHS Secretary to issue regulations setting standards for meeting the requirements under title I of ACA, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, CMS has finalized regulations establishing the certified application counselor program at 45 CFR 155.225. Specifically, 45 CFR 155.225(a) requires an Exchange to establish a certified application	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Personnel; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors **AGENCY:** CMS		<u>if any:</u> Issued revision 6/27/2014, 1/30/2015, 4/20/2015 <u>Due Date:</u> 7/28/2014; 3/31/2015; 5/20/2015		counselor program that complies with the requirements of the rule. Section 155.225(b)(1) allows each Exchange to designate certain organizations, including organizations designated by state Medicaid or CHIP agencies, which will certify their staff and volunteers to act as certified application counselors. In accordance with 45 CFR 155.225(b)(2), Exchanges can choose to certify directly individuals who seek to act as certified application counselors, designate certain organizations which will certify staff or volunteers to perform application services, or both. http://www.gpo.gov/fdsys/pkg/FR-2013-07-17/pdf/2013-17149.pdf This information collection does not include any associated forms. Appendices with registration screen shots and data collection elements, as well as a Supporting Statement for this PRA request, are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10494.html. **SUMMARY OF NIHB ANALYSIS:** No comments recommended (comments were submitted previously on the related CMS-9955-F). **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 6/27/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15073.pdf No comments recommended. CMS on 1/30/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf CMS on 4/20/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-20/pdf/2015-09009.pdf No comments recommended.	
7.kk.	**Standards for Navigators and Non-Navigator Personnel**	CMS-10472	<u>Issue Date</u>: 6/27/2014 <u>Due Date</u>:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: <u>Revision of a previously approved information collection</u>; *Title*: Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel; *Use*: Section 1321(a)(1) of ACA directs and authorizes the HHS Secretary to issue regulations setting standards for	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Request for Comment **NOTICE:** Standards for Navigators and Non-Navigator Assistance Personnel **AGENCY:** CMS		7/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/30/2015, 4/20/2015 Due Date: 3/31/2015; 5/20/2015		meeting the requirements under title I of ACA, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations finalized at 45 CFR 155.210(e)(6) and 45 CFR 155.215(g) require Navigators, as well as those non-Navigator personnel to whom 45 CFR 155.215 applies, to inform consumers of the functions and responsibilities of Navigators and non-Navigator assistance personnel (as applicable) and obtain authorization for the disclosure of consumer information to the Navigator or non-Navigator assistance personnel prior to obtaining personally identifiable information from the consumer. Navigators and non-Navigator assistance personnel to whom 45 CFR 155.215 applies also must maintain a record of the authorization provided in a form and manner as determined by the Exchange. http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15073.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 1/30/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf CMS on 4/20/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-20/pdf/2015-09009.pdf No comments recommended.	
7.vv.	**2016 Letter to Issuers in FFMs** **ACTION: Guidance** **NOTICE:** ~~Draft~~ 2016 Letter to Issuers in the Federally-Facilitated Marketplaces **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 12/19/2014 Due Date: 1/12/2015 TTAG File Date: 1/12/2015 Date of	TTAG response:	**SUMMARY OF AGENCY ACTION:** This draft 2016 Letter to Issuers in the Federally-Facilitated Marketplaces (Letter) provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-Facilitated Marketplaces (FFMs) or the Federally-Facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in those Marketplaces in 2016. Unless otherwise specified, references to the FFMs include the FF-SHOPs. Throughout this Letter, CMS identifies the areas in which states performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS notes that the policies articulated in this Letter	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.
			Subsequent Agency Action, if any: Issued Final Letter 2/20/2015		apply to the certification process for plan years beginning in 2016. Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics appear in 45 CFR Subtitle A, Subchapter B. Additional proposed requirements appear in a proposed rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016" (2016 Payment Notice proposed rule), CMS-9944-P (**see 89.h.**), published on 11/26/2014. CMS expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of ACA. Throughout the plan year, QHPs might have to correct deficiencies identified in CMS post-certification activities, as a result of the investigation of consumer complaints or oversight by state regulators or by CMS, or as a result of an industry-standard internal compliance and risk management program. QHP issuers in the FFMs also might have to meet other requirements for plan years beginning in 2016, as indicated in future rulemaking. CMS welcomes comments on this proposed guidance. To the extent that this guidance summarizes policies proposed through other rulemaking processes not yet finalized, such as the rulemaking process for the 2016 Payment Notice proposed rule, stakeholders should comment on those underlying policies through the ongoing rulemaking processes and not through the comment process for this Letter. Please send comments on other aspects of this Letter to FFEcomments@cms.hhs.gov by 1/12/2015. Interested parties should organize comments by subsections of this Letter. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016DraftLettertoIssuers12-19-2014.pdf **SUMMARY OF NIHB ANALYSIS:** This draft 2016 Issuer Letter marks the latest in a series of Issuer Letters, which guide QHP issuer operations in FFM states. Tribal representatives still have comments pending on CMS-9944-P. In that document, CMS proposed to require Summary of Benefit and Coverage documents for each plan variation. In addition, tribal representatives made several recommendations regarding Indian-specific cost-sharing variations. Tribal representatives should comment on the draft 2016 Issuer Letter, both to make	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					recommended changes and to indicate support for language contained in the document. An analysis comparing the draft 2016 Issuer Letter with the 2015 Issuer Letter is embedded below. Analysis- Draft 2016 v Final 2015 CCIIO Is **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This final 2016 Letter to Issuers in the Federally-Facilitated Marketplaces (Letter) provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-Facilitated Marketplaces (FFMs) or the Federally-Facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in those Marketplaces in 2016. Unless otherwise specified, references to the FFMs include the FF-SHOPs. Throughout this Letter, CMS identifies the areas in which States performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS notes that the policies articulated in this Letter apply to the certification process for plan years beginning in 2016. Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics appear in 45 CFR Subtitle A, Subchapter B. Additional requirements appear in a final rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016" (2016 Payment Notice Final Rule), CMS-9944-F, released on February 20, 2015. CMS expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of ACA. Throughout the plan year, QHPs might have to correct deficiencies identified in CMS post-certification activities, as a result of the investigation of consumer complaints or oversight by State regulators or by CMS, or in response to an industry-standard internal compliance and risk management program. QHP issuers in the FFMs also might have other requirements for plan years beginning in 2016, as indicated in future rulemaking. http://www.cms.gov/CCIIO/Resources/Regulations-and-	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Guidance/Downloads/2016_Letter_to_Issuers_2_20_2015.pdf	
7.ww.	**Special Protections for AI/ANs** **ACTION: Guidance** **NOTICE:** Health Insurance Marketplace Protections for American Indians and Alaska Natives **AGENCY:** CMS	CMS (no reference number)	Issue Date: 1/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This fact sheet explains the protections for AI/ANs in the Marketplace, Medicaid, and CHIP. This fact sheet addresses special enrollment periods, zero and limited cost-sharing plans, Medicaid and CHIP protections, and Indian-specific exemptions. http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/AIANs-SpecialProtections-Fact-Sheet.pdf **SUMMARY OF NIHB ANALYSIS:**	
7.xx.	**AI/AN Trust Income and MAGI** **ACTION: Guidance** **NOTICE:** American Indian and Alaska Native Trust Income and MAGI **AGENCY:** CMS	CMS (no reference number)	Issue Date: 1/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This fact sheet describes Modified Adjusted Gross Income (MAGI) and what that means for AI/AN Trust Income. This fact sheet includes frequently asked questions and answers and a list of specific types of AI/AN exempt income. http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/AIAN-Trust-Income-and-MAGI-FactSheet.pdf **SUMMARY OF NIHB ANALYSIS:**	
7.yy.	**Special Enrollment Period for Tax Season** **ACTION: Notice**	CMS (no reference number)	Issue Date: 2/20/2015 Due Date:		**SUMMARY OF AGENCY ACTION:** This press release announces a special enrollment period (SEP) for individuals who did not have health coverage in 2014 and face the fee or "shared responsibility payment" when they file their 2014 taxes in states using the Federally-Facilitated Marketplace (FFM). This SEP period will allow these individuals	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: CMS Announces Special Enrollment Period for Tax Season **AGENCY:** CMS		None NIHB File Date: Date of Subsequent Agency Action, if any:		who were unaware or did not understand the implications of this new requirement to enroll in 2015 health insurance coverage through the FFM from March 15 to April 30. http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-02-20.html **SUMMARY OF NIHB ANALYSIS:**	
7.zz.	**Hardship Exemptions for Persons Meeting Certain Criteria** **ACTION: Guidance** **NOTICE:** Guidance on Hardship Exemptions for Persons Meeting Certain Criteria **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 3/20/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance provides information about (1) hardship exemption criteria pertaining to enrollees in CHIP Buy-In coverage and Elite Athlete Health Insurance, which are not classified as minimum essential coverage (MEC), in use by Federally-Facilitated Marketplaces (FFMs) (including State Partnership Marketplaces (SPMs)) and possibly in use by State-based Marketplaces (SBMs) that process their own exemptions; (2) hardship exemption criteria pertaining to individuals who seek categorical Medicaid eligibility under section 1902(f) of the Social Security Act (Act) for "209(b)" states in use by FFMs (including SPMs) and possibly in use by SBMs; and (3) clarification of 11/21/2014 hardship exemption guidance regarding consumers enrolled in Medicaid coverage not classified as MEC provided to medically needy individuals under section 1902(a)(10)(C) of the Act. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Hardship-Exemption-Guidance-3-20-15-FINAL.pdf **SUMMARY OF NIHB ANALYSIS:**	
7.aaa.	**Ending Special Enrollment Periods for Coverage in 2014** **ACTION: Guidance** **NOTICE:** Ending Special Enrollment Periods for Coverage During Calendar	CCIIO (no reference number)	Issue Date: 3/31/2015 Due Date: None NIHB File Date:		**SUMMARY OF AGENCY ACTION:** As of 4/1/2015, CMS will no longer accept new requests that would enable consumers to enroll in a Qualified Health Plan (QHP) with 2014 coverage effective dates through the Federally-Facilitated or State Partnership Marketplaces through a Special Enrollment Period (SEP). As of 4/1/2015, all SEP requests to CMS seeking 2014 coverage, with the exception of SEPs issued as a result of an eligibility appeal described below, if eligible for retroactive coverage, will receive a coverage effective date of 1/1/2015. This guidance applies to all SEPs specified in 45 CFR §155.420 and supersedes all	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Year 2014 **AGENCY:** CCIIO		Date of Subsequent Agency Action, if any:		existing guidance on SEPs. This guidance does not apply to eligibility appeal requests and does not impact the right of a consumer to request an appeal of their eligibility determination in accordance with 45 CFR §155.505(b). http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance_on_ending_2014_SEPs.pdf **SUMMARY OF NIHB ANALYSIS:**	
7.bbb.	**Key Dates in 2015: QHP Certification in the FFM, et al.** **ACTION: Guidance** **NOTICE:** Ending Special Enrollment Periods for Coverage During Calendar Year 2014 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance provides key dates in 2015 related to qualified health plan (QHP) certification in the Federally-Facilitated Marketplace (FFM); rate review for single risk pool compliant plans; and risk adjustment, reinsurance, and risk corridors for PY 2014. Some key dates regarding QHP certification appear below. QHP Agreement/Final Certification • **Certification Notices and QHP Agreements Sent to Issuers**: 9/17/2015-9/18/2015 • **Agreements Signed by Issuers and Returned to CMS with Final Plan List**: 9/21/2015-9/25/2015 • **Validation Notice Confirming Final Plan List and Countersigned Agreements Sent to Issuers**: 10/8/2015-10/9/2015 • **Open Enrollment**: 11/1/2015-1/31/2016 http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-Key-Dates-QHP-Certification-in-the-FFM-Rate-Review-and-3Rs-final.pdf **SUMMARY OF NIHB ANALYSIS:**	
7.ccc.	**Out-of-Pocket Cost Comparison Tool for FFMs** **ACTION: Notice**	CCIIO (no reference number)	Issue Date: 5/29/2015 Due Date:	TTAG response:	**SUMMARY OF AGENCY ACTION:** CMS has developed an Out-of-Pocket (OOP) Cost Comparison Tool to help consumers make more informed choices about their health insurance coverage and to help them select a plan that will best meet their needs. The OOP Cost Tool will allow shoppers in the Federally-Facilitated Marketplaces (FFMs) to	See Table C.

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: CMS Bulletin on Proposed Out-of-Pocket (OOP) Cost Comparison Tool for the Federally-Facilitated Marketplaces (FFMs) **AGENCY:** CCIIO		6/29/2015 TTAG File Date: 6/29/2015 Date of Subsequent Agency Action, if any:		see estimates of total spending (to include premiums and cost-sharing) across various health insurance plans. This bulletin provides information and solicits comments on the proposed OOP Cost Comparison Tool, how the tool computes OOP Cost, and its incorporation into FFM Web sites. CMS anticipates that this comparison tool would become available to consumers for the 2016 annual open enrollment period (for coverage effective starting as early as 1/1/2016). CMS requests comments on the proposed OOP cost methodology outlined in this bulletin. Specifically, CMS seeks public input on the three key areas of the proposed methodology, including: (1) the utilization and cost data; (2) use of health plan cost-sharing data; and (3) user input regarding consumer demographics, such as the number of family members, age, gender, and expected health care utilization. CMS also seeks comments regarding the potential benefits of making the source code of an OOP Cost Comparison Tool available for use by State-Based Marketplaces (SBMs), including the timing and preferred format for providing this information. Interested parties should e-mail comments by 6/29/2015 to OutofPocketCostEstimator@cms.hhs.gov. http://www.gpo.gov/fdsys/pkg/FR-2014-12-12/pdf/2014-29172.pdf **SUMMARY OF NIHB ANALYSIS:** In this document, **CMS indicates that NO cost-sharing protections (meaning neither the "zero cost-sharing plan variation" nor the "limited cost-sharing plan variation" applies) for AI/ANs who enroll in Marketplace plans and have a household income less than 100 percent the federal poverty level (FPL).** Footnote 1 of this document explains an exception to rule that cost-sharing protections are available only through enrollment in a silver-level plan. For certain populations, cost-sharing protections are available through enrollment in plans at other metal levels. Footnote 1 reads: "Limited and zero CSR plan variations are available at other metal levels as well. Indians with a household income between 100-300 percent of the federal poverty level are eligible for a zero cost-sharing plan. Those with a household income between 300-400 percent of the federal poverty level are eligible to enroll in a limited cost-sharing plan. Regardless of household income, those who enroll in a Marketplace health plan will not have OOP cost for services provided by 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.
					CMS makes this statement despite the existing regulation at 45 CFR § 155.350(b), which states: "§155.350 Special eligibility standards and process for Indians … b) *Special cost-sharing rule for Indians regardless of income.* The Exchange must determine an applicant eligible for the special cost-sharing rule described in section 1402(d)(2) of the Affordable Care Act if he or she is an Indian, without requiring the applicant to request an eligibility determination for insurance affordability programs in accordance with §155.310(b) in order to qualify for this rule." The Indian-specific cost-sharing protections established at ACA section 1402(d)(2) are referred to as the "limited cost-sharing variation." **Despite the existing regulation, CMS indicates that neither the "zero cost-sharing variation" [section 1402(d)(1)] nor the "limited cost-sharing variation" [section 1402(d)(2)] is available to AI/ANs who enroll in Marketplace plans and have a household income less than 100 percent FPL or more than 400 percent FPL. Instead, CMS appears to have created a third cost-sharing protection that is available to AI/ANs who have a household income less than 100 percent FPL or more than 400 percent FPL, stating that they "will not have OOP cost for services provided by Indian health programs." This document does not mention the cost-sharing protections applying "through referral under contract health services."** <u>Summary</u> A summary of the major provisions of this guidance on the OOP Cost Comparison Tool appears below. **IV. Data Output and Consumer Display** To aid consumers while comparing health plan options, CMS anticipates displaying the sum of the OOP cost estimated and premium--calculated either on an annual or monthly basis. Alongside the estimated total spending, CMS might include a breakout of the premium and the OOP cost estimate as part of the total. CMS also might display the issuer and consumer portions of total allowed charges for the consumer in a year during which a major accident or illness occurred (high health care utilization). For all OOP cost estimates, CMS proposes rounding the values. Users would have the ability to change expected utilization levels and see the consequences in terms of estimated OOP costs	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					across all plans they consider. V. Data Used in the Computations The data used in the computations would include (1) utilization and cost data; (2) the design of health plan cost sharing; and (3) consumer input regarding consumer demographics, such as the number of family members, age, gender, and expected health care utilization. *Utilization and Cost Data*: CMS would use claims data from the MarketScan Commercial Claims and Encounters Database for calendar year 2013. These claims data are summarized into utilization tables based on age, gender, and utilization level, and CMS would update them annually. To populate the utilization tables, CMS proposes to compute the total annual allowed cost for each beneficiary represented in the data and then divide beneficiaries into 10 deciles, based on total allowed costs, within each age and gender group. For each decile and benefit category combination, CMS proposes to calculate the unit cost, utilization per member per year, and total annual allowed cost based on the claims data. *Design of Health Plan Cost Sharing*: CMS would use several data elements from the Plans and Benefits Template, including those related to deductibles, maximum out-of-pocket (MOOP) amounts, and copay/coinsurance. CMS would structure the inputs for all services consumed for Tier 1 in-network and would use the cost-sharing parameters that that apply to Tier 1 in-network services. *Consumer Input*: Consumers would enter the number of family members and the age group, gender, and utilization level for each one. Upon specifying a utilization level, a summary description of that level would appear, indicating the estimated number of physician visits, lab tests, prescriptions, hospital days, and other care corresponding to that level. Consumers could alter any input category and compare OOP costs. CMS has two options under consideration for the user interface for consumers: (1) consumers would select one of three utilization levels for each family member--low, medium, or high; or (2) the tool would compute two OOP cost estimates, and each consumer would see estimates for a scenario representing a "typical year" in which all family members experienced the "medium" utilization scenario described above and a scenario representing a year with a serious illness in which the oldest family member experienced "high" utilization. **[CMS seeks comments on which of these options**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					would best achieve the goals of facilitating informed consumer choice and fostering a well-functioning insurance market, as well as comments on any implications different approaches might have for the overall functioning of the Marketplaces.] VI. OOP Cost Computation The proposed methodology would apply to overall healthcare spending by enrollees and by the plan a series of threshold constraints on deductibles and MOOP amounts that are reached over time. When each threshold is reached, the proposed methodology redefines the process for accrual of cost sharing thereafter. Specifically, the proposed methodology steps through time (defined as a percentage of total annual allowed cost spending) in a limited number of finite increments until it reaches a spending level of 100 percent. The first increment starts at a spending level of 0 percent and then identifies the lowest spending level at which a member reaches the specified deductible in the given plan design. Once the deductible is reached, the next increment is determined. The proposed methodology becomes more complex for family plans.	
7.ddd.	**ECP Data Collection to Support QHP Certification for PY 2017** **ACTION: Request for Comment** **NOTICE:** Essential Community Provider Data Collection to Support QHP Certification for PY 2017 **AGENCY:** CMS	CMS-10561	Issue Date: 6/5/2015 **Due Date: 8/4/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Essential Community Provider Data Collection to Support QHP Certification for PY 2017; *Use*: For plan years beginning on or after 1/1/2016, HHS intends to discontinue the essential community provider (ECP) write-in process for qualified health plan (QHP) issuers entering their contracted ECPs on their ECP template as part of the QHP application. **For plan years beginning on or after 1/1/2016, HHS intends to calculate satisfaction of the 30 percent ECP threshold based exclusively on the ECPs included on the HHS ECP list appearing on the ECP template provided by the issuer. HHS will collect data on qualified and available ECPs from providers.** Providers will submit an ECP petition to appear on the HHS ECP list or provide required missing data fields to remain on the list. As required by the HHS Notice of Benefit and Payment Parameters for 2016 (CMS-9944-F), QHP issuers in the Federally-Facilitated Marketplaces (FFMs) must publish information regarding their formulary drug lists and provider directories on their Web site in an HHS-specified format at times determined by HHS. http://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13759.pdf	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					The ECPs Provider Petition for the 2017 Benefit Year, instructions for the petition, and a Supporting Statement for this PRA request are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10561.html. **SUMMARY OF NIHB ANALYSIS:** Given that this PRA request addresses ECPs, tribal organizations might want to submit comments on the proposed changes to indicate support or suggest modifications. In particular, in the notice, CMS notes that some of the listed providers identified by "federal partners" lack certain data elements enabling contract offers. In addition, tribal organizations might want to review the actual provider list to determine if any T/Us need to provide additional information. Additional analysis appears below. Analysis In the instructions for the ECPs Provider Petition for the 2017 Benefit Year, CMS notes that HRSA, IHS, and the HHS Office of the Assistant Secretary for Health/Office of Population Affairs (OASH/OPA) provided the agency with most of the providers on the non-exhaustive HHS ECP list for the 2016 benefit year. QHP (and stand-alone dental plan) issuers also could write in for consideration in their QHP application providers that met the regulatory standard but did not appear on the HHS ECP list. For the 2017 benefit year, CMS will review provider petitions for inclusion on the HHS ECP list in an effort to build a more robust list of providers from which issuers can select to satisfy the ECP standard without reliance on ECP write-ins. For the 2017 benefit year, CMS will accept petitions from providers that qualify as an ECP as defined under 45 CFR 156.235(c)--both those appearing at not appearing on the prior year HHS ECP list. Such providers include medical practitioners that serve predominantly low-income, medically underserved individuals, including (1) a health care provider defined in section 340B(a)(4) of the Public Health Service Act (PHS Act) or described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act (Act); (2) a state-owned family planning service site, governmental family planning service site, or not-for-profit family planning service site that does not receive federal funding under special programs, including under Title X of the PHS Act; or (3) an Indian health care provider, unless any of the above providers has lost its status under either of these sections, 340(B) of the PHS Act or 1927 of the Act as a result of violating federal law. Such practitioners must have authorization from the state to treat patients independently 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.
					prescribe medications. According to CMS, the agency coordinates closely with federal partners, including HRSA, IHS, and HHS OASH/OPA to update the ECP list annually and review requested corrections and additions received directly from providers. Although CMS has verified the status of the providers listed on the HHS ECP list for the 2016 benefit year, **some of the provider listings received from federal partners lack data elements critical for issuers to identify such providers for contract offerings. Therefore, providers that appear on the HHS ECP list for the 2016 benefit year must complete any required missing data fields to remain on the HHS ECP list for the 2017 benefit year.**	
8.c.	**ACA Requirements for Section 1115 Projects** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Information and Collection Requirements for Section 1115 Demonstration Projects **AGENCY:** CMS	CMS-10341	Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2015 Due Date: 3/30/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Affordable Care Act Information and Collection Requirements for Section 1115 Demonstration Projects; *Use*: CMS needs this collection to ensure that states comply with regulatory and statutory requirements related to the development, implementation, and evaluation of demonstration projects. **States seeking waiver authority under Section 1115 must meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the HHS Secretary on the implementation of approved demonstrations**. http://www.gpo.gov/fdsys/pkg/FR-2014-12-12/pdf/2014-29172.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 2/27/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04113.pdf	
10.c.	**Medicare Shared Savings Program: ACOs** **ACTION: ~~Proposed~~ Final**	CMS-1461-~~PF~~	Issue Date: 12/8/2014 Due Date:		**SUMMARY OF AGENCY ACTION:** This proposed rule addresses changes to the Medicare Shared Savings Program (Shared Savings Program), including provisions relating to the payment of Accountable Care Organizations (ACOs) participating in the Shared Savings Program. Under the Shared Savings Program, providers of services 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.
	Rule **NOTICE:** Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations **AGENCY:** CMS		2/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 6/9/2015		suppliers that participate in an ACO continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO might qualify to receive a shared savings payment if it meets specified quality and savings requirements. http://www.gpo.gov/fdsys/pkg/FR-2014-12-08/pdf/2014-28388.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This final rule addresses changes to the Medicare Shared Savings Program, including provisions relating to the payment of accountable care organizations (ACOs) participating in the program. Under the program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare fee-for-service payments under Parts A and B, but the ACO might qualify to receive a shared savings payment if it meets specified quality and savings requirements. http://www.gpo.gov/fdsys/pkg/FR-2015-06-09/pdf/2015-14005.pdf	
10.e.	**Heath Care Payment Learning and Action Network** **ACTION: Request for Comment** **NOTICE:** Generic Clearance for the Heath Care Payment Learning and Action Network **AGENCY:** CMS	CMS-10575	Issue Date: 6/26/2015 **Due Date: 8/25/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Generic Clearance for the Heath Care Payment Learning and Action Network; *Use*: CMS, through the Center for Medicare and Medicaid Innovation, develops and tests innovative new payment and service delivery models in accordance with the requirements of section 1115A and in consideration of the opportunities and factors set forth in section 1115A(b)(2) of the Social Security Act. To date, CMS has built a portfolio of 26 models (in operation or already announced) that have attracted participation from a broad array of health care providers, states, payers, and other stakeholders. During the development of models, CMS builds on ideas received from stakeholders--consulting with clinical and analytical experts, as well as with representatives of relevant federal and state agencies. On 1/26/2015, HHS announced the ambitious goal to have 30 percent of Medicare fee-for-service payments tied to alternative payment models (such as Pioneer ACOs or bundled payment arrangements) by the end of 2016 and 50 percent of payments tied to these models by the end of 2018. To reach this goal, CMS will continue to partner with stakeholders across the health care system to catalyze transformation through the use 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.
					alternative payment models. **To this end, CMS launched the Health Care Payment Learning and Action Network (LAN), an effort to accelerate the transition to alternative payment models**; **identify best practices in their implementation, collaborate with payers, providers, consumers, purchasers, and other stakeholders**; and monitor the adoption of value-based alternative payment models across the health care system. A system wide transition to alternative payment models will strengthen the ability of CMS to implement existing models and design new models that improve quality and decrease costs for CMS beneficiaries. The CMS Innovation Center will use the information collected from LAN participants potentially to inform the design, selection, testing, modification, and expansion of innovative payment and service delivery models in accordance with the requirements of section 1115A, while monitoring progress towards the HHS goal to increase the percentage of payments tied to alternative payment models across the health care system. In addition, CMS will make the requested information publically available so that LAN participants (payers, providers, consumers, employers, state agencies, and patients) can use the information to inform decision making and better understand market dynamics in relation to alternative payment models. http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/pdf/2015-15771.pdf SUMMARY OF NIHB ANALYSIS:	
11.d.	**Bid Pricing Tool** **ACTION: Request for Comment** **NOTICE:** Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs) **AGENCY:** CMS	CMS-10142	Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action,		**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	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			if any: Issued revision 1/17/2013, 10/4/2013, 12/20/2013, 9/26/2014, 12/24/2014 Due Date: 2/19/2013; 12/3/2013; 1/21/2014; 11/25/2014; 1/23/2015		for the collection of information for CY 2014 through CY 2016. **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 1/17/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2013-00858.pdf CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf CMS on 12/20/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf CMS on 9/26/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-22990.pdf CMS on 12/24/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-12-24/pdf/2014-30026.pdf	
11.f.	**Plan Benefit Package and Formulary Submission** **ACTION: Request for Comment** **NOTICE:** PBP and Formulary Submission for Medicare Advantage and Prescription Drug Plans **AGENCY:** CMS	CMS-R-262	Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 11/1/2013,		**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	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			1/17/2014, 9/26/2014, 12/19/2014 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 1/20/2015		the use of the formulary have occurred, this PRA request might provide an opportunity to comment on them. The changes proposed are to be implemented and effective by CY 2014. http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html **SUMMARY OF SUBSEQUENT AGENCY ACTION:** Based on operational changes and policy clarifications to Medicare and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2013-00858.pdf CMS on 11/1/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26107.pdf CMS on 1/17/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-00915.pdf CMS on 9/26/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-22990.pdf CMS on 12/19/2014 issued a revision of this PRA request. CMS has revised this package subsequent to the publication of the 60-day notice in the 9/26/2014 FR (79 FR 57931). http://www.gpo.gov/fdsys/pkg/FR-2014-12-19/pdf/2014-29739.pdf	
11.g.	**Medicare Advantage Reporting Requirements** **ACTION: Request for Comment** **NOTICE:** Part C Medicare Advantage Reporting Requirements and	CMS-10261	Issue Date: 10/26/2012 Due Date: 12/26/2012 NIHB File Date: None		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); *Use*: CMS initiated new Medicare Part C reporting requirements in December 2008. The initial requirements involved thirteen measures, two of which CMS has suspended from reporting because the information is available elsewhere: Measurement 10, "Agent Compensation Structure," and Measurement 11, "Agent Training and Testing." CMS added one new measure beginning 2012: "Enrollment and Disenrollment." CMS suspended the "Benefit Utilization" measure in late 2011. CMS requests the suspension of two additional	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Supporting Regulations **AGENCY:** CMS		Date of Subsequent Agency Action, if any: Issued revision 6/21/2013, 10/4/2013, 5/1/2015 Due Date: 8/20/2013; 11/4/2013; 6/30/2015		measures, "Procedure Frequency" and "Provider Network Adequacy," because equivalent data are already collected or available through other sources. CMS has added one additional data element--"CMS Issues"--to its "Grievances" measure, which currently has 10 reporting categories. CMS also proposes to make the Part C measure, "Plan Oversight of Agents," consistent with the corresponding Part D section by requiring reporting of 10, rather than six, data elements. **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 6/21/2013 issued a revision of this PRA request. According to this PRA request, information users of Part C reporting include CMS central and regional office staff members, who use this information to monitor health plans and to hold them accountable for their performance; researchers; and other government agencies, such as GAO. Health plans can use this information to measure and benchmark their performance. CMS intends to make some of these data available for public reporting as "display measures" in 2013. http://www.gpo.gov/fdsys/pkg/FR-2013-06-21/pdf/2013-14878.pdf CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 5/1/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10208.pdf	
11.j.	**Medicare Part D Reporting Requirements** **ACTION: Request for Comment** **NOTICE:** Medicare Part D Reporting Requirements **AGENCY:** CMS	CMS-10185	Issue Date: 3/15/2013 Due Date: 5/14/2013 NIHB File Date: None Date of		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Medicare Part D Reporting Requirements; *Use*: Title I, Part 423, § 423.514 describes the regulatory authority of CMS to establish reporting requirements for Part D sponsors. Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, its enrollees, and the general public, at the times and in the manner that CMS requires, statistics in the following areas: the cost of its operations; the patterns of utilization of its services; the availability, accessibility, and acceptability of its services; information demonstrating that it has a fiscally sound operation; and other matters CMS may require. CMS has identified the appropriate data needed to effectively monitor plan performance. Changes to the	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Subsequent Agency Action, if any: Issued revision 7/26/2013, 5/1/2015 Due Date: 8/26/2013; 6/30/2015		currently approved data collection instrument reflect new executive orders and legislation, as well as recent changes to CMS policy and guidance. http://www.gpo.gov/fdsys/pkg/FR-2013-03-15/pdf/2013-06038.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/26/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/1/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10208.pdf No comments recommended.	
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, 4/10/2015,		**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-	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			6/19/2015 Due Date: 1/13/2014; 6/9/2015; 7/20/2015		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 3: Writing Agents Information Sheet • Attachment 4: Compensation Structure for Writing Agents by Contract/PBP Number • Supporting Statement CMS on 4/10/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-10/pdf/2015-08289.pdf No comments recommended. CMS on 6/19/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-19/pdf/2015-15125.pdf	
11.gg.	**CY 2016 Policy and Technical Changes to Parts C and D** **ACTION: Final Rule** **NOTICE:** Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs **AGENCY:** CMS	CMS-4159-F2 **See also 11.u.**	Issue Date: 2/12/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This final rule amends the Medicare Advantage (MA) program (Part C) regulations and Medicare Prescription Drug Benefit Program (Part D) regulations to implement statutory requirements; improve program efficiencies; strengthen beneficiary protections; clarify program requirements; improve payment accuracy; and make various technical changes. Additionally, this rule finalizes two technical changes that reinstate previously approved but erroneously removed regulation text sections. **SUMMARY OF NIHB ANALYSIS:** Tribal organizations did not file comments on the proposed rule. This final rule addresses one Indian-specific issue. In this rule, CMS finalized two new provisions related to efficient dispensing of medications in long-term care facilities (§423.154(a)(2) and (a)(3)). Previously, §423.154(c) waived all requirements under §423.154(a) for I/T/U pharmacies. However, this final rule revises the language of §423.154(c) to **clarify that the new provisions do apply to I/T/U pharmacies**.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					See attached analysis for a review of additional issues. CMS-4159-F2 analysis 2015-02-10b.	
11.hh.	**Medicare Part C, Part D, and FFS CAHPS Survey** **ACTION: Request for Comment** **NOTICE:** Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey **AGENCY:** CMS	CMS-R-246	Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 5/8/2015 Due Date: 6/8/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey; *Use*: The Medicare consumer assessment of healthcare providers and systems (CAHPS) surveys serve to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. The surveys also provide data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. http://www.gpo.gov/fdsys/pkg/FR-2014-12-12/pdf/2014-29172.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/8/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-08/pdf/2015-11208.pdf No comments recommended.	
11.ii.	**Survey of Retail Community Pharmacy Prices**	CMS-10241	Issue Date: 12/19/2014 Due Date:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Survey of Retail Prices: Payment and Utilization Rates and Performance Rankings; *Use*: This study has two parts. Part I focuses on the retail community pharmacy consumer prices. It also includes reporting by the states 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.
	ACTION: Request for Comment **NOTICE:** Survey of Retail Prices: Payment and Utilization Rates and Performance Rankings **AGENCY:** CMS		2/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/25/2015 Due Date: 4/24/2015		payment and utilization rates for the 50 most widely prescribed drugs and comparing state drug payment rates with the national retail survey prices. (Effective 7/1/2013, CMS has suspended Part I of the survey, pending funding decisions.) Part II focuses on the retail community pharmacy ingredient costs. This segment surveys the average acquisition costs of all covered outpatient drugs purchased by retail community pharmacies, with prices updated on at least a monthly basis. http://www.gpo.gov/fdsys/pkg/FR-2014-12-19/pdf/2014-29741.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/25/2015 issued a revision of this PRA request. Subsequent to the publication of the 60-day notice in the 12/19/2014 FR (79 FR 75816), CMS has reduced the burden by removing requirements for Part I pending funding decisions. CMS has made no changes to Part II. http://www.gpo.gov/fdsys/pkg/FR-2015-03-25/pdf/2015-06884.pdf No comments recommended.	
11.jj.	**Changes to Requirements for Part D Prescribers** **ACTION: Interim Final Rule** **NOTICE:** Medicare Program; Changes to the Requirements for Part D Prescribers **AGENCY:** CMS	CMS-6107-IFC	Issue Date: 5/6/2015 Due Date: 7/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This interim final rule with comment period (IFC) revises requirements related to beneficiary access to covered Part D drugs. Under these revised requirements, pharmacy claims and beneficiary requests for reimbursement for Medicare Part D prescriptions, written by prescribers other than physicians and eligible professionals permitted by state or other applicable law to prescribe medications, will not get rejected at the point of sale or denied by the plan if all other requirements are met. In addition, a plan sponsor will not reject a claim or deny a beneficiary request for reimbursement for a drug when prescribed by a prescriber who does not meet the applicable enrollment or opt-out requirement without first providing provisional coverage of the drug and individualized written notice to the beneficiary. This IFC also revises certain terminology to comport with existing policy and to improve clarity. http://www.gpo.gov/fdsys/pkg/FR-2015-05-06/pdf/2015-10545.pdf **SUMMARY OF NIHB ANALYSIS:** An analysis of this IFC appears 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.
					Indian-Specific Provisions This IFC does not include any Indian-specific provisions. Summary A summary of the major provisions of this IFC appears below. **A. Enrollment** This IFC revises § 423.120(c)(6)(ii), (iii), and (iv) to allow coverage under Part D of prescriptions provided by "other authorized prescribers," defined at § 423.100 as an individual other than a physician or eligible professional authorized under state or other applicable law to write prescriptions, with an active and valid National Provider Identifier (NPI). Under this provision, Part D sponsors will not have to reject pharmacy claims or deny beneficiary requests for reimbursement for prescriptions written by "other authorized prescribers" on the basis that the prescriber has not enrolled in or has opted out of Medicare and will continue to have the ability to cover pharmacy claims at the point of sale (POS) for prescriptions written by "other authorized prescribers," provided all other existing Part D coverage requirements are met. **B. Provisional Coverage and Notice** This IFC modifies the provisions of § 423.120(c)(6) to prohibit Part D sponsors from rejecting claims or denying beneficiary requests for reimbursement for a drug on the basis of prescriber enrollment status, unless the sponsor has first: • Covered a 3-month provisional supply of the drug, as prescribed by the prescriber and if allowed by applicable law; and • Within 3 business days after adjudication of the claim or request in a form and manner specified by CMS, provided individualized written notice to the beneficiary that it is covering the drug is on a provisional basis, subject to all other Part D rules and plan coverage requirements. **C. Revision to Dates in § 423.120(c)(5) and (c)(6)** This IFC delays the applicability date of the requirements of § 423.120(c)(5), which address certain NPI submission and verification activities related to pharmacy claims for Part D drugs, as well as the requirements of § 423.120(c)(6), to January 1, 2016. **D. Rejection of Pharmacy Claims** This IFC makes a technical change to § 423.120(c)(6)(i) and (ii) by replacing language	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					that requires Part D plan sponsors to "deny" pharmacy claims that do not meet the requirements of § 423.120(c)(6) with language requiring plan sponsors to "reject" such claims. According to CMS, the use of the word "deny" in the regulation text might lead to the incorrect interpretation that plans must issue a standardized denial notice with appeal rights for rejected claims at POS, rather than follow existing requirements at§§ 423.128(b)(7)(iii) and 423.562(a)(3). E. Name on Beneficiary Reimbursement Requests This IFC makes a technical change at § 423.120(c)(6)(iii) by replacing "legal name" with "name" for beneficiary reimbursement requests. According to CMS, requiring that beneficiary requests for coverage include the legal name of the prescriber does not comport with the existing standard required for coverage determination requests at § 423.568(a) and related subregulatory guidance and imposes an undue burden on beneficiaries. F. Other Technical Changes This IFC makes a number of other minor technical changes to § 423.120(a)(6)(i) through (iv). These changes do not affect the requirements or substance of these paragraphs.	
11.kk.	**Off-Cycle Submission of Model of Care Changes** **ACTION: Request for Comment** **NOTICE:** Off-Cycle Submission of Summaries of Model of Care Changes **AGENCY:** CMS	CMS-10565	Issue Date: 6/17/2015 **Due Date:** **8/17/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Off-Cycle Submission of Summaries of Model of Care Changes; *Use*: All Medicare Advantage (MA) Special Needs Plans (SNPs) require approval by the National Committee for Quality Assurance (NCQA). The SNPs must submit Models of Care (MOC) as a component of the Medicare Advantage application process, with approval based on an NCQA evaluation using MOC scoring guidelines. Based on their scores, SNPs receive an approval for a period of 1, 2, or 3 years. CMS has begun developing an MOC off-cycle revision process to allow SNPs to revise the MOC to modify its processes and strategies for providing care during their MOC approval period. CMS will require that SNPs submit summaries of their MOC revisions for NCQA evaluation when an SNP makes significant changes to its MOC as described in the annual Announcement of Medicare Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call letter for CY 2015 and CY 2016. NCQA will review the summary of changes to verify that the revisions comport with the acceptable, high-quality standards as included in the original approved MOC.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.gpo.gov/fdsys/pkg/FR-2015-06-17/pdf/2015-14774.pdf **SUMMARY OF NIHB ANALYSIS:**	
12.d.	**Consumer Operated and Oriented Program** **ACTION: Request for Comment** **NOTICE:** Consumer Operated and Oriented (CO-OP) Program **AGENCY:** CMS	CMS-10392	Issue Date: 9/8/2014 Due Date: 11/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 11/21/2014, 1/30/2015, 4/24/2015 Due Date: 12/22/2014; 3/31/2015; 5/26/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Consumer Operated and Oriented (CO-OP) Program; *Use*: The Consumer Operated and Oriented Plan (CO-OP) program, established by section 1322 of ACA, provides for loans to establish at least one consumer-operated, qualified nonprofit health insurance issuer in each State. Issuers supported by the CO-OP program will offer at least one qualified health plan at the silver level of benefits and one at the gold level of benefits in the individual market State Health Benefit Exchanges (Exchanges). CO-Ops will offer at least two-thirds of policies or contracts open to individuals and small employers. CO-OPs will use any profits generated to lower premiums, improve benefits, improve the quality of health care delivered to their members, expand enrollment, or otherwise contribute to the stability of coverage offered. By increasing competition in the health insurance market and operating with a strong consumer focus, the CO-OP program will provide consumers more choices, greater plan accountability, increased competition to lower prices, and better models of care, benefiting all consumers, not just CO-OP members. The CO-OP program will provide nonprofits with loans to fund start-up costs and State reserve requirements in the form of Start-up Loans and Solvency Loans. An applicant can apply for (1) joint Start-up and Solvency Loans; or (2) only a Solvency Loan. Planning Loans seek to help loan recipients determine the feasibility of operating a CO-OP in a target market. Start-up Loans seek to assist loan recipients with the many start-up costs associated with establishing a new health insurance issuer. Solvency Loans seek to assist loan recipients with meeting the solvency requirements of States in which the applicant seeks to be licensed to issue qualified health plans. http://www.gpo.gov/fdsys/pkg/FR-2014-09-05/pdf/2014-21180.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 11/21/2014 issued a revision of this PRA request.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.gpo.gov/fdsys/pkg/FR-2014-11-21/pdf/2014-27640.pdf CMS on 1/30/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf CMS on 4/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09591.pdf No comments recommended.	
12.e.	**CO-OP Program Guidance Manual** **ACTION: Guidance** **NOTICE:** CO-OP Program Guidance Manual, Version 1 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 7/29/2015 **Due Date:** **8/28/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This manual provides CO-OPs with a resource to access guidance issued by the CO-OP program. CMS will compile issued guidance in this manual at least twice per year. CMS intends to continue to issue guidance to CO-OPs directly to disseminate information in a timely manner. This manual contains guidance on the following subject matters: • Core contract requirements, including the review of employment agreements and executive compensation; • Risk-based capital (RBC) requirements; • Start-up loan disbursements; and • Semi-annual and quarterly reporting requirements. This manual also includes draft guidance regarding best practices for establishing executive compensation. Per section 3.6 (d) of the Loan Agreement, CO-OPs cannot use Loan Funds to pay excessive executive compensation. The draft executive compensation guidance included in this manual provides information on the process by which the board of directors of a CO-OP should determine executive compensation. CMS intends to finalize this guidance following a 30-day comment period and will update the manual to reflect the final guidance. Interested parties should submit comments or questions on this manual to CO-OPProgram@cms.hhs.gov with the subject line "Comments on CO-OP Manual" by 8/28/2015 at 8 p.m. ET. After this 30-day comment period, CMS will update this manual and publish the final guidance on 9/28/2015.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CO-OP-Guidance-Manual-7-29-15-final.pdf SUMMARY OF NIHB ANALYSIS:	
13.k.	**Appointment of Representative** **ACTION: Request for Comment** **NOTICE:** Appointment of Representative **AGENCY:** CMS	CMS-1696	Issue Date: 2/27/2015 Due Date: 4/28/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/8/2015 Due Date: 6/8/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Appointment of Representative; *Use*: Beneficiaries, providers and suppliers, and any party seeking to appoint a representative to assist them with their initial determinations and filing appeals complete the Appointment of Representative form. This extension request proposes non-substantive changes to the form. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04115.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/8/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-08/pdf/2015-11208.pdf No comments recommended.	
16.b.	**Medicaid HCBS Waivers ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Medicaid; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment; Setting Requirements	CMS-2249-~~P2~~F2	Issue Date: 5/3/2012 Due Date: ~~6/4/2012~~ 7/2/2012 NIHB File Date: None		**SUMMARY OF AGENCY ACTION:** This proposed rule would revise Medicaid regulations to define and describe State plan home and community-based services (HCBS) under the Social Security Act (the Act) as added by the Deficit Reduction Act of 2005 and amended by ACA. This rule would offer States new flexibility in providing necessary and appropriate services to elderly and disabled populations. In particular, this rule would not require the eligibility link between HCBS and institutional care that exists under the Medicaid HCBS waiver program. This rule would describe Medicaid coverage of the optional State plan benefit to furnish HCBS and receive Federal matching funds. This proposed rule also would amend Medicaid regulations consistent with the	

Ref. #	Short Title/Current Status of Regulation/Title/ 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 due date extension 5/3/2012; Final Rule approved by OMB 1/13/2014		requirements of ACA, which amended the Act to provide authority for a 5-year duration for certain demonstration projects or waivers, at the discretion of the HHS Secretary, when they involve individuals dually eligible for Medicaid and Medicare benefits. In addition, this rule would provide an additional limited exception to the general requirement that payment for services under a State plan go directly to the individual practitioner providing a service when the Medicaid program serves as the primary source of reimbursement for a class of individual practitioners. This exception would allow payments to other parties to benefit the providers by ensuring health, welfare, and training. Finally, this rule would amend Medicaid regulations to provide home and community-based setting requirements of ACA for the Community First Choice State plan option. **SUMMARY OF NIHB ANALYSIS:**	
16.f.	**Annual Report on HCBS Waivers** **ACTION: Request for Comment** **NOTICE:** Annual Report on Home and Community Based Services Waivers and Supporting Regulations **AGENCY:** CMS	CMS-372(S)	Issue Date: 1/16/2015 Due Date: 3/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/22/2015 Due Date: 6/22/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Annual Report on Home and Community Based Services Waivers and Supporting Regulations; *Use*: CMS uses this report to compare actual data to the approved waiver estimates. In conjunction with the waiver compliance review reports, CMS will compare the information provided to that in the Medicaid Statistical Information System (MSIS) (CMS-R-284; OMB 0938-0345) report and FFP claimed on the state Quarterly Expenditure Report (CMS-64; OMB 0938-1265) to determine whether to continue the state home and community-based services waiver. State estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS-372(S) reports. http://www.gpo.gov/fdsys/pkg/FR-2015-01-16/pdf/2015-00627.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/22/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-22/pdf/2015-12497.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.h.	**Administrative Requirements for DRA Section 6071** **ACTION: Request for Comment** **NOTICE:** Administrative Requirements for Section 6071 of the Deficit Reduction Act **AGENCY:** CMS	CMS-10249	Issue Date: 1/9/2015 Due Date: 3/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/25/2015 Due Date: 4/24/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Administrative Requirements for Section 6071 of the Deficit Reduction Act; *Use*: State Operational Protocols should provide enough information such that: The CMS Project Officer and other federal officials can use it to understand the operation of the demonstration and/or prepare for potential site visits without needing additional information; the State Project Director can use it as the manual for program implementation; and external stakeholders can use it to understand the operation of the demonstration. CMS uses the financial information collection in its financial statements and shares it with the auditors who validate the financial position of the agency. The national evaluation contractor uses the Money Follows the Person Rebalancing Demonstration (MFP) Finders File, MFP Program Participation Data File, and MFP Services File to assess program outcomes, while CMS uses the information to monitor program implementation. The national evaluation contractor uses MFP Quality of Life data to assess program outcomes. The evaluation determines how participant quality of life changes after transitioning to the community. The national evaluation contractor and CMS use the semi-annual progress report to monitor program implementation at the grantee level. http://www.gpo.gov/fdsys/pkg/FR-2015-01-09/pdf/2015-00175.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/25/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-25/pdf/2015-06884.pdf No comments recommended.	
25.x.	**Medicare PPS for Inpatient Psychiatric Facilities for FY 2016**	CMS-1627-P	Issue Date: 5/1/2015 Due Date:		**SUMMARY OF AGENCY ACTION:** This proposed rule would update the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs) (freestanding IPFs and psychiatric units of an acute care hospital or critical access hospital). These changes would apply to IPF discharges occurring during	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Proposed Rule **NOTICE:** Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System-Update for Fiscal Year Beginning October 1, 2015 (FY 2016) **AGENCY:** CMS		6/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		the fiscal year (FY) beginning 1/1/2015 through 9/30/2016 (FY 2016). This proposed rule also proposes to establish a new IPF-specific market basket; update the IPF labor-related share; transition to new Core Based Statistical Area (CBSA) designations in the FY 2016 IPF Prospective Payment System (PPS) wage index; phase out the rural adjustment for IPF providers whose status changes from rural to urban as a result of the proposed wage index CBSA changes; and set new quality measures and reporting requirements under the IPF quality reporting program. This proposed rule also reminds IPFs of the 1/1/2015 implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) and updates providers on the status of IPF PPS refinements. http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-09880.pdf **SUMMARY OF NIHB ANALYSIS:**	
25.y.	**Medicare PPS for Inpatient Rehab Facilities for FY 2016** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2016 **AGENCY:** CMS	CMS-1624-~~P~~F	Issue Date: 4/27/2015 Due Date: 6/22/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 7/29/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal FY 2016 as required by the statute. This proposed rule also would adopt an IRF-specific market basket that reflects the cost structures of only IRF providers, phase in the revised wage index changes, and revise and update quality measures and reporting requirements under the IRF quality reporting program (QRP). http://www.gpo.gov/fdsys/pkg/FR-2015-04-27/pdf/2015-09617.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.z.	**PPS for Acute and Long-Term Care Hospitals for FY 2016, et al.** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program **AGENCY:** CMS	CMS-1632-~~P~~F	Issue Date: 4/30/2015 Due Date: ~~6/29/2015~~ 6/16/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 5/5/2015; Final Rule approved by OMB 7/30/2015		**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 for FY 2016. Some of these changes would implement certain statutory provisions contained in ACA, the Pathway for Sustainable Growth Reform (SGR) Act of 2013, the Protecting Access to Medicare Act of 2014, and other legislation. This proposed rule also addresses the update of the rate-of-increase limits for certain hospitals excluded from the IPPS that receive payment on a reasonable cost basis subject to these limits for FY 2016. In addition, this proposed rule would update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2016 and implement certain statutory changes to the LTCH PPS under ACA, the Pathway for SGR Reform Act of 2013, and the Protecting Access to Medicare Act of 2014. Further, this proposed rule would establish new requirements or revise existing requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) participating in Medicare, including related proposals for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare Electronic Health Record (EHR) Incentive Program. This proposed rule also would update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-09245.pdf **SUMMARY OF NIHB ANALYSIS:** This proposed rule does not include any Indian-specific provisions. However, **tribal organizations might have an interest in a proposed update to CMS estimates of the three factors used to determine Medicare disproportionate share hospital (DSH) uncompensated care payments for FY 2016**. For purposes of calculating Factor 1 and modeling the impact of this provision for this proposed rule, CMS used the Office of the Actuary February 2015 Medicare DSH estimates, which include 2012 cost report data provided to the agency by IHS hospitals. For the purposes of calculating Factor 3, because of difficulties experienced by hospitals in reporting accurate data on time, this proposed rule would hold constant the cost report years used and, in the case of IHS hospitals, rely on 2012	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					cost report data they provided to CMS. A more extensive summary of the provisions in this proposed rule is embedded below. CMS-1632-P analysis 2015-04-22a.pdf **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/5/2015 issued a document that corrects an error in the due date in the proposed rule published in the 4/30/2015 FR. This document makes the following correction: On page 24324, in the second column, in the DATES section, "June 29, 2015" should read "June 16, 2015". http://www.gpo.gov/fdsys/pkg/FR-2015-05-05/pdf/C1-2015-09245.pdf	
25.aa.	**State Agency Sheets for Verifying IPPS Exclusions** **ACTION:** Request for Comment **NOTICE:** State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations **AGENCY:** CMS	CMS-437A and CMS-437B **See also 25.t.**	Issue Date: 5/15/2015 Due Date: 7/14/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 7/24/2015 **Due Date: 8/24/2015**		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations; *Use*: For first time verification requests for exclusion from the Inpatient Prospective Payment System (IPPS), a hospital/unit must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion. Currently, all new inpatient rehabilitation facilities (IRFs) must provide written certification that the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. They also must complete form CMS-437A if they are a rehabilitation unit or complete form CMS-437B if they are a rehabilitation hospital. The State Agency (SA) must receive this information no later than 5 months before the date the hospital/unit would become subject to IRF-PPS. CMS proposes to continue to use the Criteria Worksheets (forms CMS-437A and CMS-437B) for verifying first-time exclusions from the IPPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the IPPS-excluded rehabilitation units and rehabilitation hospitals. For rehabilitation hospitals and rehabilitation units already excluded from the IPPS, annual onsite re-verification surveys by the SA are not required. These hospitals and units will receive a copy of the appropriate CMS-437 Worksheet at least 5 months prior to the beginning of their cost reporting period, so that the hospital/unit officials can complete	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					and sign an attestation statement and complete and return the appropriate CMS-437A or CMS-437B at least 5 months prior to the beginning of their cost reporting period. Fiscal Intermediaries will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for rehabilitation hospitals and rehabilitation units through a sample of medical records and the SA will verify the medical director requirement. The SA will maintain the documents unless instructed otherwise by the RO. The SA will notify the RO at least 60 days prior to the end of the rehabilitation hospital/unit cost reporting period about its compliance or non-compliance with the payment requirements. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11798.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on7/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-24/pdf/2015-18198.pdf No comments recommended.	
25.bb.	**Comprehensive Care for Joint Replacement Payment Model** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services **AGENCY:** CMS	CMS-5516-P	Issue Date: 7/14/2015 **Due Date: 9/8/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would implement a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care for Joint Replacement (CCJR) model, in which acute care hospitals in certain selected geographic areas would receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. The episode of care would include all related care within 90 days of hospital discharge from the joint replacement procedures. CMS believes this model would further its goals in improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures. http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/pdf/2015-17190.pdf An HHS press release on this proposed rule is available at http://www.hhs.gov/news/press/2015pres/07/20150709.html. An HHS fact sheet on this proposed rule is available at http://cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					items/2015-07-09.html. More information on the CCJR model is available at http://innovation.cms.gov/initiatives/ccjr/. **SUMMARY OF NIHB ANALYSIS:** This proposed rule would implement a limited, but important, payment reform under Medicare.	
25.cc.	**Revisions to Requirements for Discharge Planning for Hospitals** **ACTION: Proposed Rule** **NOTICE:** Revisions to Requirements for Discharge Planning for Hospitals, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Home Health Agencies, and Critical Access Hospitals **AGENCY:** CMS	CMS-3317-P	Issue Date: [Pending at OMB as of 7/22/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would revise the discharge planning requirements that hospitals, inpatient rehabilitation facilities, long-term care hospitals, home health agencies, and critical access hospitals must meet to participate in the Medicare and Medicaid programs. This proposed rule also would enact the discharge planning requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT). **SUMMARY OF NIHB ANALYSIS:**	
27.i.	**Risk Corridors Transitional Policy** **ACTION: Request for Comment** **NOTICE:** Risk Corridors	CMS-10532	Issue Date: 9/8/2014 Due Date: 11/4/2014 NIHB File		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Risk Corridors Transitional Policy; *Use*: Section 1342 of ACA 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 Exchange operation. Under a final rule (CMS-9954-F) published in the 3/11/2014 Federal Register (79 FR 13834), each issuer conducting business in the individual and small group markets in states that adopted the transitional policy must submit enrollment data,	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Transitional Policy **AGENCY:** CMS		Date: None Date of Subsequent Agency Action, if any: Issued new request 1/5/2015 Due Date: 2/4/2015		including enrollment in transitional policies (i.e., individual or small group health insurance coverage in states that adopted the transitional policy announced in the CMS letter dated 11/14/2013), on the "Transitional Adjustment Reporting Form" prescribed by CMS for each state in which the issuer conducts business. CMS will use the data collection to amend the risk corridors program provisions in 45 CFR Part 153 to mitigate any unexpected losses for issuers of plans subject to risk corridors attributable to the effects of this transitional policy. Specifically, CMS will use the data to calculate the risk corridors adjustment percentage, if any, in transitional states. http://www.gpo.gov/fdsys/pkg/FR-2014-09-05/pdf/2014-21180.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 1/5/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-05/pdf/2014-30800.pdf	
27.k.	**Transitional Reinsurance Program Collections for 2014** **ACTION: Guidance** **NOTICE:** The Transitional Reinsurance Program's Contribution Collections for the 2014 Benefit Year **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** Section 1341 of ACA established a transitional reinsurance program to help stabilize premiums in the individual market inside and outside of the Marketplaces. The transitional reinsurance program collects contributions from health insurance issuers and certain self-insured group health plans (collectively, "contributing entities") at an annual per capita contribution rate to fund reinsurance payments to issuers of non-grandfathered reinsurance-eligible individual market plans, the administrative costs of operating the reinsurance program, and the general fund of the U.S. Treasury for the 2014, 2015, and 2016 benefit years. ACA set the 2014 benefit year statutory collection target at $12 billion, with an estimated $10 billion for reinsurance payments and $2 billion for the general fund of the U.S. Treasury. The amount for administrative expenses for the 2014 benefit year totaled $20.3 million (78 FR 15410, 15461). To meet the $12.02 billion target for the 2014 benefit year, HHS established an annual per capita contribution rate of $63.00 in the HHS Notice of Benefit and Payment Parameters for 2014 Final Rule (78 FR 15459). Contributing entities had the option to pay the 2014 benefit year contribution: (1) in one payment remitted no later than 1/15/2015, reflecting $63.00 per covered life; or (2) in two	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					separate payments, with the first payment due by 1/15/2015, reflecting \$52.50 per covered life, and the second payment due by 11/15/2015, reflecting \$10.50 per covered life. As of 3/31/2015, HHS has collected approximately \$8.7 billion in reinsurance contributions for the 2014 benefit year, with approximately \$1 billion more scheduled for remittance on or before 11/15/2015. As finalized in the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond Final Rule (79 FR 30257), since collections fell short of the estimates for the 2014 benefit year, HHS will allocate the first \$10 billion in contributions collected wholly for reinsurance payments to issuers of non-grandfathered reinsurance-eligible individual market plans. If the statutory collection target for reinsurance payments for the 2014 benefit year gets met, HHS will allocate any contributions collected between \$10 billion and \$12.02 billion on a pro rata basis to the general fund of the U.S. Treasury and for administrative expenses. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Reinsurance-Contributions-Total-Amount-Collected-final-.pdf **SUMMARY OF NIHB ANALYSIS:**	
27.I.	**Transitional Reinsurance Program--Timing of Refunds** **ACTION: Guidance** **NOTICE:** Transitional Reinsurance Program--Timing of Contributions Refund Requests Due to Annual Enrollment Count Misreporting **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** Section 1341 of ACA established a transitional reinsurance program to help stabilize premiums in the individual market inside and outside of the Marketplaces. The transitional reinsurance program collects contributions from contributing entities (issuers and certain self-insured group health plans offering major medical coverage) to fund reinsurance payments to issuers of non-grandfathered reinsurance-eligible individual market plans, the administrative costs of operating the reinsurance program, and the general fund of the U.S. Treasury for the 2014, 2015, and 2016 benefit years. For the 2014 benefit year, contributing entities had to submit their annual enrollment count and remit their resulting contributions utilizing the "ACA Transitional Reinsurance Program Annual Enrollment and Contributions Submission Form" (Form) via www.pay.gov by 12/5/2014. Using Pay.gov, the contributing entity (or third party administrators or administrative services-only contractors on their behalf) entered their self-reported annual enrollment count in the Form, which auto-calculated the annual contribution amount due based on the 2014 annual per capita national contribution rate	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					for the 2014 benefit year of $63.00. CMS knows that some contributing entities might have misreported their annual enrollment count for the 2014 benefit year due to misapplying an allowable counting method under 45 CFR 153.405(d) through (g) or including individuals in their annual enrollment who are exempt from consideration for purposes of reinsurance contributions under 45 CFR 153.400(a), potentially resulting in an overpayment. Contributing entities generally can correct these errors by simply refiling a Form through Pay.gov. Where processing of the contribution payment has already occurred, the contributing entity generally must refile the Form with the correct annual enrollment count, with CMS refunding the payment associated with the erroneous filing. To enable CMS to provide issuers with their calculated 2014 benefit year reinsurance payment amount, for the 2014 benefit year contributing entities must send refund requests resulting from annual enrollment count misreporting to CMS by 4/30/2015 or 90 days from the date of their Form submission, whichever is later. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RIC-Guidance-Refund-Request-Deadline-final-.pdf **SUMMARY OF NIHB ANALYSIS:**	
27.m.	**Transitional Adjustment for 2014 Risk Corridors Program** **ACTION: Guidance** **NOTICE:** Transitional Adjustment for 2014 Risk Corridors Program **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/17/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** On 11/14/2013, CMS sent a letter to the insurance commissioners of the 50 states and the District of Columbia announcing a policy under which the agency will not consider certain health insurance coverage in the individual or small group markets renewed for a policy year starting after 1/1/2014, under certain conditions, to fail to comply with specified 2014 market rules (CMS transitional policy). CMS also requested that states adopt a similar non-enforcement policy. To help mitigate the effect of the CMS transitional policy on the risk pool for qualified health plan (QHP) issuers for the 2014 benefit year, the agency amended the temporary risk corridors program provisions at 45 CFR Part 153 to provide for a one-time state-level adjustment to profits and administrative expenses in the risk corridors formula (transitional adjustment). Determination of the transitional adjustment for each state relies on the percentage of enrollment in the individual and small group markets in policies under the CMS transitional policy in that state during the 2014 benefit year.	

Ref. #	Short Title/Current Status of Regulation/Title/ 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 guidance provides information on transitional adjustment data collection, calculation, and application by CMS. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RC_TransitionalAdjGuidance_5CR_041715.pdf SUMMARY OF NIHB ANALYSIS:	
27.n.	**CSR Amounts in Risk Corridors and MLR Reporting** **ACTION: Guidance** **NOTICE:** Cost-Sharing Reduction Amounts in Risk Corridors and Medical Loss Ratio Reporting **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/19/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance provides instructions to issuers regarding use of the amount of the cost-sharing reduction (CSR) portion of the advance payments in the risk corridors and medical loss ratio (MLR) calculation for the 2014 and 2015 benefit years. **On 2/13/2015, CMS announced that reconciliation of the CSR portion of the advance payments for the 2014 benefit year will occur in April 2016, rather than in April 2015.** CMS established the new timetable to enhance the accuracy of reconciliation of CSR payments to issuers and to reimburse issuers fully for reductions in cost sharing provided to eligible low- and moderate-income enrollees and AI/AN enrollees in 2014. As a result of the new timetable for CSR reconciliation, issuers will available the actual value of CSRs provided in time for risk corridors and MLR program reporting for the 2014 benefit year. Therefore, **for the purpose of adjusting allowable costs in the risk corridors calculation and incurred claims in the MLR calculation for the 2014 benefit year, issuers should use the amount of the CSR portion of the advance payments received by the issuer for 2014 (to the extent not reimbursed to the provider furnishing the item or service).** According to this guidance, **CMS intends to propose a policy in the HHS Notice of Benefit and Payment Parameters for 2017 under which the agency would implement an adjustment to the risk corridors and MLR calculations for 2015 to correct for any inaccuracies in the estimated CSR provided in 2014 reported in the 2014 risk corridors and MLR reporting form.** For the 2015 risk corridors and MLR reporting cycle, if an issuer used a certified estimate of 2014 CSRs provided on the 2014 risk corridors and MLR forms less than the actual CSRs provided (as calculated under CSR reconciliation), CMS would adjust the 2015 risk corridors payment or charge amount, as applicable, by any difference between the estimated 2014 CSR amount	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					reported in the 2014 risk corridors and MLR forms and the reconciled actual value of CSRs provided by the issuer for the 2014 benefit year. CMS would intend to implement this adjustment as a direct dollar-for-dollar adjustment to the risk corridors payment or charge amount, or as an adjustment to one of the risk corridors parameters resulting in a dollar-for-dollar adjustment to the risk corridors payment or charge amount. Issuers would make this adjustment at the time they report MLR and risk corridors data for the 2015 reporting cycle. When reporting CSR amounts for the 2015 risk corridors and MLR reporting cycle (July 2016 submission of 2015 benefit year data), issuers that elected to report advance CSR amounts in the 2014 reporting cycle and issuers that reported estimated CSR amounts exceeding the actual value of CSRs provided in 2014 should include any CSR reconciliation payments or charges for the 2014 and 2015 benefit years in their reported CSR amount for the 2015 risk corridors and MLR reporting year. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Advance-CSR-Payment-and-RC-MLR-submission_6192015.pdf **SUMMARY OF NIHB ANALYSIS:** This guidance indicates that reconciliation of advanced payments made to issuers for cost-sharing reductions for 2014 will occur, although not until April 2016.	
28.f.	**Medicaid Implementation Advanced Planning Document** **ACTION: Notice** **NOTICE:** Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template **AGENCY:** CMS	CMS-10536	Issue Date: 8/29/2014 Due Date: 10/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template; *Use*: To assess the appropriateness of state requests for enhanced federal financial participation for expenditures related to Medicaid eligibility determination systems, CMS will review the submitted information and documentation to make an approval determination for the advanced planning document. http://www.gpo.gov/fdsys/pkg/FR-2014-08-29/pdf/2014-20590.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 12/19/2014 issued a new version of this PRA request. CMS has revised this package subsequent to the publication	

Ref. #	Short Title/Current Status of Regulation/Title/ 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 new request 12/19/2014 Due Date: 1/20/2015		of the 60-day notice in the 8/29/2014 FR (79 FR 51571). http://www.gpo.gov/fdsys/pkg/FR-2014-12-19/pdf/2014-29739.pdf	
28.h.	**Medicaid Eligibility Changes Under ACA** **ACTION: Request for Comment** **NOTICE:** Medicaid Program; Eligibility Changes Under the Affordable Care Act of 2010 **AGENCY:** CMS	CMS-10410	Issue Date: 2/6/2015 Due Date: 4/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 6/26/2015 Due Date: 7/27/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Medicaid Program; Eligibility Changes Under the Affordable Care Act of 2010; *Use*: The eligibility systems are essential to the goal of increasing coverage in insurance affordability programs while reducing administrative burden on states and consumers. The electronic transmission and automation of data transfers serve as key elements in managing the expected insurance affordability program caseload that started in 2014. http://www.gpo.gov/fdsys/pkg/FR-2015-02-06/pdf/2015-02414.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 6/26/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/pdf/2015-15770.pdf No comments recommended.	
28.i.	**Income and Eligibility Verification System Reporting** **ACTION: Request for Comment**	CMS-R-74	Issue Date: 2/6/2015 Due Date: 4/7/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Income and Eligibility Verification System Reporting and Supporting Regulations; *Use*: A state Medicaid agency that currently obtains and uses information from certain sources, or with more frequency than specified, could continue to do so to the extent that the verifications prove useful and not redundant. An agency that has found it effective to verify all wage or benefit information with another	

Ref. #	Short Title/Current Status of Regulation/Title/ 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: Income and Eligibility Verification System Reporting and Supporting Regulations **AGENCY:** CMS		<u>NIHB File Date</u>: None <u>Date of Subsequent Agency Action, if any</u>: Issued extension 6/26/2015 <u>Due Date:</u> 7/27/2015		agency or with the recipient can continue these practices if it chooses. In addition, the agency can implement an approved targeting plan under 42 CFR 435.953. Agency experience should guide its decision whether to exceed these regulatory requirements on income and eligibility verification. While states can target resources when verifying income of course, agencies remain accountable for their accuracy in eligibility determinations. http://www.gpo.gov/fdsys/pkg/FR-2015-02-06/pdf/2015-02414.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 6/26/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/pdf/2015-15770.pdf No comments recommended.	
29.q.	**Penalty Relief Related to Advance Payments of PTC** **ACTION: Guidance** **NOTICE:** Penalty Relief Related to Advance Payments of the Premium Tax Credit for 2014 **AGENCY:** IRS	Notice 2015-9	<u>Issue Date:</u> 1/26/2015 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency Action, if any:</u>		**SUMMARY OF AGENCY ACTION:** This notice provides limited relief for taxpayers who have a balance due on their 2014 income tax return as a result of reconciling advance payments of the premium tax credit against the premium tax credit allowed on the tax return. Specifically, this notice provides relief from the penalty under § 6651(a)(2) of the Internal Revenue Code for late payment of a balance due and the penalty under § 6654(a) for underpayment of estimated tax. To qualify for the relief, taxpayers must meet certain requirements described in this notice. This relief applies only for the 2014 taxable year. • The § 6651(a)(2) penalty is not imposed if the taxpayer shows that the failure was due to reasonable cause and not willful neglect. • the Service will abate the § 6651(a)(2) penalty for taxable year 2014 for taxpayers who (i) are otherwise current with their filing and payment obligations; (ii) have a balance due for the 2014 taxable year due to excess advance payments of the premium tax credit; and (iii) report the amount of excess advance credit payments on their 2014 tax return timely filed, including extensions • the Service will waive the § 6654 penalty for taxable year 2014 for an underpayment of estimated tax for taxpayers who have an underpayment	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					attributable to excess advance credit payments if the taxpayers (i) are otherwise current with their filing and payment obligations; and (ii) report the amount of the excess advance credit payments on a 2014 tax return timely filed, including extensions • Taxpayers should be aware that this Notice does not extend the time to file a return. • Additionally, § 6601 imposes interest on amounts of tax not paid by the due date, determined without regard to an extension of time for payment. Taxpayers will be required to pay interest on the balance due from the original deadline to pay, which is generally April 15, 2015, even if they qualify for penalty relief under this Notice. • Taxpayers who file their returns after April 15, 2015 must fully pay the underlying liability by April 15, 2016 to be eligible for relief under this Notice. Interest will accrue until the underlying liability is fully paid. • To request a waiver of the § 6654(a) penalty as provided in this Notice, taxpayers should check box A in Part II of Form 2210, complete page 1 of the form, and include the form with their return, along with the statement: "Received excess advance payment of the premium tax credit." This relief does not apply to any underpayment of the individual shared responsibility payment resulting from the application of § 5000A because such underpayments are not subject to either the § 6651(a)(2) penalty or the § 6654(a) penalty. http://www.irs.gov/pub/irs-drop/n-15-09.pdf SUMMARY OF NIHB ANALYSIS:	
29.r.	**Victims of Domestic Abuse and Spousal Abandonment** **ACTION: Guidance** **NOTICE:** Updated Guidance on Victims of Domestic Abuse and Spousal Abandonment	CCIIO (no reference number) **See also 29.i.**	Issue Date: 7/27/2015 Due Date: None NIHB File Date:		**SUMMARY OF AGENCY ACTION:** CMS remains committed to addressing the needs of victims of domestic abuse and spousal abandonment, including an increased need for health care and the ability to enroll in health coverage apart from their abuser or abandoner. This document provides guidance on special enrollment periods, advance payments of the premium tax credit, and cost-sharing reductions for these individuals. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated-Guidance-on-Victims-of-Domestic-Abuse-and-Spousal-Abandonment_7.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: CCIIO		Date of Subsequent Agency Action, if any:		**SUMMARY OF NIHB ANALYSIS:**	
31.dd.	**Coverage of Certain Preventive Services Under ACA** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Coverage of Certain Preventive Services Under the Affordable Care Act **AGENCY:** IRS/DoL/CMS	~~REG 129786-14~~ TD 9726 DoL RIN 1210-AB67 CMS-9940-~~PF~~ **See also 31.ee. and 31.ff.**	Issue Date: 8/27/2014 Due Date: 10/21/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 7/14/2015		**SUMMARY OF AGENCY ACTION: This document proposes a change to the definition of an eligible organization that can avail itself of an accommodation with respect to coverage of certain preventive services** under section 2713 of the Public Health Service Act (PHS Act), added by ACA, as amended, and incorporated into ERISA and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. These services include women's preventive health services, as specified in guidelines supported by HRSA. As authorized by the current regulations and consistent with HRSA Guidelines, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services. Additionally, under current regulations, accommodations are available with respect to the contraceptive coverage requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations that are institutions of higher education, that effectively exempt them from this requirement. The regulations establish a mechanism for separately furnishing payments for contraceptive services on behalf of participants and beneficiaries of the group health plans of eligible organizations that avail themselves of an accommodation, and enrollees and dependents of student health insurance coverage arranged by eligible organizations that are institutions of higher education that avail themselves of an accommodation. **These rules propose and seek comments on potential changes to the definition of "eligible organization" in the regulations in light of the Supreme Court decision in *Burwell v. Hobby Lobby Stores, Inc.* (2014) to ensure that participants and beneficiaries in group health plans (and enrollees and dependents in student health insurance coverage arranged by institutions of higher education) obtain,**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					without cost sharing, coverage of the full range of FDA-approved contraceptive services, as prescribed by a health care provider, while respecting the religion-based objectives to contraceptive coverage of certain closely held for-profit entities. These proposed rules also seek comments on any additional steps the government should take to help ensure coverage of the full range of FDA-approved contraceptive services, as prescribed by a health care provider, without cost sharing, for participants and beneficiaries in group health plans (and enrollees and dependents in student health insurance coverage arranged by institutions of higher education). http://www.gpo.gov/fdsys/pkg/FR-2014-08-27/pdf/2014-20254.pdf A model notice that an eligible organization can use to inform the HHS Secretary of its religious objection to coverage of all or a subset of contraceptive services, as well as related instructions, is available at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Model-Notice-8-22-14.pdf. SUMMARY OF NIHB ANALYSIS: **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This document contains final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by ACA, as amended, and incorporated into ERISA and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. **These regulations finalize provisions from three rulemaking actions: interim final regulations issued in July 2010 related to coverage of preventive services, interim final regulations issued in August 2014 related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and proposed regulations issued in August 2014 related to the definition of "eligible organization,"** which would expand the set of entities that can avail themselves of an accommodation with respect to the coverage of contraceptive services. This rule finalizes a series of proposed provisions, specifically provisions providing an accommodation to religious organizations and closely held corporations, while ensuring access to contraceptive services for employees. Media coverage of these final regulations 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.
					• *Associated Press*: http://bigstory.ap.org/article/b675fc67af3941298d73817d94813fc3/new-birth-control-rule-employers-religious-qualms?utm_campaign=KHN%3A+Daily+Health+Policy+Report&utm_source=hs_email&utm_medium=email&utm_content=20545925&_hsenc=p2ANqtz--p-wGd6FRKbH7BEqj-fs73TFV7c-3VG1yuQD-wlUx-vdPQGMubbfOnqn4dtwQR4sn0mGrjwatM_pH-W3AlWEJmKSEnZQ&_hsmi=20545925 • *The Hill*: http://thehill.com/policy/healthcare/247507-feds-tweak-obamacare-birth-control-mandate?utm_campaign=KHN%3A+Daily+Health+Policy+Report&utm_source=hs_email&utm_medium=email&utm_content=20545925&_hsenc=p2ANqtz-9qNra821eWpPHvKVH5kYNRPDhpVLT_5pRdS7pbsLudYquUVIZuGH_qV10Vg0B3qXjIMJ7P03Sz62mCEtU8PXKFQKHAaA&_hsmi=20545925 • *New York Times*: http://www.nytimes.com/2015/07/11/us/health-laws-contraceptive-rule-eased-for-businesses-with-religious-objections.html?utm_campaign=KHN%3A+Daily+Health+Policy+Report&utm_source=hs_email&utm_medium=email&utm_content=20545925&_hsenc=p2ANqtz-9mul267uL96B-X2BdcsL8NHKs-5KWd6WrY65kRSLRIBUtQRyJSspnd93wvB5mKRukVlNtkejjHqmkp2NYgaO7zidgGjg&_hsmi=20545925&_r=0 • *Wall Street Journal*: http://www.wsj.com/articles/birth-control-coverage-rules-announced-by-obama-administration-1436544940?utm_campaign=KHN%3A+Daily+Health+Policy+Report&utm_source=hs_email&utm_medium=email&utm_content=20545925&_hsenc=p2ANqtz--BK8oax_PEyQzJ7rwJbZVa05_30_x0Wh2MgreSOMwD5AV3b3nZyv7_2GIFtpYODJE0fd5fNHrHPdDWuJbh_Z7FKnPnKQ&_hsmi=20545925	
31.gg.	Coverage of Certain Preventive Services Under ACA ACTION: Request for Comment	EBSA Form 700 (OMB 1210-0150)	Issue Date: 8/27/2014 Due Date: 10/27/2014 NIHB File		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: EBSA Form 700--Certification; *Use*: The Departments of Labor and the Treasury and HHS, concurrent with the publication of this information collection request, issued interim final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by ACA, as amended, and incorporated into ERISA and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Coverage of Certain Preventive Services Under the Affordable Care Act **AGENCY:** DoL		Date: None Date of Subsequent Agency Action, if any: Issued extension 12/11/2014, 2/27/2015 Due Date: 2/9/2015; 3/30/2015		certain preventive health services by non grandfathered group health plans and health insurance coverage. These services include women's preventive health services, as specified in guidelines supported by HRSA. As authorized by the current regulations and consistent with the HRSA Guidelines, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services. Additionally, under current regulations, accommodations are available with respect to the contraceptive coverage requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), and student health insurance coverage arranged by eligible organizations that are institutions of higher education, that effectively exempt them from this requirement. The regulations require organizations seeking accommodation to self-certify that they meet the definition of an eligible organization. Organizations must send a copy of the self-certification to an issuer or third-party administrator. Organization seeking the accommodation must maintain the self-certification/notification in a manner consistent with the record retention requirements under section 107 of the ERISA, which generally requires maintenance of records for six years. EBSA Form 700 serves as the form used by eligible organizations for their self-certification. The interim final regulations augment the final regulations and revise the EBSA Form 700 ICR in light of the Supreme Court interim order in connection with an application for an injunction in *Wheaton College v. Burwell* (2014) (Wheaton order). Specifically, the interim final regulations continue to allow eligible organizations to notify an issuer or third-party administrator using EBSA Form 700, as set forth in the July 2013 final regulations. In addition, the interim final regulations permit an alternative process, consistent with the Wheaton order, under which eligible organizations could notify the HHS Secretary that they will not act as the plan administrator or claims administrator with respect to, or contribute to the funding of, coverage of all or a subset of contraceptive services. The notification must include information sufficient to identify the plan, plan type (including whether it is a church plan within the meaning of ERISA section 3(33)), and the identity and mailing addresses of any third-party administrators. http://www.gpo.gov/fdsys/pkg/FR-2014-08-27/pdf/2014-20253.pdf **SUMMARY OF NIHB ANALYSIS:**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					SUMMARY OF SUBSEQUENT AGENCY ACTION: DoL on 12/11/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-12-11/pdf/2014-29060.pdf DoL on 2/27/2015 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04094.pdf	
31.kk.	**ACA Uniform Explanation of Coverage Documents** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Uniform Explanation of Coverage Documents **AGENCY:** IRS	TD 9575 (OMB 1545-2229)	Issue Date: 9/15/2014 Due Date: 11/14/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/26/2015 Due Date: 3/30/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Affordable Care Act Uniform Explanation of Coverage Documents; *Use*: This document contains regulations regarding disclosure of the summary of benefits and coverage and the uniform glossary for group health plans and health insurance coverage in the group and individual markets under ACA. This document implements the disclosure requirements to help plans and individuals better understand their health coverage, as well as other coverage options. http://www.gpo.gov/fdsys/pkg/FR-2014-09-15/pdf/2014-21961.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** IRS on 2/26/2015 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2015-02-26/pdf/2015-04021.pdf No comments recommended.	
31.ll.	**Data Submission for the FFE User Fee Adjustment** **ACTION: Request for Comment**	CMS-10492 **See also 31.c.**	Issue Date: 9/29/2014 Due Date: 11/28/2014		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Data Submission for the Federally-Facilitated Exchange User Fee Adjustment; *Use*: The final rule "Coverage of Certain Preventive Services Under the Affordable Care Act," published by HHS and the Departments of the Treasury and Labor in the 7/2/2013 FR (78 FR 39870), sets forth regulations regarding coverage for certain preventive services under section 2713 of the Public Health Service Act (PHS Act), as	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Data Submission for the Federally-Facilitated Exchange User Fee Adjustment **AGENCY:** CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 7/14/2015 **Due Date: 8/13/2015**		added by ACA, as amended, and incorporated into ERISA and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services, including certain contraceptive services, in non-exempt, non-grandfathered group health plans and health insurance coverage. The final rule establishes accommodations with respect to group health plans established or maintained by eligible organizations (and group health insurance coverage offered in connection with such plans). Eligible organizations must self-certify that they qualify for this accommodation and provide a copy of such self-certification to their third party administrators. The final rule also sets forth processes and standards to fund the payments for the contraceptive services provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described previously, through an adjustment in the Federally-Facilitated Exchange (FFE) user fee payable by an issuer participating in an FFE. To facilitate the FFE user fee adjustment and ensure that these user fee adjustments reflect payments for contraceptive services provided under this accommodation and that the adjustment is applied to the appropriate participating issuer in an FFE, the final rule requires an information collection from applicable participating issuers and third party administrators. In particular, the final regulations at 45 CFR 156.50(d)(2)(i) provide that a participating issuer that seeks an FFE user fee adjustment must submit to HHS in the year following the benefit year in which payments for contraceptive services were made under the previously mentioned accommodation, identifying information for the participating issuer, each third party administrator, and each self-insured group health plan, as well as the total dollar amount of the payments for contraceptive services provided during the applicable calendar year under the accommodation. The final regulations at 45 CFR 156.50(d)(2)(iii) also require the third party administrator to submit to HHS identifying information for the third party administrator, the participating issuer, and each self-insured group health plan, as well as the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year, the total dollar amount of payments made for contraceptive services, and an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2). Furthermore, to determine the potential number of submissions provided by third party administrators and to allow HHS to prepare to receive submissions in calendar year 2015, the final regulations at 45 CFR 156.50(d)(2)(ii) require third party administrators to submit to HHS a notification that the third party administrator intends for a participating	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					issuer to seek an FFE user fee adjustment, by the later of 1/1/2014, or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization. Additionally, a health insurance issuer providing payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations to provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments. The burden associated with these processes includes the time for applicable participating issuers and third party administrators to submit identifying information and total payments made for contraceptive services in the prior calendar year and for third party administrators to notify HHS of their intent to seek the user fee adjustment. HHS estimates 488 third party administrators, 48 QHP issuers, and 325 fully insured issuers of eligible organizations will submit this information. HHS anticipates that participating issuers in an FFE seeking a user fee adjustment and third party administrators with respect to which the FFE user fee adjustment is received will submit this information electronically. http://www.gpo.gov/fdsys/pkg/FR-2014-09-29/pdf/2014-23132.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/14/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/pdf/2015-17285.pdf No comments recommended.	
31.mm.	**2016 Actuarial Value Calculator** **ACTION: Guidance** **NOTICE:** ~~Draft~~ 2016 Actuarial Value Calculator	CCIIO (no reference number)	Issue Date: 11/21/2014 Due Date: None NIHB File		**SUMMARY OF AGENCY ACTION:** Under the Essential Health Benefits, Actuarial Value, and Accreditation final rule at 78 FR 12834 (EHB Final Rule) published in the Federal Register on February 25, 2013, HHS requires use of an Actuarial Value (AV) Calculator by issuers of non-grandfathered health insurance plans offered in the individual and small group markets, both inside and outside of the Affordable Insurance Exchanges (Exchanges, or Marketplaces) for the purposes of determining levels of coverage. Section 1302(d)(2)(A) of ACA stipulates that calculation of AV must occur based 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.
	AGENCY: CCIIO		Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 1/16/2015		provision of essential health benefits (EHB) to a standard population. The statute groups health plans into four tiers: bronze, with an AV of 60 percent; silver, with an AV of 70 percent; gold, with an AV of 80 percent; and platinum, with an AV of 90 percent. The EHB Final Rule allows a *de minimis* variation of +/- 2 percentage points of AV for each tier. The AV Calculator represents an empirical estimate of the AV calculated in a manner that provides a close approximation to the actual average spending by a wide range of consumers in a standard population. This draft document details the specific methodologies used in the AV calculation. The revised version of this draft document incorporates updates to account for the draft 2016 AV Calculator. The first part of this draft document provides background that includes an overview of the regulation that allows HHS to make updates to the AV Calculator, as well as the updates incorporated into the draft 2016 AV Calculator. For the second part of the document, CCIIO provides a detailed description of the development of the standard population and the AV Calculator methodology. The first section details the data and methods used in constructing the continuance tables used to calculate AV in combination with the user inputs. The second section describes the AV Calculator interface and the calculation of actuarial value based on the interface and the continuance tables. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-2016-AVC-Methodology-MASTER-for-112114.pdf The draft 2016 AV Calculator is available at http://www.cms.gov/cciio/resources/regulations-and-guidance/index.html. **SUMMARY OF NIHB ANALYSIS:** No Indian-specific or tribal-specific elements are referenced in the AV calculator methodology. In particular, on page 29, there is a discussion of the ability to use the AV Calculator to determine if silver-level cost-sharing variations offered for individuals with incomes at or below 250% FPL (73%, 87%, 94%) meet the AV targets. There is not a similar discussion of the "zero cost-sharing variation" or the "limited cost-sharing variation." In other regulations (CMS-9964-F), CMS assigned an AV of 100% to the zero cost-sharing variation and an AV of 87% or 94% to the limited cost-sharing variation, depending on the metal tier selected.	

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					It may be warranted to ask CMS if not including the two Indian-specific cost-sharing variations in the page 29 discussion (and in the AV Calculator) was an oversight-- and therefore limits the usefulness of the AV calculator--or was intentional. If, for example, the zero cost-sharing variation was included in the AV Calculator, issuers might be able to check their cost-sharing protection design against the AV Calculator to confirm that it meets the 100% AV standard. NOTE: Given that the limited cost-sharing variation was assigned an AV of 87%, it is uncertain whether the AV Calculator would work for this cost-sharing variation, as the lower AV level for the limited cost-sharing variation must be a factor of enrollees not securing a referral (which would reduce the cost-sharing protections experienced by the enrollee) rather than the plan having some cost-sharing requirements for certain services. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CCIIO on 1/16/2014 issued a final version of this guidance. This document revises the 2015 version and updates the draft 2016 version, released on 11/21/2014, in response to comments received. Specifically, this document incorporates updates to account for the final 2016 AV Calculator. The first part of this document provides background that includes an overview of the regulation allowing HHS to make updates to the AV Calculator, as well as the updates incorporated into the final 2016 AV Calculator. For the second part of the document, CCIIO provides a detailed description of the development of the standard population and the AV Calculator methodology. The first section details the data and methods used in constructing the continuance tables involved in calculating AV in combination with the user inputs. The second section describes the AV Calculator interface and the calculation of actuarial value based on the interface and the continuance tables. The final 2016 AV Calculator is available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2016-AV-Calculator-011514.xlsm. CCIIO notes that this does not affect any 2015 plans and applies only for 2016 plans. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2016-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.
31.nn.	**Notification of Objection to Covering Contraceptive Services** **ACTION: Request for Comment** **NOTICE:** Employer Notification to HHS of its Objection to Providing Coverage for Contraceptive Services **AGENCY:** CMS	CMS-10535	Issue Date: 12/8/2014 Due Date: 2/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/6/2915 Due Date: 4/6/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Employer Notification to HHS of its Objection to Providing Coverage for Contraceptive Services; *Use*: The proposed rules titled "Coverage of Certain Preventive Services Under the Affordable Care Act" (79 FR 51118) would continue to require each closely-held, for-profit corporation seeking treatment as an eligible organization to provide notification that it will not act as the plan administrator or claims administrator with respect to, or contribute to the funding of, coverage of all or a subset of contraceptive services. Issuers and third party administrators providing payments for contraceptive services for participants and beneficiaries in plans of eligible organizations would have to meet the notice requirements as set forth in the 2013 final regulations. http://www.gpo.gov/fdsys/pkg/FR-2014-12-08/pdf/2014-28632.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/6/2015 issued a revision of this PRA request. According to CMS, the interim final regulations titled "Coverage of Certain Preventive Services Under the Affordable Care Act" (79 FR 51092) continue to allow eligible organizations that have religious objections to providing contraceptive coverage to notify an issuer or third party administrator using EBSA Form 700, as set forth in the July 2013 final regulations. In addition, the interim final regulations permit an alternative process under which an eligible organization could notify the HHS Secretary that it will not act as the plan administrator or claims administrator with respect to, or contribute to the funding of, coverage of all or a subset of contraceptive services. http://www.gpo.gov/fdsys/pkg/FR-2015-03-06/pdf/2015-05165.pdf No comments recommended.	
31.oo.	**Amendments to Excepted Benefits** **ACTION: ~~Proposed~~ Final Rule**	~~REG-132751-14~~ TD 9714 DoL RIN 1210-	Issue Date: 12/23/2014 Due Date: 1/22/2015		**SUMMARY OF AGENCY ACTION:** This document contains proposed rules that would amend the regulations regarding excepted benefits under ERISA, the Internal Revenue Code (the Code), and the Public Health Service Act related to limited wraparound coverage. Excepted benefits generally are exempt from the requirements added to those laws by HIPAA and ACA.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Amendments to Excepted Benefits **AGENCY:** IRS/DoL/CMS	AB70 CMS-9946-~~P2~~F2	NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 3/18/2015		http://www.gpo.gov/fdsys/pkg/FR-2014-12-23/pdf/2014-30010.pdf **SUMMARY OF NIHB ANALYSIS:** These proposed regulations provide a series of conditions that must apply for certain wraparound benefits to qualify as "excepted benefits," thereby not impacting the ability of an employee to access premium tax credits in an Exchange if the individual otherwise qualifies for premium tax credits. **Background**: The 2013 proposed regulations outlined requirements under which certain employer-sponsored wraparound coverage provided under a group health plan would qualify as excepted benefits when offered to individuals who could have received the benefits provided in the wraparound coverage through their primary employer-sponsored group health plan but did not enroll in that plans because it was unaffordable. The 2013 proposed regulations sought to allow a plan sponsor to pursue equity in coverage by maintaining a comparable level of benefits for all potential enrollees, including not only higher-income workers enrolled in the primary employer-sponsored group health plan but also lower-income workers enrolled in non-grandfathered individual market coverage. Under the 2013 proposed regulations, employer-provided wraparound coverage would constitute excepted benefits (limited wraparound coverage) and therefore would not disqualify an employee from eligibility for the premium tax credit and cost-sharing reductions, if five conditions were met. After consideration of comments on the 2013 proposed regulations, the Departments are publishing these proposed regulations to address limited wraparound coverage and solicit comment before promulgation of final regulations on limited wraparound benefits. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This document contains final regulations that amend the regulations regarding excepted benefits under ERISA, the Internal Revenue Code, and the Public Health Service Act to specify requirements for limited wraparound coverage to qualify as an excepted benefit. Excepted benefits generally are exempt from the requirements added to those laws by HIPAA and ACA. http://www.gpo.gov/fdsys/pkg/FR-2015-03-18/pdf/2015-06066.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.
31.pp.	**Summary of Benefits and Coverage and Uniform Glossary** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Summary of Benefits and Coverage and Uniform Glossary **AGENCY:** IRS/DoL/CMS	~~REG-145878-14~~ TD 9764 DoL RIN 1210-AB69 CMS-9938-~~P~~F	Issue Date: 12/30/2014 Due Date: 3/2/2015 TTAG File Date: 2/28/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 6/16/2015	TTAG response:	**SUMMARY OF AGENCY ACTION:** This document contains proposed regulations regarding the summary of benefits and coverage (SBC) and the uniform glossary for group health plans and health insurance coverage in the group and individual markets under ACA. It proposes changes to the regulations that implement the disclosure requirements under section 2715 of the Public Health Service Act (PHS Act) to help plans and individuals better understand their health coverage, as well as to gain a better understanding of other coverage options for comparison. It proposes changes to documents required for compliance with section 2715 of the PHS Act, including a template for the SBC, instructions, sample language, a guide for coverage example calculations, and the uniform glossary. A CMS fact sheet on these proposed regulations is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/SBC-Proposed-Rule-Fact-Sheet-122214.pdf An HHS press release describing these proposed regulations is embedded below. HHS Interg Notification SBC 2014 Links to a number of proposed supporting materials related the SBC and uniform glossary appear below: Proposed SBC Blank Template: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/blank-template-12-19-14-FINAL.pdf Proposed Uniform Glossary: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Uniform-Glossary-12-19-14-FINAL.pdf Proposed SBC Sample Completed Template: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Sample-completed-sbc-12-19-14-FINAL.pdf Proposed Why This Matters language for SBC "No" Answers: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Why-This-Matters-No-Answers-FINAL.pdf	See Table C.

TABLE B: SUMMARY OF NOTICES & REGULATIONS
UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Proposed Why This Matters language for SBC "Yes" Answers: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Why-This-Matters-Yes-Answers-FINAL.pdf Proposed Instructions for Completing the SBC--Individual Health Insurance Coverage: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Instructions-Individual-12-19-14-FINAL.pdf Proposed Instructions for Completing the SBC--Group Health Plan Coverage: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Instructions-Group-12-19-14-FINAL.pdf Proposed Guide for Coverage Examples Calculations--Maternity Scenario: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Maternity-Scenario-MarketScan-Data-DRAFT-v4-NHE-2.pdf Proposed Coverage Examples Narrative--Maternity Scenario: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/maternity-narrative.pdf Proposed Guide for Coverage Examples Calculations--Diabetes Scenario: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Diabetes-Scenario-MarketScan-Data-DRAFT-v3-NHE.PDF **SUMMARY OF NIHB ANALYSIS:** These proposed regulations, which would make modifications to the content of the Summary of Benefits and Coverage (SBC) documents, contain no Indian-specific provisions. Other recent proposed regulations pertaining to the SBC documents appeared in CMS-9944-P (**see 89.h.**). Tribal representatives provided comments on CMS-9944-P, which would mandate the release of an SBC by an issuer for each cost-sharing variation. A review of these proposed regulations is embedded below. CMS-9938-P Summary of Benefits a	

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					Tribal organizations did previously submit recommendations--and CMS agreed--on the need for an SBC for each of the Indian-specific cost-sharing variations that a plan must offer (limited cost-sharing variation and zero cost-sharing variation). Tribal representatives might wish to submit a comment on this proposed rule to: • Express continued support for the addition of the requirement (as proposed in CMS-9944-P) for issuers to prepare and make available SBCs for each Indian-specific cost-sharing variation; • Indicate the potential need for modifications to the SBC template as issuers work to incorporate the required plan information into SBCs for the Indian-specific cost-sharing variations; • Encourage CMS to review the SBCs prepared by issuers for the Indian-specific cost-sharing variations and engage with tribal representatives to determine any need for modifications to the SBC template; and • Recommend **that CMS provide sample language--for use by QHP issuers in the preparation of the SBCs--to describe how the "zero" and "limited" cost-sharing variations impact deductibles, co-insurance, etc., for in-network and out-of-network providers** (to address confusion on the part of some issuers on the fact that the Indian-specific cost-sharing protections apply uniformly to in-network and out-of-network providers, except for the issue of balance billing). **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This document contains final regulations regarding the summary of benefits and coverage (SBC) and the uniform glossary for group health plans and health insurance coverage in the group and individual markets under ACA. It finalizes changes to the regulations that implement the disclosure requirements under section 2715 of the Public Health Service Act to help plans and individuals better understand their health coverage, as well as gain a better understanding of other coverage options for comparison. http://www.gpo.gov/fdsys/pkg/FR-2015-06-16/pdf/2015-14559.pdf A CMS fact sheet on these final regulations is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Fact-	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Sheet_SBCFinalRule-6-11-15-MM-508.pdf.	
31.qq.	**FAQ About Excepted Benefits** **ACTION: Guidance** **NOTICE:** FAQs About Affordable Care Act Implementation: Excepted Benefits **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 2/13/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance, prepared jointly by HHS and the Departments of Labor and the Treasury (collectively, the Departments), answers an additional Frequently Asked Question (FAQ) regarding implementation of ACA, specifically addressing the issue of excepted benefits. The Departments have become aware of health insurance issuers selling supplemental products that provide a single benefit. At least one issuer has characterized this type of coverage as an excepted benefit. These issuers claim that the products meet the criteria for supplemental coverage to qualify as an excepted benefit outlined in guidance and seek to fill the gaps of primary coverage in the sense that they provide a benefit not covered under the primary group health plan. This guidance answers the question of whether health insurance coverage that supplements group health coverage by providing additional categories of benefits qualifies as supplemental excepted benefits. According to this guidance: "It depends. The Departments' prior guidance provided an enforcement safe harbor for supplemental insurance products that are specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles. In determining whether insurance coverage sold as a supplement to group health coverage can be considered 'similar supplemental coverage' and an excepted benefit, the Departments will continue to apply the applicable regulations and the four criteria indicated in the guidance discussed above. In addition, the Departments intend to propose regulations clarifying the circumstances under which supplemental insurance products that do not fill in cost-sharing under the primary plan are considered to be specifically designed to fill gaps in primary coverage. Specifically, the Departments intend to propose that coverage of additional categories of coverage would be considered to be designed to 'fill in the gaps' of the primary coverage only if the benefits covered by the supplemental insurance product are not an essential health benefit (EHB) in the State where it is being marketed. If any benefit in the coverage is an EHB in the State where it is marketed, the insurance coverage would not be an excepted benefit under our intended proposed regulations, and would have to comply with the applicable provisions of title XXVII of PHS Act, part 7 of ERISA, and chapter 100 the Code. We note that this standard applies to coverage that purports to qualify as an excepted	

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					benefit as 'similar supplemental coverage provided to coverage under a group health plan' under PHS Act section 2791(c)(4), ERISA section 733(c)(4), and Code section 9832(c)(4). This standard does not apply to other circumstances where the coverage may qualify as another category of excepted benefits, such as limited excepted benefits under section 2791(c)(2), ERISA section 733(c)(2), and Code section 9832(c)(2). Pending publication and finalization of the above proposed regulations, the Departments will not initiate an enforcement action if an issuer of group or individual health insurance coverage fails to comply with the provisions of the PHS Act, ERISA, and the Code, as amended by the Affordable Care Act, with respect to health insurance coverage that (1) provides coverage of additional categories of benefits that are not EHB in the applicable State (as opposed to filling in cost-sharing gaps under the primary plan); (2) complies with the applicable regulatory requirements and meets all of the criteria in the existing guidance on 'similar supplemental coverage'; and (3) has been filed and approved with the State (as may be required under State law). As noted above, for purpose of the second criterion of the existing guidance, coverage would be considered designed to 'fill gaps in primary coverage' even if it does not include coverage of cost-sharing under the group health plan, only if the benefits are not covered by the group health plan and are not EHBs in the State. The Departments encourage States that have primary enforcement authority over the provisions of the PHS Act, as amended by the Affordable Care Act, to utilize the same enforcement discretion under such circumstances." http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Supplmental-FAQ_2-13-15-final.pdf SUMMARY OF NIHB ANALYSIS:	
31.rr.	**Minimum Essential Coverage Application Review Process** **ACTION: Guidance** **NOTICE:** Insurance Standards Bulletin Series: CCIIO Sub-Regulatory Guidance: Minimum	CCIIO (no reference number)	Issue Date: 2/13/2015 Due Date: None NIHB File Date: Date of		**SUMMARY OF AGENCY ACTION:** Section 5000A of the Internal Revenue Code (the Code), as added by ACA, provides that individuals must maintain minimum essential coverage (MEC), pay the individual shared responsibility payment, or qualify for an exemption. Section 5000A(f) of the Code defines MEC as any of the following: (1) coverage under a specified government sponsored program; (2) coverage under an eligible employer-sponsored plan; (3) coverage under a health plan offered in the individual market within a State; and (4) coverage under a grandfathered health plan. In addition, section 5000A(f)(1)(E) of the Code authorizes HHS, in coordination with the Department 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.
	Essential Coverage Application Review Process **AGENCY:** CCIIO		Subsequent Agency Action, if any:		Treasury (Treasury), to designate other health benefits coverage as MEC. The departments have implemented this authority both through additional designations in regulations or guidance of types of coverage as MEC, and in regulations providing for a process for applying for MEC designation under specified conditions. The departments also issued regulations providing for an administrative process for applying for MEC status, with eligibility for designation under this process conditioned on meeting certain standards, including compliance with "substantially all" ACA requirements. On 10/3/12013, CCIIO issued further guidance on this administrative process. The October 2013 guidance separately specified that certain types of foreign group health coverage are MEC. This guidance clarifies the existing standard of review for the MEC application process: it does not designate additional categories of MEC. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/MEC-Guidance-final-2-13-15.pdf **SUMMARY OF NIHB ANALYSIS:**	
31.ss.	**Excise Tax on High Cost Employer Health Coverage** **ACTION: Guidance** **NOTICE:** Section 4980I--Excise Tax on High Cost Employer-Sponsored Health Coverage **AGENCY:** IRS	Notice 2015-16	Issue Date: 2/23/2015 Due Date: 5/15/2015 NIHB File Date: 5/15/2015 Date of Subsequent Agency Action, if any:	NIHB response:	**SUMMARY OF AGENCY ACTION:** This notice seeks to initiate and inform the process of developing regulatory guidance regarding the excise tax on high cost employer-sponsored health coverage under § 4980I of the Internal Revenue Code (Code). Section 4980I, added to the Code by ACA, applies to taxable years beginning after 12/31/2017. Under this provision, if the aggregate cost of "applicable employer-sponsored coverage" (referred to in this notice as applicable coverage) provided to an employee exceeds a statutory dollar limit, which is revised annually, the excess is subject to a 40 percent excise tax. This notice describes potential approaches with regard to a number of issues under § 4980I, which IRS might incorporate in future proposed regulations, and invites comments on these potential approaches. The issues addressed in this notice primarily relate to (1) the definition of applicable coverage, (2) the determination of the cost of applicable coverage, and (3) the application of the annual statutory dollar limit to the cost of applicable coverage. The Department of the Treasury (Treasury) and IRS invite comments on the issues addressed in this notice and on any other issues under § 4980I.	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.
					Treasury and IRS anticipate issuing another notice, before the publication of proposed regulations under § 4980I, describing and inviting comments on potential approaches to a number of issues not addressed in this notice, including procedural issues relating to the calculation and assessment of the excise tax. After considering the comments on both notices, Treasury and IRS anticipate publishing proposed regulations under § 4980I. The proposed regulations will provide further opportunity for comment, including an opportunity to comment on the issues addressed in the preceding notices. http://www.irs.gov/pub/irs-drop/n-15-16.pdf **SUMMARY OF NIHB ANALYSIS:** Determining the extent to which this tax would apply to plans offered by tribal employers might prove useful. A summary of this notice is embedded below. PDF 2015-03-17 Summary of IRS Notic	
31.tt.	**ACA Section 2715 Summary Disclosures** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Section 2715 Summary Disclosures **AGENCY:** DoL	DoL (OMB 1210-0147)	Issue Date: 2/27/2015 Due Date: 3/30/2015 NIHB File Date: None 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*: Affordable Care Act Section 2715 Summary Disclosures; *Use*: Public Health Service Act section 2715 directed HHS and the Departments of Labor and the Treasury (collectively, the Departments), in consultation with the National Association of Insurance Commissioners (NAIC) and a working group comprised of stakeholders, to develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, and policyholders and certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. The subject information collection relates to the provision of the following: A summary of benefits and coverage, which includes coverage examples; a uniform glossary of health coverage and medical terms; and notice of modifications. Group health plans and health insurance issuers must use the Summary of Benefits and Coverage template and instructions for completing the template, as authorized by the Departments, to satisfy the section 2715 disclosure requirements. ACA section 2715	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					authorizes this information collection. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04094.pdf SUMMARY OF NIHB ANALYSIS:	
31.uu.	**ACA Implementation FAQs (SBC)** **ACTION: Guidance** **NOTICE:** Affordable Care Act Implementation FAQs **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 3/30/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance, prepared jointly by HHS and the Departments of Labor and the Treasury (collectively, the Departments) answers an additional Frequently Asked Question (FAQ) regarding implementation of ACA. In a December 2014 notice of proposed rulemaking, the Departments proposed changes to summary of benefits and coverage (SBC) regulations, as well as a new SBC template and associated documents. Changes to the SBC regulations, template, and associated documents would apply beginning 9/1/2015. This guidance answers the question of when the Departments intend to finalize changes to the regulations, SBC template, and associated documents. According to this guidance: "The Departments intend to finalize changes to the regulations in the near future, which are intended to apply in connection with coverage that would renew or begin on the first day of the first plan year (or, in the individual market, policy year) that begins on or after 1/1/2016 (including open season periods that occur in the Fall of 2015 for coverage beginning on or after 1/1/2016). **The Departments also intend to utilize consumer testing and offer an opportunity for the public, including the National Association of Insurance Commissioners, to provide further input before finalizing revisions to the SBC template and associated documents**. The Departments anticipate the new template and associated documents will be finalized by January 2016 and will apply to coverage that would renew or begin on the first day of the first plan year (or, in the individual market, policy year) that begins on or after 1/1/2017 (including open season periods that occur in the Fall of 2016 for coverage beginning on or after 1/1/2017). The Departments are fully committed to updating the template and associated documents (including the uniform glossary) to better meet consumers' needs as quickly as possible."	

Ref. #	Short Title/Current Status of Regulation/Title/ 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/aca_implementation_faqs24.html **SUMMARY OF NIHB ANALYSIS:** The December 2014 proposed rule (CMS-9938-P) included updates to the 2012 regulations regarding the summary of benefits and coverage (SBC), as well as changes to related documents, including an SBC template, instructions, sample language, a guide for coverage example calculations, and a uniform glossary. Comments on the proposed rule closed on 3/2/2015. According to this guidance, CMS plans to finalize the updated SBC regulations in the near future and have them apply to the 2016 plan year as proposed in the rule. However, this guidance indicates that CMS, to allow additional time for testing and comment, will delay the finalization of the related documents (possibly until January 2016) and will not have them apply until the 2017 plan year, rather than the 2016 plan year as proposed in the rule. This guidance does not specify how the delay in the finalization of the documents will interact with the updated regulations. CMS finalized the new requirement for QHP issuers to prepare SBCs for each of the two Indian-specific cost-sharing variations as part of a separate rule (CMS-9944-F); whether the delay in the finalization of the documents will have any effect on this requirement remains uncertain.	
31.vv.	**EHBs: List of the Largest Three Small Group Products by State** **ACTION: Guidance** **NOTICE:** Essential Health Benefits: List of the Largest Three Small Group Products by State **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/8/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This document provides information to facilitate State selection of the benchmark plans that will serve as the reference plan for the essential health benefits (EHBs). Using data from HealthCare.gov, this document provides a list of the three largest small group insurance products ranked by enrollment in the first quarter of 2014 for each State. In addition, this document provides a list of the three largest nationally available Federal Employee Health Benefit Program (FEHBP) plans, another benchmark option under 45 CFR 156.100(a). This document also provides the single largest Federal Employees Dental and Vision Insurance Program (FEDVIP) dental and vision plans based on enrollment in the first quarter of 2014. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/largest-smgroup-products-4-8-15-508d-pdf-Adobe-Acrobat-Pro.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.
31.xx.	**ACA Implementation FAQs (Preventive Services)** **ACTION: Guidance** **NOTICE:** FAQs About Affordable Care Act Implementation **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 5/11/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance, prepared jointly by HHS and the Departments of Labor and the Treasury (collectively, the Departments) answers additional Frequently Asked Questions (FAQs) regarding implementation of ACA, specifically on the issue of coverage of preventive services. Section 2713 of the Public Health Service Act (PHS Act) and its implementing regulations relating to coverage of preventive services require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for, and prohibit the imposition of cost-sharing requirements with respect to, certain preventive services. If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, the plan or issuer can use reasonable medical management techniques to determine any such coverage limitations. As described in a previous FAQ, PHS Act section 2713 addresses coverage for evidence-based items or services with a rating of "A" or "B" in the current recommendations of the USPSTF, as well as coverage for preventive care and screenings as provided for in comprehensive guidelines supported by HRSA. This FAQ answers the following related questions: • **Q1: Must a plan or issuer cover without cost sharing recommended genetic counseling and BRCA genetic testing for a woman who has not been diagnosed with BRCA-related cancer but who previously had breast cancer, ovarian cancer, or other cancer?** A1: Yes. • **Q2: If a plan or issuer covers some forms of oral contraceptives, some types of IUDs, and some types of diaphragms without cost sharing, but excludes completely other forms of contraception, will the plan or issuer comply with PHS Act section 2713 and its implementing regulations?** A2: No. • **Q3: If multiple services and FDA-approved items within a contraceptive method are medically appropriate for an individual patient, what is a plan or issuer required to cover without cost sharing?**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					A3: If multiple services and FDA-approved items within a contraceptive method are medically appropriate for an individual, the plan or issuer may use reasonable medical management techniques to determine which specific products to cover without cost sharing with respect to that individual. However, **if the individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing.** The plan or issuer must defer to the determination of the attending provider with respect to the individual involved. • **Q4: If a plan or issuer covers oral contraceptives (such as the extended/continuous use contraceptive pill), can it impose cost sharing on all items and services within other FDA-identified hormonal contraceptive methods (such as the vaginal contraceptive ring or the contraceptive patch)?** A4: No. • **Q5: Can plans or issuers limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity or recorded gender?** A5: No. • **Q6: If a plan or issuer covers dependent children, is the plan or issuer required to cover without cost sharing recommended women's preventive care services for dependent children, including recommended preventive services related to pregnancy, such as preconception and prenatal care?** A6: Yes. • **Q7: If a colonoscopy is scheduled and performed as a preventive screening procedure for colorectal cancer pursuant to the USPSTF recommendation, is it permissible for a plan or issuer to impose cost sharing with respect to anesthesia services performed in connection with the preventive colonoscopy?**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					A7: No. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf **SUMMARY OF NIHB ANALYSIS:** This guidance provides clarity on coverage and cost-sharing for preventive services, including contraceptives.	
31.yy.	**ACA Information Returns Reference Guide** **ACTION: Guidance** **NOTICE:** Affordable Care Act (ACA) Information Returns (AIR): AIR Submission Composition and Reference Guide, Version 1.0 **AGENCY:** IRS	IRS (no reference number)	Issue Date: June 2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This document provides guidance to all types of external transmitters about composing and sending compliant submissions to IRS. This document includes information for three types of transmitters: • **Issuers**: Businesses filing their own ACA Information Returns (AIR), regardless of whether they must file electronically (transmit 250 or more of the same type of information return) or volunteer to file electronically; the term issuer includes any individual required to report coverage on Form 1095-B and any applicable large employer required to report offers of coverage on Form 1095-C and file associated transmittals on Form 1094-B or 1094-C. • **Transmitters**: Third parties sending the electronic information return data directly to IRS on behalf of any business required to file. • **Software developers**: Organizations writing either origination or transmission software according to IRS specifications. This document covers details on composing and submitting Form 1094/1095-Bs and Form 1094/1095-Cs by transmitters to IRS. The scope of the document addresses the Application to Application interface (A2A-application based via SOAP messages exchanged between client and exposed Web Service endpoints) and the Web User Interface (Web UI-browser-based requiring human initiation). This document seeks to provide sufficient technical information to allow transmitters to compose and send valid submissions comprising Form 1094/1095Bs and Form 1094/1095Cs. This document addresses transmission of *Receipt* ID--which forms the basis for uniquely identifying Form 1094 and Form 1095 records within a transmission--from AIR to the transmitter as part of the synchronous session initiated by the transmitter	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					to send the submission. http://www.irs.gov/PUP/for_taxpros/software_developers/information_returns/AIR_Composition_and_Reference_Guide.pdf Draft versions of the 2015 Form 1094/1095-Bs and Form 1094/1095-Cs are available online (see links below). Form 1094-B: http://www.irs.gov/pub/irs-dft/f1094b--dft.pdf Form 1095-B: http://www.irs.gov/pub/irs-dft/f1095b--dft.pdf Form 1094-C: http://www.irs.gov/pub/irs-dft/f1094c--dft.pdf Form 1095-C: http://www.irs.gov/pub/irs-dft/f1095c--dft.pdf SUMMARY OF NIHB ANALYSIS:	
39.e.	**Basic Health Program: Federal Funding Methodology for 2016** **ACTION:** ~~Proposed~~ **Final Methodology** **NOTICE:** Basic Health Program; Federal Funding Methodology for Program Year 2016 **AGENCY:** CMS	CMS-2391-~~P~~FN	Issue Date: 10/23/2014 Due Date: 11/24/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Methodology 2/20/2015		**SUMMARY OF AGENCY ACTION:** This document provides the methodology and data sources necessary to determine federal payment amounts made in program year 2016 to states that elect to establish a Basic Health Program under ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges. http://www.gpo.gov/fdsys/pkg/FR-2014-10-23/pdf/2014-25257.pdf CMS recently released three new documents related to BHP, including: • **Proposed 2016 BHP Payment Notice**: This document provides the methodology and data sources necessary to determine federal payment amounts made in program year 2016 to states that elect to establish a BHP. https://www.federalregister.gov/articles/2014/10/23/2014-25257/basic-health-program-federal-funding-methodology-for-program-year-2016 • **BHP Blueprint**: States will use this document to make an official request for certification of a BHP as set forth in 42 CFR §600.110. This document, designed to collect the program design choices of the state and to provide a full description of the operations and management of the program and its	

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					compliance with the federal rules, reflects the BHP final rule that codified program establishment standards, eligibility and enrollment, benefits, delivery of health care services, transfer of funds to participating states, and HHS oversight relating to BHP. **In this document, "Section 2: Public Input" includes the following instructions, "If the state has federally recognized tribes, list them below. Provide an assurance that they were included in public comment and note if comments were received [by checking the relevant boxes]."** http://www.medicaid.gov/basic-health-program/downloads/bhp-blueprint.pdf • **State Report for Health Insurance Exchange Premiums**: This document collects information from states operating State-Based Marketplaces to support the determination of federal payment amounts to states that elect to establish a BHP. http://www.medicaid.gov/basic-health-program/downloads/premium-data-collection-tool.zip **SUMMARY OF NIHB ANALYSIS:** No comments recommended, as CMS proposes to use the same methodology in use for 2015 for 2016. While the BHP final rule in March 2014 codified the overall statutory requirements and basic procedural framework for the funding methodology, it did not contain the specific information necessary to determine federal payments. CMS anticipated that the methodology would be based on data and assumptions that would reflect ongoing operations and experience of BHP programs as well as the operation of the Exchanges. For this reason, the BHP final rule indicated that the development and publication of the funding methodology, including any data sources, would be addressed in a separate annual BHP Payment Notice. Payment rates published in draft form in this notice are expected to be finalized in February 2015 and would apply to BHP program year 2016, beginning in January 2016. (In the 3/12/2014 FR (79 FR 13887), CMS published the final payment methodology, titled "Basic Health Program; Federal Funding Methodology for Program Year 2015,"that sets forth the methodology that will be used to calculate the federal BHP payments for the 2015 program year.) In this notice, CMS is proposing a methodology that is the same as the 2015 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.
					methodology, with updated values but no changes in methods. Through CMS-2380-F and CMS-2380-FN, tribal representatives made a series of recommendations. These recommendations were either adopted by CMS or, if not adopted, responded to by the agency in the preamble to the final action. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This document provides the methodology and data sources necessary to determine federal payment amounts made in program year 2016 to states that elect to establish a Basic Health Program under ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through the Affordable Insurance Exchanges. http://www.gpo.gov/fdsys/pkg/FR-2015-02-24/pdf/2015-03662.pdf	
40.	**State Plan Base Plan Pages** **ACTION: Request for Comment** **NOTICE:** State Plan Under Title XIX of the Social Security Act **AGENCY:** CMS	CMS-179	Issue Date: 12/29/2011 Due Date: 2/14/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/23/2012; issued extension 4/20/2015, 6/26/2015 Due Date:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: State Plan Under Title XIX of the Social Security Act; *Use*: State Medicaid agencies complete the plan pages, and CMS reviews the information to determine if the State has met all of the provisions that it has chosen to implement. If the requirements are met, CMS will approve the amendments to the State Medicaid plan, giving the State the authority to implement the flexibilities. For a State to receive Medicaid Title XIX funding, it must have an approved Title XIX State plan. **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/23/2015 issued a revision of this PRA request. CMS on 4/20/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-20/pdf/2015-09008.pdf CMS on 6/26/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/pdf/2015-15770.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.
			4/23/2012; 6/19/2015; 7/27/2015			
41.e.	**New Safe Harbors** **ACTION: Notice** **NOTICE:** Solicitation of New Safe Harbors and Special Fraud Alerts **AGENCY:** HHS OIG	OIG-123-N	Issue Date: 12/30/2014 Due Date: 3/2/2015 TTAG File Date: 3/2/2015 Date of Subsequent Agency Action, if any:	TTAG response:	**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-2014-12-30/pdf/2014-30156.pdf **SUMMARY OF NIHB ANALYSIS:** This notice provides another opportunity to tribal representatives to make a case for I/T/U-specific safe harbors.	See Table C.
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		**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:**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			revision 2/22/2013, 11/22/2013, 1/31/2014, 1/30/2015, 4/24/2015 Due Date: 3/25/2013; 1/21/2014; 3/5/2014; 3/31/2015; 5/26/2015		**SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 2/22/2013 issued a revision of this PRA request. The 60-day Federal Register notice published on 12/4/2012 (77 FR 71801), pertained to the 2012 MLR Annual Reporting Form and Instructions, and the comment period closed on 2/4/2013. CMS received a total of 4 public comments on 25 specific issues regarding the notice of the revised MLR PRA package. Most of the comments addressed clarifying the instructions or correcting typographical errors, the removal of calculated cells and the ability of issuers to copy and paste data onto the form, and the inclusion of a credibility indicator for small issuers to eliminate the need for small issuers to fill out the complete MLR reporting form. CMS have taken into consideration all of the proposed suggestions and has made changes to the 2012 MLR Annual Reporting Form and Instructions. http://www.gpo.gov/fdsys/pkg/FR-2013-02-22/pdf/2013-04015.pdf CMS on 11/22/2013 issued a revision of this PRA request. Based upon experience in the MLR data collection and evaluation process, CMS has updated its annual burden hour estimates to reflect the actual numbers of submissions, rebates, and rebate notices. The 2013 MLR Reporting Form and instructions also reflect changes for the 2013 reporting year and beyond set forth in the March 2012 update to 45 CFR 158.120(d)(5) regarding aggregation of student health plans on a nationwide basis, similar to expatriate plans. In addition, the instructions address recent applicability guidance issued by the Departments of Labor and Treasury and HHS concerning expatriate plan reporting prior to plan years ending before or on 12/31/2015. In 2014, issuers likely will send fewer notices and rebate checks to policyholders and subscribers, resulting in a reduction in burden. However, the requirement to report data on student health plans will increase burden for some issuers. CMS estimates a net reduction in total information collection burden. http://www.gpo.gov/fdsys/pkg/FR-2013-11-22/pdf/2013-28049.pdf 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	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					requirements for businesses in run-off. CMS has considered all of the proposed suggestions and has revised the 2013 MLR Annual Reporting Form and Instructions. http://www.gpo.gov/fdsys/pkg/FR-2014-01-31/pdf/2014-02061.pdf CMS on 1/30/2015 issued a revision of this PRA request. Based upon experience in the MLR data collection and evaluation process, CMS has updated its annual burden hour estimates to reflect the actual numbers of submissions, rebates, and rebate notices. In addition, CMS has updated its annual burden hour estimates to reflect the additional burden related to the risk corridors data submission requirements. The 2014 MLR Reporting Form and instructions reflect changes for the 2014 reporting year and beyond set forth in the March 2013 update to 45 CFR part 158 regarding the MLR reporting and rebate distribution deadlines and the accounting for the transitional reinsurance, risk adjustment, and risk corridors. CMS also has revised the 2014 MLR Reporting Form and instructions to include the reporting elements required under the risk corridors data submission requirements in 45 CFR 153.530. In 2015, issuers likely will send fewer notices and rebate checks to policyholders and subscribers, reducing burden for QHP issuers. However, the requirement to report the risk corridors data will increase burden for QHP issuers. CMS estimates a net reduction in total burden from 294,911 to 271,600. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf CMS on 4/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09591.pdf No comments recommended.	
48.h.	**Q&A on MLR Reporting and Rebate Requirements** **ACTION: Guidance**	CCIIO 2015-0001	Issue Date: 5/27/2015 Due Date: None		**SUMMARY OF AGENCY ACTION:** This bulletin provide guidance regarding: (1) the limited circumstances in which a health insurance issuer can, for MLR reporting purposes, exclude agent and broker fees or commissions from earned premium under 45 CFR §158.130 and (2) to whom a health insurance issuer must provide MLR rebates payable under section 2718 of the Public Health Service Act (PHS Act), as added 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.
	NOTICE: CCIIO Technical Guidance: Questions and Answers Regarding the Medical Loss Ratio (MLR) Reporting and Rebate Requirements **AGENCY:** CCIIO		NIHB File Date: Date of Subsequent Agency Action, if any:		ACA, and the implementing regulation at 45 CFR §158.240, when a portion or all of the premium gets paid with advance payments of the premium tax credit. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/MLR-Guidance-Earned-Premium-and-APTC-Rebates-20150527.pdf **SUMMARY OF NIHB ANALYSIS:**	
49.a.	**Reporting and Returns of Medicare Overpayments** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; Reporting and Returning of Overpayments **AGENCY:** CMS	CMS-6037-P	Issue Date: 2/16/2012 Due Date: 4/16/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension notice 2/17/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would require providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date which is 60 days after the date on which the overpayment was identified; or any corresponding cost report is due, if applicable. **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 2/17/2015 issued a document (CMS-6037-RCN) to announce the extension of the timeline for publication of the "Medicare Program; Reporting and Returning of Overpayments" final rule. CMS has issued this notice in accordance with the Social Security Act (the Act), which requires provision of notice in the FR if exceptional circumstances cause the agency to publish a final rule more than 3 years after the publication date of the proposed rule. In this case, the complexity of the rule and scope of comments warrants the extension of the timeline for publication. http://www.gpo.gov/fdsys/pkg/FR-2015-02-17/pdf/2015-03072.pdf	
50.e.	**Initial Plan Data Collection to Support QHP Certification** **ACTION: Request for Comment**	CMS-10433	Issue Date: 11/21/2012 Due Date: 12/21/2012 NIHB File		**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	

Ref. #	Short Title/Current Status of Regulation/Title/ 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: Initial Plan Data Collection to Support Qualified Health Plan Certification and Other Financial Management and Exchange Operations **AGENCY:** CMS		Date: None Date of Subsequent Agency Action, if any: Issued revision 11/1/2013, 2/10/2014, 7/30/2014; issued extension 2/11/2015, 4/28/2015 Due Date: 12/31/2013; 3/12/2014; 8/27/2014; 4/13/2015; 5/28/2015		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 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	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					• 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. CMS on 7/30/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15075.pdf CMS on 2/11/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-11/pdf/2015-02852.pdf Issues might exist pertaining to gathering data from QHPs on contract offerings to Indian health care providers, but tribal representatives likely should direct these comments to the underlying regulations rather than the associated PRA notice. As such, no comments recommended. CMS on 4/28/2014 issued an extension of this PRA request http://www.gpo.gov/fdsys/pkg/FR-2015-04-28/pdf/2015-09849.pdf No comments recommended, but this PRA notice might provide an opportunity to comment on the need for QHP issuers to report offerings of contracts to Indian health care providers (IHCPs), report their number of contracts with IHCPs, or address other compliance issues.	
50.v.	**Medical Expenditure Panel Survey--Insurance Component** **ACTION: Request for Comment** **NOTICE:** Medical Expenditure Panel Survey--	AHRQ (OMB 0935-0110)	Issue Date: 1/10/2014 Due Date: 3/11/2014 NIHB File Date: None		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Medical Expenditure Panel Survey--Insurance Component; *Use*: The Medical Expenditure Panel Survey--Insurance Component (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	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Insurance Component **AGENCY:** AHRQ		Date of Subsequent Agency Action, if any: Issued revision 3/31/2014, 2/18/2015, 5/7/2015; issued extension 6/11/2015 Due Date: 4/30/2014; 4/20/2015; 6/8/2015; **8/10/2015**		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 AHRQ on 2/18/2015 issued a revision of this PRA request. To ensure that the MEPS-IC can capture important changes in the employer-sponsored health insurance market due to the implementation of ACA, AHRQ will field a longitudinal survey in 2015 to include a sample of 5,000 small private sector employers that responded to the 2014 MEPS-IC. The OMB clearance approved on 11/21/2013 included the 2014 longitudinal survey, a survey of 3,000 respondents to the 2013 MEPS-IC, but did not include the 2015 longitudinal survey because AHRQ had not finalized the sample size. This information collection request includes no other changes. http://www.gpo.gov/fdsys/pkg/FR-2015-02-18/pdf/2015-02905.pdf No comments recommended. AHRQ on 5/7/2015 issued a revision of this PRA request. AHRQ received no comments in response to the 60-day notice on this information collection published in the 2/18/2015 FR. http://www.gpo.gov/fdsys/pkg/FR-2015-05-07/pdf/2015-10981.pdf	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					No comments recommended. AHRQ on 6/11/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-11/pdf/2015-14197.pdf	
50.aa.	**SHOP Effective Date and Termination Notice Requirements** **ACTION: Request for Comment** **NOTICE:** Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements **AGENCY:** CMS	CMS-10555	Issue Date: 3/9/2015 Due Date: 5/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements; *Use*: CMS requires that, for plan years beginning on or after 1/1/2017, the Small Business Health Options Program (SHOP) must ensure that a qualified health plan (QHP) issuer notifies qualified employees, enrollees, and new enrollees in a QHP through the SHOP of the effective date of coverage. As required by the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameter for 2016 (CMS-9944-F), published on 2/27/2015, if any enrollee has his or her coverage terminated through the SHOP due to non-payment of premiums or a loss of eligibility to participate in the SHOP, the SHOP must notify the enrollee or the qualified employer of the termination of such coverage. In the termination of coverage, the SHOP must include the termination date and reason for termination to the enrollee or qualified employer. http://www.gpo.gov/fdsys/pkg/FR-2015-03-09/pdf/2015-05420.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended.	
50.bb.	**FAQs on Flexibilities for State-Based SHOP Direct Enrollment** **ACTION: Guidance** **NOTICE:** Flexibilities for State-Based SHOP Direct Enrollment--Frequently Asked Questions (FAQs)	CCIIO (no reference number)	Issue Date: 6/1/2015 Due Date: None NIHB File Date: Date of		**SUMMARY OF AGENCY ACTION:** This guidance answers the following frequently asked questions regarding flexibilities for the Small Business Health Options Program (SHOP): • **Q1. Can State-based Small Business Health Options Programs (SHOPs) allow direct enrollment for 2015? And 2016? Can employers who use direct enrollment to purchase a SHOP QHP in such circumstances access the Small Business Health Care Tax Credit, if they are otherwise eligible?** A1. Yes as a transition to full online functionality when certain criteria are met.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	AGENCY: CCIIO		Subsequent Agency Action, if any:		… • **Q2. Can states use existing, approved Section 1311 grant funds for the work of establishing SHOP online functionality and, if necessary, can states request a no cost extension?** A2. If the work of establishing SHOP online functionality is part of a state's approved work plan under its current Section 1311 grant award, states may use existing, approved grant funds for that work during an approved transition period so long as the funds are still available under the terms of the grant. States may also request a no cost extension to use grant funds on these activities in accordance with CMS' 1311 grants policy … • **Q3. What should issuers and a State-based SHOP tell small employers about direct enrollment in SHOP?** A3. In a State-based Marketplace using SHOP direct enrollment during a transition period, small employers will enroll in SHOP QHPs directly with SHOP issuers or by working with their agent or broker. In such a state, to claim the Small Business Health Care Tax Credit, an otherwise eligible small business must enroll in a SHOP QHP, and must also file an application to participate in the SHOP and receive a favorable determination of eligibility. When a State-based SHOP using direct enrollment provides notice of a favorable eligibility determination, it should also provide information to the small employer about how to file for the Small Business Health Care Tax Credit with the Internal Revenue Service. SHOP QHP issuers in a state where SHOP direct enrollment is permitted during a transition period can assist small employers in accessing the Small Business Health Care Tax Credit by making clear which QHP offerings are available through the SHOP and providing information to inform small employers who enroll in SHOP QHPs of the next steps to access the tax credit. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/SBM-SHOP-Transitional-Flexibility-FAQ-Rev-5-29-2015.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.
50.cc.	**FAQs on SBM Options for Shared Responsibility Exemptions** **ACTION: Guidance** **NOTICE:** Frequently Asked Questions on State-Based Marketplace Options for Implementing Exemptions from the Shared Responsibility Payment **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 7/28/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance answers the following frequently asked questions regarding State-Based Marketplace (SBM) options for implementing exemptions from the shared responsibility payment: • **Q1. Can a State-based Marketplace (SBM) continue to utilize the option provided for under 45 CFR 155.625(b) to have the Department of Health and Human Services (HHS) process exemption applications for the shared responsibility payment?** A1. Yes. ... Based on HHS's operation of this service, we have determined that the HHS exemption option is an efficient process for SBMs that has minimized confusion for consumers. We, therefore, intend to propose regulations that would authorize this option on a permanent basis, and, in the interim, will not take any enforcement action against SBMs that continue to use the HHS service for exemptions beyond the start of open enrollment for 2016. • **Q2. Does 45 CFR 155.625(b) apply only to SBMs?** A2. This option applies only to SBMs utilizing their own eligibility and enrollment platform. ... • **Q3. How does an SBM notify HHS that it intends to elect the HHS exemptions option under 45 CFR 155.625(b)?** A3. An SBM must inform HHS in writing whether it will process its own exemption applications or adopt HHS exemption eligibility determinations. An SBM should contact its CCIIO State Officer for more information. If electing to use the HHS exemption option, the SBM must meet the conditions under 45 CFR 155.625(b) ... If an SBM elects to develop the capacity to grant certificates of exemption, HHS remains committed to providing technical assistance to SBMs to support their implementation of these capabilities. ... • **Q4. If electing to use the HHS option for exemptions under 45 CFR 155.625(b), what information must an SBM furnish to HHS?**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					A4. As a condition of using the HHS exemption option, the SBM must furnish HHS with "any information available through the Exchange that is necessary for an applicant to utilize the process administered by HHS" under 45 CFR 155.625(b)(2). ... • **Q5. Must an SBM that elects to set up its own exemption process use an electronic system?** A5. Electronic exemption application capabilities are not a requirement. At this time, an SBM may use a paper and manual process to handle exemption applications. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/SBM-Exemption-Processing-FAQ-7-21-15.pdf **SUMMARY OF NIHB ANALYSIS:**	
52.f.	**OASIS Collection Requirements as Part of the CoPs for HHAs** **ACTION: Request for Comment** **NOTICE:** OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations **AGENCY:** CMS	CMS-R-245	Issue Date: 6/21/2013 Due Date: 8/20/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 11/8/2013, 8/29/2014; issued		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations; *Use*: Home Health Agencies (HHAs) must use the OASIS data set as a condition of participation (CoP) in the Medicare program. Since 1999, Medicare CoPs have mandated that HHAs use the OASIS data set when evaluating adult non-maternity patients receiving skilled services. Agencies integrate OASIS, a core standard assessment data set, into their own patient-specific, comprehensive assessment to identify patient need for home care that meets their medical, nursing, rehabilitative, social, and discharge planning needs. http://www.gpo.gov/fdsys/pkg/FR-2013-06-21/pdf/2013-14878.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 11/8/2013 issued a revision of this PRA request. Subsequent to the publication of the 60-day FR notice on 6/21/2013, CMS has revised the data set by rewording the text.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			extension 11/24/2014, 2/6/2015 Due Date: 12/9/2013; 9/12/2014; 1/23/2015; 3/9/2015		http://www.gpo.gov/fdsys/pkg/FR-2013-11-08/pdf/2013-26822.pdf CMS on 8/9/2014 issued a revision of this PRA request. According to CMS, OMB approved the OASIS-C1 information collection request on 2/6/2014. CMS originally planned to use OASIS-C1 to coincide with the original implementation of ICD-10 on 10/1/2014. However, on 4/1/2014, the Protecting Access to Medicare Act of 2014 (PAMA) took effect. This legislation prohibits CMS from adopting ICD-10 coding prior to 10/1/2015. Because CMS based OASIS-C1 on ICD-10 coding, it cannot implement OASIS-C1 prior to 10/1/2015. The passage of the PAMA Act left CMS with the dilemma of how to collect OASIS data in the interim. CMS created the OASIS-C1/ICD-9 version, an interim version of the OASIS-C1 data item set, in response to the legislatively mandated ICD-10 delay. Five items in OASIS-C1 require ICD-10 codes. In the OASIS-C1/ICD-9 version, CMS has replaced these items with the corresponding items from OASIS-C that use ICD-9 coding. The OASIS-C1/ICD-9 version also incorporates updated clinical concepts, modified item wording and response categories, and improved item clarity. In addition, the OASIS-C1/ICD-9 version includes a significant decrease in provider burden through the deletion of a number of non-essential data items from the OASIS-C data item set. http://www.gpo.gov/fdsys/pkg/FR-2014-08-29/pdf/2014-20577.pdf CMS on 11/24/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-11-24/pdf/2014-27756.pdf CMS on 2/6/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-06/pdf/2015-02413.pdf	
52.j.	**Moratoria on Enrollment of Ambulances and HHAs** **ACTION: Notice**	CMS-6046-N CMS-6047-N CMS-6059-N2 CMS-6059-	Issue Date: 2/4/2014 Due Date: None		**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	

Ref. #	Short Title/Current Status of Regulation/Title/ 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, Medicaid, and CHIP: Announcement of New and Extended Temporary Moratoria on Enrollment of Ambulances and Home Health Agencies **AGENCY:** CMS	N3	NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension notice 8/1/2014, 2/2/2015, 7/27/2015		**SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 8/1/2014 issued a document (CMS-6047-N) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies (HHAs) in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2014-08-01/pdf/2014-18174.pdf CMS on 2/2/2015 issued a document (CMS-6059-N2) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies (HHAs) in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2015-02-02/pdf/2015-01696.pdf CMS on 7/27/2015 issued a document (CMS-6059-N3) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies, subunits, and branch locations in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2015-07-28/pdf/2015-18327.pdf	
52.I.	**Home Health Agency Conditions of Participation** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies **AGENCY:** CMS	CMS-3819-P	Issue Date: 10/9/2014 Due Date: ~~12/8/2014~~ 1/7/2015 NIHB File Date: None Date of		**SUMMARY OF AGENCY ACTION:** This proposed rule would revise the current conditions of participation (CoPs) that home health agencies (HHAs) must meet to participate in the Medicare and Medicaid programs. The proposed requirements would focus on the care delivered to patients by home health agencies, reflect an interdisciplinary view of patient care, allow home health agencies greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes would serve as an integral part of an overall CMS effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while eliminating unnecessary procedural burdens on providers.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Subsequent Agency Action, if any: Issued due date extension 12/1/2014		**SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 12/1/2014 issued a notice (CMS-3819-N) that extends the comment period for the proposed rule titled "Conditions of Participation for Home Health Agencies" and published in the 10/9/2014 FR (79 FR 61164). This notice extends the comment period for the proposed rule, which would have ended on 12/8/2014, for 30 days. http://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-28266.pdf	
52.n.	**OASIS-C1/ICD-10 ACTION: Request for Comment** **NOTICE:** Outcome and Assessment Information Set (OASIS) OASIS-C1/ICD-10 **AGENCY:** CMS	CMS-10545	Issue Date: 1/9/2015 Due Date: 3/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/25/2015 Due Date: 4/24/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Outcome and Assessment Information Set (OASIS) OASIS-C1/ICD-10; *Use*: Home health agencies (HHAs) must collect the outcome and assessment information data set (OASIS) to participate in the Medicare program. CMS requests a new OMB control number for the proposed revised OASIS item set, referred to hereafter as OASIS-C1/ICD-10. OMB on 10/7/2014 approved the current version of the OASIS-C1/ICD-9 data set (OMB 0938-0760), which will remain in use until the implementation of the ICD-10 coding system, currently scheduled for 10/1/2015. http://www.gpo.gov/fdsys/pkg/FR-2015-01-09/pdf/2015-00175.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF AGENCY ACTION:** CMS on 3/25/2015 issued a new version of this PRA request. Subsequent to the publication of the 60-day notice in the 1/9/2015 FR (80 FR 1419), CMS has made a minor typographical correction to the data set. http://www.gpo.gov/fdsys/pkg/FR-2015-03-25/pdf/2015-06884.pdf	
52.o.	**Conditions of Participation for Home Health Agencies** **ACTION: Request for**	CMS-10539	Issue Date: 4/24/2015 Due Date:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies (HHAs); *Use*: Section 1861(o) of the Social Security Act (Act) specifies certain conditions of participation (CoPs) that a home health agency must meet 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.
	Comment **NOTICE:** Conditions of Participation for Home Health Agencies (HHAs) **AGENCY:** CMS		6/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 7/2/2015 **Due Date: 8/3/2015**		participate in the Medicare program. Existing regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program also must meet the Medicare CoPs. In particular, section 1861(o)(6) of the Act requires an HHA to meet the CoPs specified in section 1891(a) of the Act and such other CoPs as the HHS Secretary finds necessary in the interest of the health and safety of patients. Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable Federal, State, and local laws. Under the authority of sections 1861(o), 1871 and 1891 of the Act, the HHS Secretary proposes to establish in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements would appear in 42 CFR 484 as Conditions of Participation for Home Health Agencies. The CoPs apply to an HHA as an entity as well as the services furnished to each individual under the care of the HHA, unless a condition remains specifically limited to Medicare beneficiaries. Under section 1891(b) of the Act, the HHS Secretary must assure that the CoPs, and their enforcement, protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies generally conduct surveys of HHAs to determine whether they comply with the CoPs. This information collection request is associated with Home Health Agency Conditions of Participation (**see 52.I.**) published on10/9/2014. http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09592.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/2/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-02/pdf/2015-16281.pdf	
52.p.	**Home Health PPS Rate Update for CY 2016, et al.**	CMS-1625-P	Issue Date: 7/10/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would update Home Health Prospective Payment System (HH PPS) rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Proposed Rule **NOTICE:** Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements **AGENCY:** CMS		**Due Date: 9/4/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		supply (NRS) conversion factor under the Medicare PPS for home health agencies (HHAs), effective for episodes ending on or after January 1, 2016. As required by ACA, this proposed rule implements the third year of the four-year phase-in of the rebasing adjustments to the HH PPS payment rates. This proposed rule provides information on CMS efforts to monitor the potential impacts of the rebasing adjustments. This rule also proposes: • Reductions to the national, standardized 60-day episode payment rate in CY 2016 and CY 2017 of 1.72 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (nominal case-mix growth) between CY 2012 and CY 2014; • **An home health value-based purchasing (HHVBP) model to begin January 1, 2016, in which all Medicare-certified HHAs in selected states must participate;** • Changes to the home health quality reporting program requirements; and • Minor technical regulations text changes. Finally, this proposed rule would update the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking and provide an update on the Report to Congress regarding the home health study. **SUMMARY OF NIHB ANALYSIS:** This proposed rule would implement significant payment reforms. In a recent *Modern Healthcare* article, HHAs criticized this proposed rule, which they said would reduce Medicare payments by about $350 million. This proposed rule includes the third year of a four-year phased "rebasing" of the standardized 60-day home care episode rate, as required by ACA, to recover several years of overpayments, as well as an additional 1.72 percent reduction in the standard episode rate in 2016 and 2017 to account for "nominal" growth in case-mix intensity. In addition, this proposed rule outlines the 2016 launch a new value-based purchasing system required by ACA. Under the program, CMS would apply a 5 percent annual payment reduction or increase for HHAs in nine randomly selected states, with the payment adjustment to increase to 8 percent in later years. HHAs deny that they have received overpayments and counter that they help hold down	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					overall health care costs by keeping beneficiaries out of the hospital. According to the Visiting Nurse Associations of America, the rebasing will leave HHAs with a -9.77 percent margin on Medicare patients. The complete article is available at http://www.modernhealthcare.com/article/20150707/NEWS/150709949?utm_source=modernhealthcare&utm_medium=email&utm_content=20150707-NEWS-150709949&utm_campaign=financedaily. CMS will identify the randomly selected states using the following process: In § 484.310, CMS proposes to codify the names of the states selected utilizing a proposed methodology, with one state selected from each of nine groupings. For each of these groupings, CMS proposes to use state borders to demarcate which Medicare certified HHAs would have to compete in this model. The selected states currently include: **Massachusetts** from Group 1, **Maryland** from Group 2, **North Carolina** from Group 3, **Florida** from Group 4, **Washington** from Group 5, **Arizona** from Group 6, **Iowa** from Group 7, **Nebraska** from Group 8, and **Tennessee** from Group 9. CMS stated, "Thus, if our methodology is finalized as proposed, all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee will be required to compete in this model. **However, should the methodology we propose in this rule change as a result of comments received during the rulemaking process, it could result in different states being selected for the model. In such an event, we would apply the final methodology and announce the selected states in the final rule**" (80 FR 39873).	
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:** **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:			
60.k.	**Application for Qualified Entity to Receive Medicare Data** **ACTION: Request for Comment** **NOTICE:** Application to Be a Qualified Entity to Receive Medicare Data for Performance Measurement **AGENCY:** CMS	CMS-10394	Issue Date: 9/8/2014 Due Date: 11/4/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 4/20/2015 Due Date: 5/20/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Application to Be a Qualified Entity to Receive Medicare Data for Performance Measurement; *Use*: Section 10332 of ACA requires the HHS Secretary to make standardized extracts of Medicare claims data under Parts A, B, and D available to "qualified entities" for the evaluation of the performance of providers of services and suppliers. The statute provides the HHS Secretary with discretion to establish criteria to determine whether an entity can use claims data to evaluate the performance of providers of services and suppliers. CMS at section 42 CFR 401.703 seeks to evaluate an organization for eligibility across three areas: Organizational and governance capabilities, addition of claims data from other sources (as required in the statute), and data privacy and security. CMS-10394 servers as the application through which organizations will provide information to CMS to determine whether they will receive approval as a qualified entity. http://www.gpo.gov/fdsys/pkg/FR-2014-09-05/pdf/2014-21180.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 4/20/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-20/pdf/2015-09009.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.
62.	**External Quality Review of Medicaid MCOs** **ACTION: Request for Comment** **NOTICE:** External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs) and Supporting Regulations **AGENCY:** CMS	CMS-R-305	Issue Date: 5/31/2012 Due Date: 7/2/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/19/2014, 4/10/2015 Due Date: 2/17/2015; 5/11/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: External Quality Review Protocols; *Use*: States will use the results of Medicare reviews, Medicare accreditation services, and Medicaid external quality reviews to assess the quality of care provided to Medicaid beneficiaries by managed care organizations and to provide information on the quality of care provided to the general public upon request. CMS has revised Protocols 1, 2, 3, 4, 5, 7, and the External Quality Review Background since the publication of the 60-day notice in the 2/17/2012 FR (77 FR 9661). **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 12/19/2014 issued an extension of this PRA request. According to CMS, state agencies must provide to the EQR organization (EQRO) information obtained through methods consistent with the protocols specified by CMS. The EQRO uses this information to determine the quality of care furnished by an MCO. In addition, Medicaid/CHIP enrollees and potential enrollees use this information to make informed choices regarding the selection of their providers. **It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid/CHIP MCOs**. States use this information during their oversight of these organizations. http://www.gpo.gov/fdsys/pkg/FR-2014-12-19/pdf/2014-29741.pdf CMS on 4/10/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-10/pdf/2015-08288.pdf No comments recommended.	
64.c.	**Tribal Consultation Policy** **ACTION: Notice** **NOTICE:** Tribal Consultation Policy	Treasury (no reference number)	Issue Date: 12/3/2014 Due Date: 4/2/2015	NIHB response:	**SUMMARY OF AGENCY ACTION:** This notice announces an interim policy outlining the guiding principles for all Department of Treasury (Treasury) bureaus and offices engaging with tribal Governments on matters with tribal implications. Treasury will update the policy periodically and refine it as needed to reflect ongoing engagement and collaboration with tribal partners.	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: Treasury		NIHB File Date: 4/2/2015 Date of Subsequent Agency Action, if any:		http://www.gpo.gov/fdsys/pkg/FR-2014-12-03/pdf/2014-28383.pdf **SUMMARY OF NIHB ANALYSIS:** To their credit, the Department of Treasury and IRS recently have taken actions of great benefit to Indian country as a result of consulting with groups such as NIHB and its Medicare-Medicaid Policy Committee, but many issues remain outstanding, particularly those involving the employer shared responsibility requirement under ACA.	
66.c.	**Additional Requirements for Charitable Hospitals** **ACTION: Final Rule** **NOTICE:** Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return **AGENCY:** IRS	TD 9708 **See also 66.a. and 66.b.**	Issue Date: 12/31/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued corrections 3/11/2015, 5/4/2015		**SUMMARY OF AGENCY ACTION:** This document contains final regulations that provide guidance regarding the requirements for charitable hospital organizations added by ACA. These final regulations will affect charitable hospital organizations. These final regulations provide guidance on the requirements described in section 501(r), the entities that must meet these requirements, and the reporting obligations relating to these requirements under section 6033. In addition, the final regulations provide guidance on the consequences described in sections 501(r)(1), 501(r)(2)(B), and 4959 for failing to satisfy the section 501(r) requirements. http://www.gpo.gov/fdsys/pkg/FR-2014-12-31/pdf/2014-30525.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF AGENCY ACTION:** IRS on 3/11/2015 issued two documents that contain corrections to final regulations (TD 9708) published in the 12/31/2014 FR (79 FR 78954). As published, the final regulations contain errors that might prove misleading and need clarification. The first document makes corrections to the text of the final regulations, and the second makes corrections to 26 CFR parts 1 and 53. http://www.gpo.gov/fdsys/pkg/FR-2015-03-11/pdf/2015-05520.pdf http://www.gpo.gov/fdsys/pkg/FR-2015-03-11/pdf/2015-05519.pdf IRS on 5/4/2015 issued two documents that contain corrections to final regulations (TD 9708) published in the 12/31/2014 FR (79 FR 78954). As published, the final regulations contain errors that might prove misleading and need clarification. The first document makes corrections to the text of the final regulations, and the second makes corrections to 26 CFR part 1.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.gpo.gov/fdsys/pkg/FR-2015-05-04/pdf/2015-10341.pdf http://www.gpo.gov/fdsys/pkg/FR-2015-05-04/pdf/2015-10340.pdf	
67.g.	**FAQs on Use of 1311 Funds for Establishment Activities** **ACTION: Guidance** **NOTICE:** FAQs on the Clarification of the Use of 1311 Funds for Establishment Activities **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/8/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** CMS publishes these frequently asked questions (FAQs) to provide recipients of grants under section 1311 of ACA with further guidance on the appropriate uses of establishment grant funds after 1/1/2015. These FAQs supplement and further clarify the first two questions and answers in prior CMS guidance titled "FAQs on the Use of 1311 Funds and No Cost Extensions" and published 3/14/2014. This most recent guidance answers the following questions: • **Q1. For current Marketplace Grantees, including those who have or are applying for a No Cost Extension, are there any activities that are not allowable?** A1. Yes. Per section 1311(d)(5) of the Affordable Care Act, Marketplaces must be self-sustaining beginning January 1, 2015, and funds may not be used for ongoing operations. ... • **Q2. May Marketplace Grantees seek an extension of their grant project period?** A2. Yes, consistent with existing Department of Health and Human Services' (HHS) grant rules and policies, grantees may request No Cost Extensions (NCE) to extend the project period in order to complete establishment activities that were part of the grantees' approved work plan under a specific grant where the grantee reasonably requires additional time to complete those activities. ... http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FINAL-1311-FAQ-06-08-15.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.
70.b.	**Medicare Fee-for-Service Prepayment Medical Review** **ACTION: Request for Comment** **NOTICE:** Medicare Fee-for-Service Prepayment Medical Review **AGENCY:** CMS	CMS-10417	Issue Date: 9/21/2012 Due Date: 10/22/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/27/2015, 6/5/2015 Due Date: 4/28/2015; 7/6/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Medicare Fee-for-Service Prepayment Medical Review; *Use*: Medicare contractors request the information required under this collection to determine proper payment or suspicion of fraud. Medicare contractors request the information from providers or suppliers submitting claims for payment from the Medicare program when data analysis indicates aberrant billing patterns or other information that might present a vulnerability to the Medicare program. **SUMMARY OF NIHB ANALYSIS:** None. **SUMMARY OF AGENCY ACTION:** CMS on 2/27/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04115.pdf CMS on 6/5/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13755.pdf	
70.d.	**Revisions to PFS and Other Changes to Part B for CY 2015** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to	CMS-1612-~~P~~FC	Issue Date: 7/11/2014 Due Date: 9/2/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued	NIHB response:	**SUMMARY OF AGENCY ACTION:** is major proposed rule addresses changes to the physician fee schedule (PFS), 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. The Social Security Act (the Act) requires CMS to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. Under the Act, CMS must establish of RVUs for three categories of resources--work, practice expense (PE), and malpractice (MP) expense--and must set payment amounts each year for all physician services, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. This rule proposes RVUs for calendar year (CY 2015) for the PFS and other Medicare Part B payment policies. In addition, this proposed	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.

	Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015
	
	AGENCY: CMS
			Final Rule 11/13/2014; issued correction 12/31/2014, 3/20/2015
			
			Due Date: 12/30/2014
			
			NIHB File Date: 12/23/2014
					rule includes discussions and proposals regarding:
					
					• Mis-valued PFS Codes;
					• Telehealth Services;
					• Chronic Care Management Services;
					• Establishing Values for New, Revised, and Mis-valued Codes;
					• Updating the Ambulance Fee Schedule regulations;
					• Changes to Core-Based Statistical Areas for Ambulance Payment; and
					• Updating the:
					  o Physician Compare Web site;
					  o Physician Quality Reporting System;
					  o Medicare Shared Savings Program;
					  o Electronic Health Record (EHR) Incentive Program; and
					  o Value-Based Payment Modifier and the Physician Feedback Program.
					
					http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-15948.pdf
					
					SUMMARY OF NIHB ANALYSIS: This proposed rule includes no I/T/U-specific provisions.
					
					SUMMARY OF SUBEQUENT AGENCY ACTION: This major final rule with comment period addresses changes to the physician fee schedule (PFS) 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. This final rule addresses the following areas:
					
					• Resource-Based Practice Expense (PE) Relative Value Units (RVUs);
					• Potentially Misvalued Services Under PFS;
					• Malpractice RVUs;
					• Geographic Practice Cost Indices (GPCIs);
					• Medicare Telehealth Services;
					• Valuing New, Revised, and Potentially Misvalued Codes;
					• Establishing RVUs for CY 2015;
					• Chronic Care Management (CCM);
					• Therapy Caps for CY 2015;	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					• Definition of Colorectal Cancer Screening Tests; • Payment of Secondary Interpretation of Images; • Conditions Regarding Permissible Practice Types for Therapists in Private Practice; • Payments for Practitioners Managing Patients on Home Dialysis • Sustainable Growth Rate; • Ambulance Extender Provisions; • Changes in Geographic Area Delineations for Ambulance Payment • Clinical Laboratory Fee Schedule; • Removal of Employment Requirements for Services Furnished "Incident to" Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Visits; • Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models; • Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests; • Private Contracting/Opt-Out; • Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements; • Reports of Payments or Other Transfers of Value to Covered Recipients; • Physician Compare Web Site; • Physician Payment, Efficiency, and Quality Improvements--Physician Quality Reporting System; • Electronic Health Record (EHR) Incentive Program; • Medicare Shared Savings Program; • Value-Based Payment Modifier and Physician Feedback Program; • Establishment of the FQHC Prospective Payment System (FQHC PPS); • Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes; and • Interim Final Revisions to the EHR Incentive Program. A majority of the provisions of this regulation are in the form of final rules, but other provisions of the Final Rule that are open for comment are: A. Ambulance Extender Provisions B. Changes in Geographic Area Delineations for Ambulance Payment C. Clinical Laboratory Fee Schedule	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					D. Removal of Employment Requirements for Services Furnished "Incident to" Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Visits E. Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models F. Local Coverage Determination Process for Clinical Diagnostic Laboratory Tests G. Private Contracting/Opt-Out H. Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements I. Reports of Payments or Other Transfers of Value to Covered Recipients J. Physician Compare Web Site K. Physician Payment, Efficiency, and Quality Improvements--Physician Quality Reporting System L. Electronic Health Record (EHR) Incentive Program M. Medicare Shared Savings Program N. Value-Based Payment Modifier and Physician Feedback Program O. Establishment of the Federally Qualified Health Center Prospective Payment System (FQHC PPS) P. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes Q. Interim Final Revisions to the Electronic Health Record (EHR) Incentive Program http://www.gpo.gov/fdsys/pkg/FR-2014-11-13/pdf/2014-26183.pdf CMS on 12/31/2014 issued a document (CMS-1612-CN) to correct technical errors that appeared in the final rule with comment period published in the 11/13/2014 FR and titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015." http://www.gpo.gov/fdsys/pkg/FR-2014-12-31/pdf/2014-30663.pdf CMS on 3/20/2015 issued a document (CMS-1612-F2) to correct technical errors that appeared in the final rule with comment period published in the 11/13/2014 FR (79 FR 67547-68092) and titled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015." This final rule took effect on 1/1/.2015.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.gpo.gov/fdsys/pkg/FR-2015-03-20/pdf/2015-06427.pdf	
70.e.	**Revisions to PFS and Other Changes to Part B for CY 2016** **ACTION: Proposed Rule** **NOTICE:** Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 **AGENCY:** CMS	CMS-1631-P	Issue Date: 7/15/2015 Due Date: **9/8/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION: This major proposed rule addresses changes to the physician fee schedule (PFS) and other Medicare Part B payment policies to ensure that CMS payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.** The Social Security Act (Act) requires CMS to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires CMS to establish RVUs for three categories of resources--work, practice expense (PE); and malpractice (MP) expense--and each year establish by regulation payment amounts for all physician services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. This proposed rule would establish RVUs for CY 2016 for the PFS and other Medicare Part B payment policies. In addition, this proposed rule includes discussions and proposals regarding: • Potentially misvalued PFS codes; • Telehealth services; • Advance care planning services; • Establishing values for new, revised, and misvalued codes; • Target for relative value adjustments for misvalued services; • Phase-In of significant RVU reductions; • "Incident to" policy; • Portable x-ray transportation fee; • Updating the ambulance fee schedule regulations; • Changes in geographic area delineations for ambulance payment; • Chronic care management services for RHCs and FQHCs; • HCPCS coding for RHCs; • Payment to grandfathered tribal federally qualified health centers (FQHCs) that existed as provider-based clinics on or before April 7, 2000; • Payment for biosimilars under Medicare Part B;	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					• Physician Compare Web site; • Physician Quality Reporting System; • Medicare Shared Savings Program; • Electronic Health Record (EHR) Incentive Program; and • Value-based payment modifier and the Physician Feedback Program. http://www.gpo.gov/fdsys/pkg/FR-2015-07-15/pdf/2015-16875.pdf **SUMMARY OF NIHB ANALYSIS: In response to concerns raised by TTAG, this proposed rule includes a provision under which tribal facilities that were grandfathered in as Medicare provider-based entities on or before April 7, 2000, and that subsequently had a change of status from IHS-operated to tribal-operated, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital such that the organization no longer meets the Medicare conditions of participation to become certified as grandfathered tribal FQHCs.** **Under the authority in section 1834(o) of ACA to "include adjustments ... determined appropriate by the HHS Secretary," CMS proposes that these grandfathered tribal FQHCs receive payments of the lesser of their charges or a grandfathered tribal FQHC PPS rate of $307, which equals the Medicare outpatient per visit payment rate paid to them as a provider-based department, as set annually by IHS, rather than the FQHC PPS per visit base rate of $158.85, with coinsurance equal to 20 percent of the lesser of the actual charge or the grandfathered tribal FQHC PPS rate**. These grandfathered tribal FQHCs would have to meet all FQHC certification and payment requirements. This FQHC PPS adjustment for grandfathered tribal clinics would not apply to a currently certified tribal FQHC, a tribal clinic that was not provider-based as of April 7, 2000, or an IHS-operated clinic that is no longer provider-based to a tribally-operated hospital. This provision also would not apply in cases in which both the hospital and its provider-based clinic(s) are tribally-operated. A recent *Modern Healthcare* article reported on several key provisions in this proposed rule. A summary appears below. **Telehealth**: This proposed rule would revise the Medicare telehealth policy to include	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					payments for in-home treatments for end-stage renal disease, although requiring an in-person clinical examination of the catheter-access site by a physician, certified nurse specialist, nurse practitioner, or physician assistant. In addition, this proposed rule would add certified registered nurses anesthetists to the list of qualified telehealth providers for certain services, including evaluation and management. CMS also seeks comments on how to better pay for collaborative care consultations between primary care physicians and specialists requiring "extensive discussion, information-sharing, and planning." CMS rejected requests to include payments for telehealth evaluation and management, tele-rehabilitation services, palliative care, pain management, and patient-navigation services for cancer patients. **Quality incentive programs**: This proposed rule would make a number of changes to the Physician Quality Reporting System, the incentive program for the meaningful use of electronic health records, and the value-based payment modifier--all of which would become components of a new Merit-Based Incentive Payment System. This proposed rule also would establish several new Medicare Physician Compare Web site components, including a green check mark next to the name of providers that received an upward adjustment for cost and quality. In addition, CMS seeks comments on whether to expand the Comprehensive Primary Care Initiative. **Advance care planning**: This proposed rule includes a provision that would establish two new advance care planning codes in Medicare beginning in 2016. Providers would use the codes when discussing patient choices for advance directives and completing necessary forms--one code for the first 30 minutes and a second code for additional 30-minute periods. However, this proposed rule would not set values for these codes, and according to CMS, this provision "does not mean that Medicare has made a national coverage determination regarding the service." CMS also could make advance care planning "an optional element" of the annual beneficiary wellness visit. The complete article is available at http://www.modernhealthcare.com/article/20150708/NEWS/150709923?utm_source=modernhealthcare&utm_medium=email&utm_content=20150708-NEWS-150709923&utm_campaign=mh-alert.	
71.m.	**Medicare ESRD PPS,**	CMS-1614-	Issue Date:		**SUMMARY OF AGENCY ACTION:** This rule proposes to update and make revisions to	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Quality Incentive Program, and DMEPOS **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies **AGENCY:** CMS	~~PF~~	7/11/2014 Due Date: 9/2/2014 NIHB File Date: Date of Subsequent Agency Action, if any: Issued Final Rule 11/6/2014; issued correction 3/13/2015		the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. This rule also proposes to set forth requirements for the ESRD quality incentive program (QIP), including payment years (PYs) 2017 and 2018. In addition, this rule proposes to make a technical correction to remove outdated terms and definitions. Further, this rule proposes to: • **Set forth the methodology for adjusting Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP);** • Make alternative payment rules for DME and enteral nutrition under the Medicare DMEPOS CBP; • Clarify the statutory Medicare hearing aid coverage exclusion and specify devices not subject to the hearing aid exclusion; • Update the definition of minimal self-adjustment regarding the specialized training that suppliers need to provide custom fitting services if they do not have certification as orthotists; • Clarify the Change of Ownership (CHOW) and provide for an exception to the current requirements; • Revise the appeal provisions for termination of a contract and notification to beneficiaries under the Medicare DMEPOS CBP; and • Add a technical change related to submitting bids for infusion drugs under the Medicare DMEPOS CBP. http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-15840.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBEQUENT AGENCY ACTION:** This final rule will update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. This rule also finalizes requirements for the ESRD quality incentive program (QIP), including for payment years (PYs) 2017 and 2018. This final rule also will make a technical correction to remove outdated terms and definitions. In addition, this final rule: • Sets forth the methodology for adjusting Durable Medical Equipment,	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP); • Makes alternative payment rules for certain DME under the Medicare DMEPOS CBP; • Clarifies the statutory Medicare hearing aid coverage exclusion and specifies devices not subject to the hearing aid exclusion; • Will not update the definition of minimal self-adjustment; • Clarifies the Change of Ownership (CHOW) and provides for an exception to the current requirements; • Revises the appeal provisions for termination of a CBP contract, including the beneficiary notification requirement under the Medicare DMEPOS CBP; and • Makes a technical change to the regulation related to the conditions for awarding contracts for furnishing infusion drugs under the Medicare DMEPOS CBP. http://www.gpo.gov/fdsys/pkg/FR-2014-11-06/pdf/2014-26182.pdf CMS on 3/13/2015 issued a document (CMS-1614-CN) to correct technical errors that appeared in the final rule published in the 11/6/2014 FR (79 FR 66120) and titled "End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies." On page 66184 of the preamble, CMS has found errors in the performance standard, achievement threshold, and benchmark values presented in the Numerical Values for the Performance Standards for the Payment Year (PY) 2017 End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) Clinical Measures Using the Most Recently Available Data table for PY 2017 of the ESRD QIP (Table 23). Specifically, CMS calculated the numerical values published for the Standardized Readmission Ratio clinical measure using only 6 months of data from calendar year 2013 instead of the full 12 months, as specified under its finalized policy (79 FR 66183). This technical correction ensures that these numerical standards align with the finalized policies for the PY 2017 ESRD QIP. http://www.gpo.gov/fdsys/pkg/FR-2015-03-13/pdf/2015-05766.pdf	
71.n.	Medicare ESRD PPS and Quality Incentive Program	CMS-1628-P	Issue Date: 7/1/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2016. The proposals in this rule would ensure that ESRD facilities	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Proposed Rule **NOTICE:** Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program **AGENCY:** CMS		Due Date: 8/25/2015 NIHB File Date: Date of Subsequent Agency Action, if any:		receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during CY 2016. **This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP) for CY 2016.** In an effort to incentivize ongoing quality improvement among eligible providers, the ESRD QIP proposes to establish and revise requirements for quality reporting and measurement, including the inclusion of new quality measures for payment year (PY) 2019 and beyond and updates to programmatic policies for the PY 2017 and PY 2018 ESRD QIP. http://www.gpo.gov/fdsys/pkg/FR-2015-07-01/pdf/2015-16074.pdf **SUMMARY OF NIHB ANALYSIS:** This proposed rule would implement an incentive payment adjustment for ESRD services.	
72.e.	**PPS and Consolidated Billing for SNFs for FY 2016, et al.** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection **AGENCY:** CMS	CMS-1622-~~P~~F	Issue Date: 4/20/2015 Due Date: 6/19/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 7/29/2015		**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 2016. In addition, it includes a proposal to specify a SNF all-cause, all-condition hospital readmission measure, as well as a proposal to adopt that measure for a new SNF Value-Based Purchasing (VBP) Program and a discussion of SNF VBP Program policies under consideration for future rulemaking to promote higher quality and more efficient health care for Medicare beneficiaries. Additionally, this proposed rule would implement a new quality reporting program for SNFs as specified in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). It also would amend the requirements that a long-term care (LTC) facility must meet to qualify to participate as an SNF in the Medicare program or a nursing facility (NF) in the Medicaid program. These requirements would implement the provision in ACA regarding the submission of staffing information based on payroll data. http://www.gpo.gov/fdsys/pkg/FR-2015-04-20/pdf/2015-08944.pdf **SUMMARY OF NIHB ANALYSIS:**	
72.f.	**Skilled Nursing Facility**	CMS-10387	Issue Date:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection 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.
	PPS and Consolidated Billing **ACTION: Request for Comment** **NOTICE:** Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing **AGENCY:** CMS		7/21/2015 **Due Date: 9/21/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		Reinstatement of a previously approved collection; *Title*: Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing; *Use*: CMS seeks approval of a reinstatement of a Change of Therapy OMRA for Skilled Nursing Facilities (SNFs). As described in CMS-1351-F, CMS finalized the assessment effective 10/1/2011. SNFs must submit this assessment. The COT OMRA includes a subset of resident assessment information developed for use by SNFs to satisfy a Medicare payment requirement. The burden associated with this involves the SNF staff time required to complete the COT OMRA, SNF staff time to encode the data, and SNF staff time spent in transmitting the data. SNFs must complete a COT OMRA when a resident receives a sufficient level of rehabilitation therapy to qualify for an Ultra High, Very High, High, Medium, or Low Rehabilitation category and when the intensity of therapy (as indicated by the total reimbursable therapy minutes (RTM) delivered and other therapy qualifiers, such as number of therapy days and disciplines providing therapy) changes to such a degree that it would no longer reflect the RUG-IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. The COT OMRA, a type of required PPS assessment, uses the same item set as the End of Therapy (EOT) OMRA. http://www.gpo.gov/fdsys/pkg/FR-2015-07-21/pdf/2015-17824.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended.	
77.d.	**National Provider Identifier Application and Update Form** **ACTION: Request for Comment** **NOTICE:** National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408	CMS-10114	Issue Date: 9/12/2014 Due Date: 11/12/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408; *Use*: Health care providers use the National Provider Identifier (NPI) Application and Update Form to apply for NPIs and furnish updates to the information they supplied on their initial applications, as well as to deactivate their NPIs if necessary. CMS has revised the NPI Application/Update form to provide additional guidance on how to complete the form accurately. This collection includes clarification on information required on applications/changes. Minor changes on the application/update form include adding a "Subpart" check box in the Other Name section and a revision within the PRA Disclosure Statement. This collection also includes changes to the instructions. http://www.gpo.gov/fdsys/pkg/FR-2014-09-12/pdf/2014-21798.pdf	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	AGENCY: CMS		extension 11/21/2014, 1/16/2015 Due Date: 12/22/2014; 2/17/2015		**SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF AGENCY ACTION:** CMS on 11/21/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-11-21/pdf/2014-27640.pdf CMS on 1/16/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-16/pdf/2015-00626.pdf	
77.e.	**Requirements for the Health Plan Identifier** **ACTION: Request for Information** **NOTICE:** Request for Information Regarding the Requirements for the Health Plan Identifier **AGENCY:** CMS	CMS-0026-NC	Issue Date: 5/29/2015 **Due Date: 7/28/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This request for information seeks public comment regarding the health plan identifier (HPID), including the requirements regarding health plan enumeration and the requirement to use the HPID in electronic health care transactions. http://www.gpo.gov/fdsys/pkg/FR-2015-05-29/pdf/2015-13047.pdf **SUMMARY OF NIHB ANALYSIS:**	
78.h.	**Wage Index and Payment Rates for Hospices for FY 2015, et al.** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Medicare Program;	CMS-1609-~~P~~F	Issue Date: 5/8/2014 Due Date: 7/1/2014 NIHB File Date: None		**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 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	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	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		<u>Date of Subsequent Agency Action, if any:</u> Issued Final Rule 8/22/2014; issued correction 4/30/2015		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:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This final rule will update the hospice payment rates and the wage index for fiscal year (FY) 2015 and continue the phase-out of the wage index budget neutrality adjustment factor (BNAF). This rule provides an update on hospice payment reform analyses, potential definitions of "terminal illness" and "related conditions," and information on potential processes and appeals for Part D payment for drugs while beneficiaries are under a hospice election. This rule will specify timeframes for filing the notice of election and the notice of termination/revocation; add the attending physician to the hospice election form and require hospices to document changes to the attending physician; require hospices to complete their hospice aggregate cap determinations within 5 months after the cap year ends and remit any overpayments; and update the hospice quality reporting program. <u>**In addition, this rule provides 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 hospice reporting of diagnoses on hospice claims.**</u> Finally, the rule will make a technical regulation text change. **Note:** The underlined statement above references two sections of this final rule: • **Section III.C.**, which provides guidance on determining Medicare beneficiary eligibility for hospice (CMS notes that this discussion only provides background information regarding current procedures for determining eligibility for hospice services under the Medicare hospice benefit and beneficiary appeal rights); 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.
					• **Section III.J.**, which discusses the delay in the implementation of ICD-10-CM and clarifies appropriate diagnosis reporting on hospice claims per ICD-9-CM Coding Guidelines (CMS notes that it will return claims to the provider if the claim listed a non-specific symptom diagnosis as the principal hospice diagnosis). http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-18506.pdf CMS on 4/30/2014 issued a document (CMS-1609-CN) to correct technical errors that appeared in the final rule published in the 8/22/2014 FR (79 FR 50451) and titled "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." This document makes the following corrections: 1. On page 50492, in Table 8--"Hospice Experience of Care Survey Quality Measures and Their Items", after the quality measure description of "Getting help for Symptoms" and before the quality measure description of "Information Continuity" add the following quality measure description to read as follows: **Providing Support for Religious and Spiritual Beliefs** (Support for religious or spiritual beliefs includes talking, praying, quiet time, or other ways of meeting your religious or spiritual needs.) While your family member was in hospice care, how much support for your religious or spiritual beliefs did you get from the hospice team? 2. On page 50493, in Table 9--Data Submission Dates 2015-1016 For CAHPS Hospice Survey, under the quarterly data submission deadline column the date "November 1, 2015" is corrected to read "November 11, 2015". http://www.gpo.gov/fdsys/pkg/FR-2015-04-30/pdf/2015-10169.pdf	
78.i.	**Prior Authorization Form for Beneficiaries Enrolled in Hospice**	CMS-10538	Issue Date: 10/3/2014		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Prior Authorization Form for Beneficiaries Enrolled in Hospice; *Use*: The prescriber or hospice (or the Part D sponsor, if the prescriber or hospice provides the	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Request for Comment **NOTICE:** Prior Authorization Form for Beneficiaries Enrolled in Hospice **AGENCY:** CMS		Due Date: 12/2/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 1/23/2015 Due Date: 2/23/2015		information verbally) of the beneficiary would complete the form. The Part D sponsor would use the Information provided on the form to establish coverage of the drug under Medicare Part D. Per statute, drugs necessary for the palliation and management of the terminal illness and related conditions do not qualify for payment under Part D. The standard form provides a vehicle for the hospice provider, prescriber, or sponsor to document that the drug prescribed is "unrelated" to the terminal illness and related conditions. It also gives a hospice organization the option to communicate a change in the hospice status and care plan of the beneficiary to Part D sponsors. http://www.gpo.gov/fdsys/pkg/FR-2014-10-03/pdf/2014-23613.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF AGENCY ACTION:** CMS on 1/23/2015 issued a new version of this PRA request. CMS has revised this package subsequent to the publication of the 60-day notice in 10/3/2014 FR (79 FR 59772). http://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01127.pdf	
78.j.	**Hospice Rate Update for FY 2016** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Medicare Program; FY 2016 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements **AGENCY:** CMS	CMS-1629-~~PF~~	Issue Date: 5/5/2015 Due Date: 6/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Final Rule approved by OMB 7/29/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would update the hospice payment rates and the wage index for FY 2016, including implementing the last year of the phase-out of the wage index budget neutrality adjustment factor (BNAF). This proposed rule also discusses recent hospice payment reform research and analyses and proposes to differentiate payments for routine home care (RHC) based on the beneficiary length of stay and to implement a service intensity add-on (SIA) payment for services provided in the last 7 days of the life of a beneficiary, under certain conditions. In addition, this rule would implement changes to the aggregate cap calculation mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the federal fiscal year starting in FY 2017, make changes to the hospice quality reporting program, and include a clarification regarding diagnosis reporting on the hospice claim. http://www.gpo.gov/fdsys/pkg/FR-2015-05-05/pdf/2015-10422.pdf **SUMMARY OF NIHB ANALYSIS:**	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
78.k.	**Hospice Survey and Deficiencies Report Form** **ACTION: Request for Comment** **NOTICE:** Hospice Survey and Deficiencies Report Form and Supporting Regulations **AGENCY:** CMS	CMS-643	Issue Date: 6/19/2015 **Due Date: 8/18/2015** 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*: Hospice Survey and Deficiencies Report Form and Supporting Regulations; *Use*: CMS uses the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and State Medicaid agencies, which have comparable authority under Medicaid, use the information. The information on the Hospice Survey and Deficiencies Report Form gets coded for entry into the OSCAR system. The CMS regional offices and the CMS central office components analyze the data for program evaluation and monitoring purposes. The public can access the information upon request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-19/pdf/2015-15126.pdf **SUMMARY OF NIHB ANALYSIS:**	
83.b.	**Claims Processing and Information Retrieval Systems** **ACTION: Proposed Rule** **NOTICE:** Medicaid Program; Mechanized Claims Processing and Information Retrieval Systems (90/10) **AGENCY:** CMS	CMS-2392-P	Issue Date: 4/16/2015 Due Date: 6/15/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would extend enhanced funding for Medicaid eligibility systems as part of a state mechanized claims processing system and would update conditions and standards for such systems, including adding to and updating current Medicaid Management Information System (MMIS) conditions and standards. These changes would allow states to improve customer service and support the dynamic nature of Medicaid eligibility, enrollment, and delivery systems. This proposed rule would make changes to CFR part 42, §§ 433.110, 433.111, 433.112, 433.116, 433.119, and 433.120, which provide for the 90 percent enhanced federal financial participation (FFP) for design, development, and implementation activities for Medicaid eligibility and enrollment (E&E) systems to continue on an ongoing basis. The proposed changes would allow states to complete fully modernized E&E systems and would support the dynamics of national Medicaid enrollment and delivery system needs. The changes also would set forth additional criteria for the submission, review, and approval of Advance Planning Documents (APDs).	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					In addition, this proposed rule would make changes to provisions within 45 CFR part 95, subpart F, § 95.611. These changes would align all Medicaid IT requirements with existing policy for MMIS pertaining to prior approvals when states release acquisition solicitation documents or execute contracts above a certain threshold amounts. In addition, this proposed rule would amend § 95.611(a)(2) by removing the reference to 45 CFR 1355.52. http://www.gpo.gov/fdsys/pkg/FR-2015-04-16/pdf/2015-08754.pdf **SUMMARY OF NIHB ANALYSIS:** Tribal representatives might wish to make recommendations related to ensuring (1) I/T/U are paid correctly; (2) AI/AN enrollees/IHS beneficiaries are identified and receive the correct cost-sharing protections; and (3) AI/AN and I/T/U-related data are made available in a useable format.	
89.h.	**Notice of Benefit and Payment Parameters for 2016** **ACTION:** ~~Proposed~~ Final Rule **NOTICE:** Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 **AGENCY:** CMS	CMS-9944-~~P~~F	Issue Date: 11/26/2014 Due Date: 12/22/2014 TTAG File Date: 12/22/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 2/27/2015	TTAG response:	**SUMMARY OF AGENCY ACTION:** This proposed rule would set forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-Facilitated Exchanges. It also would provide additional standards for the annual open enrollment period for the individual market for benefit years beginning on or after 1/1/2016, essential health benefits, qualified health plans, network adequacy, quality improvement strategies, the Small Business Health Options Program, guaranteed availability, guaranteed renewability, minimum essential coverage, the rate review program, the medical loss ratio program, and other related topics. http://www.gpo.gov/fdsys/pkg/FR-2014-11-26/pdf/2014-27858.pdf A fact sheet on this proposed rule is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Fact-Sheet-11-20-14.pdf **SUMMARY OF NIHB ANALYSIS:** This proposed rule might provide an opportunity to revisit the CMS regulation on cost-sharing protections for AI/ANs as it pertains to families with AI/AN and non-AI/AN members. A draft memo from Mim Dixon is embedded below.	See Table C.

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Memo re New Strategy for Definitio <u>Detailed analysis:</u> **This proposed rule addresses, at least in part, two recommendations made by tribal representatives:** 1. **CMS is placing in regulations the requirement contained in the 2015 Issuer Letter whereby issuers are to offer contracts to all Indian health care providers in the QHP's service area. The exact language of the provision (shown below from the preamble to the proposed rule and the proposed regulatory language) might need adjustment.** Requirement to offer to contract <u>PREAMBLE: Essential Community Providers</u>: "**The rule proposes to codify the standard** used for 2015 for the FFM, that issuers seeking qualified health plan certification in the FFM subject to the general essential community provider standard would be required to offer provider contracts to: (a) all available Indian health providers in the service area; and (b) at least one essential community provider in each essential community provider category (i.e., Federally Qualified Health Clinics, Ryan White providers, family planning providers, hospitals, and others) in each county in the service area, where a provider in that category is available." PROPOSED REGULATION: "(ii) The issuer of the plan offers contracts to-- (A) All available Indian health providers in the service area, applying the special terms and conditions necessitated by federal law and regulations as referenced in the recommended model QHP addendum for Indian health providers developed by HHS…" [§ 155.235(a)(2)(ii)] 2. **CMS also is establishing a requirement on issuers to issue a Summary of Benefits and Coverage for each plan variation.** Requirement to issue Summary of Benefits and Coverage (SBC)	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					PREAMBLE: "While individual health insurance issuers (including QHP issuers) must provide an SBC for each benefit package, current regulations do not specifically address an issuer's responsibilities to provide an SBC reflecting a QHP with cost-sharing reductions applied, known as a plan variation of the QHP. Consequently, a consumer who is eligible for cost-sharing reductions may receive an SBC that does not accurately represent the cost sharing he or she will be responsible for when receiving essential health benefits. Under the authority stated above, we propose to amend § 156.420 to add § 156.420(h) and require QHP issuers to provide SBCs that accurately represent plan variations in a manner consistent with the requirements set forth at § 147.200 to ensure that consumers have access to SBCs that accurately represent cost-sharing responsibilities for all coverage options, including plan variations, and are provided adequate notice of the plan variations." PROPOSED REGULATION: **§ 156.420 Plan variations.** * * * * * (h) *Notice.* No later than the first day of the Exchange open enrollment period for the 2016 benefit year, for each plan variation that an issuer offers in accordance with the rules of this section, an issuer must provide a summary of benefits and coverage that accurately represents each plan variation consistent with the requirements set forth in § 147.200 of this subchapter." 3. **The proposed rule also codifies the exemption process for the hardship exemption from the tax penalty for IHS-eligible persons.** [§ 155.605(g)(6)(iii)] 4. **The proposed rule also corrects a subsection reference in order to refer to the definition of Indian under Medicaid (the subsection that was recently changed.)** PREAMBLE: "Second, we propose amending § 155.605(g)(6)(i) to correct the citation to 42 CFR 447.50 by changing it to 42 CFR 447.51, which cross-references the Medicaid definition for Indian." A list of select provisions in the proposed rule is attached. Select Provisions in CMS-9944 2014-12-	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Also attached is a copy of the tribal recommendations on requiring issuers to provide a SBC (Summary of Benefits and Coverage) for each (Indian-specific) plan variation. TTAG Letter to CCIIO - QHPs and AI **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This final rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-Facilitated Exchanges. It also finalizes additional standards for the individual market annual open enrollment period for the 2016 benefit year, essential health benefits, qualified health plans, network adequacy, quality improvement strategies, the Small Business Health Options Program, guaranteed availability, guaranteed renewability, minimum essential coverage, the rate review program, the medical loss ratio program, and other related topics. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf A CCIIO fact sheet on this final rule is available at http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2016-PN-Fact-Sheet-final.pdf.	
89.i.	**Information Collection for Machine-Readable Data for QHPs** **ACTION: Request for Comment** **NOTICE:** Information Collection for Machine-Readable Data for Provider Network and Prescription	CMS-10558	Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: None Date of Subsequent		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs; *Use*: For plan years beginning on or after 1/1/2016, qualified health plan (QHP) issuers must make available provider and formulary data in a machine-readable format. As required by the final rule titled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016" (CMS-9944-F) and published in the 2/27/2015 FR (80 FR 10750), QHP issuers in the Federally-Facilitated Marketplaces (FFMs) must publish information regarding their formulary drug lists and provider directories on their Web site in an HHS-specified format at times determined by HHS.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Formulary Content for FFM QHPs **AGENCY:** CMS		Agency Action, if any: Issued new request 6/26/2015 Due Date: 7/27/2015		http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-07089.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF AGENCY ACTION:** CMS on 6/26/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-26/pdf/2015-15770.pdf No comments recommended.	
89.j.	**ACA Implementation FAQs (Cost-Sharing Limitations)** **ACTION: Guidance** **NOTICE:** FAQs About Affordable Care Act Implementation **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 5/26/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance, prepared jointly by HHS and the Departments of Labor and the Treasury (collectively, the Departments) answers additional Frequently Asked Questions (FAQs) regarding implementation of ACA, specifically on the issues of cost-sharing limitations and provider non-discrimination. Public Health Service (PHS) Act section 2707(b), as added by ACA, requires a non-grandfathered group health plan to ensure that any annual cost sharing imposed under the plan does not exceed the limitations provided for under section 1302(c)(1) of ACA. In the final HHS Notice of Benefit and Payment Parameters for 2016 (2016 Payment Notice), HHS clarified that under section 1302(c)(1) of ACA, the self-only maximum annual limitation on cost sharing applies to each individual, regardless of whether the individual is enrolled in self-only coverage or in coverage other than self-only. In response to this clarification, the Departments received questions regarding the application of the clarification to self-funded and large group health plans. This FAQ answers the following related questions: • **Q1. The 2016 Payment Notice clarified that under section 1302(c)(1) of the Affordable Care Act, the self-only maximum annual limitation on cost sharing applies to each individual, regardless of whether the individual is enrolled in self-only coverage or in coverage other than self-only. Does PHS Act section 2707(b) apply this requirement to all non-grandfathered group health plans?** A1. Yes. PHS Act section 2707(b) applies this requirement to all non-grandfathered group health plans, including non-grandfathered self-insured and large group health plans. ...	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					• **Q2. Does the clarification of section 1302(c)(1) of the Affordable Care Act apply for plan or policy years that begin in 2015?** A2. No. The Departments will apply this clarification only for plan or policy years that begin in or after 2016. • **Q3. Does the clarification of section 1302(c)(1) of the Affordable Care Act apply to self-only coverage or other coverage that is not self-only coverage under a high-deductible health plan (HDHP) as defined at section 223(c)(2) of the Internal Revenue Code?** A3. Yes. The clarification of section 1302(c)(1) also applies to non-grandfathered HDHPs. Regarding the issue of provider non-discrimination, PHS Act section 2706(a), as added by ACA, states that a "group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law." PHS Act section 2706(a) "shall not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer," and nothing this section prevents "a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures." Similar language appears in section 1852(b)(2) of the Social Security Act and HHS implementing regulations. On 4/29/2013, the Departments issued FAQs that addressed, among other issues, provider nondiscrimination requirements under PHS Act section 2706(a). Subsequently, the Senate Committee on Appropriations issued a report dated 7/11/2013 (to accompany S 1284) raising questions about the FAQs addressing provider nondiscrimination. The Departments published a request for information (RFI) on 3/12/2014 seeking comment on all aspects of interpretation of PHS Act section 2706(a). The RFI specifically solicited comments on access, costs, other federal and state laws, and feasibility. The Departments received more than 1,500 comments in response to the RFI. The House Committee on Appropriations subsequently issued an explanatory statement dated	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					12/11/2014 (to accompany 113 HR 83) directing CMS to provide a corrected FAQ or provide an explanation. This FAQ responds to the explanatory statement: • **Q4. What is the Departments' approach to PHS Act section 2706(a)?** A4. In light of the breadth of issues identified in the comments to the RFI, the Departments are re-stating their current enforcement approach to PHS Act section 2706(a). Until further guidance is issued, the Departments will not take any enforcement action against a group health plan, or health insurance issuer offering group or individual coverage, with respect to implementing the requirements of PHS Act section 2706(a), as long as the plan or issuer is using a good faith, reasonable interpretation of the statutory provision ... • **Q5. Does Q2 in FAQs about Affordable Care Act Implementation Part XV continue to apply?** A5. No. Q2 in FAQs about Affordable Care Act Implementation Part XV, which previously provided guidance from the Departments on PHS Act section 2706(a), is superseded by this FAQ and notation will be made on the Departments' websites to reflect this modification. ... http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part-XXVII-MOOP-2706-FINAL.pdf SUMMARY OF NIHB ANALYSIS:	
89.k.	**Eligibility Determinations for Indian-Specific CSRs** **ACTION: Letter to CCIIO** **NOTICE:** Request for Confirmation that Eligibility Determinations for Indian-Specific Cost-Sharing	TTAG (no reference number)	Issue Date: 6/26/2015 Due Date: None NIHB File Date:		**SUMMARY OF AGENCY ACTION:** This letter asks CMS to engage with TTAG to review the regulations implementing the Indian-specific cost-sharing protections established under ACA and verify the appropriate implementation of these protections in the computer programs and guidance documents for the Federally-Facilitated Marketplace (FFM), pursuant to the relevant regulations. In addition, this letter suggests the potential need for a similar effort focused on State-Based Marketplaces (SBMs). According to this letter, Indian Marketplace enrollees and their providers--both Indian health care providers (IHCPs) and non-IHCPs--have experienced serious and systemic	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.
	Protections Are Being Made Consistent with ACA and Implementing Regulations **AGENCY:** TTAG		Date of Subsequent Agency Action, if any:		problems related to eligibility determinations for the two Indian-specific cost-sharing variations (CSVs)--the "02" (or zero) CSV and the "03" (or limited) CSV. This letter notes that this issue might lead to dramatically lower enrollment of Indians in Marketplace coverage. Specifically, this letter states that, although Indian Marketplace applicants who qualify for the "02" CSV generally receive a designation of "02" in their eligibility determination letter, those who should qualify for the "03" CSV generally do not receive a specific designation in their letter, raising concerns about improper application of the "03" designation during the eligibility determination process. In addition, this letter states that qualified health plan issuers (QHP) in many cases have violated the prohibition against reducing payments to providers who furnish services to individuals with Indian-specific cost-sharing protections by the amount of deductibles or co-payments they would have otherwise paid without these protections—a problem that might result in part from the issues with eligibility determinations for the "03" CSV, as some QHP issuers might not know they must apply cost-sharing protections. This letter provides a series of recommendations to address the issues with the eligibility determination process for the Indian-specific CSVs (see Table C). A copy of this letter is embedded below. TTAG Letter to CCIIO - Eligibility for CSVs - **SUMMARY OF NIHB ANALYSIS:**	
92.v.	**Q&A on Outreach by Medicaid MCOs to Former Enrollees** **ACTION: Guidance** **NOTICE:** Question and	CCIIO (no reference number)	Issue Date: 2/21/2014 Due Date: None NIHB File		**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.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Answer on Outreach by Medicaid Managed Care Contractors and Health Insurance Issuers to Former Enrollees **AGENCY:** CCIIO		Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 1/15/2015		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:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CCIIO on 1/15/2015 issued a revised version of this guidance. This document removes the following sentence from the end of the answer included in the previous version of this guidance: "**However, a Medicaid MCO may not reach out to current Medicaid beneficiaries**." http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MCOs-1-15-15.pdf	
92.hh.	**Annual Eligibility Redetermination Notices, et al.** **ACTION: Request for Comment** **NOTICE:** Annual Eligibility Redetermination, Product Discontinuation, and Renewal Notices **AGENCY:** CMS	CMS-10527	Issue Date: 11/4/2014 Due Date: 1/5/2015 NIHB File Date: NIHB File Date: None Date of Subsequent Agency Action, if any: Issued		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Annual Eligibility Redetermination, Product Discontinuation, and Renewal Notices; *Use*: Section 1411(f)(1)(B) of ACA directs the HHS Secretary to establish procedures to redetermine the eligibility of individuals on a periodic basis in appropriate circumstances. Section 1321(a) of ACA provides authority for the HHS Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, Qualified Health Plans (QHPs), and other components of title I of ACA. Under section 2703 of the Public Health Service Act (PHS Act), as added by ACA, and sections 2712 and 2741 of the PHS Act, enacted by HIPAA, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies. The final rule "Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges" (79 FR 52994) provides that an Exchange can choose to conduct	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			extension 1/23/2015 Due Date: 2/23/2015		the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the coverage year; or (3) using an alternative proposed by the Exchange and approved by the HHS Secretary. The guidance document "Guidance on Annual Redeterminations for Coverage for 2015" contains the procedures that the Secretary has specified for the 2015 coverage year, as noted in (2) above. These procedures will apply to the Federally-Facilitated Exchange. Under this option, the Exchange will provide three notices, which the Exchange can combine. The final rule also amends the requirements for product renewal and re-enrollment (or non-renewal) notices sent by QHP issuers in the Exchanges and specifies content for these notices. The accompanying guidance document "Form and Manner of Notices When Discontinuing or Renewing a Product in the Group or Individual Market" provides standard notices for product discontinuation and renewal sent by issuers of individual market QHPs and issuers in the individual market. Issuers in the small group market can use the draft Federal standard small group notices released in the June 26, 2014, bulletin "Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group or Individual Market" or any forms of the notice otherwise permitted by applicable laws and regulations. States enforcing ACA can develop their own standard notices for product discontinuances, renewals, or both, provided the State-developed notices provide at least the same level of protection as the Federal standard notices. http://www.gpo.gov/fdsys/pkg/FR-2014-11-04/pdf/2014-26041.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 1/23/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01127.pdf No comments recommended.	
92.kk.	**Summary of Benefits and Coverage and Uniform Glossary**	CMS-10407	Issue Date: 11/24/2014		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Summary of Benefits and Coverage and Uniform Glossary; *Use*: Section 2715 of the Public Health Service Act directs HHS, the	

Ref. #	Short Title/Current Status of Regulation/Title/ 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:** Summary of Benefits and Coverage and Uniform Glossary **AGENCY:** CMS		Due Date: 1/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/24/2015 Due Date: 3/26/2015		Department of Labor (DoL), and the Department of the Treasury (collectively, the Departments), in consultation with the National Association of Insurance Commissioners (NAIC) and a working group comprised of stakeholders, to "develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, and policyholders and certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage." To implement these disclosure requirements, collection of information requests relate to the provision of the following: summary of benefits and coverage, which includes coverage examples; a uniform glossary of health coverage and medical terms; and a notice of modifications. http://www.gpo.gov/fdsys/pkg/FR-2014-11-24/pdf/2014-27756.pdf Documents associated with this PRA request, including a blank "Summary of Coverage" template, which tribal representatives have requested that CMS require QHPs to provide for Indian-specific cost-sharing variations, are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1251222.html. **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 2/24/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-24/pdf/2015-03650.pdf No comments recommended.	
92.II.	**Health Benefit Plan Network Access and Adequacy Model Act** **ACTION: Request for Comment**	NAIC (no reference number)	Issue Date: 11/12/2014 Due Date: 1/12/2015 TTAG File	TTAG response:	**SUMMARY OF AGENCY ACTION:** This draft Act includes model language regarding network adequacy in health plans. The Act seeks to: • Establish standards for the creation and maintenance of networks by health carriers; and • Assure the adequacy, accessibility, transparency, and quality of health care services offered under a network plan by (1) establishing requirements for	See Table C.

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Health Benefit Plan Network Access and Adequacy Model Act (Draft) **AGENCY:** NAIC		Date: 1/12/2015 Date of Subsequent Agency Action, if any:		written agreements between health carriers offering network plans and participating providers regarding the standards, terms, and provisions under which the participating provider will provide covered benefits to covered persons and (2) requiring network plans to have and maintain publicly available access plans consistent with Section 5B of this Act that consist of policies and procedures for assuring the ongoing sufficiency of provider networks. NAIC seeks comments on this draft Act by 1/12/2015. The revisions to this version of the Act reflect changes made from the existing model. Interested parties should submit comments by e-mail only to Jolie Matthews at jmatthews@naic.org. Information regarding the NAIC Network Adequacy Model Review (B) Subgroup, responsible for reviewing and considering revisions to the Act, is available at http://www.naic.org/committees_b_rftf_namr_sg.htm. **SUMMARY OF NIHB ANALYSIS:** NAIC, rather than CMS, has prepared this draft Act. CMS has indicated (in CMS-9944-P, **see 89.h.**) that it will look to NAIC model Act prior to revising the Marketplace access standards.	
92.mm.	**Rate Review Requirements** **ACTION: Guidance** **NOTICE:** Insurance Standards Bulletin Series: Questions and Answers Regarding Rate Review Requirements **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 3/31/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This Bulletin provides guidance on when health insurance issuers can round premium rates to the nearest dollar. Specifically, this guidance answers the question of whether a state can allow issuers to round premiums for non-grandfathered single risk pool compliant plans in the individual or small group (or merged) markets in their respective state to the nearest dollar. According to this guidance: "Yes. Premiums for non-grandfathered plans in the individual or small group (or merged) markets generally are rounded to the nearest penny. However, states enforcing the federal single risk pool and fair health insurance premiums requirements under 45 CFR §§ 156.80 and 147.102 may allow issuers to round premiums to the nearest dollar, as long as all of the following conditions are met: • The premiums are based on unrounded rates, which are calculated based on an index rate for the market and applicable plan level adjustments and premium rating factors in compliance with the single risk pool and fair health insurance premiums requirements under 45 CFR §§ 156.80 and 147.102.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					• Premiums are rounded to the nearest dollar only based on unrounded rates, plan level adjustments, and premium rating factors. This means that premiums can only be rounded one time and only after all of the permitted plan level adjustments and applicable premium rating factors have been applied to the rate (i.e., after family size, geographic rating factor, age rating factor, and, if applicable, tobacco rating factor are taken into account). Issuers may not round rates at intermediate steps in the rate development process. • The practice of rounding premiums is done consistently across the risk pool. If an issuer rounds premiums for one plan in the risk pool, the issuer must round premiums for all plans in the risk pool. • Fractions of $0.50 or higher are rounded up to the nearest dollar and fractions of less than $0.50 are rounded down to the nearest dollar. If the rounded premium rates vary by more than 3:1 for like individuals who are age 21 and older who vary in age, or by more than 1.5:1 for like individuals who vary in tobacco use, the issuer must adjust the rates to bring them into compliance with the 3:1 age rating factor limit and the 1.5:1 tobacco rating factor limit. In direct enforcement states, HHS enforces the single risk pool and fair health insurance premiums provisions. In these states, issuers must continue to round premiums to the nearest penny unless instructed otherwise in future guidance." http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RR_Guidance_on_Premium_Rounding.pdf **SUMMARY OF NIHB ANALYSIS:**	
92.nn.	**Rate Filing Justifications for Single Risk Pool Coverage** **ACTION: Guidance** **NOTICE:** Insurance Standards Bulletin Series: CCIIO Sub-Regulatory	CCIIO (no reference number)	Issue Date: 4/14/2015 Due Date: None NIHB File Date:		**SUMMARY OF AGENCY ACTION:** This Bulletin provides guidance on the timing of submission and posting of information about rate increases as required by section 2794 of the Public Health Service Act (PHS Act) and regulations at 45 CFR Part 154. Specifically, this Bulletin provides guidance on the timing for health insurance issuers to submit Rate Filing Justifications for proposed rate increases in the individual and small group markets. It also provides guidance on the timing for states with an effective rate review program to provide public access to information regarding proposed rate increases subject to review and final rate increases. The timelines specified in this Bulletin apply to rates filed in 2015 (2015 filing year) for single risk pool compliant	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Guidance: Timing of Submission and Posting of Rate Filing Justifications for the 2015 Filing Year for Single Risk Pool Compliant Coverage Effective on or after January 1, 2016 **AGENCY:** CCIIO		Date of Subsequent Agency Action, if any:		coverage (including both qualified health plans (QHPs) and non-QHPs) effective on or after 1/1/2016. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-on-rate-review-timeline-final.pdf **SUMMARY OF NIHB ANALYSIS:**	
92.oo.	**Eligibility Redeterminations for Marketplace Coverage** **ACTION: Guidance** **NOTICE:** Guidance on Annual Eligibility Redeterminations and Re-Enrollments for Marketplace Coverage for 2016 **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/22/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** 45 CFR 155.335(a)(2) provides that a Health Insurance Marketplace has three options to redetermine eligibility for enrollment in a qualified health plan (QHP) through the Marketplace and insurance affordability programs on an annual basis. 45 CFR 155.335(a)(2)(ii) provides that one of these options involves a set of alternative procedures specified by the HHS Secretary annually for the applicable benefit year. Accordingly, **this guidance describes these alternative procedures for benefit year 2016. Each Federally-Facilitated Marketplace (FFM) will implement these procedures, which incorporate some modifications from the alternative procedures specified by the HHS Secretary for benefit year 2015 to accommodate the programmatic and operational experience gained during the process for 2015**. Like the alternative procedures specified by the HHS Secretary for benefit year 2015, the alternative procedures described in this guidance preserve a core feature of the annual redetermination process, namely, that in general, an enrollee can take no action and retain coverage for 2016, an important part of promoting continuity of coverage while limiting administrative burden for enrollees, issuers, and Marketplaces.. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/annual-redeterminations-for-coverage-42215.pdf **SUMMARY OF NIHB ANALYSIS:** A TSGAC memo on the 2016 redetermination process is embedded below.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					PDF TSGAC Memo - Annual Eligibility Rede	
92.pp.	**ACA Reporting Requirements for Health Coverage Providers** **ACTION: Guidance** **NOTICE:** ACA: Responsibilities for Health Coverage Providers--Understanding Reporting Requirements of the Health Care Law **AGENCY:** IRS	Publication 5215	Issue Date: 4/22/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This document provides a basic overview of the reporting requirements for providers of health coverage under ACA, describes the entities affected by these requirements, and provides affected entities with information about forms, related information, and how and when to file them. Under ACA, any entity that provides minimum essential coverage (MEC) to individuals must report the coverage to IRS and provide the covered individuals with information about the coverage to help them when filing their federal tax return. These requirements affect: • Health insurance issuers or carriers; • The executive department or agency of a governmental unit providing coverage under a government-sponsored program; • Plan sponsors of self-insured group health plan coverage; and • Sponsors of coverage that HHS has designated as MEC. http://www.irs.gov/pub/irs-pdf/f5215.pdf **SUMMARY OF NIHB ANALYSIS:**	
92.qq.	**Evaluation of EDGE Data Submissions** **ACTION: Guidance** **NOTICE:** EDGE Server Data Bulletin--Evaluation of EDGE Data Submissions **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/24/2015 Due Date: None NIHB File Date: Date of		**SUMMARY OF AGENCY ACTION:** This bulletin provides guidance on the operational processes that CMS will use to evaluate EDGE server data submitted by issuers. This analysis will help CMS determine whether an issuer has provided access to EDGE server data sufficient for CMS to calculate reinsurance payments and apply the HHS risk adjustment methodology. The integrity of payments and charges under the HHS-operated risk adjustment program and payments under the reinsurance program depend upon the data submitted by issuers to their EDGE servers. For example, risk adjustment data submissions for one issuer can materially affect the risk adjustment transfers for all other issuers in a market	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Subsequent Agency Action, if any:		in a state. Under 45 CFR §153.740(b), if an issuer of a risk adjustment covered plan fails to establish an EDGE server or fails to provide HHS with access to the required data on the EDGE server, such that CMS cannot apply the federally certified risk adjustment methodology, HHS will assess a default risk adjustment charge. Similarly, under 45 CFR §153.420 and §153.740(a), if an issuer eligible for reinsurance payments fails to establish an EDGE server or meet certain data requirements, the issuer might forgo reinsurance payments that it otherwise might have received. This bulletin describes how CMS intends to evaluate the sufficiency in terms of quantity and quality of the data made accessible to CMS on an EDGE server. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-guidance-42415-final.pdf **SUMMARY OF NIHB ANALYSIS:**	
92.rr.	**EDGE Data Submission Grace Period** **ACTION: Guidance** **NOTICE:** EDGE Server Data Bulletin--EDGE Data Submission Grace Period **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** The integrity of the financial transfers under the ACA risk adjustment and reinsurance programs depend upon the submission of complete and accurate enrollment and claims data. To permit issuers to complete the loading and testing of the required data to their EDGE servers, CMS will provide a grace period for issuers to submit and update EDGE server data for the 2014 benefit year financial transfers through Friday, 3/15/2015, 4 p.m. ET. During the grace period, issuers can submit data not accepted by April 30 and correct data already accepted on the EDGE servers. This grace period will not delay CMS transmission of risk adjustment and reinsurance results to issuers by 6/30/2015, but will permit CMS to assist issuers further in complying with the data submission requirements necessary to run a credible and effective risk adjustment and reinsurance program in each State. EDGE servers will accept no data from any issuer for the 2014 benefit year financial transfers after Friday, 5/15/2015, 4 p.m. ET. Issuers should plan to submit all data additions and corrections well in advance of this deadline to allow time to address any submission errors and to support success in the risk adjustment and reinsurance data submission processes for this year.	

Ref. #	Short Title/Current Status of Regulation/Title/ 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/Regulations-and-Guidance/Downloads/EDGE_Data_Grace_Period_Guidance4-27-15.pdf SUMMARY OF NIHB ANALYSIS:	
92.ss.	**Rate Review Requirements in States with SBMs** **ACTION: Guidance** **NOTICE:** Insurance Standards Bulletin Series: Questions and Answers Regarding Rate Review Requirements **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 5/13/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This bulletin provides guidance regarding uniform rate review timelines in states that operate a State-Based Marketplace (SBM). This bulletin answers the question of whether the uniform rate review timeline with respect to 2015 rate filings for single risk pool compliant coverage effective on or after 1/1/2016 applies to states with an SBM. According to this bulletin: "Yes. The new uniform rate filing deadlines for single risk pool compliant plans apply in all states. However, for 2015 rate filings for coverage effective on or after January 1, 2016 only, CMS will not consider a state with an effective rate review program that operates an SBM and does not utilize the Federally-Facilitated Marketplace (FFM) platform (and issuers offering coverage in such state) to be out of compliance with the uniform rate submission, posting, and finalization timeline for single risk pool compliant plans (including both QHPs and non-QHPs) offered in such state as long as the state meets all of the following conditions: • Sets a uniform submission deadline for proposed rate increases for single risk pool compliant plans no later than June 5, 2015; • Uniformly posts on the state's website at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its website (or provides CMS's web address for such information) for all proposed rate increases for single risk pool compliant plans that are subject to review no later than June 19, 2015; • Finalizes all single risk pool compliant submissions in the Health Insurance and Oversight System (HIOS) by October 9, 2015; and • Uniformly posts on the state's website at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its website (or provides CMS's web address for such information) for all final rate increases for single risk pool compliant plans no later than November 1, 2015. States with effective rate review programs that operate an SBM and elect to exercise this	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					flexibility must ensure that the information they release to the public is made available at a uniform time for all proposed and final rate increases for single risk pool compliant coverage (including QHPs and non-QHPs), as applicable, in the relevant market segment and without regard to whether coverage is offered through or outside of an Exchange." http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SBM-Uniform-Timeline-QA-5-13-15-Finalv2.pdf SUMMARY OF NIHB ANALYSIS:	
92.tt.	QIS Implementation Plan and Progress Report ACTION: Request for Comment NOTICE: Quality Improvement Strategy Implementation Plan and Progress Report AGENCY: CMS	CMS-10540	Issue Date: 6/19/2015 Due Date: 7/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: *Type of Information Collection Request*: New collection; *Title*: Quality Improvement Strategy Implementation Plan and Progress Report; *Use*: Section 1311(c)(1)(E) of ACA requires qualified health plans (QHPs) offered through an Exchange to implement a quality improvement strategy (QIS) as described in section 1311(g)(1). Section 1311(g)(3) of ACA specifies the guidelines under Section 1311(g)(2) shall require the periodic reporting to the applicable Exchange the activities that a qualified health plan has conducted to implement a strategy as described in section 1311(g)(1). CMS intends to have QHP issuers complete the QIS Plan and Reporting Template annually for initial certification and subsequent annual updates of progress in implementation of their strategy. The template will include topics to assess issuer compliance in creation of a payment structure that provides increased reimbursement or other incentives to improve the health outcomes of plan enrollees, prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities, as described in Section 1311(g)(1) of ACA. http://www.gpo.gov/fdsys/pkg/FR-2015-06-19/pdf/2015-15125.pdf SUMMARY OF NIHB ANALYSIS:	
92.uu.	Information Distribution on PTCs and CSRs for	CCIIO (no reference	Issue Date: 6/12/2015		SUMMARY OF AGENCY ACTION: Under 45 CFR 156.1255, an insurance issuer in the individual market that 1) re-enrolls coverage for an enrollment group in a QHP offered	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	FFM Coverage **ACTION: Guidance** **NOTICE:** Distribution of Information Regarding Advance Payments of the Premium Tax Credit (APTC) and Cost-Sharing Reductions (CSRs) in Federal Standard Notices for Coverage Offered Through the Federally-Facilitated Marketplaces **AGENCY:** CCIIO	number)	Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		through a Marketplace (including a renewal with modifications) or 2) discontinues a product that includes plans offered through a Marketplace and, consistent with State law, automatically enrolls an enrollee in a QHP under a different product offered by the same QHP issuer through the Marketplace must include information in the notice about the premium tax credit portion of the advance payments (APTC) for the upcoming coverage year to inform all policyholders of their expected monthly premium payment should they not update their application information and not make a plan selection by the last date for plan selection for the coverage effective January 1 of the upcoming benefit year. This document provides guidance on CMS requirements related to this distribution of information. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-on-Distribution-of-Information-Regarding-APTC-and-CSR-061215.pdf **SUMMARY OF NIHB ANALYSIS:**	
92.vv.	**FAQs on Uniform Modification and Plan/Product Withdrawal** **ACTION: Guidance** **NOTICE:** Uniform Modification and Plan/Product Withdrawal FAQ **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/15/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance answers the following FAQs on uniform modification and plan/product withdrawal: • **Q1. An issuer stops offering Product X at the end of 2015, and in 2016 begins offering Product Y. Is Product Y a new product?** A1. It depends. If the differences between Product X and Product Y qualify as a uniform modification of coverage, then, for purposes of federal law, Product Y is not a new product. ... Only if the changes are outside the scope of changes contemplated by the uniform modification rules would, for purposes of federal law, Product X be considered to have been discontinued, and Product Y be considered a new product. ... • **Q2. An issuer makes changes within a product but submits it as a new product. The state determines that the product changes are within the standards for uniform modification of coverage. Is the issuer required to revert to the product's former Health Insurance Oversight System (HIOS) product identifier (ID)?**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					A2. HIOS product IDs should change only when a new product is being submitted, as determined by the uniform modification of coverage standards. If a product remains the same product, consistent with the uniform modification standards, it should continue to use the same HIOS product ID. If a product is a different product based on the uniform modification standards, the new product should use a different HIOS product ID. However, for products that will be offered for plan years beginning in 2016, issuers that submitted product IDs in a manner inconsistent with this guidance will not be expected to update their HIOS product IDs, unless otherwise required by the applicable state regulator. ... • **Q3. If an issuer removes a plan from a product or adds a plan to a product, would such a change be considered a discontinuance of that product?** A3. An issuer will not trigger a product discontinuance by removing a plan from a product or adding a plan to a product, unless by removing a plan, the issuer exceeds the scope of a uniform modification for the product (e.g., the product no longer covers a majority of the same service area). ... • **Q4. If an issuer makes minor changes to a plan's cost sharing, has it changed the plan's "cost-sharing structure" such that the change will not be considered a uniform modification, and a product discontinuance is triggered under 45 CFR 147.106(e)(3)(iv)?** A4. Because the regulations do not define the term "cost-sharing structure," CMS will defer to a state's reasonable interpretation of this provision. Furthermore, a state has the discretion to broaden the standards in 45 CFR 147.106(e)(3)(iv), as stated in 45 CFR 147.106(e)(4), such that changes in cost sharing within the same metal tier level could be considered a uniform modification rather than a product discontinuance. ... • **Q5. If an issuer changes all of its products in a market such that the changes do not qualify under the uniform modification rules (resulting in a product discontinuance), will the issuer be considered to have performed a market withdrawal, and be subject to the 5-year prohibition**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					on market reentry? A5. Yes. For purposes of federal law, market withdrawal occurs when a carrier discontinues <u>all</u> of its products within the applicable market in a state (individual market, small group market, or large group market). ... http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/uniform-mod-and-plan-wd-FAQ-06-15-2015.pdf SUMMARY OF NIHB ANALYSIS:	
92.ww.	**Standard Notices of Product Discontinuation and Renewal** **ACTION: Guidance** **NOTICE:** Guidance on Federal Standard Notices of Product Discontinuation and Renewal in Connection with the Open Enrollment Period for the 2016 Coverage Year **AGENCY:** CCIIO	CCIIO (no reference number)	<u>Issue Date:</u> 7/7/2015 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency Action, if any</u>:		**SUMMARY OF AGENCY ACTION:** Under the guaranteed renewability provisions of title XXVII of the Public Health Service Act and their implementing regulations, in any case in which a health insurance issuer decides to discontinue offering a particular product (as defined in 45 CFR 144.103) in the group or individual market, the issue can discontinue that product in accordance with applicable state law in such market only if, among other things, the issuer provides notice in writing, in a form and manner specified by HHS, to each plan sponsor or individual, as applicable, provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of such discontinuation at least 90 calendar days prior to the date of the discontinuation. On 9/2/2014, CMS released a bulletin providing guidance and Federal standard notices of product discontinuation and renewal. In the bulletin, CMS announced a temporary safe harbor from enforcement of the 90-day requirement in the individual market under certain conditions in connection with the open enrollment period for the 2015 coverage year. This guidance announces that CMS will exercise the same enforcement discretion for the 2016 coverage year and that issuers should continue to use the Federal standard notices provided in the 9/2/2014, bulletin, subject to the additional information provided in CMS guidance released on 6/12/2015. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-on-Notices-of-Product-Discontinuation-and-Renewal-for-the-2016-Coverage-Year.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.
99.d.	**FAQs About ACA Implementation (Wellness Programs)** **ACTION: Guidance** **NOTICE:** FAQs About Affordable Care Act Implementation **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 4/16/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This guidance, prepared jointly by HHS and the Departments of Labor and the Treasury (collectively, the Departments) answers additional Frequently Asked Questions (FAQs) regarding implementation of ACA, specifically on the issue of wellness programs. Under Public Health Service Act (PHS Act) section 2705, ERISA section 702, and Internal Revenue Code (the Code) section 9802 and implementing regulations, group health plans and health insurance issuers in the group and individual market generally cannot discriminate against participants, beneficiaries, and individuals in eligibility, benefits, or premiums based on a health factor. An exception to this general prohibition allows premium discounts, rebates, or modification of otherwise applicable cost sharing (including copayments, deductibles, or coinsurance) in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs. The wellness program exception applies to group health coverage but not individual market coverage. On 6/3/2013, the Departments issued final regulations under PHS Act section 2705 and the related provisions of ERISA and the Code that address the requirements for wellness programs provided in connection with group health coverage. Among other provisions, these regulations set the maximum permissible reward under a health-contingent wellness program in a group health plan (and any related health insurance coverage) at 30 percent of the cost of coverage (or 50 percent for wellness programs designed to prevent or reduce tobacco use). These regulations also address the reasonable design of health-contingent wellness programs and the reasonable alternatives necessary to avoid prohibited discrimination. In the preamble to these regulations, the Departments stated that they anticipated issuing future sub-regulatory guidance as necessary. This guidance addresses the following FAQs raised since the publication of the wellness program regulations: 1. **Q1: What does it mean that a health-contingent wellness program must be "reasonably designed"?** Under section 2705 of the PHS Act and the wellness program regulations, a health-contingent wellness program must be reasonably designed to promote health or prevent disease. ... Wellness programs designed to dissuade or discourage enrollment in the plan or program by individuals who are sick or potentially have high claims experience will not be considered reasonably designed under the Departments' wellness program regulations. A program that collects a substantial level of sensitive personal health information without assisting individuals to make behavioral changes such as stopping smoking, managing	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					diabetes, or losing weight, may fail to meet the requirement that the wellness program must have a reasonable chance of improving the health of, or preventing disease in, participating individuals. Programs that require unreasonable time commitments or travel may be considered overly burdensome. Such programs will be scrutinized and may be subject to enforcement action by the Departments. The wellness program regulations also state that, in order to be reasonably designed, an outcome-based wellness program must provide a reasonable alternative standard to qualify for the reward for all individuals who do not meet the initial standard that is related to a health factor. This approach is intended to ensure that outcome-based wellness programs are more than mere rewards in return for results in biometric screenings or responses to a health risk assessment, and are instead part of a larger wellness program designed to promote health and prevent disease, ensuring the program is not a subterfuge for discrimination or underwriting based on a health factor. 2. **Q2: Is compliance with the Departments' wellness program regulations determinative of compliance with other laws?** No. The fact that a wellness program that complies with the Departments' wellness program regulations does not necessarily mean it complies with any other provision of the PHS Act, the Code, ERISA, (including the COBRA continuation provisions), or any other State or Federal law, such as the Americans with Disabilities Act or the privacy and security obligations of the Health Insurance Portability and Accountability Act of 1996, where applicable. Satisfying the rules for wellness programs also does not determine the tax treatment of rewards provided by the wellness program. ..." http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Tri-agency-Wellness-FAQS-4-16-15pdf-AdobeAcrobat-Pro.pdf **SUMMARY OF NIHB ANALYSIS:**	
99.e.	**FAQs on Market Reforms and Wellness Programs** **ACTION: Guidance**	CCIIO (no reference number)	Issue Date: 4/16/2015 Due Date: None		**SUMMARY OF AGENCY ACTION:** Under Public Health Service Act (PHS Act) section 2705, ERISA section 702, and Internal Revenue Code (Code) section 9802 and their implementing regulations, group health plans and health insurance issuers in the group and individual market generally cannot discriminate against participants, beneficiaries, and individuals in eligibility, benefits, or premiums based on a health factor. An exception	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Frequently Asked Questions on Health Insurance Market Reforms and Wellness Programs **AGENCY:** CCIIO		NIHB File Date: Date of Subsequent Agency Action, if any:		to this general prohibition allows premium discounts, rebates, or modification of otherwise applicable cost sharing (including copayments, coinsurance, or deductibles) in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs. The wellness program exception applies to group health coverage, but not individual market coverage. ACA added new rating reforms in section 2701 of the PHS Act and section 1312(c) of ACA. Section 2701 of the PHS Act restricts the variation in premium rates charged by a health insurance issuer for non-grandfathered health insurance coverage offered in the individual or small group market to certain specified factors. The factors include: family size, rating area, age, and tobacco use (within specified limits). Section 1312(c) of ACA generally requires an issuer to consider all enrollees in all health plans (except for grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. ACA also added section 2702 of the PHS Act, which generally requires a health insurance issuer that offers non-grandfathered health insurance coverage in the group or individual market in a State to offer coverage to and accept every employer and individual in the State that applies for such coverage. On 2/27/2013, HHS published final regulations implementing the market reforms under sections 2701 and 2702 of the PHS Act and section 1312(c) of ACA. On 6/3/2013, HHS and the Departments of Labor and the Treasury issued final regulations under PHS Act section 2705 and the related provisions of ERISA and the Code to address the requirements for wellness programs provided in connection with group health coverage. The following Frequently Asked Questions (FAQs) address several issues raised since the publication of the market reform rules and the wellness program regulations. The responses provide the CMS interpretation of how the market reform rules apply to wellness programs. 1. **Q1: May an issuer limit its offering of a wellness program in connection with a particular health insurance product to only certain employer groups enrolling in that product, such as employers in certain industry classifications?** No. If an issuer offers a wellness program in connection with a particular product that is approved for sale in a market within a State, and the rewards under the program affect the health insurance coverage for that product, including the premiums, benefits, cost sharing, provider network or service area, then the offering of the	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					wellness program would be considered a part of the plan design, and that plan design must generally be made available to every employer in the State and market that applies for such coverage, in accordance with the requirements of section 2702 of the PHS Act. The issuer cannot make a wellness program selectively available only to certain employers. ... This applies only to issuers offering health insurance coverage that is governed by the guaranteed availability provisions of section 2702 of the PHS Act, as added by the Affordable Care Act. 2. **Q2: Do the rating rules of section 2701 of the PHS Act prevent an issuer from offering premium discounts, rebates or other incentives for wellness programs other than those designed to prevent or reduce tobacco use?** No. Although providing a premium discount, rebate or other reward under a non-tobacco-related wellness program effectively varies the premium based on a factor not described in section 2701 of the PHS Act, the law specifically permits such rewards in connection with a wellness program meeting the standards of section 2705(j) of the PHS Act. 3. **Q3: When establishing the index rate and plan-level adjustments under the single risk pool provision, may an issuer take into account the penalties or rewards expected to be provided under a wellness program (whether health-contingent or participatory)?** No. The penalties or rewards associated with participation in a wellness program (participatory or health-contingent) may be applied to individual participants' premiums or contributions (or otherwise accrue to individuals), but may not be used to establish an issuer's index rate for a market, or any permitted plan-level adjustments, under the single risk pool provision at 45 CFR 156.80. Any such penalties or rewards may be retained or paid out by the issuer or by the employer, as applicable, pursuant to the terms of the wellness program and in accordance with the wellness program regulations. This guidance is applicable to health insurance issuers subject to the single risk pool requirement for rates effective on or after January 1, 2016. Issuers subject to the single risk pool requirement must establish rates consistent with this guidance and without regard to the rewards or penalties expected to be provided under a wellness program. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/HHS-wellness-FAQs-4-16-15-pdf-AdobeAcrobatPro.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.
109.d.	**COBRA Coverage Requirements for Group Health Plans** **ACTION: Request for Comment** **NOTICE:** Continuation Coverage Requirements Application to Group Health Plans **AGENCY:** IRS	REG-209485-86/TD 8812 (OMB 1545-1581)	Issue Date: 10/8/2014 Due Date: 12/8/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/30/2014 Due Date: 1/29/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Continuation Coverage Requirements Application to Group Health Plans; *Use*: The regulations require group health plans to provide notices to individuals entitled to elect COBRA (Consolidated Omnibus Budget Reconciliation Act of 1985) continuation coverage of their election rights. Individuals who wish to obtain the benefits provided under the statute must provide plans notices in cases of divorce from the covered employee, a child no longer considered dependent under the terms of the plan, and disability. Most plans will require that elections of COBRA continuation coverage occur in writing. In cases where qualified beneficiaries are short by an insignificant amount in a payment made to the plan, the regulations require the plan to notify the qualified beneficiary if the plan does not wish to treat the tendered payment as full payment. If a health care provider contacts a plan to confirm coverage of a qualified beneficiary, the regulations require that the plan disclose to the qualified beneficiary his or her complete rights to coverage. http://www.gpo.gov/fdsys/pkg/FR-2014-10-08/pdf/2014-24070.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 12/30/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-12-30/pdf/2014-30376.pdf	
111.e.	**Establishment of Multi-State Plan Program for Exchanges** **ACTION: ~~Proposed~~ Final Rule** **NOTICE:** Patient Protection and Affordable Care Act;	OPM RIN 3206-AN12	Issue Date: 11/24/2014 Due Date: 12/24/2014 NIHB File Date: None		**SUMMARY OF AGENCY ACTION:** This proposed rule would implement modifications to the Multi-State Plan (MSP) Program based on the experience of the program to date. OPM established the MSP Program pursuant to section 1334 of ACA. This proposed rule would clarify the approach used to enforce the applicable requirements of the ACA with respect to health insurance issuers that contract with OPM to offer MSP options. This proposed rule would amend MSP standards related to coverage area, benefits, and certain contracting provisions under section 1334 of ACA. This document also would make non-substantive technical changes.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges **AGENCY:** OPM		Date of Subsequent Agency Action, if any: Issued Final Rule 2/24/2015; issued correction 3/30/2015		http://www.gpo.gov/fdsys/pkg/FR-2014-11-24/pdf/2014-27793.pdf **SUMMARY OF NIHB ANALYSIS:** This proposed rule modifies the standards for the Multi-State Plan (MSP) program codified at 45 C.F.R. Part 800 (published as a final rule on March 11, 2013, pursuant to section 1334 of the ACA) and seeks comments on certain provisions of the final rule. OPM seeks comments on the existing definition for "group of issuers," with which OPM may contract under the MSP program, and whether the definition allows for "alternative structures, such as decentralized health insurance issuers or organizations," to apply to offer MSP options as a group. OPM also proposes to replace "Multi-State Plan" with "Multi-State Plan option," which will be defined as "a discrete pairing of a package of benefits with particular cost sharing (which does not include premium rates or premium rate quotes) that is offered pursuant to a contract with OPM pursuant to section 1334 of the Affordable Care Act and meets the requirements of 45 CFR part 800." OPM further proposes to add a definition for "State-level issuer" as a health insurance issuer designated by the MSP issuer to offer an MSP option or MSP options. The current regulations, 45 C.F.R. § 800.104(b), allow OPM to enter into a contract with a MSP issuer even if the issuer's MSPs for a State is not statewide. However, the regulations currently require the MSP issuer to submit a plan for eventually expanding coverage throughout the State. The proposed rule would delete the requirement that an issuer submit such a plan. Instead, OPM intends to negotiate with MSP issuers to determine their MSP coverage area. This change is in response to feedback from potential MSP issuers expressing concern about "the challenges of rapidly expanding access to MSP coverage both within and across State lines." OPM also notes that very few MSP issuers have offered MSP SHOP options in the initial years of the program and that timing and resources may prevent issuer participation, and seeks comments on when MSP issuers should be required to participate on the SHOPs. The proposed rule increases MSP issuer flexibility to choose to offer a package of benefits consistent with either a State's EHB benchmark plan or any EHB benchmark plan selected by OPM on a state-by-state basis. In response to apparent confusion about the prescription drug formulary standards of OPM-selected benchmarks, OPM proposes to clarify that OPM will negotiate a formulary with MSP issuers. OPM also seeks comment on the feasibility of substituting an OPM-selected benchmark plan formulary with the formulary from the respective State's EHB benchmark plan. The proposed rule also makes minor and technical corrections, changes, and clarifications to the application	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					and contracting process, collection of MSP program user fees, quality assurance, compliance enforcement, termination of plan requirements, and information disclosure, and clarifies the non-renewal provisions to distinguish between non-renewal of the MSP contract and non-renewal of a State-level issuers participation in the contract as well as the considerations in evaluating prudent business practices. Finally, the proposed rule adopts a new requirement that MSP issuers provide disclosure of coverage or exclusion of certain abortion services before a consumer enrolls in an MSP option. Comments may be warranted regarding the proposal to delete the requirement that contracting MSP providers submit a plan for statewide coverage when its coverage in a state is not currently statewide, as this change is likely to impact coverage options in rural and underserved areas. **SUMMARY OF SUBSQENT AGENCY ACTION:** This final rule implements modifications to the Multi-State Plan (MSP) Program based on the experience of the program to date. OPM established the MSP Program pursuant to ACA. This final rule clarifies the approach used to enforce the applicable standards of ACA with respect to health insurance issuers that contract with OPM to offer MSP options; amends MSP standards related to coverage area, benefits, and certain contracting provisions under section 1334 of ACA; and makes non-substantive technical changes. http://www.gpo.gov/fdsys/pkg/FR-2015-02-24/pdf/2015-03421.pdf **NOTE:** Tribal organizations made 16 recommendations on the OPM rule that initially established the Multi-State Plan Program (MSPP). In a final rule issued on March 11, 2013, OPM accepted only one of these recommendations in full but either accepted in part or acknowledged by other means most of the others; the rule did not address four of the recommendations. In the Q1 FY 2015 NIHB evaluation report, a comparison of the proposed version to this latest final rule with the unaccepted recommendations previously categorized as having "potential for future actions" indicated that OPM had not addressed any of these recommendations. The proposed rule also included no Indian-specific provisions. A prior analysis of the proposed rule recommended that tribal organizations consider commenting on a proposal to delete the requirement that contracting MSP providers submit a plan for statewide coverage when their coverage in a state is not currently statewide, as this change likely would impact coverage options in rural and underserved areas; tribal organizations opted not to comment.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					In the final rule, in clarifying the status of the Program and how OPM is implementing the standards set under § 800.104, OPM deleted the standard for an MSP issuer to submit a plan to become statewide in § 800.104(b), and added a requirement that the MSP issuer service area for MSP coverage shall be greater than or equal to any service area proposed by the issuer for QHP coverage. OPM on 3/30/2015 issued a document to correct the final rule that appeared in the 2/24/2015 FR (80 FR 9649). This document makes the following corrections to the final rule: 1. On page 9655, in the third column, the heading "List of Subjects in 5 CFR part 800" is revised to read, "List of Subjects in 45 CFR part 800." 2. On page 9655, in the third column, the last paragraph should be revised to read: "Accordingly, the U.S. Office of Personnel Management is revising part 800 to title 45, Code of Federal Regulations, to read as follows:" http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-07330.pdf	
112.c.	**Expanded Access to Non-VA Care Through Veterans Choice** **ACTION: Interim Final Rule** **NOTICE:** Expanded Access to Non-VA Care Through Veterans Choice Program **AGENCY:** VA	VA RIN 2900-AP24	Issue Date: 11/5/2014 Due Date: 3/5/2015 NIHB File Date: 3/5/2015 Date of Subsequent Agency Action, if any: Issued start date notice	NIHB response:	**SUMMARY OF AGENCY ACTION:** VA amends its medical regulations concerning its authority for eligible veterans to receive care from non-VA entities and providers. The Veterans Access, Choice, and Accountability Act of 2014 directs VA to establish a program to furnish hospital care and medical services through non-VA health care providers to veterans who either cannot receive care within the wait-time goals of the Veterans Health Administration or who qualify based on their place of residence (the Veterans Choice Program, or the "Program"). The law also requires VA to publish an interim final rule establishing this program. This interim final rule defines the parameters of the Veterans Choice Program and clarifies aspects affecting veterans and the non-VA providers that will furnish hospital care and medical services through the Veterans Choice Program. http://www.gpo.gov/fdsys/pkg/FR-2014-11-05/pdf/2014-26316.pdf **SUMMARY OF NIHB ANALYSIS:** Under "eligible entities and providers," the following definition is provided: "Section 17.1530 defines requirements for non-VA entities and	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.
			11/21/2014, issued interim final rule (amendment) 4/24/2015 Due Date: 5/26/2015		health care providers to be eligible to be reimbursed for furnishing hospital care and medical services to eligible veterans under the Program. Paragraph (a) of this section provides that an entity or provider must be accessible to the veteran and be one of the four entities specified in section 101(a)(1)(B) of the Act. These include any health care provider that is participating in the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including any physician furnishing services under such program; any Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act (42 U.S.C. 1396d(l)(2)(B)); the Department of Defense; or **the Indian Health Service. Outpatient health programs or facilities operated by a tribe or tribal organization under the Indian Self-Determination and Education Assistance Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act are defined as Federally-qualified health centers in section 1905(l)(2)(B) of the Social Security Act and would be eligible providers under section 101(a)(1)(B).**" Under this definition, I/T/Us are included as eligible providers, either as a Medicare participating provider or as an FQHC under SSA 42 U.S.C. 1396d(l)(2)(B). **SUMMARY OF SUBSQENT AGENCY ACTION:** VA on 11/21/2014 issued a start date notice. In the interim final rule, VA established start dates for participation in the Veterans Choice Program (the "Program") for different groups of veterans depending upon their basis of eligibility to participate. In those regulations, VA stated that veterans eligible based upon their inability to schedule an appointment within the wait-time goals of the Veterans Health Administration can start receiving hospital care and medical services under the Program no later than 12/5/2014. VA also stated that, if these veterans had a start date earlier than 12/5/2014, VA would publish a notice in the FR advising the public of the faster implementation schedule. This notice announces that 11/17/2014 serves as the start date for veterans eligible to participate in the Program. http://www.gpo.gov/fdsys/pkg/FR-2014-11-21/pdf/2014-27581.pdf VA on 4/24/2015 issued an interim final rule that amends its medical regulations implementing section 101 of the Veterans Access, Choice, and Accountability Act of 2014, which directed VA to establish a program to furnish hospital care and medical services through eligible non-VA health care providers to eligible veterans who either cannot obtain care within the wait-time goals of the Veterans Health Administration or who qualify based on their place of residence (Veterans Choice Program). VA published an interim final rule implementing the Veterans Choice Program on 11/5/2014. Under	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					current law, VA uses a straight-line or geodesic distance to determine eligibility based on place of residence. This interim final rule modifies how VA measures the distance from the residence of a veteran to the nearest VA medical facility. This modified standard will consider the distance the veteran must drive to the nearest VA medical facility, rather than the straight-line or geodesic distance to such a facility. http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09370.pdf No comments recommended.	
112.d.	**I/T/U Payment for Physician and Non-Hospital-Based Services** **ACTION: Proposed Rule** **NOTICE:** Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated with Non-Hospital-Based Care **AGENCY:** IHS	IHS RIN 0917-AA12	Issue Date: 12/5/2014 Due Date: ~~1/20/2015~~ 2/4/2015 NIHB File Date: 2/4/2015 Date of Subsequent Agency Action, if any: Issued due date extension 1/14/2015	NIHB response:	**SUMMARY OF AGENCY ACTION:** This proposed rule would amend IHS Purchased and Referred Care (PRC), formally known as Contract Health Services (CHS), regulations to apply Medicare payment methodologies to all physician and other health care professional services and non-hospital based services either authorized under such regulations or purchased by urban Indian organizations (UIOs). Specifically, it proposes that the health programs operated by IHS, Tribes, tribal organizations, or UIOs (collectively, I/T/U programs) will pay the lowest of the amount provided for under the applicable Medicare fee schedule, prospective payment system, or Medicare waiver; the amount negotiated by a repricing agent, if available; or the usual and customary billing rate. IHS might use repricing agents to determine whether it would benefit from savings by utilizing negotiated rates offered through commercial health care networks. This proposed rule seeks comment on how to establish reimbursement that remains consistent across Federal health care programs, aligns payment with inpatient services, and enables IHS to expand beneficiary access to medical care. http://www.gpo.gov/fdsys/pkg/FR-2014-12-05/pdf/2014-28508.pdf **SUMMARY OF NIHB ANALYSIS:** NIHB strongly supports expanding Medicare-Like Rates beyond hospital-based providers and believes this proposed rule serves as a good step toward achieving that goal. However, as drafted, this proposed rule does not provide the flexibility necessary to ensure continued access to care for AI/ANs through the Purchased/Referred Care (PRC) programs. Without a mechanism to ensure such flexibility, this proposed rule could operate to deny many AI/ANs access to critically important and life-saving services. This proposed rule requires revisions to provide the flexibility needed to ensure continued access to care while still lowering costs.	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.
					SUMMARY OF SUBSQENT AGENCY ACTION: IHS on 1/14/2015 issued a document that extends the comment period for the Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated with Non-Hospital-Based Care proposed rule published in 12/5/2014 FR (79 FR 72160). This document extends the comment period for the proposed rule, which would have ended on 1/20/2015, to 2/4/2015. http://www.gpo.gov/fdsys/pkg/FR-2015-01-14/pdf/2015-00400.pdf	
112.e.	**Tribal Consultation on VA/IHS Reimbursement Agreements** **ACTION: Notice** **NOTICE:** Section 102(c) of the Veterans Access, Choice, and Accountability Act of 2014 **AGENCY:** VA	VA (no reference number)	Issue Date: 12/30/2014 Due Date: 1/14/2015 TSGAC File Date: 1/14/2015 Date of Subsequent Agency Action, if any:	TSGAC response:	**SUMMARY OF AGENCY ACTION:** As required by section 102(c) of the Veterans Access, Choice, and Accountability Act of 2014, the VA Secretary and the IHS Director will jointly submit to Congress a report on the feasibility and advisability of entering into and expanding certain reimbursement agreements. **VA seeks Tribal Consultation on section 102(c).** **Specifically, VA seeks Tribal Consultation in the form of written comments concerning the feasibility and advisability of IHS and tribal health programs entering into agreements with VA for reimbursement of the costs of direct care services provided to eligible veterans who are not AI/ANs.** http://www.gpo.gov/fdsys/pkg/FR-2014-12-30/pdf/2014-30527.pdf **See 112.c. for information on the Veterans Choice Program.** Summary of Section 102 Section 102, titled, "Enhancement of Collaboration Between Department of Veterans Affairs and Indian Health Service," directs the VA Secretary, in consultation with the IHS Director, to conduct outreach to each medical facility operated by a Tribe or tribal organization through a contract or compact with the IHS under ISDEAA to raise awareness of the ability of such facilities, Tribes, and tribal organizations to enter into agreements under which VA reimburses them for health care provided to veterans who are 1) eligible for health care at such facilities and 2) enrolled in the VA patient enrollment system (or fall under a certain limited exception). Section 102 also requires the VA Secretary to establish metrics for assessing the	See Table C.

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					performance by VA and IHS in increasing access to health care, improving quality and coordination of health care, promoting effective patient-centered collaboration and partnerships between VA and IHS, and ensuring health-promotion and disease-prevention services are appropriately funded and available for beneficiaries under both health care systems. In addition, under section 102, within 180 days of enactment, **the VA Secretary and IHS Director of must jointly submit to Congress a report on the feasibility and advisability of the following:** • **Entering into agreements for the reimbursement by VA of the costs of direct care services provided through organizations receiving amounts pursuant to grants made or contracts entered into under section 503 of the Indian Health Care Improvement Act to veterans who are otherwise eligible to receive health care from such organizations; and** • **Including the reimbursement of the costs of direct care services provided to veterans who are not AI/ANs in agreements between VA and IHS or a Tribe or tribal organization operating a medical facility through a contract or compact with the IHS under ISDEAA.** **SUMMARY OF NIHB ANALYSIS:**	
112.f.	**IHS Reimbursement Rates for CY 2015** **ACTION: Notice** **NOTICE:** Reimbursement Rates for Calendar Year 2015 **AGENCY:** IHS	IHS (no reference number)	Issue Date: 4/2/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This notice announces that the IHS Director, under the authority of sections 321(a) and 322(b) of the Public Health Service Act and the Indian Health Care Improvement Act, has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for CY 2015 for Medicare and Medicaid beneficiaries, beneficiaries of other Federal programs, and recoveries under the Federal Medical Care Recovery Act. This notice does not include Medicare Part A inpatient rates, as they are paid based on the prospective payment system. Since the inpatient rates set forth in this notice do not include all physician services and practitioner services, additional payment is available to the extent that those services are provided. CY 2015 Rates Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services) Lower 48 States $2,443	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Alaska .... $2,926 Outpatient Per Visit Rate (Excluding Medicare) Lower 48 States .... $350 Alaska .... $601 Outpatient Per Visit Rate (Medicare) Lower 48 States .... $307 Alaska .... $564 Medicare Part B Inpatient Ancillary Per Diem Rate Lower 48 States .... $516 Alaska .... $956 Outpatient Surgery Rate (Medicare): Established Medicare rates for freestanding Ambulatory Surgery Centers. **Effective Date for CY 2015 Rates:** Consistent with previous annual rate revisions, the CY 2015 rates will take effect for services provided on/or after 1/1/2015, to the extent consistent with payment authorities including the applicable Medicaid State plan. http://www.gpo.gov/fdsys/pkg/FR-2015-04-07/pdf/2015-07779.pdf **SUMMARY OF NIHB ANALYSIS:** A TSGAC briefing memo comparing CY 2015 and CY 2014 rates is embedded below. TSGAC Memo - IHS Reimbursement Rates	
112.g.	**Receipt of Non-VA Care Under Veterans Choice Program** **ACTION: Request for**	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program; *Use*: **Section 17.1515 requires eligible veterans to notify VA whether the veteran elects to receive authorized non-VA care through the Veterans Choice Program**, get placed on an electronic waiting	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Comment **NOTICE:** Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program **AGENCY:** VA		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015 Due Date: 6/15/2015		list, or get scheduled for an appointment with a VA health care provider. Section 17.1515(b)(1) also allows eligible veterans to specify a particular non-VA entity or health care provider, if that entity or provider meets certain requirements. http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf **SUMMARY OF NIHB ANALYSIS:** How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. **SUMMARY OF SUBSQENT AGENCY ACTION:** CMS on 5/15/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended.	
112.h.	**Health Care Plan Information for Veterans Choice Program** **ACTION: Request for Comment** **NOTICE:** Health Care Plan Information for the Veterans Choice Program **AGENCY:** VA	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015 Due Date: 6/15/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Health Care Plan Information for the Veterans Choice Program; *Use*: **Section 17.1510(d) requires eligible veterans to submit to VA information about their health care plan to participate in the Veterans Choice Program.** http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf **SUMMARY OF NIHB ANALYSIS:** How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. **SUMMARY OF SUBSQENT AGENCY ACTION:** CMS on 5/15/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
112.i.	**Submission of Medical Records Under Veterans Choice Program** **ACTION: Request for Comment** **NOTICE:** Submission of Medical Record Information under the Veterans Choice Program **AGENCY:** VA	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/15/2015 Due Date: 6/15/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Submission of Medical Record Information under the Veterans Choice Program; *Use*: Participating eligible entities and providers must submit a copy of any medical record related to hospital care or medical services furnished under the Veterans Choice Program to an eligible veteran. http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf **SUMMARY OF NIHB ANALYSIS:** How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. **SUMMARY OF SUBSQENT AGENCY ACTION:** CMS on 5/15/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended.	
112.j.	**Submission of Credentials by Eligible Entities or Providers** **ACTION: Request for Comment** **NOTICE:** Submission of Information on Credentials and Licenses by Eligible Entities or Providers **AGENCY:** VA	VA (OMB 2900-0823)	Issue Date: 2/19/2015 Due Date: 4/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Submission of Information on Credentials and Licenses by Eligible Entities or Providers; *Use*: **Section 17.1530 requires eligible entities and providers to submit verification that the entity or provider maintains at least the same or similar credentials and licenses as those required of VA health care providers, as determined by the VA Secretary.** http://www.gpo.gov/fdsys/pkg/FR-2015-02-19/pdf/2015-03354.pdf **SUMMARY OF NIHB ANALYSIS:** How this PRA notice applies to veterans who are IHS beneficiaries remains uncertain. A review of this document in regard to decisions by IHS beneficiaries who are veterans to elect to receive care at I/T/U facilities might prove useful. **SUMMARY OF SUBSQENT AGENCY ACTION:** CMS on 5/15/2015 issued an extension	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			extension 5/15/2015 Due Date: 6/15/2015		of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11678.pdf No comments recommended.	
117.d.	**National Implementation of the Hospital CAHPS Survey** **ACTION: Request for Comment** **NOTICE:** National Implementation of the Hospital CAHPS Survey **AGENCY:** CMS	CMS-10102	Issue Date: 3/13/2015 Due Date: 5/12/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/29/2015 Due Date: 6/29/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: National Implementation of the Hospital CAHPS Survey; *Use*: Since 2006, the HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey--also known as the CAHPS Hospital Survey or Hospital CAHPS, a standardized survey instrument and data collection methodology--has measured patient perspectives of hospital care. While many hospitals collect information on patient satisfaction, HCAHPS created a national standard for collecting and public reporting information that enables valid comparisons across all hospitals to support consumer choice. http://www.gpo.gov/fdsys/pkg/FR-2015-03-13/pdf/2015-05796.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/29/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-29/pdf/2015-12993.pdf	
121.i.	**Site Investigation for Diagnostic Testing Facilities** **ACTION: Request for Comment** **NOTICE:** Site Investigation for Independent Diagnostic	CMS-10221	Issue Date: 1/16/2015 Due Date: 3/17/2015 NIHB File Date: None		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Site Investigation for Independent Diagnostic Testing Facilities (IDTFs); *Use*: CMS enrolls Independent Diagnostic Testing Facilities (IDTFs) into the Medicare program via a uniform application, form CMS-855B. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process, as well as identified and prevented fraudulent IDTFs from entering the Medicare program. As part of this process, CMS requires verification of compliance with IDTF performance standards. The site investigation form for IDTFs provides a standardized, uniform tool to gather information that tells CMS whether 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.
	Testing Facilities (IDTFs) **AGENCY:** CMS		Date of Subsequent Agency Action, if any: Issued extension 3/30/2015 Due Date: 4/29/2015		IDTF meets certain standards (as found in 42 CFR 410.33(g)) and where it practices or renders its services. CMS has used the site investigation form in the past to aid in verifying compliance with the required performance standards found in 42 CFR 410.33(g). CMS has made no revisions to this form since the last submission for OMB approval. http://www.gpo.gov/fdsys/pkg/FR-2015-01-16/pdf/2015-00627.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/30/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-07219.pdf No comments recommended.	
121.j.	**Site Investigation for Suppliers of DMEPOS** **ACTION: Request for Comment** **NOTICE:** Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) **AGENCY:** CMS	CMS-R-263	Issue Date: 1/16/2015 Due Date: 3/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/30/2015 Due Date:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); *Use*: CMS enrolls suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) into the Medicare program via a uniform application, form CMS 855S. Implementation of enhanced procedures for verifying the enrollment information has improved the enrollment process, as well as identified and prevented fraudulent DMEPOS suppliers from entering the Medicare program. As part of this process, CMS requires verification of compliance with supplier standards. The site investigation form provided a standardized, uniform tool to gather information from a DMEPOS supplier that tells CMS whether it meets certain qualifications (as found in 42 CFR 424.57(c)) and where it practices or renders its services. CMS has used the site investigation form in the past to aid in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). CMS has made no revisions to this form since the last submission for OMB approval. http://www.gpo.gov/fdsys/pkg/FR-2015-01-16/pdf/2015-00627.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.
			4/29/2015		**SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/30/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-07219.pdf No comments recommended.	
121.k.	**Verification of Clinic Data--Rural Health Clinic Form** **ACTION: Request for Comment** **NOTICE:** Verification of Clinic Data--Rural Health Clinic Form and Supporting Regulations **AGENCY:** CMS	CMS-29	Issue Date: 1/23/2015 Due Date: 3/24/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/30/2015 Due Date: 4/29/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Verification of Clinic Data--Rural Health Clinic Form and Supporting Regulations; *Use*: The form serves as an application for suppliers of Rural Health Clinic (RHC) services requesting participation in the Medicare program. This form initiates the process of obtaining a decision as to whether applicants meet the conditions for certification as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Automated Survey Process Environment (ASPEN) and related survey and certification databases by the CMS Regional Offices. http://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01128.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/30/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-07219.pdf No comments recommended.	
121.l.	**Medicare Enrollment Application: Reassignment of Benefits** **ACTION: Request for**	CMS-855R	Issue Date: 2/6/2015 Due Date: 4/7/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Medicare Enrollment Application: Reassignment of Medicare Benefits ; *Use*: The CMS-855R enrollment application allows physicians and non-physician practitioners to reassign their Medicare benefits to a group practice and to gather information from the individual that tells CMS who he/she is, where he/she renders	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Comment **NOTICE:** Medicare Enrollment Application: Reassignment of Medicare Benefits **AGENCY:** CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 4/20/2015 Due Date: 5/20/2015		services, and information necessary to establish correct claims payment. CMS periodically evaluates and revises the CMS-855R enrollment application to simplify and clarify the information collection without jeopardizing its need to collect specific information. **CMS has made very few minor revisions to the CMS-855R (Reassignment of Benefits) Medicare enrollment application (OMB 0938-1179)**. CMS has revised two sections within the form to maintain sync with online and paper forms. The previously approved CMS-855R section 2 collected information regarding the individual practitioner reassigning benefits and section 3 collected information regarding the organization/group receiving the reassigned benefits. CMS has reversed these two sections but has not revised information or data collection within these sections. With the exception of this section reversal and adding the word "optional" to sections 4 and 5 (primary practice location and contact person information), CMS has made no other revisions. These revisions offer no new data collection in this revision package. The addition of the optional choice in sections 4 and 5 could potentially reduce the burden to providers who choose not to complete either or both optional sections. http://www.gpo.gov/fdsys/pkg/FR-2015-02-06/pdf/2015-02414.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 4/20/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-20/pdf/2015-09009.pdf No comments recommended.	
125.	**Interest Rate on Overdue Debts** **ACTION: Notice**	HHS (no reference number)	Issue Date: 12/28/2012 Due Date: None		**SUMMARY OF AGENCY ACTION:** Section 30.18 of HHS claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that HHS becomes entitled to recovery. The rate must equal or exceed the current value of funds rate set by the Department of Treasury	

Ref. #	Short Title/Current Status of Regulation/Title/ 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: Notice of Interest Rate on Overdue Debts **AGENCY:** HHS		NIHB File Date: Date of Subsequent Agency Action, if any: Issued revisions 3/5/2013, 4/23/2013, 7/23/2013, 11/12/2013, 9/2/2014, 10/27/2014, 1/27/2015		or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities," unless the HHS Secretary waives interest in whole or part or a statute, contract, or repayment agreement prescribes a different rate. The Secretary of the Treasury may revise this rate quarterly. HHS publishes this rate in the Fed Reg. The current rate of 10 3⁄8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2012. This interest rate is effective until the Secretary of the Treasury notifies the HHS of any change. **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** Under the 3/5/2013 revision, the current rate of 105/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2012. This interest rate will remain effective until the Secretary of the Treasury notifies HHS of any change. http://www.gpo.gov/fdsys/pkg/FR-2013-03-05/pdf/2013-04945.pdf Under the 4/23/2013 revision, the current rate of 101/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 3/31/2013. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-04-23/pdf/2013-09578.pdf Under the 7/23/2013 revision, the current rate of 103/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2013. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-07-23/pdf/2013-17683.pdf Under the 11/12/2013 revision, the current rate of 101/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2013. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-11-12/pdf/2013-26994.pdf	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Under the 9/2/2014 revision, the current rate of 103/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2014-09-02/pdf/2014-20773.pdf Under the 10/27/2014 revision, the current rate of 10 3/4%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2014-10-27/pdf/2014-25443.pdf Under the 1/27/2015 revision, the current rate of 10 1/2%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2015-01-27/pdf/2015-01429.pdf	
126.a.	**Medicare Rural Hospital Flexibility Grant Program** **ACTION: Request for Comment** **NOTICE:** Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination **AGENCY:** HRSA	HRSA (OMB 0915-0363)	Issue Date: 12/28/2012 Due Date: 60 days (approx. 3/1/2013) NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination; *Use*: The Medicare Rural Hospital Flexibility Program (Flex), authorized by Section 4201 of the Balanced Budget Act of 1997 (BBA) and reauthorized by Section 121 of the Medicare Improvements for Patients and Providers Act of 2008, seeks to support improvements in the quality of health care provided in communities served by Critical Access Hospitals (CAHs); to support efforts to improve the financial and operational performance of the CAHs; and to support communities in developing collaborative regional and local delivery systems. This program also assists in the conversion of qualified small rural hospitals to CAH status. For this program, HRSA developed performance measures to provide data useful to the program and to allow the agency to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover principal areas of interest to the Office of Rural Health Policy (ORHP), including: (a) Quality reporting; (b)	

Ref. #	Short Title/Current Status of Regulation/Title/ 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 new request 4/26/2013; issued revision 5/27/2015 Due Date: 30 days (approx. 5/28/2013); 7/27/2015		quality improvement interventions; (c) financial and operational improvement initiatives; and (d) multi-hospital patient safety initiatives. http://www.gpo.gov/fdsys/pkg/FR-2012-12-31/pdf/2012-31399.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 4/26/2013 issued a new version of this PRA request. In response to comments on the original request, ORHP adjusted the burden estimate based on new calculations. http://www.gpo.gov/fdsys/pkg/FR-2013-04-26/pdf/2013-09946.pdf CMS on 5/27/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-27/pdf/2015-12700.pdf No comments recommended.	
128.e.	**Electing a Federal External Review Process** **ACTION: Guidance** **NOTICE:** Instructions for Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage on How to Elect a Federal External Review Process **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 6/15/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This technical guidance sets forth instructions regarding the election of a federally-administered external review process using the Health Insurance Oversight System (HIOS). This technical guidance applies to health insurance issuers that offer group and individual health coverage and use a federally-administered external review process in accordance with Technical Release 2011-02 (TR 2011-02). This technical guidance also applies to self-insured, non-federal governmental health plans and amends prior technical guidance pertaining to such plans released on 6/22/2011. These provisions do not apply to plans and issuers in connection with grandfathered health plans. http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/20150608-HHS-SRG-on-elections-FINAL-6-8-15-MM508.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.
128.f.	**ACA Internal Claims and Appeals and External Review Procedures** **ACTION: Request for Comment** **NOTICE:** Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-Grandfathered Plans **GENCY:** DoL	DoL (OMB 1210-0144)	Issue Date: 10/15/2014 Due Date: 12/15/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 7/23/2015 **Due Date: 8/21/2015**		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-Grandfathered Plans; *Use*: ACA added Public Health Service Act (PHS Act) section 2719, which provides rules relating to internal claims and appeals and external review processes. DoL, in conjunction with the Department of the Treasury and HHS (collectively, the Departments), on 7/23/2010 issued interim final regulations (75 FR 43330) that set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503-1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the DoL Secretary in paragraph (b)(2)(ii) of the regulations. In addition, PHS Act section 2719 and the interim final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. The regulations provide a basis for determining when plans and issuers must comply with an applicable State external review process and when they must comply with the Federal external review process. The claims procedure regulation imposes information collection requirements as part of the reasonable procedures that an employee benefit plan must establish regarding the handling of a benefit claim. These requirements include third-party notice and disclosure requirements that the plan must satisfy by providing information to participants and beneficiaries of the plan. On 6/24/2011, DoL amended the interim final regulations. Two amendments revised the ICR. The first amendment provides that plans no longer must include diagnosis and treatment codes on notices of adverse benefit determination and final internal adverse benefit determination. Instead, they must notify claimants of the opportunity to receive the codes on request and plans and issuers must provide the codes upon request. The second amendment changes the method plans and issuers must use to determine who qualifies to receive a notice in a culturally and linguistically appropriate manner and the information provided to these individuals. The previous rule used the number 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.
					employees at a firm as the basis. The new rule uses as the basis whether a participant or beneficiary resides in a county where ten percent or more of the population residing in the county is literate only in the same non-English language. http://www.gpo.gov/fdsys/pkg/FR-2014-10-15/pdf/2014-24447.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/23/2015 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2015-07-23/pdf/2015-18002.pdf No comments recommended.	
132.e.	**Outpatient and Ambulatory Surgery CAHPS Survey** **ACTION: Request for Comment** **NOTICE:** Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey **AGENCY:** CMS	CMS-10500	Issue Date: 10/4/2013 Due Date: 12/3/2013 NIHB File Date: None Date of Subsequent Agency Action: Issued new request 12/27/2013; issued revision 1/16/2015, 5/1/2015 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 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 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 CMS on 1/16/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-16/pdf/2015-00627.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.
			1/27/2014; 3/17/2015; 6/1/2015		CMS on 5/1/2015 issued a revision of this PRA request. CMS has revised the package subsequent to the publication of the 60-day notice in the 1/16/2015 FR (80 FR 2430). Previously, the package had the title "Outpatient/Ambulatory Surgery Patient Experience of Care Survey (O/ASPECS)." http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10207.pdf No comments recommended.	
132.g.	**HCAHPS Survey Mode Experiment** **ACTION: Request for Comment** **NOTICE:** Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Mode Experiment **AGENCY:** CMS	CMS-10542	Issue Date: 11/28/2014 Due Date: 1/27/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 2/13/2015 Due Date: 3/16/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Mode Experiment; *Use*: CMS publicly reports hospital-level scores derived from national implementation of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey on its Hospital Compare Web site. The HCAHPS initiative allows vendors to select one mode of survey administration from four approved administration protocols (mail only, telephone only, mail-telephone mixed mode, and touch-tone IVR only). Before public reporting, CMS adjusts HCAHPS scores for the selected mode of administration, using mail administration as the comparison mode, to correct for any inflation or deflation of scores that result from mode. The current mode adjustments employed for HCAHPS are the product of two separate mode experiments conducted using different versions of the survey and different sample. The planned HCAHPS mode experiment seeks to conduct a mode experiment of sufficient sample and scale to determine if the mode adjustments currently employed for the 32-item HCAHPS core survey need revision. An additional goal involves collecting empirical evidence on the effect of the number of additional supplemental items on survey response rate and patterns of response to the HCAHPS core demographic items (known as "About You" items). http://www.gpo.gov/fdsys/pkg/FR-2014-11-28/pdf/2014-28137.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 2/13/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-13/pdf/2015-03036.pdf	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					No comments recommended.	
132.h.	**EDPEC Survey Mode Experiment** **ACTION: Request for Comment** **NOTICE:** Emergency Department Patient Experience of Care (EDPEC) Survey Mode Experiment **AGENCY:** CMS	CMS-10543	Issue Date: 11/28/2014 Due Date: 1/27/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 2/13/2015 Due Date: 3/16/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Emergency Department Patient Experience of Care (EDPEC) Survey Mode Experiment; *Use*: This survey supports the six national priorities for improving care from the National Quality Strategy developed by HHS as directed under ACA to create national aims and priorities to guide local, state, and national efforts to improve the quality of health care. The six priorities include: making care safer by reducing harm caused by the delivery of care; ensuring the engagement of each individual and family as partners in their care; promoting effective communication and coordination of care; promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease; working with communities to promote wide use of best practices to enable healthy living; and making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models. In 2012, CMS launched the development of the Emergency Department Patient Experience of Care Survey (EDPEC) to measure the experiences of patients (18 and older) with emergency department care. This survey will provide patient experience with care data that enables comparisons of emergency department and support for improving the quality of patient experience in the emergency department. http://www.gpo.gov/fdsys/pkg/FR-2014-11-28/pdf/2014-28137.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 2/13/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-13/pdf/2015-03036.pdf No comments recommended.	
132.i.	**Hospital National Provider Survey** **ACTION: Request for Comment**	CMS-10550	Issue Date: 3/20/2015 Due Date: 5/19/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Hospital National Provider Survey; *Use*: Section 3104 of ACA requires that the Secretary of HHS conduct an assessment of the quality and efficiency impact of the use of endorsed measures in specific Medicare quality reporting and incentive programs. ACA further specifies that the initial assessment must occur no later than	

Ref. #	Short Title/Current Status of Regulation/Title/ 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: Hospital National Provider Survey **AGENCY:** CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/5/2015 Due Date: 7/6/2015		3/1/2012 and once every 3 years thereafter. CMS developed and tested this planned data collection as part of the 2015 Impact Report and will conduct data collection for reporting in the 2018 Impact Report. This data collection, which involves hospital quality leaders, includes: (1) A semi-structured qualitative interview and (2) a standardized survey. CMS will analyze the data from the qualitative interviews and standardized surveys to provide it with information on the quality and efficiency impact of measures that it uses to assess care in the hospital inpatient and outpatient settings. The surveys seek to understand whether the use of performance measures has led to changes in provider behavior and where undesired effects have occurred as a result of implementing quality and efficiency measures. The survey also will help identify characteristics associated with high performance, which, if understood, could assist in leveraging improvements in care among lower performing hospitals. The survey seeks to assess the impacts of the measures that CMS uses in the context of public reporting (pay-for-reporting) and value-based purchasing programs. http://www.gpo.gov/fdsys/pkg/FR-2015-03-20/pdf/2015-06408.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 6/5/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13755.pdf	
132.j.	**Nursing Home National Provider Survey** **ACTION: Request for Comment** **NOTICE:** Nursing Home National Provider Survey **AGENCY:** CMS	CMS-10551	Issue Date: 3/20/2015 Due Date: 5/19/2015 NIHB File Date: None Date of Subsequent		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Nursing Home National Provider Survey; *Use*: Section 3104 of ACA requires that the Secretary of HHS conduct an assessment of the quality and efficiency impact of the use of endorsed measures in specific Medicare quality reporting and incentive programs. ACA further specifies that the initial assessment must occur no later than 3/1/2012 and once every 3 years thereafter. CMS developed and tested this planned data collection as part of the 2015 Impact Report and will conduct data collection for reporting in the 2018 Impact Report. This data collection, which involves nursing home quality leaders, includes: (1) A semi-structured qualitative interview and (2) a standardized survey. CMS will analyze the data	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Agency Action, if any: Issued new request 6/5/2015 Due Date: 7/6/2015		from the qualitative interviews and standardized surveys to provide it with information on the quality and efficiency impact of measures that it uses to assess care in nursing homes delivering skilled nursing care. The surveys seek to understand whether the use of performance measures has led to changes in provider behavior (both at the nursing home-level and at the frontline of care) and whether undesired effects have occurred as a result of implementing quality and efficiency measures. The survey also will help identify characteristics associated with high performance, which, if understood, could assist in leveraging improvements in care among lower performing nursing homes. The survey seeks to assess the impacts of the measures that CMS uses in the context of public reporting (pay-for-reporting) and quality improvement. http://www.gpo.gov/fdsys/pkg/FR-2015-03-20/pdf/2015-06408.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 6/5/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13755.pdf	
134.d.	**Hospital and Health Care Complexes (Cost Report)** **ACTION: Request for Comment** **NOTICE:** Hospital and Health Care Complexes and Supporting Regulations **AGENCY:** CMS	CMS-2552-10	Issue Date: 5/10/2013 Due Date: 7/9/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 7/26/2013, 2/6/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Hospital and Health Care Complexes and Supporting Regulations in 42 CFR 413.20 and 413.24; *Use*: Medicare Part A institutional providers must provide adequate cost data to receive Medicare reimbursement (42 CFR 413.24(a)). Providers must submit the cost data to their Medicare Fiscal Intermediary (FI)/Medicare Administrative Contractor (MAC) through the Medicare cost report (MCR). CMS seeks a revision of the Hospital and Hospital Health Care Complex Cost Report, form CMS-2552-10. Hospitals participating in the Medicare program use form CMS 2552-10 to report the health care costs to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries. CMS has proposed the revisions to meet legislative requirements in ACA and the Temporary Payroll Tax Cut Continuation Act of 2011. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2013-11035.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 7/26/2013 issued a revision	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Due Date: 8/26/2013; 4/7/2015		of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18004.pdf CMS on 2/6/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-06/pdf/2015-02414.pdf The proposed revisions incorporate changes related to hospice care and a PPS system for FQHCs. Some Indian health care providers might have an interest in this PRA notice.	
134.k.	**SNF and SNF Health Care Complex Cost Report** **ACTION: Request for Comment** **NOTICE:** Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report **AGENCY:** CMS	CMS-2540-10	Issue Date: 6/27/2014 Due Date: 8/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 8/29/2014; issued revision 5/1/2015 Due Date: 9/29/2014; 6/30/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report; *Use*: Providers of services participating in the Medicare program must, under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g), 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. Skilled Nursing Facilities (SNFs) and Skilled Nursing Facility Complexes participating in the Medicare program use form CMS-2540-10 to report health care costs to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries. http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15075.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 8/29/2014 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-08-29/pdf/2014-20589.pdf CMS on 5/1/2015 issued a revision of this PRA request. The revisions made to the SNF cost report comport with the statutory requirement for hospice payment reform in § 3132 of ACA. http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10208.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.
134.l.	**Federally Qualified Health Center Cost Report Form** **ACTION: Request for Comment** **NOTICE:** Federally Qualified Health Center Cost Report Form **AGENCY:** CMS	CMS-224-14	Issue Date: 12/19/2014 Due Date: 2/17/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Federally Qualified Health Center Cost Report 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 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. CMS requires the CMS-224-14 cost report to determine reasonable costs incurred by a provider in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. http://www.gpo.gov/fdsys/pkg/FR-2014-12-19/pdf/2014-29741.pdf **SUMMARY OF NIHB ANALYSIS:**	
135.e.	**Reform of Requirements for Long-Term Care Facilities** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities **AGENCY:** CMS	CMS-3260-P	Issue Date: 7/16/2015 **Due Date: 9/14/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would revise the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs. These proposed changes are necessary to reflect the substantial advances made over the past several years in the theory and practice of service delivery and safety. These proposals also serve as an integral part of CMS efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers. http://www.gpo.gov/fdsys/pkg/FR-2015-07-16/pdf/2015-17207.pdf **SUMMARY OF NIHB ANALYSIS:**	
137.c.	**Transcatheter Mitral Valve Repair National Coverage Decision**	CMS-10531	Issue Date: 12/12/2014 Due Date:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD); *Use*: The CMS National Coverage Determination (NCD) titled, "Transcatheter Mitral Valve Repair (TMVR)," requires this data collection. Medicare covers the TMVR	

Ref. #	Short Title/Current Status of Regulation/Title/ 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:** Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD) **AGENCY:** CMS		2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 3/6/2015 Due Date: 4/6/2015:		device only when specific conditions are met, including that the heart team and hospital submit data in a prospective, national, audited registry. The data includes patient-, practitioner-, and facility-level variables that predict outcomes such as all-cause mortality and quality of life. The Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TMVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TMVR technologies for the treatment of mitral regurgitation (MR). The data also will include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ-10) to assess heath status, functioning, and quality of life. The KCCQ allows the derivation of an overall summary score from the physical function, symptoms (frequency and severity), social function, and quality of life domains. The data collected and analyzed in the TVT Registry will help determine if TMVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Social Security Act. Furthermore, data from the Registry will assist the medical device industry and the FDA in surveillance of the quality, safety, and efficacy of new medical devices to treat mitral regurgitation. For purposes of the TMVR NCD, the TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, CMS will make data available for research purposes under the terms of a data use agreement that only provides de-identified datasets. http://www.gpo.gov/fdsys/pkg/FR-2014-12-12/pdf/2014-29172.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/6/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-06/pdf/2015-05165.pdf No comments recommended.	
145.c.	**Health Insurance Providers Fee**	REG-143416-14	Issue Date: 2/26/2015		**SUMMARY OF AGENCY ACTION:** This document contains proposed regulations that provide rules for the definition of a covered entity for purposes of the fee imposed by section 9010 of ACA. Elsewhere in this issue of the FR, IRS has issued temporary	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Proposed Rule **NOTICE:** Health Insurance Providers Fee **AGENCY:** IRS	**See also 145.b.**	Due Date: 5/27/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		regulations (TD 9711). The text of those temporary regulations also serves as the text of these proposed regulations. The proposed regulations clarify certain terms in section 9010. The proposed regulations affect individuals engaged in the business of providing health insurance for U.S. health risks. http://www.gpo.gov/fdsys/pkg/FR-2015-02-26/pdf/2015-03945.pdf **SUMMARY OF NIHB ANALYSIS:** A summary of these proposed regulations is embedded below. REG-143416-14 analysis 2015-03-18.	
145.d.	**Health Insurance Providers Fee** **ACTION: Final/Temporary Rule** **NOTICE:** Health Insurance Providers Fee **AGENCY:** IRS	TD 9711 **See also 145.a.**	Issue Date: 2/26/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This document contains temporary regulations that provide rules for the definition of a covered entity for purposes of the fee imposed by section 9010 of ACA. The temporary regulations clarify certain terms in section 9010. The temporary regulations affect persons engaged in the business of providing health insurance for U.S. health risks. The text of the temporary regulations also serves as the text of the proposed regulations (REG-143416-14) published in elsewhere in this issue of the FR. http://www.gpo.gov/fdsys/pkg/FR-2015-02-26/pdf/2015-03944.pdf **SUMMARY OF NIHB ANALYSIS:** A summary of these temporary regulations is embedded below. REG-143416-14 analysis 2015-03-18.	
148.b.	**Data for Medicare Part B Drugs and Biologicals**	CMS-10110	Issue Date: 7/21/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: Data for Medicare Part B Drugs and Biologicals; *Use*: In accordance with section 1847A of the Social Security Act (Act),	

Ref. #	Short Title/Current Status of Regulation/Title/ 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:** Data for Medicare Part B Drugs and Biologicals **AGENCY:** CMS		**Due Date: 9/21/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in calendar year (CY) 2005. The ASP data reporting requirements appear in section 1927 of the Act. CMS uses the reported ASP data to establish the Medicare payment amounts. CMS revised the reporting template in CY 2011 to facilitate accurate collection of ASP data. CMS also created an accompanying user guide with instructions on the template and an explanation of the data elements in the template. http://www.gpo.gov/fdsys/pkg/FR-2015-07-21/pdf/2015-17824.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended.	
152.	**Medicare and Medicaid Survey, Certification, and Enforcement** **ACTION:** ~~Proposed~~ Final Rule **NOTICE:** Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures **AGENCY:** CMS	CMS-3255-~~PF~~	Issue Date: 4/5/2013 Due Date: ~~6/4/2013~~ 7/5/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued notice of due date extension 5/24/2013; issued Final Rule 5/22/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would revise the survey, certification, and enforcement procedures related to CMS oversight of national accreditation organizations (AOs). These revisions would implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). These revisions also would clarify and strengthen CMS oversight of AOs that apply for, and receive, recognition and approval of an accreditation program in accordance with the Social Security Act. http://www.gpo.gov/fdsys/pkg/FR-2013-04-05/pdf/2013-07950.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/24/2013 issued a notice (CMS 3255-N) that extends the comment period for the Survey, Certification and Enforcement Procedures proposed rule, published in the 4/5/2013, Federal Register (78 FR 20564 through 20581), from 6/4/2013 to 7/5/2013. http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12462.pdf CMS on 5/22/2015 issued a final rule that revises the survey, certification, and enforcement procedures related to CMS oversight of national accrediting organizations (AOs). The revisions implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The revisions also clarify and strengthen CMS oversight of AOs that apply for, and receive, recognition and approval of an accreditation program in accordance with the statute. This final rule also extends some provisions, which apply to Medicare-participating providers, to Medicare-participating	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					suppliers subject to certification requirements and clarifies the definition of "immediate jeopardy." http://www.gpo.gov/fdsys/pkg/FR-2015-05-22/pdf/2015-12087.pdf	
154.b.	**Medicaid/CHIP Managed Care** **ACTION: Proposed Rule** **NOTICE:** Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability **AGENCY:** CMS	CMS-2390-P	Issue Date: [Pending at OMB as of 3/19/2015] Issue Date: 6/1/2015 Due Date: 7/27/2015 NIHB File Date: 7/27/2015; TTAG also filed comments 7/27/2015 Date of Subsequent Agency Action, if any:	NIHB response: TTAG response:	**SUMMARY OF AGENCY ACTION:** This proposed rule would modernize the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The proposed rule would align the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through qualified health plans (QHPs) and Medicare Advantage (MA) plans; implement statutory provisions; strengthen actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; and promote the quality of care and strengthen efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries. It also would ensure appropriate beneficiary protections and enhance policies related to program integrity. This proposed rule would also require states to establish comprehensive quality strategies for their Medicaid and CHIP programs, regardless of how they provide services to beneficiaries. In addition, this proposed rule would implement provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) and addresses third party liability for trauma codes. http://www.gpo.gov/fdsys/pkg/FR-2015-06-01/pdf/2015-12965.pdf A CMS PowerPoint presentation on this proposed rule (screen shots) is embedded below. PDF Medicaid Managed Care Proposed Rules. A KCMU issue brief on this proposed rule is available at http://files.kff.org/attachment/issue-brief-awaiting-new-medicaid-managed-care-rules-key-issues-to-watch. A *National Journal* article on this proposed rule is available at http://www.nationaljournal.com/health-care/new-medicaid-rules-could-be-epic-20150514. **SUMMARY OF NIHB ANALYSIS:** This proposed rule includes the following Indian-	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.
					specific provisions: 1. *Standards for Contracts Involving Indians, Indian Health Care Provider, and Indian Managed Care Entities (§438.14)*: This section would implement section 5006(d) of the American Reinvestment and Recovery Act of 2009 (ARRA), which created section 1932(h) of the Social Security Act (Act) governing the treatment of Indians, Indian health care providers, and Indian managed care entities participating in Medicaid managed care programs. This section would expand the standards that apply the provisions of section 1932(h) of the Act to prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) through the authority under section 1902(a)(4) of the Act. In this section and for this purpose, CMS proposes in paragraph (a) to define the following terms: "Indian," "Indian health care provider (IHCP)," and "Indian managed care entity (IMCE)" consistent with statutory and existing regulatory definitions. In paragraph (b), CMS proposes that: • Each managed care organization (MCO), PIHP, PAHP, and primary care case manager (PCCM) entity contract must demonstrate sufficient IHCPs in the managed care network and access to services for Indian enrollees; • IHCPs receive payment for covered services provided to Indian enrollees eligible to receive services from these providers, whether or not the IHCP participates in the managed care network; • Any Indian enrolled in a non-IMCE and eligible to receive services from a participating IHCP can choose the IHCP as his or her primary care provider, as long as that provider has capacity to furnish the services; • Indian enrollees can obtain covered services from out-of-network IHCPs; and • In any state where timely access to covered services cannot occur because of an inadequate number of IHCPs, CMS would consider an MCO, PIHP, or PAHP to have met the standard for adequacy of IHCP providers either if Indian enrollees can access out-of-state IHCPs or the state deems the lack of IHCP providers a justification of good cause for disenrollment of an Indian from both the MCO, PIHP, or PAHP and the state managed care program in accordance with §438.56(c). **[CMS seeks comment on other ways to approach this issue].**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Proposed §438.14(c) outlines payment standards. Proposed paragraph (c)(1) specifies that when an IHCP participates in Medicaid as a FQHC but not as a participating provider with an MCO, PIHP, or PAHP, it must receive FQHC payment rates, including any supplemental payment due from the state. Where the IHCPs does not participate in Medicaid as a FQHC, proposed paragraph (c)(2) would have the MCO, PIHP, or PAHP payment equal the payment it would receive using a fee-for-service (FFS) payment methodology under the state plan or the applicable encounter rate, regardless of its contracting status with the MCO, PIHP, or PAHP. Proposed paragraph (d) would implement the statutory provision permitting an IMCE to restrict its enrollment to Indians in the same manner as Indian health programs can restrict the delivery of services to Indians without violating the standards in §438.3(d). **[CMS seeks comment on the overall approach to this section, including whether these proposals would ensure that Indian enrollees have timely and integrated access to covered services consistent with section 5006 of ARRA. In addition, CMS seeks comment on how to facilitate a coordinated approach for care for Indian enrollees who receive services from a non-participating IHCP and who need Medicaid covered services through a referral to a specialty provider. CMS also seeks comment on the potential barriers to contracting with managed care plans for IHCPs and what technical assistance and resources it should make available to states, managed care plans, and IHCPs to facilitate these relationships (such resources might include an I/T/U contract addendum, similar to the ones created for QHPs and organizations delivering the Medicare Part D benefit).]** 2. *Requirement Related to Indians, Indian Health Care Providers, and Indian Managed Care Entities (§457.1208)*: Section 2107(e)(1)(M) of the Act, as added by section 5006 of ARRA, specifies that the provisions related to managed care contracts that involve Indians, IHCPs, and IMCEs at sections 1932(a)(2)(C) and 1932(h) of the Act apply to CHIP. As such, CMS proposes to align CHIP with Medicaid when MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities enroll Indians at §438.14, which effectuates sections 1932(a)(2)(C) and 1932(h) of the Act. This would appear to extend the protection first enacted in the Balance Budget Act of 1997 to permit AI/ANs to decline to enroll in Medicaid managed care.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
157.c.	**Right of Appeal for Medicare Secondary Payer Determination** **ACTION:** ~~Proposed~~ **Final 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-~~PF~~	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/27/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would implement provisions of the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act), which requires CMS to provide a right of appeal and an appeal process for liability insurance (including self-insurance), no-fault insurance, and workers' compensation laws or plans when Medicare pursues a Medicare Secondary Payer (MSP) recovery claim directly from the liability insurance (including self-insurance), no fault insurance, or workers' compensation law or plan. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30661.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This final rule implements provisions of the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act) requiring CMS to provide a right of appeal and an appeal process for liability insurance (including self-insurance), no-fault insurance, and workers' compensation laws or plans when Medicare pursues a Medicare Secondary Payer (MSP) recovery claim directly from the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04143.pdf	
164.b.	**Medicare Secondary Payer and "Future Medicals"** **ACTION: Proposed Rule** **NOTICE:** Medicare Secondary Payer and "Future Medicals" **AGENCY:** CMS	CMS-6047	Issue Date: [Approved by OMB 10/9/2014] 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:**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
168.	**Enrollee Satisfaction Survey Data Collection** **ACTION: Request for Comment** **NOTICE:** Enrollee Satisfaction Survey Data Collection **AGENCY:** CMS	CMS-10488	Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 11/1/2013; issued revision 4/28/2015, 7/24/2015 **Due Date:** 12/2/2013; 6/29/2015; **8/24/2015** NIHB File Date: 12/2/2013; TTAG also filed comments 12/2/2013	NIHB response: TTAG response:	**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Enrollee Satisfaction Survey Data Collection; *Use*: Section 1311(c)(4) of the ACA requires HHS to develop an enrollee satisfaction survey system that assesses consumer experience with qualified health plans (QHPs) offered through an Exchange. It also requires public display of enrollee satisfaction information by the Exchange to allow individuals to compare enrollee satisfaction levels between comparable plans. HHS intends to establish an enrollee satisfaction survey system that assesses consumer experience with the Marketplaces and the qualified health plans (QHPs) offered through the Marketplaces. The surveys will include topics to assess consumer experience with the Marketplace, such as enrollment and customer service, as well as experience with the health care system, such as communication skills of providers and ease of access to health care services. CMS has considered using the Consumer Assessment of Health Providers and Systems (CAHPS) principles (http://www.cahps.ahrq.gov/about.htm) for developing the surveys. CMS also has considered an application and approval process for enrollee satisfaction survey vendors that want to participate in collecting ESS data. The application form for survey vendors includes information regarding organization name and contact(s) as well as minimum business requirements such as relevant survey experience, organizational survey capacity, and quality control procedures. CMS plans two rounds of developmental testing for the Marketplace and QHP surveys. The 2014 survey field tests will help determine psychometric properties and provide an initial measure of performance for Marketplaces and QHPs to use for quality improvement. Based on field test results, CMS will further refine the questionnaires and sampling designs to conduct the 2015 beta test of each survey. CMS plans to request clearance for two additional rounds of national implementation with public reporting of scores for each survey in the future. CMS will include a summary of findings from the testing rounds when requesting clearance for the additional two rounds of national implementation with public reporting, which will take place in 2016 and 2017. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf **SUMMARY OF NIHB ANALYSIS:** This PRA request might warrant comments similar those provided on the Medicaid enrollee survey (CMS-10493) to ensure adequate inclusion of AI/ANs and I/T/Us in surveys. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 11/1/2013 issued a new version of this PRA request.	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.
					http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26107.pdf Analysis from Sam Ennis: The surveys that CMS has proposed include no questions geared toward the AI/AN experience, other than one about AI/AN status as part of an examination of the background of respondents. These surveys should include AI/AN-specific elements to ensure that CMS and CCIIO receive feedback from AI/ANs about their questions, comments, and concerns related to their experiences with Marketplaces and QHPs. CMS on 4/28/2015 issued a revision of this PRA request. **CMS requests clearance for the national implementation of the QHP survey, beginning in 2016.** http://www.gpo.gov/fdsys/pkg/FR-2015-04-28/pdf/2015-09850.pdf CMS on 7/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-07-24/pdf/2015-18198.pdf No comments recommended.	
172.b.	**Testing and Research for Medicare Beneficiary Survey** **ACTION: Request for Comment** **NOTICE:** Generic Clearance for Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS) **AGENCY:** CMS	CMS-10549	Issue Date: 1/30/2015 Due Date: 3/31/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/2/2015 Due Date:		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Generic Clearance for Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS); *Use*: This OMB clearance package seeks to clear a Generic Clearance to support an effort to evaluate the operations and content of the Medicare Current Beneficiary Survey (MCBS). MCBS--a continuous, multipurpose survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries sponsored by CMS--serves as the only comprehensive source of information on the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. The core of the MCBS includes a series of interviews with a stratified random sample of the Medicare population, including aged and disabled enrollees, residing in the community or in institutions. Questions involve enrollee patterns of health care use, charges, insurance coverage, and payments over time. Respondents are asked about their sources of health care coverage and payment, their demographic characteristics, their health and work history, and their family living circumstances. In addition to collecting information through the core questionnaire, MCBS collects information 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.
			5/4/2015		special topics through supplements. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf **SUMMARY OF NIHB ANALYSIS:** This PRA might warrant further review to determine the need for comments on the procedures and content for the Medicare beneficiary survey, in particular with regard to whether the sample size for AI/AN is adequate to generate statistically valid findings. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 4/2/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-02/pdf/2015-07322.pdf No comments recommended.	
172.c.	**Medicare Beneficiary and Family-Centered Satisfaction Survey** **ACTION: Request for Comment** **NOTICE:** Medicare Beneficiary and Family-Centered Satisfaction Survey **AGENCY:** CMS	CMS-10393	Issue Date: 7/21/2015 **Due Date: 9/21/2015** 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*: Medicare Beneficiary and Family-Centered Satisfaction Survey; *Use*: The data collection methodology used to determine Medicare beneficiary satisfaction flows from the proposed sampling approach. Based on recent literature on survey methodology and response rates by mode, CMS recommends using a data collection done primarily by mail. A mail-based methodology will achieve the goals of being efficient, effective, and minimally burdensome for beneficiary respondents. CMS anticipates that a mail-based methodology could yield a response rate of approximately 60 percent. To achieve this response rate, CMS recommends a 3-staged approach to data collection: 1. Mailout of a covering letter, the paper survey questionnaire, and a postage-paid return envelope. 2. Mailout of a postcard that thanks respondents and reminds the non-respondents to return their survey. 3. Mailout of a follow-up covering letter, the paper survey questionnaire, and a postage-paid return envelope. Through the pilot test, CMS will determine the achievable response rate using this approach. If necessary, CMS can add a pre-notification letter, additional mailout reminders, and a telephone non-response step to the protocol to achieve the desired response rate.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.gpo.gov/fdsys/pkg/FR-2015-07-21/pdf/2015-17824.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended.	
174.f.	**FEHBP: Rate Setting for Community-Rated Plans** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Federal Employees Health Benefits Program; Rate Setting for Community-Rated Plans **AGENCY:** OPM	OPM (RIN 3206-AN00)	Issue Date: 1/17/2015 Due Date: 3/9/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 6/10/2015		**SUMMARY OF AGENCY ACTION:** This proposed rule would make changes to the Federal Employees Health Benefits Acquisition Regulation (FEHBAR). These changes would: Define which subscriber groups might qualify as similarly sized subscriber groups (SSSGs); require SSSGs to use a traditional community rating; establish that traditional community-rated Federal Employees Health Benefits Program (FEHBP) plans must select only one, rather than two, SSSGs; and make conforming changes to FEHBP contract language to account for the new medical loss ratio (MLR) standard for most community-rated FEHBP plans. http://www.gpo.gov/fdsys/pkg/FR-2015-01-07/pdf/2014-30633.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** This final rule makes changes to the Federal Employees Health Benefits Acquisition Regulation (FEHBAR). These changes: define which subscriber groups might qualify as similarly sized subscriber groups (SSSGs); require SSSGs to use a traditional community rating; establish that traditional community-rated Federal Employees Health Benefits Program (FEHBP) plans must select only one, rather than two, SSSGs; and make conforming changes to FEHBP contract language to account for the new medical loss ratio (MLR) standard for most community-rated FEHBP plans. http://www.gpo.gov/fdsys/pkg/FR-2015-06-10/pdf/2015-14219.pdf	
180.	**Flu Vaccination Standard for Certain Providers and Suppliers** **ACTION: Request for Comment**	CMS-3213-F	Issue Date: [Approved by OMB on 4/18/2014] Due Date:		**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	

Ref. #	Short Title/Current Status of Regulation/Title/ 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: Influenza Vaccination Standard for Certain Participating Providers and Suppliers **AGENCY:** CMS		NIHB File Date: Date of Subsequent Agency Action, if any:		to develop policies and procedures that will allow them to offer vaccinations for pandemic influenza in case of a future pandemic influenza event. **SUMMARY OF NIHB ANALYSIS:**	
181.b.	**Nondiscrimination Under ACA** **ACTION: Proposed Rule** **NOTICE:** Nondiscrimination Under the Patient Protection and Affordable Care Act **AGENCY:** HHS OCR	HHS OCR RIN 0945-AA02	Issue Date: [Pending at OMB as of 4/29/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would implement prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability, as provided in section 1557 of ACA. Section 1557 provides protection from discrimination in health programs and activities of covered entities. This section also identifies additional forms of Federal financial assistance to which the section will apply. **SUMMARY OF NIHB ANALYSIS:**	
184.e.	**Fecal Occult Blood Testing Under CLIA** **ACTION: Proposed Rule** **NOTICE:** Clinical Laboratory Improvement Amendments (CLIA); Fecal Occult Blood (FOB) Testing **AGENCY:** CMS	CMS-3271-P	Issue Date: 11/7/2014 Due Date: 1/6/2015 NIHB File Date: None Date of Subsequent		**SUMMARY OF AGENCY ACTION:** This proposed rule would amend the Clinical Laboratory Improvement Amendments (CLIA) regulations to clarify that the waived test categorization applies to only non-automated fecal occult blood tests. In addition, the proposed rule would remove the hemoglobin by copper sulfate method from the list of waived tests if commenters confirm that laboratories no longer use the method. http://www.gpo.gov/fdsys/pkg/FR-2014-11-07/pdf/2014-26559.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 Action, if any:			
184.f.	**Laboratory Personnel Report** **ACTION: Request for Comment** **NOTICE:** Laboratory Personnel Report (CLIA) and Supporting Regulations **AGENCY:** CMS	CMS-209	Issue Date: 11/28/2014 Due Date: 1/27/2015 NIHB File Date: None 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*: Laboratory Personnel Report (CLIA) and Supporting Regulations; *Use*: The information collected on this survey form serves the administrative pursuit of the congressionally mandated program with regard to regulation of laboratories participating in CLIA. The surveyor will provide the laboratory with CMS-209. While the surveyor performs other aspects of the survey, the laboratory will complete CMS-209 by recording the personnel data needed to support their compliance with the personnel requirements of CLIA. The surveyor will then use this information in choosing a sample of personnel to verify compliance with the personnel requirements. Information on personnel qualifications of all technical personnel ensures that the sample is representative of the entire laboratory. http://www.gpo.gov/fdsys/pkg/FR-2014-11-28/pdf/2014-28137.pdf **SUMMARY OF NIHB ANALYSIS:**	
184.g.	**Survey Report Form for CLIA** **ACTION: Request for Comment** **NOTICE:** Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations **AGENCY:** CMS	CMS-1557	Issue Date: 12/24/2014 Due Date: 2/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 3/6/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations; *Use*: Surveyors use the form to report findings during a CLIA survey. For each type of survey conducted (i.e., initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. http://www.gpo.gov/fdsys/pkg/FR-2014-12-24/pdf/2014-30027.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 3/6/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-03-06/pdf/2015-05165.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.
			Due Date: 4/6/2015		No comments recommended.	
184.h.	**CLIA Exemption for Laboratories in New York** **ACTION: Notice** **NOTICE:** Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit-Holding Laboratories in the State of New York **AGENCY:** CMS	CMS-3308-N	Issue Date: 3/27/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This notice announces that laboratories located in and licensed by the State of New York with a valid permit under New York State Public Health Law Article 5, Title V, are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of 6 years. http://www.gpo.gov/fdsys/pkg/FR-2015-03-27/pdf/2015-07113.pdf **SUMMARY OF NIHB ANALYSIS:**	
184.i.	**Post Clinical Laboratory Survey Questionnaire** **ACTION: Request for Comment** **NOTICE:** Post Clinical Laboratory Survey Questionnaire and Supporting Regulations **AGENCY:** CMS	CMS-668B	Issue Date: 5/22/2015 Due Date: 7/21/2015 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*: Post Clinical Laboratory Survey Questionnaire and Supporting Regulations; *Use*: Clinical Laboratory Improvement Amendments (CLIA) laboratories use form CMS-668B to express their satisfaction with the survey process and to make recommendations for improvement. Surveyors furnish this form to all laboratories that receive either an onsite survey or the Alternate Quality Assessment Survey (i.e., paper survey of quality indicators). CMS performs an overview evaluation of the completed forms. Each calendar year, a summary of the information collected gets sent to the state and CMS Regional Offices. http://www.gpo.gov/fdsys/pkg/FR-2015-05-22/pdf/2015-12498.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
185.g.	**Safe Harbor for FQHC Arrangements** **ACTION: Request for Comment** **NOTICE:** Safe Harbor for Federally Qualified Health Centers Arrangements **AGENCY:** HHS OIG	HHS-OS-0990-0322-60D HHS-OS-0990-0322-30D	Issue Date: 10/1/2014 Due Date: 12/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 1/23/2015 Due Date: 2/23/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Safe Harbor for Federally Qualified Health Centers Arrangements; *Use*: HHS OIG seeks an approval by OMB on an extension for data collection 0990-0322, which involves requirements associated with a voluntary safe harbor for Federally Qualified Health Centers under the Federal anti-kickback statute. The safe harbor protects certain arrangements involving goods, items, services, donations, and loans provided by individuals and entities to certain health centers funded under section 330 of the Public Health Service Act. http://www.gpo.gov/fdsys/pkg/FR-2014-10-01/pdf/2014-23322.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 1/23/2015 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01098.pdf No comments recommended.	
189.b.	**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: 1/22/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This notice provides an update of the HHS poverty guidelines to account for the increase in prices as measured by the Consumer Price Index for the last calendar year. http://www.gpo.gov/fdsys/pkg/FR-2015-01-22/pdf/2015-01120.pdf **SUMMARY OF NIHB ANALYSIS:** A table comparing the 2015 HHS poverty guidelines with the 2014 guidelines is embedded below. HHS Poverty Guidelines 2014-2015 Medicaid will use the 2015 poverty guidelines for eligibility determinations for the remainder of 2015 and until HHS issues revised guidelines in 2016. (The Marketplace	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					will continue to use the 2014 poverty guidelines for 2015 QHP enrollment.) A TSGAC handout on the use of these poverty guidelines is embedded below. TSGAC Revised- 2015 FPL Handout - Medica	
193.b.	**Executive Summary Form for Research Identifiable Data** **ACTION: Request for Comment** **NOTICE:** Executive Summary Form for Research Identifiable Data **AGENCY:** CMS	CMS-10522	Issue Date: 7/11/2014 Due Date: 9/9/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 11/4/2014; 2/27/2015 Due Date: 12/4/2014; 3/30/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: Executive Summary Form for Research Identifiable Data; *Use*: CMS has responsibility for administering Medicare, Medicaid, and CHIP. CMS collects data to support its mission and operations. These data include information about Medicare beneficiaries, Medicare claims, Medicare providers, and Medicaid eligibility and claims. CMS discloses the identifiable data consistent with the routine uses identified in the Privacy Act Systems of Records notices published in the Federal Register and the limitations on uses and disclosures set out in the HIPAA Privacy Rule. The Division of Privacy Operations & Compliance (DPOC) in the Office of E-Health Standards and Services receives and reviews all requests for identifiable data. The DPOC staff and the CMS Privacy Officer review the requests to determine if legal authorization exists for disclosure of the data. If legal authorization exists, the office reviews the request to ensure that it seeks the minimal data necessary and approved for the project. Requests for identifiable data for research purposes require approval by the CMS Privacy Board. To assist the CMS Privacy Board with its review of research data requests, OIPDA has developed the Executive Summary (ES) forms. The ES collects all the information that the CMS Privacy Board needs to review and make a determination on whether the request meets the requirements for release of identifiable data for research purposes. CMS currently has three versions of the ES Form and an ES Supplement for Requestors of the National Death Index (NDI) Causes of Death Variables. Each meets the need for a different type of requestor. http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-16076.pdf **SUMMARY OF NIHB ANALYSIS:** Tribal organizations might want to comment on data sources and allowable uses, if issues are identified. In particular, the TTAG Data Subcommittee might identify issues of concern.	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/4/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-11-04/pdf/2014-26040.pdf CMS on 2/27/2015 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04113.pdf	
194.c.	**Enrollment and Re-Certification of Entities in the 340B Program** **ACTION: Request for Comment** **NOTICE:** Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations **AGENCY:** HRSA	HRSA (OMB 0915-0327)	Issue Date: 9/30/2014 Due Date: 12/1/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 4/21/2015 Due Date: 5/21/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations; *Use*: Section 602 of 102, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act), provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign with the HHS Secretary a Pharmaceutical Pricing Agreement (PPA) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula ("ceiling price"). Section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the HHS Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities. The system must include the following: • Developing and publishing, through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection; • Comparing regularly the ceiling prices calculated by the HHS Secretary with the quarterly pricing data reported by manufacturers to the HHS Secretary; • Performing spot checks of sales transactions by covered entities; and • Inquiring into the cause of any pricing discrepancies identified and either taking, or requiring manufacturers to take, appropriate corrective action in response to such price discrepancies. The HRSA Office of Pharmacy Affairs (OPA) has previously obtained approval for information collections in support of 340B covered entity recertification and registration, as well as registration of contract pharmacy arrangements and the PPA itself. OPA seeks	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					comments on an additional information collection in response to the above pricing verification requirements. http://www.gpo.gov/fdsys/pkg/FR-2014-09-30/pdf/2014-23183.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** HRSA on 4/21/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-21/pdf/2015-09079.pdf No comments recommended.	
194.d.	**340B Ceiling Price and CMPs Regulation** **ACTION: Proposed Rule** **NOTICE:** 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation **AGENCY:** HRSA	HRSA RIN 0906-AA89	Issue Date: 6/17/2015 **Due Date: 8/17/2015** NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would apply to all drug manufacturers required to make their drugs available to covered entities under the 340B Drug Pricing Program. This proposed rule sets forth the calculation of the ceiling price and application of civil monetary penalties. http://www.gpo.gov/fdsys/pkg/FR-2015-06-17/pdf/2015-14648.pdf **SUMMARY OF NIHB ANALYSIS:** This proposed rule represents one proposal in a string of possible 340B Drug Pricing Program-related modifications.	
194.e.	**340B Program Omnibus Guidelines** **ACTION: Proposed Rule**	HRSA RIN 0906-AB08	Issue Date: [Pending at OMB as of 5/6/2015]		**SUMMARY OF AGENCY ACTION:** **SUMMARY OF NIHB ANALYSIS:**	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: 340B Program Omnibus Guidelines **AGENCY:** HRSA		Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:			
196.	**Patient Rights CoPs and Conditions for Coverage** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Program; Revisions to Certain Patient's Rights Conditions of Participation and Conditions for Coverage **AGENCY:** CMS	CMS-3302-P	Issue Date: 12/12/2014 Due Date: 2/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would revise the applicable conditions of participation (CoPs) for providers, conditions for coverage (CfCs) for suppliers, and requirements for long-term care facilities to ensure that certain requirements conform with the Supreme Court decision in *United States v. Windsor*, 570 U.S.12, 133 S.Ct. 2675 (2013), and HHS policy. Specifically, CMS proposes to revise certain definitions and patients' rights provisions to ensure that same-sex spouses in legally valid marriages receive equal rights in Medicare and Medicaid participating facilities. http://www.gpo.gov/fdsys/pkg/FR-2014-12-12/pdf/2014-28268.pdf **SUMMARY OF NIHB ANALYSIS:**	
198.c.	**Branded Prescription Drug Fee** **ACTION: Request for Comment** **NOTICE:** Branded Prescription Drug Fee	REG-112805-10 (OMB 1545-2209)	Issue Date: 3/17/2015 Due Date: 5/18/2015 NIHB File Date: None		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Branded Prescription Drug Fee; *Use*: Section 9008 of ACA imposes an annual fee on manufacturers and importers of branded prescription drugs that have gross receipts of over $5 million from the sales of these drugs to certain government programs (covered entity/covered entities). Section 51.7T(b) of IRS temporary regulations provide that the agency will send each covered entity notification of its preliminary fee calculation by May 15 of the fee year. If a covered entity chooses to dispute the preliminary fee calculation, the covered entity must follow the procedures for	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	AGENCY: IRS		Date of Subsequent Agency Action, if any: Issued extension 5/29/2015 Due Date: 6/29/2015		submitting an error report established in §51.8T. IRS will use the data voluntarily supplied by a covered entity that disputes its preliminary fee calculation to verify the accuracy of the data and the calculation used to determine the fee. http://www.gpo.gov/fdsys/pkg/FR-2015-03-17/pdf/2015-06073.pdf **SUMMARY OF NIHB ANALYSIS:** No comments recommended. **SUMMARY OF SUBSEQUENT AGENCY ACTION:** IRS on 5/29/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-29/pdf/2015-13008.pdf	
199.a.	**National CLAS Standards in Health and Health Care** **ACTION: Request for Comment** **NOTICE:** National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care: Evaluation of Awareness, Adoption, and Implementation **AGENCY:** HHS	HHS-OS-0990-New-60D HHS-OS-0990-New-30D	Issue Date: 9/26/2014 Due Date: 11/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/19/2014 Due Date: 1/20/2015		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: New collection; *Title*: National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care: Evaluation of Awareness, Adoption, and Implementation; *Use*: The HHS Office of Minority Health (OMH) seeks new OMB approval for data collection on an evaluation project titled "National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care: Evaluation of Awareness, Adoption, and Implementation." **This assessment seeks to describe and examine systematically the awareness, knowledge, adoption, and implementation of the HHS OMH National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards) in a sample of health and health care organizations and to use the resultant data to develop a preliminary model of implementation to guide organizational adoption and implementation of the National CLAS Standards.** Originally released in 2001, the HHS OMH National CLAS Standards include recommended action steps intended to advance health equity, improve quality, and help eliminate health care disparities. The National CLAS Standards, revised in 2013, include 15 Standards that provide health and health care organizations with a blueprint for successfully implementing and maintaining culturally and linguistically appropriate services. Despite increased recognition of the National CLAS Standards as a fundamental tool for health and health care organizations to use in their efforts to become more culturally and linguistically competent, neither the original nor the enhanced National CLAS Standards	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					have undergone systematic evaluation in terms of public awareness, organizational adoption and implementation, or impact on health services outcomes. A need exists to collect information from health and health care organizations to understand how and to what extent the intended audiences have utilized the National CLAS Standards. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-23000.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** HHS on 12/19/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-12-19/pdf/2014-29740.pdf	
199.b.	**CLAS County Data** **ACTION: Guidance** **NOTICE:** CLAS County Data **AGENCY:** CCIIO	CCIIO (no reference number)	Issue Date: 12/12/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 1/7/2015, 2/9/2015		**SUMMARY OF AGENCY ACTION:** Public Health Service Act (PHS Act) section 2719 requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered health insurance coverage to provide relevant notices in a culturally and linguistically appropriate manner. The regulations implementing section 2719 require these plans and issuers to make certain accommodations for notices sent to an address in a county meeting a threshold percentage of people literate only in the same non-English language (10 percent or more of the population residing, as determined based on American Community Survey (ACS)). **Section 2715 of the PHS Act requires group health plans and health insurance issuers offering group and individual coverage to provide the summary of benefits and coverage (SBC) and uniform glossary in a culturally and linguistically appropriate manner.** The regulations implementing section 2715 adopt the ten percent threshold set forth in the section 2719 implementing regulations. This guidance includes all counties that meet or exceed the 10 percent threshold (rounded to the nearest percent) for the 2009-2013 ACS data and applies until the next edition. CMS will update this list annually following the release of the applicable ACS data. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data_12-05-14_clean_508.pdf **SUMMARY OF NIHB ANALYSIS:**	

Ref. #	Short Title/Current Status of Regulation/Title/ 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: CCIIO on 1/7/2015 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data-01-07-15-508.pdf CCIIO on 2/9/2015 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data.pdf	
200.	**Mental Health Parity Rules for Medicaid and CHIP** **ACTION: Proposed Rule** **NOTICE:** Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and ABPs **AGENCY:** CMS	CMS-2333-P	Issue Date: 4/10/2015 Due Date: 6/9/2015 NIHB File Date: None Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** This proposed rule would address application of certain requirements set forth in the Public Health Service Act (PHS Act), as amended by the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), to coverage offered by Medicaid managed care organizations (MCOs), Medicaid Alternative Benefit Plans (ABPs), and CHIP. HHS and the Departments of Labor and the Treasury (collectively, the Departments) published interim final regulations implementing MHPAEA on 2/2/ 2010 (75 FR 5410), and final regulations applicable to group health plans and health insurance issuers on 11/13/2013 (78 FR 68240) (MHPAEA final regulations). The MHPAEA final regulations did not apply to Medicaid MCOs, ABPs, or CHIP state plans. This rule proposes regulations to address how the MHPAEA requirements in section 2726 of the PHS Act, as implemented in the MHPAEA final regulations, will apply to MCOs, ABPs and CHIP. **This proposed rule would not apply mental health parity requirements to state plan services provided to beneficiaries covered only through a fee-for-service (FFS) delivery system, even if care for other beneficiaries is delivered through a managed care delivery system. However, CMS strongly encourages states to consider changes to the state plan benefit package to comport with the mental health parity requirements of section 2726 of the PHS Act**. http://www.gpo.gov/fdsys/pkg/FR-2015-04-10/pdf/2015-08135.pdf An article that provides a "checklist for states" regarding this proposed rule is available at http://www.nashp.org/the-mental-health-parity-and-equity-addictions-act-proposed-rules-a-checklist-for-states/.	

Table B: Summary of Notices & Regulations Updated through 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					SUMMARY OF NIHB ANALYSIS: This proposed rule generally mirrors the policies set forth in the MHPAEA final regulations to implement the statutory provisions that **require MCOs, ABPs, and CHIP to comply with certain requirements of section 2726 of the PHS Act (mental health parity requirements). This proposed rule would incorporate these requirements into CMS regulations, requiring compliance within 18 months of the publication of the final rule.** Under section 1932(b)(8) of the Social Security Act (Act), Medicaid MCOs must comply with the requirements of subpart 2 of part A of title XXVII of the PHS Act, to the same extent that those requirements apply to a health insurance issuer that offers group health insurance. Subpart 2 includes mental health parity requirements added by MHPAEA at section 2726 of the PHS Act (as renumbered; formerly section 2705 of the PHS Act). Under section 1937(b)(6) of the Act, Medicaid ABPs (**see note 1 below**) that are not offered by an MCO (**see note 2 below**) and that provide both medical and surgical benefits and mental health (MH) or substance use disorder (SUD) benefits must ensure that financial requirements and treatment limitations for such benefits comply with the mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, now renumbered 2726(a) of the PHS Act), in the same manner as such requirements apply to a group health plan. The section 1937 provision applies only to ABPs that are not offered by MCOs; ABPs offered by MCOs currently must comply with these requirements under section 1932(b)(8) of the Act. [**Note 1**. States have the option to provide alternative benefit plans/packages specifically tailored to meet the needs of certain Medicaid population groups, target residents in certain areas of the state, or provide services through specific delivery systems instead of following the traditional Medicaid benefit plan. ABPs mirror the more narrow benefit packages common in the (non-Medicaid) private health insurance market. [**Note 2**. States have the option to provide services through a managed care delivery mechanism using entities other than MCOs, such as prepaid inpatient health plans (PIHPs) or prepaid ambulatory health plans (PAHPs). In many instances, states will provide the medical/surgical services through an MCO but will not include in the MCO benefit package some or all of their MH/SUD state plan services, delivering them instead through a PIHP or a PAHP or a nonmanaged care delivery system, typically FFS. The statutory provisions making mental health parity requirements applicable to MCOs do not explicitly address the situation in which medical/surgical benefits and MH/SUD benefits	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					included in coverage are furnished through separate but interrelated and interdependent service delivery systems, requiring additional guidance. This proposed rule generally would require that each MCO enrollee in a state must have access to a set of benefits meeting the requirements of this rule regardless of whether the MH/SUD services are provided by the MCO or through another service delivery system.] Section 2103(c)(6) of the Act requires state CHIP plans that provide both medical and surgical benefits and mental health or substance use disorder benefits to ensure financial requirements and treatment limitations for such benefits comply with mental health parity requirements of the PHS Act (referencing section 2705(a) of the PHS Act, now renumbered as section 2726(a) of the PHS Act) to the same extent as such requirements apply to a group health plan. In addition, section 2103(f)(2) of the Act requires that CHIP benchmark or benchmark equivalent plans comply with all of the requirements of subpart 2 of part A of the title XXVII of the PHS Act, which includes the mental health parity requirements of the PHS Act, insofar as such requirements apply to health insurance issuers that offer group health insurance coverage. CMS estimates that this proposed rule would benefit approximately 21.6 million Medicaid beneficiaries and 850,000 CHIP beneficiaries in 2015, based on service utilization estimates from 2012 Medicaid and CHIP enrollment. In addition, according to CMS, by increasing access to and utilization of MH/SUD benefits, this proposed rule could result in a reduction of medical and surgical costs. CMS also predicts that the proposed rule could result in small increases in costs and capitated rates. <u>Main Provisions of Proposed Rule</u> A brief summary of the provisions of this proposed rule appears below. *A. Meaning of Terms (§438.900, §440.395, §457.496)* The definitions of terms in this proposed rule include most terms included in the MHPAEA final regulation at 45 CFR 146.136(a), but this proposed rule would modify or add several terms to reflect the terminology used in the Medicaid program and CHIP statutes, regulations, or policies and exclude some terms not relevant to the Medicaid program or CHIP. *B. Parity Requirements for Aggregate Lifetime and Annual Dollar Limits* Sections 438.905 and 457.496(c) of this proposed rule address the parity requirements for aggregate lifetime and annual dollar limits and would apply these requirements	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					generally the same as under the MHPAEA final regulations (45 CFR 146.136(b)). *C. Parity Requirements for Financial Requirements and Treatment Limitations* Sections 438.910, 440.395(b), and 457.496(d) of this proposed rule would set forth parity requirements for financial requirements and treatment limitations. *D. Cumulative Financial Requirements (§438.910(c)(3), §440.395(b)(3)(iii), §457.496(d)(3)(iii))* As in the MHPAEA final regulation at 45 CFR 146.136(c)(2)(v), this proposed rule would not allow any separate cumulative financial requirement (separate for mental health/substance use disorder (MH/SUD) or medical/surgical) for affected entities but would permit quantitative treatment limitations to accumulate separately for medical/surgical and MH/SUD services as long as they comply with the general parity requirement. *E. Compliance with Other Cost-Sharing Rules (§438.910(c)(4))* Section 438.910(c)(4) of this proposed rule would reiterate the requirement that some cost-sharing structures in a state Medicaid program or CHIP may have to change to comply with MHPAEA with a cross-reference to the cost-sharing rules applicable to MCOs, PIHPs, or, PAHPs. *F. Nonquantitative Treatment Limitations (NQTLs) (§438.910(d), §440.395(b)(4), and §457.496(d)(4))* Sections 438.910(d), 440.395(b)(4), and 457.496(d)(4) of this proposed rule would prohibit the imposition of any NQTL to MH/SUD benefits unless certain requirements are met and provides an illustrative list of NQTLs. *G. Application to CHIP and EPSDT Deemed Compliance (§457.496(b))* This section of the proposed rule addresses requirements related to CHIP. *H. Availability of Information (§438.915, §440.395(c), §457. 496(e))* These sections of the proposed rule would apply the requirements imposed on the health insurance issuer through the MHPAEA final regulations regarding availability of information in a similar manner to MCOs and to PIHPs and PAHPs that provide coverage to MCO enrollees. *I. Application to EHBs and other ABP Benefits (§440.395 and §440.347)*	

Ref. #	Short Title/Current Status of Regulation/Title/ 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 section of the proposed rule addresses parity requirements for ABPs that provide both medical/surgical benefits and MH or SUD benefits, as well as EHB requirements for ABPs. *J. Application of Parity Requirements to the Medicaid State Plan* This proposed rule would apply the requirements of section 2726 of the PHS Act incorporated through section 1932 of the Act to the benefits offered by the MCO (or, if benefits are carved out, to all benefits provided to MCO enrollees regardless of service delivery system) but would not apply them to all Medicaid state plan benefit designs. [**These requirements do not directly apply to the benefit design for Medicaid non-ABP state plan services. States that have individuals enrolled in MCOs and have MH/SUD services offered through FFS will have the option of amending their non-ABP state plan to make it consistent with the provisions in this proposed rule or offering MH/SUD services through a managed care delivery system (MCOs, PIHPs, and/or PAHPs) to comply**.] *K. Scope and Applicability of the Proposed Rule (§438.920(a) and (b), §440.395(d), and §457.496(f)(1))* Sections 438.920, 440.395(d), and 457.496(f) of this proposed rule address its applicability and scope. *L. Scope of Services (§438.920(c), §457.496(f)(2))* This proposed rule would not require an MCO, PIHP, or PAHP to provide any MH/SUD benefits for conditions or disorders beyond the conditions or disorders covered as required by their contract with the state, and for MCOs, PIHPs, or PAHPs that provide benefits for one or more specific MH conditions or SUDs under their contracts, this rule would not require them to provide benefits for additional MH conditions or SUDs. *M. ABP State Plan Requirements (§440.395(d))* This proposed rule would add a section in part 440, subpart C requiring states using ABPs to provide sufficient information in ABP state plan amendment requests to assure compliance with MHPAEA. *N. Increased Cost Exemption* This proposed rule would change payment provisions in part 438 to allow states to include the cost of providing additional services or removing or aligning treatment	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					limitations in their actuarially sound rate methodology where such costs are necessary to comply with the MHPAEA parity provisions. *O. Enforcement, Managed Care Rate Setting (§438.6(e)), and Contract Review and Approval (§ 438.6(n))* This proposed rule would require the state Medicaid agency to include contract provisions requiring compliance with parity requirements in all applicable MCO, PIHP, and PAHP contracts. *P. Applicability and Compliance (§438.930, §440.395(d), §457.496(f))* This proposed rule would take effect on the date of the publication of the final rule but would allow MCOs, PIHPs, PAHPs, and states to have 18 months to comply with its provisions. • **Medicaid MCOs, PIHPs, or PAHPs would have to comply with the specific provisions in this proposed rule in contract years starting 18 months after the publication of the final rule (new managed care contracts, or amendments, would have to comply in most cases).** • **States would have 18 months after the publication of the final rule to make ABPs compliant with the provisions in this proposed rule.** • **States would have 18 months after the publication of the final rule to make CHIP plans compliant with the provisions in this proposed rule.** *Q. Utilization Management* This proposed rule would eliminate current language from existing regulations that require Medicaid agencies to evaluate the need for admissions to mental hospitals.	
201.	**Use of Restraint and Seclusion in Psychiatric Facilities** **ACTION: Request for Comment** **NOTICE:** Use of Restraint	CMS-R-306	Issue Date: 1/30/2015 Due Date: 3/31/2015 NIHB File Date: None		**SUMMARY OF AGENCY ACTION:** *Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations; *Use*: Psychiatric residential treatment facilities must report deaths, serious injuries, and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They also must provide residents the restraint and seclusion policy in writing and document in resident records all activities involving the use of restraint and seclusion.	

TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 7/31/2015

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations **AGENCY:** CMS		Date of Subsequent Agency Action, if any: Issued extension 5/1/2015 Due Date: 6/1/2015		http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** CMS on 5/1/2015 issued a revised an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-01/pdf/2015-10207.pdf No comments recommended.	
202.	**Health Needs of the AI/AN LGBT Community** **ACTION: Request for Information** **NOTICE:** Notice of Request for Information **AGENCY:** IHS	IHS (no reference number)	Issue Date: 6/5/2015 Due Date: 7/6/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued meeting notice 7/22/2015		**SUMMARY OF AGENCY ACTION:** IHS seeks broad public input as it begins efforts to advance and promote the health needs of the AI/AN Lesbian, Gay, Bisexual, and Transgender (LGBT) community. In summer 2015, IHS will hold a public meeting to garner information from individuals on AI/AN LGBT health issues. Through this meeting, IHS seeks to gain a better understanding of the health care needs of AI/AN LGBT individuals so that it can implement health policy and health care delivery changes to advance the health care needs of the AI/AN LGBT community. IHS aims to increase community access to and engagement with agency leadership and secure a legacy of transparent, accountable, fair, and inclusive decision-making specific to AI/AN LGBT individuals. This request for information seeks public comment on the dimensions of the health needs of the AI/AN LGBT community. http://www.gpo.gov/fdsys/pkg/FR-2015-06-05/pdf/2015-13774.pdf **SUMMARY OF NIHB ANALYSIS:** **SUMMARY OF SUBSEQUENT AGENCY ACTION:** IHS on 7/22/2015 issued a notice to announce a public meeting on efforts to advance and promote the health needs of the AI/AN Lesbian, Gay, Bisexual, and Transgender (LGBT) community on July 27, 2015, from 9 a.m. to 4:30 p.m. ET, at 801 Thompson Avenue, Rockville, MD 20852. Interested parties can submit written statements to Lisa Neel, MPH, Program Coordinator, Office of	

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Clinical and Preventive Services, IHS, 801 Thompson Avenue, Suite 300, Rockville, MD 20852. Individuals who plan to attend the meeting should RSVP to Lisa Neel at lisa.neel@ihs.gov or by telephone at 301-443-4305. http://www.gpo.gov/fdsys/pkg/FR-2015-07-23/pdf/2015-18002.pdf	
203.	**Medicaid Estate Recovery Rules and Protections for AI/ANs** **ACTION: Guidance** **NOTICE:** Medicaid Estate Recovery: Rules and Protections for American Indians and Alaska Natives **AGENCY:** CMS	CMS (no reference number)	Issue Date: May 2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		**SUMMARY OF AGENCY ACTION:** Section 5006 of ARRA exempts certain Indian income, resources, and property from Medicaid Estate Recovery rules. This brochure explains the Medicaid Estate Recovery rules and the exemptions and protections for AI/ANs. Developed with input from TTAG, IHS, and HHS Intergovernmental and External Affairs (HHS IEA), this brochure supports CMS outreach and education efforts designed to encourage AI/AN enrollment in agency programs. Additional outreach and education resources for AI/ANs and Indian health care providers are available at http://go.cms.gov/AIAN-OutreachEducationResources. http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/MedicaidEstate-Recovery-Rules-and-Protections-for-Indians-Brochure.pdf **SUMMARY OF NIHB ANALYSIS:**	

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 7/31/2015

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
1.I.	**EHR Incentive Program--Stage 3** **ACTION: Proposed Rule** **NOTICE:** Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 3 **AGENCY:** CMS	CMS-3310-P Issue Date: 3/30/2015 Due Date: 5/29/2015 NIHB File Date: 5/29/2015; TTAG also filed comments 5/29/2015 Date of Subsequent Agency Action, if any:	NIHB/TTAG recommendations-- 1. **Regulations/Definitions Across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs**: • a. **Single Reporting Period Aligned to Calendar Year**: The proposed rule would create a single electronic health record (EHR) reporting period aligned to the calendar year would help achieve a stated goal of Stage 3 to realign and simplify the reporting process; CMS should retain this provision in the final rule. • b. **Specification of Means of Data Transmission**: For Stage 3, the proposed rule would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective; in the final rule, CMS should grant IHS, tribal health clinics, urban Indian clinics (I/T/Us) the same allowance, given the difficulties with Internet access in Indian Country. • c. **"Topping Out"**: The proposed rule would eliminate the need for providers to report individually on measures for which they have already met the meaningful use (MU) threshold ("topping out"), thereby lessening the reporting burden; CMS should retain this provision in the final rule but should take into consideration that I/T/Us might not "top out" on the most basic measures, calling for flexibility in the way the agency determines if a provider has met the MU threshold.	No subsequent Agency action taken (as of 7/31/2015).

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
			• d. **Paper-Based Formats**: The proposed rule would not allow the continued use of paper-based formats for certain objectives and measures in Stage 3; CMS should exclude I/T/Us from the provision because of the lack of Internet access in Indian Country. • e. **HIPAA Security Rules**: HIPAA Security Rules require covered entities and business associates to conduct a security risk analysis to assess the potential risks to the electronic protected health information (ePHI) they create, receive, maintain, or transmit, but most, if not all, I/T/Us cannot afford the run this analysis as needed to meet the MU requirements in the proposed rule; CMS should take this into consideration in the final rule. • f. **Electronic Prescribing (eRx)**: eRx serves as one of eight objectives for MU in 2017 and subsequent years, and the proposed rule would require eligible professionals (EPs) to generate and transmit permissible prescriptions electronically and eligible hospitals and critical access hospitals (CAHs) to generate and transmit permissible discharge prescriptions electronically--requirements that I/T/U would have difficulty meeting because of the rural nature of Indian Country; CMS should exclude I/T/Us from these requirements in the final rule. • g. **Clinical Decision Support (CDS)**: CDS--which concerns positive impact on the quality, safety, and efficiency of care delivery--serves as another of the eight objectives for MU in 2017, but I/T/Us will have difficulty achieving MU if they must have computerized	

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			alerts and reminders for providers and patients, information displays or links, context-aware knowledge retrieval specifications, InfoButtons, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information as the proposed rule would require; CMS should exclude I/T/Us from these requirements in the final rule. • h. **Computerized Provider Order Entry (CPOE)**: I/T/Us also would have difficulty meeting the proposed objective regarding CPOE for Stage 3, as the proposed rule would require including diagnostic imaging--such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology--not commonly found in Indian Country; CMS should exclude I/T/Us from these requirements in the final rule. • i. **Patient Electronic Access to Health Information**: In addition, I/T/Us would have difficulty meeting the proposed objective that, as required by the proposed rule, allows patients to view, download, and transmit their health information to a third party and engage in patient-centered communication for care planning and care coordination, as well as have timely access to their full health record, as these providers (and their patients) lack the necessary tools; in the final rule, CMS should exclude I/T/Us and their patients from the "no paper allowed" doctrine for Stage 3 and reconsider requirements on application-program interfaces (APIs) for Indian Country.	

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
			• j. **Patient Electronic Access to Health Information Exclusion**: The proposed rule would exclude from this objective any clinic located in a county in which 50 percent or more of its housing units lack 4 Mbps broadband availability and in which a significant section of the patient population does not have access to broadband Internet; CMS should retain this exclusion in the final rule. • k. **Coordination of Care Through Patient Engagement**: CMS should retain in the final rule an exclusion from this objective for any clinic located in a county in which 50 percent or more of its housing units lack 4 Mbps broadband availability and in which a significant section of the patient population does not have access to broadband Internet. • l. **Transitions of Care**: This proposed objective seeks to ensure the electronic transmission or capture of a summary of care record and the incorporation of this record into the EHR for patients seeking care among different providers in the care continuum, as well as to encourage reconciliation of health information for the patient; the summary of care measure in this objective raises some concerns based on the current status of health information exchange and the ability to partner with other organizations at this time, and as such, CMS should consider a more practical approach that would allow for a demonstration of the capability of a facility and consider implementation of rates in the future. • m. **Public Health and Clinical Data Registry Reporting**: This objective focuses on the importance of	

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			the ongoing lines of communication that should exist between providers and public health agencies (PHAs) or between providers and clinical data registries (CDRs); this objective raises concerns because of the proposed requirement on bidirectional immunization exchange, a functionality that will require unanticipated additional development for vendors in the current year, and CMS as such, CMS should reconsider this requirement. 2. **Certified EHR Technology (CEHRT) Requirements**: • a. **Consolidating Reporting**: The proposed rule seeks to (1) avoid redundant or duplicative reporting and align certain aspects of the reporting clinical quality measures (CQMs) component of MU under the Medicare EHR Incentive Program and Physician Quality Reporting System (PQRS) for EPs and (2) avoid redundant or duplicative reporting of CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs in the inpatient prospective payment system (IPPS); CMS should retain these provisions in the final rule. • b. **Electronic Reporting of CQMs**: For 2018 and subsequent years, the proposed rule would require providers participating in Medicare to report CQMs electronically, where feasible, and remove the option of attestation to CQMs, except in circumstances where electronic reporting is not feasible; for I/T/Us in Indian Country where electronic reporting is not feasible, CMS	

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			should allow an alternative process. • c. **HITECH Act Exemption**: The HITECH Act requires reductions in payments to EPs, eligible hospitals, and CAHs that do not meet MU requirements, but the HHS secretary has the authority to exempt an affected EP if this reduction would result in a significant hardship; CMS should grant I/T/Us in Indian Country a permanent exemption.	
7.vv.	**2016 Letter to Issuers in FFMs** **ACTION: Guidance** **NOTICE:** ~~Draft~~ 2016 Letter to Issuers in the Federally-Facilitated Marketplaces **AGENCY:** CCIIO	CCIIO (no reference number) Issue Date: 12/19/2014 Due Date: 1/12/2015 TTAG File Date: 1/12/2015 Date of Subsequent Agency Action, if any: Issued Final Letter 2/20/2015	TTAG recommendations-- 1. **Application of Requirements Related to Indian Health Providers (IHPs)**: The requirements in the 2016 Issuer Letter apply solely to issuers when offering qualified health plans (QHPs) through the Federally-Facilitated Marketplace (FFM); CMS should extend these requirements to issuers when offering QHPs in State-Based Marketplaces. 2. **Requirement for Issuers to Offer Contracts to IHCPs**: The draft 2016 Issuer Letter does not retain a provision in the 2015 Issuer Letter (page 20) requiring issuers--in cases in which they fail to meet the 30 percent essential community provider (ECP) guideline--to attest in a narrative justification to having made good faith contract offers to all IHCPs in a QHP service area and instead states on page 26, "If an issuer's application does not satisfy the 30 percent ECP standard *as well as the requirement to offer contracts in good faith to all available Indian health providers in the service area*," the issuer must provide a narrative justification	In the 2/20/2015 Final Letter-- 1. **Application of Requirements Related to Indian Health Providers (IHPs)**: Not accepted. 2. **Requirement for Issuers to Offer Contracts to IHPs**: Not accepted. CMS finalized this statement as proposed.

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
			(emphasis added); CMS should delete the italicized phrase, as it would allow an issuer to offer a QHP through the FFM without having made good faith contract offers to all available IHPs. TTAG made additional recommendations regarding issues addressed in the 2016 Issuer Letter in comments submitted separately in response to CMS-9944-P (**see 89.h.**)	
7.ccc.	**Out-of-Pocket Cost Comparison Tool for FFMs** **ACTION: Notice** **NOTICE:** CMS Bulletin on Proposed Out-of-Pocket (OOP) Cost Comparison Tool for the Federally-Facilitated Marketplaces (FFMs) **AGENCY:** CCIIO	CCIIO (no reference number) Issue Date: 5/29/2015 Due Date: 6/29/2015 TTAG File Date: 6/29/2015 Date of Subsequent Agency Action, if any:	TTAG recommendations-- 1. **Eligibility for Indian-Specific Cost-Sharing Protections**: Footnote 1 in the CMS Bulletin on the Proposed OOP Cost Comparison Tool (OOP CCT) includes an inaccurate description of the eligibility criteria for each of the two Indian-specific cost-sharing variations (CSVs); CCIIO should replace this description (both in this document and in all other documents that contain a similar description) with the corrected version below: • "Zero cost-sharing variation" protections are available to individuals who meet the ACA definition of Indian, have household income between 100 percent and 300 percent of the federal poverty level (FPL), qualify for premium tax credits, and enroll in coverage through the Marketplace. • "Limited cost-sharing variation" protections are available to individuals who meet the ACA definition of Indian, have household income of any level, and enroll in coverage through the Marketplace.	No subsequent Agency action taken (as of 7/31/2015).

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
			o Individuals eligible for the limited cost-sharing variation do not have to qualify for premium tax credits and can decide *not* to request an eligibility determination for insurance affordability programs (e.g., premium tax credits). 2. **Applicability of CSVs in Silver-Level Plans**: To ensure that the OOP CCT benefits individuals receiving one of the CSVs--either those available to the general population (sometimes referred to as the "04," "05," and "06" variant codes) or available to Indians (sometimes referred to as "02" or "03" variant codes)--CCIIO should incorporate into the tool the impact of these cost-sharing protections to the computations made and the consumer-focused information displayed; CCIIO also should add a fourth factor, "applicable cost-sharing variation," to the description of the "data inputs" for the tool. 3. **Applicability of Indian-Specific CSVs at All Metal Levels**: Displaying the impact of the Indian-specific CSVs for each plan offered at each metal level will prove critical to helping an Indian applicant understand the impact of the available cost-sharing protections, and the absence of such information will present an inaccurate depiction of the Indian-specific CSVs, and of Marketplace enrollment generally; CCIIO should ensure that the OOP CCT displays the impact of the Indian-specific CSV for which an Indian applicant qualifies for plans at each metal level. 4. **Estimated Impact of Balance Billing**: The CMS Bulletin includes no discussion of the potential impact of "balance billing," a practice under which out-of-network providers can	

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
			charge patients more than the amounts agreed upon by the plan issuer and the providers, or of a related concern, the breadth of a plan provider network, although both of these factors will prove important to Indian applicants in comparing potential OOP costs under various plan options; to address these issues in the OOP CCT, CCIIO should: • Include a standard statement (with an illustrative example) that services received from out-of-network providers might result in charges beyond the amounts shown in the OOP CCT and that the narrower the offering of in-network providers, the greater the likelihood a plan enrollee might experience balance billing charges; or • Provide a specific estimate of balance billing charges experienced under Marketplace coverage and adjust these estimated charges by the breadth of the provider network included under each plan offered. 5. **Out-of-Network Provider Charges**: Under "Health Plan Cost Sharing Design, i. Plan and Benefits Data," the CMS Bulletin states that the "inputs would be structured for all services that are consumed for Tier-1 in-network … services," and as with balance billing charges, providing an indication of potential OOP costs arising from services received from out-of-network providers will prove important to an applicant making an informed plan choice; to enable OOP CCT users to tailor the information displayed, CCIIO should add an option that allows users to display "OOP for all in-network providers" or "OOP for in-network and out-of-	

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
			network providers." 6. **Availability and Use of OOP CCT**: CCIIO has designed the OOP CCT for use under the Federally-Facilitated Marketplace (FFM); CCIIO should make the OOP CCT available for adoption by State-Based Marketplaces (SBMs).	
31.pp.	**Summary of Benefits and Coverage and Uniform Glossary** **ACTION:** **~~Proposed~~ Final Rule** **NOTICE:** Summary of Benefits and Coverage and Uniform Glossary **AGENCY:** IRS/DoL/CMS	~~REG-145878-14~~ TD 9764 DoL RIN 1210-AB69 CMS-9938-~~PF~~ Issue Date: 12/30/2014 Due Date: 3/2/2015 TTAG File Date: 2/28/2015 Date of Subsequent Agency Action, if any: Issued Final Rule 6/16/2015	TTAG recommendations-- 1. **Review of Summary of Benefits and Coverage (SBC) template**: The SBC template might require some modifications as qualified health plan (QHP) issuers work to incorporate the required plan information for the two Indian-specific cost-sharing variations; CMS should review the SBC template to determine any need for modifications to accommodate the information necessary for the "limited" and "zero" cost-sharing variations and engage with tribal representatives on this review. 2. **Review of SBCs for Accuracy:** In the past, tribal representatives have found inaccuracies in some of the SBCs voluntarily prepared by some QHP issuers to describe the Indian-specific cost-sharing variations; CMS should review SBCs to assess the accuracy of the application of the "limited" and "zero" cost-sharing variations. 3. **Sample Language:** To address confusion on the part of some QHP issuers, CMS should provide sample language, for use by issuers in the preparation of SBCs, to describe how the "zero" and "limited" cost-sharing variations impact deductibles, co-insurance, etc. for in-network and out-of-network providers.	In the 6/16/2015 Final Rule-- 1. **Review of Summary of Benefits and Coverage (SBC) template:** Not accepted. CMS did not address this issue. 2. **Review of SBCs for Accuracy:** Not accepted. CMS did not address this issue. 3. **Sample Language:** Not accepted. CMS did not address this issue.

RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
31.ss.	**Excise Tax on High Cost Employer Health Coverage** **ACTION: Guidance** **NOTICE:** Section 4980I--Excise Tax on High Cost Employer-Sponsored Health Coverage **AGENCY:** IRS	Notice 2015-16 Issue Date: 2/23/2015 Due Date: 5/15/2015 NIHB File Date: 5/15/2015 Date of Subsequent Agency Action, if any:	NIHB recommendations-- 1. **Exclusion of Tribal Employers from the Excise Tax Based on Longstanding Rules of Statutory Interpretation**: Section 9001 of ACA, which established Internal Revenue Code (Code) section 4980I, applied the excise tax to excess benefits provided under "applicable employer-sponsored coverage," as defined in subsection 4980I(d)(l); this subsection, however, does not mention coverage administered by Tribes or tribal organizations, despite specifically addressing state governments and the federal government, and under longstanding rules of statutory interpretation, IRS should consider the decision by Congress to exclude these entities from Section 4980I as a deliberate action and, as such, should exclude tribal coverage from the excise tax. 2. **Exclusion of Tribal Employers from the Excise Tax Based on Policy Considerations**: Congress has recognized the importance of maintaining and improving the health of Indians, as well as ensuring their access to health care services, as part of the federal Indian trust responsibility, but the application of the excise tax to tribal employers that administer their own plans would undercut these goals by forcing tribal employers to 1) pay the tax and divert funding from necessary services, 2) replace existing coverage specifically designed to meet the needs of the tribal workforce with lower-cost and less appropriate coverage, or 3) eliminate coverage; these policy considerations support excluding tribal coverage from the excise tax, and IRS should acknowledge them in any future regulations on this issue.	No subsequent Agency action taken (as of 7/31/2015).

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
			3. **Exclusion of Coverage Provided to Tribal Member Employees from the Excise Tax Based on the Definition of "Applicable Employer-Sponsored Coverage"**: The term "applicable employer-sponsored coverage" under section 4980I means coverage "under any group health plan made available to the employee by an employer which is excludable from the employee's gross income under section 106" of the Code or "would be so excludable if it were employer-provided coverage (within the meaning of such section 106)"; coverage for Tribal member employees, however, is excluded from income pursuant to section 139D, not section 106, and, as such, does not fall under the definition of "applicable employer-sponsored coverage" in section 4980I, and IRS should clarify this distinction to ensure that the excise tax is not levied against coverage provided by a tribal employer to a tribal member employee, as well as consult with tribal organizations regarding application of the tax to Tribes. 4. **Exclusion of Certain Benefits from the Scope of the Excise Tax**: IRS requested comments on whether it should exclude certain benefits--1) certain types of onsite medical coverage, 2) Employee Assistance Program (EAP) benefits, and 3) self-insured dental and vision coverage--from the scope of the excise tax; the agency should exclude all three of these benefits from the excise tax and should expand the exclusions to include services provided at the nearest appropriate tribal health program (whether or not on site) and services provided to any employee by an I/T/U program for workplace-related health issues. 5. **Adoption of "Permissive Disaggregation" Rules**: In most cases, IRS will determine the value of coverage for the	

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			purposes of the excise tax by evaluating the average plan cost among all "similarly situated beneficiaries," and regarding this issue, the agency requested comments on whether it should issue "permissive disaggregation" rules under which employers could designate plan beneficiaries as "similarly situated" based on either a broad standard or a more specific standard; IRS should adopt broad permissive disaggregation rules that maximize employer flexibility to group plan beneficiaries according to the unique needs of its workforce. 6. **Adoption of a Past Cost Method for Calculating Plan Value**: IRS requested comments on the manner in which self-insured plans would calculate plan values to compare against the statutory threshold, proposing three primary options--1) an actuarial method that would calculate the cost of coverage for a given determination period using "reasonable actuarial principles and practices," 2) a past cost method that would make the cost of coverage equal to the cost to the plan for similarly situated beneficiaries for the preceding determination period (adjusted for inflation), or 3) an actual cost method that would make the cost of coverage equal to the actual costs paid by the plan to provide coverage for the preceding determination period; IRS should adopt some version of the past cost method, excluding overhead expenses from this calculation, and should consult with tribal organizations to address the specifics of this issue. 7. **Application of "Good Faith Interpretation" in Implementation of "Controlled Group Rules"**: Section 4980I states that, for the purposes of calculating plan values, the "controlled group rules" imposed by ERISA apply; however, IRS has explicitly reserved application of the	

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			controlled group rules to governmental employers and has stated that governmental entities can "apply a reasonable, good faith interpretation" of the rules in other ACA-related contexts--such as the employer mandate--and, as such, the agency should recognize, either in future regulations or guidance, that the good faith interpretation of the controlled group rules by Tribes applies for the purposes of both the employer mandate and the excise tax and that satisfying the standard in one context will equally satisfy the standard in the other.	
41.e.	**New Safe Harbors ACTION: Notice** **NOTICE:** Solicitation of New Safe Harbors and Special Fraud Alerts **AGENCY:** HHS OIG	OIG-123-N Issue Date: 12/30/2014 Due Date: 3/2/2015 TTAG File Date: 3/2/2015 Date of Subsequent Agency Action, if any:	TTAG recommendations-- The comments generally reiterate recommendations that tribal organizations made on 2/27/2012 in response to OIG-120-N (**see 41.a.**). To date, HHS OIG has not adopted any of these recommendations. In regard to OIG-123-N, specific recommendations appear below. 1. **Safe Harbor for Waiver of Beneficiary Coinsurance and Deductibles**: HHS OIG should extend to AI/ANs eligible for IHS services the current safe harbor for a reduction or waiver of the obligation of a Medicare or State health care program beneficiary to pay coinsurance or deductibles. 2. **New Safe Harbors for Indian Health Care Providers (IHCPs)**: HHS OIG should create the following safe harbors: • a. A safe harbor specific to I/T/U providers, modeled after the existing safe harbor authorizing Federally	No subsequent Agency action taken (as of 7/31/2015).

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
			Qualified Health Centers "to accept certain remuneration that would otherwise implicate the anti-kickback statute when the remuneration furthers a core purpose of the Federal health centers program: ensuring the availability and quality of safety net health care services to otherwise underserved populations"; • b. A safe harbor authorizing exchanges or transfers of value among and between IHCPs; • c. A safe harbor authorizing IHCPs to share other resources, including practitioner services and facility space, among one another; and • d. A safe harbor authorizing IHCPs to offer free or reduced-cost goods or services to IHS-eligible individuals to encourage healthy lifestyle choices and the use of preventive care, improve public safety, facilitate keeping health care appointments, etc.	
64.c.	**Tribal Consultation Policy** **ACTION: Notice** **NOTICE:** Tribal Consultation Policy **AGENCY:** Treasury	Treasury (no reference number) Issue Date: 12/3/2014 Due Date: 4/2/2015 NIHB File Date: 4/2/2015	NIHB recommendations-- **Employer Shared Responsibility Requirement**: Under the current IRS interpretation of the employer shared responsibility requirement under ACA, tribal employers would have to incur the costs of purchasing health coverage for their member employees or pay a penalty for not offering them coverage--in either case requiring them to pay for coverage for many tribal members only because they work for the Tribe--but this interpretation does not comport with congressional intent, the federal trust responsibility, or CCIIO policies encouraging Tribes to enroll their members in the Marketplace without regard to the fact that an offer of coverage by a tribal employer would disqualify them from	No subsequent Agency action taken (as of 7/31/2015).

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
		Date of Subsequent Agency Action, if any:	available subsidies; IRS should revise its Interim Tribal Consultation Policy to ensure active consultation with Tribes to address this and other issues as the agency interfaces with other federal agencies responsible for implementing ACA.	
89.h.	**Notice of Benefit and Payment Parameters for 2016** **ACTION:** ~~Proposed~~ **Final Rule** **NOTICE:** Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 **AGENCY:** CMS	CMS-9944-~~PF~~ Issue Date: 11/26/2014 Due Date: 12/22/2014 TTAG File Date: 12/22/2014 Date of Subsequent Agency Action, if any: Issued Final Rule 2/27/2015	TTAG recommendations-- 1. **Requirement on Summary of Benefits and Coverage (SBC)**: The proposed rule would establish a requirement that QHP issuers prepare an SBC for each plan variation, such as the "zero cost-sharing variation" and the "limited cost-sharing variation"; in regard to this requirement, CMS should: • a. **Retention**: Retain this requirement, as to date, information on Indian-specific cost-sharing protections provided by issuers to consumers, if any, often proves confusing or incorrect, prompting some AI/ANs to decide not to enroll in coverage through a Marketplace; • b. **Encouraging Issuer Compliance**: Encourage issuers to prepare SBCs for use during the 2015 benefit year but no later than the first day of the Marketplace open enrollment period for the 2016 benefit year; • c. **Regulatory Cross-Reference**: Add a cross-reference to the requirement to prepare an SBC in the	In the 2/20/2015 Final Letter-- 1. **Requirement on Summary of Benefits and Coverage (SBC)**: • a. **Retention:** Accepted. CMS approved this provision as proposed. • b. **Encouraging Issuer Compliance**: Accepted in part. CMS approved the requirement that QHP issuers provide SBCs for plan variations no later than the first day of the next Marketplace open enrollment period for the individual market for the 2016 benefit year, specifying this date as November 1, 2015. • c. **Regulatory Cross-Reference**: Not accepted.

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 7/31/2015

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
			regulation on SBCs (45 § 147.200) by inserting in §147.200 the following language (in brackets and bold): "*§147.200 Summary of benefits and coverage and uniform glossary. (a) Summary of benefits and coverage--(1) In general. A group health plan (and its administrator as defined in section 3(16)(A) of ERISA), and a health insurance issuer offering group or individual health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for* ***[each plan variation of]*** *each benefit package* ***[, as indicated in §156.420(h)]*** *without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section*"; and • d. **Examples Regarding Compliance**: In the preamble to the final rule, and in subsequent guidance documents, provide examples of when QHP issuers must provide SBCs to comply with the requirements set forth in § 147.200 and § 156.420(h) and the circumstances, if any, under which a single SBC can satisfy the requirement for multiple plans. 2. **Hardship Exemption**: The proposed rule includes a provision that would codify the newly established process for obtaining the hardship exemption from the tax penalty for IHS-eligible individuals; in regard to this provision, CMS should: • a. **Retention**: Retain this provision (§ 155.605(g)(6)(iii)), which would make agency regulations consistent with revised IRS regulations; and	CMS did not modify § 147.200 in the final rule. • d. **Examples Regarding Compliance**: Not accepted. CMS did not address this issue. 2. **Hardship Exemption**: • a. **Retention**: Accepted. CMS approved this provision as proposed.

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. **Paper-Based Application Process**: Refocus attention on fixing the paper-based exemption application process through Federally-Facilitated Marketplaces by allocating sufficient resources and making the current status of individual applications--as well as applications in the aggregate--more transparent.	• b. **Paper-Based Application Process**: Not accepted. CMS did not address this issue specifically but stated, "We remain committed to improving the Exchange exemptions process." [80 FR 10802]
			3. **Code Citation to Definition of Indian Under Medicaid**: The proposed rule includes a provision that would amend § 155.605(g)(6)(i) by changing the citation to 42 § 447.50 to 42 § 447.51, which cross-references the definition of Indian used for Medicaid purposes; CMS should retain this provision.	3. **Code Citation to Definition of Indian Under Medicaid**: Accepted. CMS approved this provision as proposed.
			4. **Network Adequacy and Essential Community Provider Provisions**: The proposed rule would codify some of the network adequacy and essential community provider (ECP) provisions that appear in the CCIIO 2015 Issuer Letter and apply solely under the FFM, including 1) codifying the requirement that QHP issuers offer contracts to all Indian health care providers (IHCPs), 2) requiring/encouraging "good faith" offers pertaining to payment rates, 3) adding a requirement that QHP-IHCP contracts apply the special terms and conditions under Federal law pertaining to IHCPs (contained in the QHP Addendum), and 4) applying the requirement that QHP issuers offer contracts to IHCPs; in regard to these provisions, CMS should:	4. **Network Adequacy and Essential Community Provider Provisions**:
			• a. **Mandatory Offer**: Retain the requirement that QHP issuers offer contracts to all IHCPs in the QHP service	• a. **Mandatory Offer**: 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
			area;	CMS approved this provision as proposed.
			• b. **30 Percent ECP Standard**: At a minimum, maintain the minimum standard of contracting with at least 30 percent of available ECPs until such time as quantitative evidence indicates that enrollees have reasonable and timely access to health care services;	• b. **30 Percent ECP Standard**: Accepted. CMS approved this provision as proposed. According to CMS, "Based on our QHP certification reviews for the 2015 benefit year and the ongoing strengthening of our ECP list, we believe that specifying the ECP inclusion percentage in HHS guidance for the 2016 benefit year provides desirable flexibility at this time for HHS further examine the adequacy of this inclusion standard for ensuring access to care for low-income, medically underserved individuals for future years." [80 FR 10835]
			• c. **"Good Faith" Contract Offers**: Retain the provision requiring "good faith" contract offers to IHCPs, but 1) clarify that the minimum payment rate provision exists as a requirement rather than an "expectation" and 2) include the minimum payment rate requirement in the final regulations, rather than limiting it to the preamble;	• c. **"Good Faith" Contract Offers**: Accepted in part. CMS approved this provision as proposed and stated, "We do not intend to prescribe such specificity regarding contract negotiations between parties. Therefore, we are not requiring a minimum payment rate provision, and instead reiterate our expectation that QHP issuers offer contracts in good faith" [80 FR XXXXX]. In addition, CMS codified the inclusion of IHCPs in the definition of ECP to "emphasize that these providers are among the ECP groups to which issuers must extend contract offers in good faith to satisfy §156.235(a)." [80 FR 10835]
			• d. **QHP Addendum Language**: Modify the language	• d. **QHP Addendum Language**: 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
			referencing the QHP Addendum to make it consistent with the wording of the CCIIO 2015 Issuer Letter, as the proposed rule appears to require application of the Indian-specific provisions in Federal law but not (as required in the CCIIO 2015 Issuer Letter) actual use of the Addendum;	According to CMS, "We believe the requirement that issuers apply the special terms and conditions necessitated by Federal law and regulations as referenced in the recommended model QHP addendum, along with encouraging issuer use of the recommended model QHP addendum in guidance, strikes the desirable balance between allowing the minimal flexibility that issuers have requested while ensuring inclusion of the fundamental provisions of the model QHP addendum within the issuer contractual offers to the Indian health providers. Therefore, while we strongly encourage issuers to use the model QHP Addendum, we are not requiring that they do so." [80 FR 10836]
			• e. **"Alternative Standard" for Issuers**: Strengthen the "alternative standard" for QHP issuers to comply with ACA requirements by 1) adding a requirement that they indicate efforts taken to date to meet the ECP standard and 2) making publicly available their narrative description of efforts taken to date, as well as their plan on "how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year"; and	• e. **"Alternate Standard" for Issuers**: Not accepted. CMS modified this provision but did not address the recommended requirements.
			• f. **State-Based Marketplace (SBM) Standards**: Add language to the preamble of the final rule "urging" SBMs to apply the IHCP contracting standards to QHPs offered through SBMs.	• f. **State-Based Marketplace (SBM) Standards**: Accepted. CMS stated, "We urge State Exchanges to employ the same standard when examining adequacy of ECPs as

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
				outlined in §156.235, including the requirement that issuers offer contracts to all Indian health providers in the plan's service area." [80 FR 10837]
			5. **Application of Cost-Sharing Protections for AI/AN Families**: Responses from CMS to earlier comments from tribal organizations indicated a willingness to address problems with the application of cost-sharing protections for families with AI/AN and non-AI/AN members beginning with the 2016 benefit year, but the proposed rule does not address this issue; in regard to this concern, CMS should 1) implement tribal recommendations (made on CMS-9964-P in December 2012) to eliminate the potential for an increase in the aggregate premiums and to prevent shifting of out-of-pocket (OOP) liabilities to non-Indian family members or 2) provide as an administrative convenience the ability of other IHS-eligible family members to enroll in the same zero cost-sharing variation or limited cost-sharing variation in which Indian members of the family qualify.	5. **Application of Cost-Sharing Protections for AI/AN Families**: Not accepted. CMS did not address this issue.
			6. **AI/AN Family Tag-Along Policy**: At the request of tribal organizations, CCIIO issued guidance to enrollment assisters on November 15, 2014, indicating that family members of individuals eligible for the Monthly Special Enrollment Period (SEP) for Indians can enroll in Marketplace coverage with the eligible individuals, and although the proposed rule would make several modifications to SEP regulations (§155.420), it would not codify this provision; in regard to this provision, CMS should add this provision to the final rule by inserting in §155.420(d)(8) the following language (in bold): "(8) The qualified individual who is an Indian, as defined by section 4	6. **AI/AN Family Tag-Along Policy**: Not accepted. CMS stated, "An Indian as provided under section 4(d) of the Indian Self Determination and Education Assistance Act (ISDEAA) and section 4 of the Indian Health Care Improvement Act (IHCIA) is defined as an individual who is a member of an Indian tribe. Both ISDEAA and IHCIA have nearly identical language that refers to a number of Indian entities that are included in this definition on the basis that they are recognized as eligible for the special programs and services provided by the United States to Indians

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
			of the Indian Health Care Improvement Act, **or his or her dependent,** may enroll in a QHP or change from one QHP to another one time per month."	because of their status as Indians. As such, the statute specifically provides the special enrollment period defined in paragraph (d)(8) of this section as applying to the individual who is eligible for special programs and services because of their status as an Indian, and not their dependents." [80 FR 10799]
			7. **Maximum Out-of-Pocket Costs for Individuals**: The proposed rule includes language clarifying (for the 2016 benefit year and beyond) that the annual limitation on cost-sharing for self-only coverage applies to all individuals, regardless of whether the individual is covered by a self-only plan or a family plan, with the limit let at $6,850 in 2016; CMS should retain this provision.	7. **Maximum Out-of-Pocket Costs for Individuals**: Accepted. CMS approved this provision as proposed. Other Points of Interest: • **Contract Offers to IHCPs**: One (non-tribal representative) commenter recommended that, "if issuers met the ECP standard in the previous year, issuers not be required every year to offer contracts to all Indian health care providers in the service area and to at least one ECP in each ECP category in each county in the service area." [80 FR 10836-7] CMS retained this provision as preferred by tribal representatives. • **Removal of IHCPs as ECPs**: One (non-tribal representative) commenter recommended that CMS remove IHCPs as a major ECP category "due to the overlapping requirement that issuers offer contracts to

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
				all Indian health providers in the service area." [80 FR 108367] CMS retained this provision as preferred by tribal representatives.
89.k.	**Eligibility Determinations for Indian-Specific CSRs** **ACTION: Letter to CCIIO** **NOTICE:** Request for Confirmation that Eligibility Determinations for Indian-Specific Cost-Sharing Protections Are Being Made Consistent with ACA and Implementing Regulations **AGENCY:** TTAG	TTAG (no reference number) Issue Date: 6/26/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	TTAG recommendations-- 1. **Eligibility**: CCIIO should-- • Audit the eligibility determination algorithm used by the Federally-Facilitated Marketplace (FFM) to confirm implementation of the eligibility determinations for the two Indian-specific cost-sharing variations (CSVs) in the application computer program and the determination process according to federal regulations and discuss the findings with TTAG. • Indicate on the FFM determination letters the specific cost-sharing variation for which an Indian applicant has qualified (the "02" or "03" CSV) and provide a summary description of the relevant Indian-specific CSV. 2. **General Protections**: CCIIO should-- • Increase education of qualified health plan (QHP) issuers on Indian-specific cost-sharing protections by: o Providing language on the Indian-specific CSVs for inclusion in QHP Summary of Benefits and	No subsequent Agency action taken (as of 7/31/2015).

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
			Coverage documents due by October 2015. o Requiring issuers to indicate on their insurance cards the type of CSV applicable to the enrollee. • Communicate the availability of the Health Insurance Complaint System (HICS) and permit tribal sponsors of enrollees to submit multiple (repeat) cases involving a single QHP but multiple QHP enrollees in one HICS submission. • Ensure QHP issuers apply the Indian-specific CSVs correctly, drawing upon filings through HICS to identify erroneous application of Indian-specific CSVs, and prioritize conducting broader audits of the application of Indian-specific CSVs. 3. **Payments to Indian Health Care Providers**: CCIIO should-- • Ensure QHP issuers make full payments to Indian health care providers, without deducting waived cost-sharing amounts. • Communicate availability of HICS and permit providers to submit multiple (repeat) cases involving a single QHP in one submission. 4. **Shorthand Descriptions of Indian-Specific CSVs**: CCIIO should consider adopting one or more of the following abbreviated descriptions for use by CMS when it requires a shorthand version of the explanation of the Indian-specific CSV--	

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
			• OPTION 1: 00 - Non-Exchange variant 01 - Exchange variant (no CSR) **02 - Open to Indians between 100% and 300% FPL** **03 - Open to Indians of any income level, or income not determined** 04 - 73% AV Level Silver Plan CSR 05 - 87% AV Level Silver Plan CSR 06 - 94% AV Level Silver Plan CSR" • OPTION 2: o "02" or "Zero cost-sharing variation" protections are available to persons who meet the ACA's definition of Indian, have household income between 100 and 300 percent FPL, are eligible for premium tax credits, and enroll in coverage through a Marketplace. o "03" or "Limited cost-sharing variation" protections are available to persons who meet the ACA's definition of Indian, have any household income level, and enroll in coverage through a Marketplace. ▪ Persons eligible for the limited cost-sharing variation do not have to be eligible for premium tax credits and can decide to not request an eligibility determination for insurance affordability programs (*e.g.*, premium tax credits).	

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 7/31/2015

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
			• OPTION 3: o "Zero cost-sharing variation" ("02") Protections available to persons enrolled in coverage through a Marketplace who: ▪ Meet the ACA's definition of Indian ▪ Have household income between 100 and 300 percent FPL ▪ Qualify for premium tax credits o "Limited cost-sharing variation" ("03") Protections available to persons enrolled in coverage through a Marketplace who: ▪ Meet the ACA's definition of Indian ▪ Have household income of any level ▪ Do or do not qualify for premium tax credits To receive the "02" or "03" protections, an individual cannot be enrolled in a family plan with individuals who are not eligible for the "02" or "03" protections.	
92.II.	**Health Benefit Plan Network Access and Adequacy Model Act**	NAIC (no reference number) Issue Date:	TTAG recommendations-- 1. **Inclusion of Indian Health Providers (IHPs) in Networks**: The most geographically accessible and culturally appropriate primary care providers often work in clinics and	No subsequent Agency action taken (as of 7/31/2015).

RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
	ACTION: Request for Comment **NOTICE:** Health Benefit Plan Network Access and Adequacy Model Act (Draft) **AGENCY:** NAIC	11/12/2014 Due Date: 1/12/2015 TTAG File Date: 1/12/2015 Date of Subsequent Agency Action, if any:	hospitals operated by IHS, Tribes, and tribal organizations, and although it would make sense for health carriers to include IHPs in their networks, barriers to this practice exist; to reduce these barriers, NAIC should: • Include in the Model Act a section specific to IHPs that the 34 states with federally-recognized Tribes could adopt and other states could choose to omit; and/or • Amend the language throughout the Model Act to accommodate the distinctive characteristics of IHPs. 2. **Definition of Essential Community Provider (ECP)**: The Model Act does not include a definition of ECP, although one exists; NAIC should add the following language: "Essential community provider" means a provider that serves predominantly low income, medically underserved individuals, including a provider defined in Section 340B(a)(4) of the PHSA and a tax exempt entity that meets the requirements of that standard except that it does not receive funding under that section. Drafting Note: The term "essential community provider" is not used in this Act. However, the term is defined in this section to alert states that having a certain number or percentage of essential community providers in a provider network is a requirement that a qualified health plan (QHP) must satisfy in order to be offered on a health insurance exchange under the federal Affordable Care Act (ACA) and implementing regulations.	

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
			3. **Definition of Health Care Professional**: The Model Act defines a health care professional as "a physician or other health care practitioner licensed, accredited or certified to perform specified health services *consistent with state law*" (emphasis added); the phrase "consistent with state law" might prove problematic for IHPs because federal law allows professionals licensed in a different state to practice in IHS and tribal facilities, and as such, NAIC should revise this definition. 4. **Definition of IHP**: The Model Act includes no definitions related to Indian health care; NAIC should add the following definition of IHP: A facility or program that is funded in part by the federal government or a federally-recognized Tribe to serve primarily American Indians and Alaska Natives, including the federal Indian Health Service, facilities and programs that are operated by Tribes and Tribal Organizations, and urban Indian clinics (also called "I/T/U"). 5. **Geographic Accessibility**: Section 5, Part A of the Model Act creates the standard of network adequacy with regard to types of providers, and Part B allows health carriers to use any of eight reasonable criteria, which include (3) Geographic accessibility and (4) Geographic population dispersion; the concept of geographic population dispersion might prove contradictory, providing an exception to geographic accessibility, and as such, NAIC should seek to ensure that, if IHPs (or other types of providers) already	

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
			operate in remote areas or areas with low population density, health carriers offer networks that include these providers. 6. **Obtaining Covered Benefits from Out-of-Network Providers**: Section 5, Part C of the Model Act addresses the two cases in which health carriers must allow covered individuals to obtain covered benefits from out-of-network providers; NAIC should add a third case to specify that AI/ANs can access services from geographically accessible IHPs, a provision that already exists in current law and Medicaid and qualified health plan (QHP) regulations. 7. **Access Plans**: The Model Act requires health carriers to submit access plans that describe or contain 11 items; NAIC should add to item (2), "The health carrier's procedures for making and authorizing referrals within and outside its network, if applicable," details about how plans in states with IHPs will coordinate with Indian health facilities for referrals, as well as add an additional item that requires carriers in states with federally-recognized Tribes to document their good faith efforts to include IHPs in their networks. 8. **Anti-Discrimination Provisions**: Section 6, F(3) of the Model Act includes provisions to prevent discrimination against providers in the establishment of health carrier networks; to prevent discrimination against IHPs, NAIC should include, either in a special Indian health section or in the section related to anti-discrimination, a requirement that carriers make a good faith effort to offer provider contracts to all IHPs.	

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
112.c.	**Expanded Access to Non-VA Care Through Veterans Choice** **ACTION: Interim Final Rule** **NOTICE:** Expanded Access to Non-VA Care Through Veterans Choice Program **AGENCY:** VA	VA RIN 2900-AP24 Issue Date: 11/5/2014 Due Date: 3/5/2015 NIHB File Date: 3/5/2015 Date of Subsequent Agency Action, if any: Issued start date notice 11/21/2014	NIHB recommendations-- In light of the critical role I/T/Us play in the provision of health care to veterans, as well as the pivotal role veterans have within AI/AN communities, VA should take steps to ensure the inclusion of tribal and urban Indian health programs within its overall consultative and regulatory framework; specifically, VA should address the following issues: 1. **Use of Existing Agreements**: In the Preamble to the Interim Final Rule, VA states that it will "to the maximum extent practicable and consistent with the requirements of section 101, use existing sharing agreements, existing contracts, and other processes available at VA medical facilities prior to using provider agreements" under section 101; VA should follow through with this comment and use existing sharing agreements with I/T/U facilities to implement section 101, rather than requiring these facilities to negotiate new agreements. 2. **Inclusion of Tribes in Consultation**: Although IHS plays an important role in the funding and support of tribal and urban Indian health programs, the agency cannot speak for these programs; VA should include Tribes in any consultation on the implementation of the Interim Final Rule, as opportunities might exist for Tribes to offer services or programs that IHS cannot.	No subsequent Agency action taken (as of 7/31/2015).

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 7/31/2015

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
112.d.	**I/T/U Payment for Physician and Non-Hospital-Based Services** **ACTION: Proposed Rule** **NOTICE:** Payment for Physician and Other Health Care Professional Services Purchased by Indian Health Programs and Medical Charges Associated with Non-Hospital-Based Care **AGENCY:** IHS	IHS RIN 0917-AA12 Issue Date: 12/5/2014 Due Date: ~~1/20/2015~~ 2/4/2015 NIHB File Date: 2/4/2015 Date of Subsequent Agency Action, if any: Issued due date extension 1/14/2015	NIHB recommendations-- 1. **Treatment of Professional Services Under Existing Medicare-Like Rate Regulations**: The titles for Subpart I and Section 136.201 erroneously suggest that current Medicare-Like Rate regulations do not apply to care provided by physicians and other health care professionals; IHS should clarify that the rule applies to all non-hospital providers (including non-hospital based physicians and other health care professionals). 2. **Section 136.201(a)(1)(3)**: Section 136.201 states that I/T/Us can pay only the lowest of either (1) the Medicare-Like Rate; (2) a rate negotiated by the I/T/U or its repricing agent; or (3) the amount the provider "bills the general public for the same service," but (3) seems vague and might result in misinterpretation; IHS should change this provision to the amount the provider "accepts as payment for the same service from nongovernmental entities, including insurance providers." 3. **Need for Exceptions in New Section 136.201(b)**: Section 136.201(a) cites Medicare-Like Rates as the highest rates IHS could pay, and this lack of discretion renders this provision unworkable in many areas in Indian country; IHS should allow I/T/Us the discretion and flexibility to deal with unique circumstances that might necessitate negotiating a rate different from, or even higher than, the Medicare-Like Rate by adding the following sections to the rule: • a. **Section 136.201(b)(1)**: This section, which would	No subsequent Agency action taken (as of 7/31/2015).

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
			apply to Tribes and tribal organizations that have negotiated agreements with IHS under the Indian Self-Determination and Education Act and urban Indian organizations, would make clear that they have the right to choose not to apply the rule; and • b. **Section 136.201(b) (2)**: This section would allow I/T/Us, when necessary, to negotiate a rate with providers higher than the rate provided for in Section 136.201(a), capping the rate at no more than what the provider charges non-governmental entities, including insurance providers, for the same service. 4. **Tribal Consultation**: The proposed rule would have significant tribal implications and substantial direct effects on one or more Tribes; IHS should engage in tribal consultation before finalizing the rule.	
112.e.	**Tribal Consultation on VA/IHS Reimbursement Agreements** **ACTION: Notice** **NOTICE:** Section 102(c) of the Veterans Access, Choice, and Accountability Act of 2014	VA (no reference number) Issue Date: 12/30/2014 Due Date: 1/14/2015 TSGAC File Date: 1/14/2015	TSGAC recommendations-- 1. **Direct Communication with Tribal Health Programs**: VA should establish communication with tribal and urban health programs regarding all aspects of its implementation of the Veterans Access, Choice and Accountability Act of 2014 and other department initiatives, as IHS cannot speak for these programs. 2. **Inclusion of Tribal Health Programs in New Agreement Negotiations**: To the extent that VA considers new model language or agreements to streamline contracting with I/T/Us to provide services to AI/ANs, in addition to IHS representatives, any negotiations or discussions should	No subsequent Agency action taken (as of 7/31/2015).

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 7/31/2015

RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
	AGENCY: VA	Date of Subsequent Agency Action, if any:	include tribal and urban health program representatives to ensure recognition of the differences between IHS and tribal and urban health programs. 3. **Inclusion of Tribal Health Programs in Development of Performance Metrics**: Tribal and urban Indian health program representatives should serve as participants in satisfying the requirement of section 102(b) of identifying and developing the performance metrics for both VA and IHS under their Memorandum of Understanding regarding increasing access to health care, improving quality and coordination of health care, promoting effective patient-centered collaboration and partnerships between VA and IHS, and ensuring funding and availability of health-promotion and disease-prevention services for beneficiaries under both health care systems. 4. **Recommendation for Entering and Expanding Agreements with I/T/Us**: In its report to Congress, VA should recommend entering agreements with I/T/Us for reimbursement of the costs of services provided to eligible non-AI/AN veterans and, when possible, using and expanding these agreements to accelerate the implementation of all aspects of the efforts by VA to expand access to health care to eligible veterans.	
154.b.	**Medicaid/CHIP Managed Care** **ACTION: Proposed Rule**	CMS-2390-P Issue Date: 6/1/2015 Due Date:	NIHB/TTAG recommendations-- 1. **Clarification States Cannot Obtain a Waiver of § 1932(a)(2)(C)**: Although CMS has consistently rejected attempts by states to force AI/ANs into managed care through section 1115 waivers, the agency should codify this	No subsequent Agency action taken (as of 7/31/2015).

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: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability **AGENCY:** CMS	7/27/2015 NIHB File Date: 7/27/2015; TTAG also filed comments 7/27/2015 Date of Subsequent Agency Action, if any:	policy in the final rule, as Medicaid managed care entities (MCEs) lack experience or incentive to work with Indian health systems. 2. **Section 483.14(b)(1)--Network Adequacy**: Proposed § 438.14(b)(1) would require MCEs to have "sufficient" IHCPs in their networks; in the final rule, CMS should amend this section to require that MCEs demonstrate sufficiency by 1) offering network provider agreements using an Indian Managed Care Addendum at the request of IHCPs in their service area (**see the model Addendum embedded below**); 2) allowing into their networks any IHCP that seeks to participate; and 3) waiving for IHCPs any limitation placed on the number of providers in their networks. 3. **Oversight of Managed Care Plans**: To promote strong oversight of states and their managed care plans to ensure their compliance with the Indian-specific requirements in proposed § 438.14, CMS in the final rule should: • Cross-reference the quality assessment requirements in proposed section 438, Subpart E with § 438.14; • Require that managed care plans actively and regularly provide verification of compliance with the Indian-specific requirements; • Require states to hold their managed care plans accountable, with consequences for failing to meet the IHCP network adequacy and other Indian-specific requirements; and • Offer technical assistance by maintaining a current list of the IHCPs in managed care plan service areas to allow the plans to know who to contact about	

TABLE C: NIHB RECOMMENDATIONS AND EVALUATION OF AGENCY'S SUBSEQUENT ACTIONS UPDATED THROUGH 7/31/2015

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
			participating in their networks. 4. **Section 483.14(b)(5)--Access to Services in States with Few or No IHCPs**: Proposed § 483.14(b)(5) provides that, in states where a guarantee of timely access to covered services cannot occur because of the presence of "few or no" IHCPs, CMS would consider MCEs in compliance with the network adequacy standards of § 483.14(b)(1) if Indian enrollees can access out-of-state IHCPs or the "circumstance is deemed to be good cause for disenrollment from both the [MCE] and the State's managed care program in accordance with section 438.56(c)"; in the final rule, CMS should remove the phrase "few or" from this section and, regarding good cause for disenrollment, add the stipulation that "there is a fee-for-service alternative." 5. **Sections 483.14(b) and 438.9(b)--Non-Emergency Transportation**: States can contract with entities that provide only non-emergency medical transportation (NEMT), and although these prepaid ambulatory health plans (PAHPs)--referred to as NEMT-PAHPs--must meet the requirements identified in proposed § 438.9(b), the special provisions applicable to other MCE contracts involving AI/ANs, IHCPs, and Indian managed care entities (IMCEs) appear in § 438.14; CMS should amend the final rule to ensure that these provisions also apply to NEMT-PAHPs, as many IHCPs provide their patients with various nonemergency transportation services. 6. **Sections 483.14(b)(2) and (c)(2)--Payment to IHCPs**: Proposed §§ 483.14(b)(2) and (c)(2) would implement the payment requirement provisions of ARRA; to address some uncertainty about which payment rates apply, CMS in the	

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
			final rule should amend these sections to clarify that IHCPs have the right to payment at either the rate set out in the State plan or the encounter rate, whichever is higher. 7. **Waiver of Referral and Prior Authorization Requirements**: Managed care plans routinely impose referral and prior authorization requirements that do not comport with how IHCPs coordinate care, both within their own health systems and with outside providers through purchase/referred care; to address this issue, CMS should include in the final rule a provision under which MCEs must waive referral and prior authorization requirements for a network primary care provider if the patient receives his or her primary care through an IHCP that applies the same standards. 8. **Enrollment Protections**: • a. **Monthly Special Enrollment Periods**: The proposed rule would allow individuals required to enroll in a managed care program to change plans without cause within 90 days of enrollment in a plan and once every 12 months; to better align Medicaid with enrollment in a QHP--a goal indicated in the preamble--CMS in the final rule should provide monthly special enrollment periods during which AI/ANs required to enroll in a managed care program can opt into a plan or change plans without cause. • b. **Initial Selection Period**: The proposed rule would allow individuals required to enroll in a managed care program a minimum period of 14 days between the date they are notified that they must enroll in the program	

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			and the date on which the they become covered by the default MCE; in the final rule, CMS should extend this period to 30 days for AI/ANs, many of whom live in remote areas with no Internet access and slow mail delivery. 9. **Section 438.71--Beneficiary Support System**: Proposed § 438.71 appears to prohibit a Medicaid provider from assisting patients with enrollment in managed care plans; to better align the Medicaid managed care regulations with ACA regulations for Navigators and certified application counselors, CMS in the final rule should clarify that IHCP participation in a network, or network service area, does not constitute a conflict of interest in assisting patients with enrollment in plans. 10. **Suspension of Payments to a Network Provider**: The proposed rule would allow certain MCEs to retain recoveries of overpayments made to providers excluded from Medicaid participation or made as a result of fraud, waste or abuse; to avoid conflicts of interest and foster partnership among CMS, states, MCEs, and providers, in ensuring proper use of the complex Medicaid billing process, CMS in the final rule should revise this provision by requiring affected MCEs to "return to the state any collection of overpayments made to a network provider who was barred from the Medicaid program or the result of fraud, waste, or abuse." 11. **Section 438.10--Information Standards**: Proposed § 438.10 would require standardized managed care definitions and terminology and model enrollee	

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
			handbooks and notices for use by managed care plans, but AI/ANs also need information that clearly states they can continue to access their IHCP whether they in-network or out-of-network and that explains other special protections for Indians; CMS should address this issue in the final rule. 12. **Medicaid Estate Recovery**: The proposed rule does not include Medicaid estate recovery--an issue that has meaning for AI/ANs tied to historical trauma and federal Indian law--as one of the topics listed for standardized consumer information for potential enrollees; at a minimum, CMS in the final rule should ensure that potential enrollees undergo a determination process and receive either an exemption from estate recovery or a definitive statement informing them they do not qualify for an exemption. 13. **Section 438.4--Capitation Rates**: Proposed § 438.4 would require states to develop capitation rates for MCEs serving Medicaid enrollees in accordance with generally accepted actuarial principles and practices, with the qualifier that any "proposed differences among capitation rates according to covered populations must not be based on the Federal financial participation [FFP] percentage associated with the covered populations"--a provision that might cause uncertainty among states as they attempt to comply and potential confusion among CMS staff as they conduct related enforcement activities, particularly as applied to Indian health care programs; in the final rule, CMS should indicate that a state can develop capitation rates higher than they would set them otherwise as a result of the anticipated	

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
			enrollment of IHS beneficiaries in the Medicaid managed care plan, including an Indian Medicaid managed care plan. 14. **Tribal Consultation**: The proposed rule has the potential to significantly impact both AI/AN access to Medicaid and tribal health care program reimbursement, indicating a need for CMS to work directly with the TTAG and other tribal entities to ensure that the final rule reflects suggestions from Indian Country about minimizing any disruption for individual AI/ANs or Tribes as a whole, but to date no meaningful tribal consultation has occurred; CMS should address this issue prior to the finalization of the rule.	
168.	**Enrollee Satisfaction Survey Data Collection** **ACTION: Request for Comment** **NOTICE:** Enrollee Satisfaction Survey Data Collection **AGENCY:** CMS	CMS-10488 Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued	NIHB/TTAG recommendations-- 1. **Questions Specific to AI/ANs--Marketplace Survey**: To address questions specific to the experiences of AI/ANs, CMS should include a section titled "American Indians and Alaska Natives and Other Individuals Eligible to Receive Services from an Indian Health Care Provider," which should solicit responses to the below questions. • a. Whether the Marketplace provides specific information on how it determines "Indian" status for both Medicaid and QHPs, as well as the process by which an individual can challenge an unfavorable determination; • b. What types of documents that the Marketplace accepts as proof of AI/AN status, as well as the ease of	In the 4/28/2015 and 7/24/2015 revisions: 1. **Questions Specific to AI/ANs--Marketplace Survey**: N/A. CMS did not include a revised version of the Marketplace Survey in this PRA request.

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
		new request 11/1/2013; issued revision 4/28/2015, 7/24/2015 Due Date: 12/2/2013; 6/29/2015; **8/24/2015** NIHB File Date: 12/2/2013; TTAG also filed comments 12/2/2013	uploading or otherwise providing these documents; • c. Whether the Marketplace informs AI/ANs of their eligibility for a special monthly enrollment period; • d. Whether the Marketplace explains (1) the existence of AI/AN-specific cost-sharing protections under both QHPs and Medicaid; (2) the differences in eligibility for cost-sharing protections in QHPs compared with Medicaid; and (3) the manner in which an AI/AN can establish eligibility for any relevant cost-sharing protection; • e. Whether the Marketplace specifically explains (1) how AI/ANs and IHS-eligibles can apply for exemptions from the shared responsibility payment; the differences in the exemption process for members of federally recognized Indian tribes and shareholders in Alaska Native Regional or Village Corporations as compared to IHS-eligibles; and (3) the actual process for obtaining the exemptions; and • f. What interaction the AI/AN individual has experienced with any enrollment assisters or similar Marketplace personnel concerning AI/AN-specific enrollment issues. 2. **Questions Specific to AI/ANs--QHP Survey**: To address questions specific to the experiences of AI/ANs, CMS should include a section titled "American Indians and Alaska Natives and Other Individuals Eligible to Receive Services from an Indian Health Care Provider," which should solicit responses to the below questions. • a. How the QHP interacts with both the individual AI/AN	2. **Questions Specific to AI/ANs--QHP Survey**:

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

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			use the following set of questions to address this issue: "Question 1: Please indicate all of the following that apply to you: a. **American Indian or Alaskan Native.** I am a person having origins in any of the original peoples of North, Central, or South America. b. **Asian.** I am a person having origins in any of the countries of Asia. c. **Black.** I am a person having origins in any of the black racial groups of Africa. d. **Pacific Islander or Native Hawaiian.** I am a person having origins in Hawaii, the Philippines, or other Pacific Island. e. **White.** I am a person having origins in any of the original peoples of Europe, North Africa, or the Middle East. **[For those who check 'a. AI/AN,'** ***regardless of any other race or ethnicity they check*****, CMS should ask:]** Question 2a: Are you a member of a federally recognized Indian tribe or a shareholder in an Alaska Native Regional or Village Corporation? a. Yes b. No c. Don't Know Question 2b: Have you ever obtained health services	

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			from an Indian Health Service, tribal, or urban Indian health program, or are you eligible to do so? a. Yes b. No c. Don't Know" • b. **Recent Provider Visit Questions**: In the section of questions (3-9) in the QHP survey about whether an individual went to a "clinic, emergency room, or doctor's office" in the past several months, add "Indian health facility" as a possible response. • c. **"Personal Doctor" Questions**: In the section of questions in the QHP survey (21-38) about having a "personal doctor," change this term to "regular source of health care," as in most I/T/U facilities, individuals might see various providers, including doctors, nurse practitioners, physician assistants, and community health aides.	• b. **Recent Provider Visit Questions**: Not accepted. • c. **"Personal Doctor" Questions**: Not accepted.

RRIAR INDEX: HEALTH REFORM
UPDATED THROUGH 7/31/2015

RRIAR Index: Health Reform[1]					
From left-to-right in the table, the term is listed (*e.g.*, "Indian-specific ACA provisions"); the subtopic is listed (*e.g.*, "Cost-sharing reductions"); the RRIAR entry number is shown (*e.g.*, "7.a"); in parenthesis, the page number in Table B is shown first in red (*e.g.*, "(18)") and the page number in Table C is shown second in blue, underlined (*e.g.*, "(16)"). The RRIAR entry numbers and page numbers are listed in the column associated with the most recent edition of the RRIAR in which they appear.					
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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.06)	
Indian-specific ACA provisions					
Cost-sharing reductions					
Eligibility			89.a. (/43)	89.k (130/23)	
General	7.a. (18/16), 7.c. (24/67), 7.g. (29/76), 29.a. (70/112)	7.u. (32/12), 50.d. (136/61), 50.h. (140/68), 89.a. (194/79),	31.w. (133/14), 31.x. (135/16)	7.ww. (23), 7.xx. (23), 27.n. (56), 89.h. (124/16)	

[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).

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

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

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

RRIAR INDEX: HEALTH REFORM
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		89.b. (195/87), 111.b. (238/96), 111.c. (240/102)			
Definition of Indian	7.a. (18/16), 7.b. (21/22), 7.c. (24/67), 7.d. (26/75)	7.u. (32/12), 31.e. (94/40), 50.d. (136/61), 50.f. (138/64), 50.h. (140/68), 89.a. (194/79), 111.b. (238/96)			
Essential community providers	7.a. (18/16), 7.b. (21/22)	7.i. (19), 7.n. (23/1), 50.c. (135/54), 111.b. (238/96)	7.ee. (29/4), 92.cc. (255)	7.vv. (20/6), 7.ddd. (29), 50.e. (90), 89.h. (124/16), 92.ll. (134/26)	
Exemption from tax penalty		31.e. (94/40), 31.g. (103/44), 31.q. (114/47)	7.mm. (42), 31.v. (133/13)	7.ww. (23), 89.h. (124/16)	
Fees	116. (154)	89.a. (194/79)		145.c. (175)	
Implementation of section 402 of IHCIA			50.q. (173), 50.r. (175), 50.x. (179/30)		
Indian addendum	7.b. (21/22)	50.c. (135/54), 111.a. (237/94), 111.b. (238/96)	7.ee. (29/4)	7.vv. (20/6), 89.h. (124/16)	
Issuer regulations (Indian-specific concerns)	7.a. (18/16), 7.b. (21/22), 7.g. (29/76)	7.n. (23/1), 89.a. (194/79), 89.b. (195/87),	7.ee. (29/4), 50.t. (176/29), 65. (199/36),	7.vv. (20/6), 31.pp. (71/10), 89.h. (124/16),	

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		111.a. (237/94)	92.u. (242/49), 92.cc. (255)	92.ll. (134/26), 168. (181/39)	
Premium sponsorship	7.a. (18/16), 7.b. (21/22), 7.g. (29/76), 29.a. (70/112)	50.d. (136/61), 111.a. (237/94), 111.b. (238/96)	7.b. (3), 7.ee. (29/4), 50.q. (173), 50.r. (175), 50.x. (179/30), 65. (199/36)	7.vv. (20/6)	
Tribal consultation			64.a. (196/31), 64.b (198/33)	64.c. (105/15)	
Tribal Employer Participation in FEHBP			174.d. (317)		
Tobacco use (ceremonial)		50.d. (136/61), 50.f. (138/64), 50.h. (140/68), 92.a. (202/91)			
1311 Funding for Change orders		67.c. (164)	67.d. (202), 67.f. (203)	50.bb. (94), 67.g. (107)	
Basic Health Program	39.a. (80/123)		39.b. (155/19), 39.c. (157/23), 39.d. (159)	39.e. (84)	
Consumer assistance grants		67.a. (162)			
Consumer Operated and Oriented Plan (CO-OP) Program	12.a. (44), 12.b. (46/94)	12.c. (58)		12.d. (43), 12.e. (44)	
Cost-sharing reductions	7.a. (18/16), 45. (87)	29.f. (89), 50.d. (136/61),	29.g. (107/12), 29.h. (108),	27.n. (56), 89.k (130/23),	

RRIAR Index: Health Reform[1]

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		50.h. (140/68), 50.n. (146), 89.a. (194/79), 89.b. (195/87), 89.d. (198), 89.f. (201), 111.c. (240/102)	31.w. (133/14), 50.w (178), 89.g. (226)	92.uu. (141)	
Early retiree reinsurance program		88.a. (193), 88.b. (194)			
Electronic funds transfers	63.a. (113)	63.b. (159)			
Employer requirements (see also Shared responsibility)					
Coverage		29.d. (88), 31.i. (107), 92.l. (211), 92.m. (212)	92.bb. (254), 92.jj. (266)		
Excise tax				31.ss. (77/11)	
Notices		7.x. (34), 7.z. (36)			
Reporting		31.k. (108)	31.o. (129), 31.p. (130), 31.z. (137), 31.cc. (142), 31.jj. (148)	31.yy. (83)	
Self-funded, non-federal governmental plans			92.ee. (259)		
Employer tax credits			31.m. (127), 31.n. (128)		

RRIAR Index: Health Reform[1]

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Essential health benefits					
Excepted benefits		31.i. (107)	31.t. (131)	31.oo. (70), 31.qq. (75)	
General				31.vv. (80)	
Preventive services	31.a. (74/115), 31.b. (77)	31.c. (91), 31.j. (108)	31.y. (136), 31.ee. (144), 31.ff. (145)	31.dd. (61), 31.gg. (63), 31.ll. (65), 31.xx. (80)	
Standards	7.g. (29/76), 31.a. (74/115), 45. (87), 50.b. (98)	31.d. (93)	92.aa. (253)		
Exchanges					
Federally-facilitated and state-partnership					
Benefit and payment parameters (see **Notice of Benefit and Payment Parameters**)					
Blueprint for approval	7.f. (29)		7.y. (27)		
Certified application counselors		7.o. (26/3), 7.u. (32/12), 28.c. (84/30)	92.u. (242/49), 7.oo. (44)		
Eligibility and enrollment	7.c. (24/67), 7.g. (29/76)	7.s. (30/11), 7.w. (34), 7.aa. (37), 7.cc. (39), 7.dd. (40), 50.d. (136/61),	7.ff. (33), 7.qq. (47), 7.rr. (48), 7.uu. (51), 67.e. (202), 92.dd. (257/52)	92.hh. (132), 92.oo. (137)	

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		50.h. (140/68), 50.k. (143/73)			
Enrollee satisfaction	7.a. (18/16)			168. (181/39)	
General	7.a. (18/16), 7.b. (21/22), 7.e. (27)	7.i. (19), 89.c. (198/89)	7.b. (3), 7.ss. (50) 92.u. (242/49)		
Guidance (other)					
Agent/broker		7.r. (29)			
General	7.g. (29/76)		31.u. (132)		
Issuer		7.n. (23/1)	7.ee. (29/4), 7.gg. (35), 7.hh. (36)	7.vv. (20/6), 7.bbb. (25)	
Health insurance affordability programs (see **Cost-sharing reductions and Premium tax credits**)					
Information collection/reporting/ security/transactions		7.j. (20), 7.k. (21), 7.m. (22), 29.e. (89/39), 68. (164)	29.o. (117), 29.p. (118), 31.cc. (142)	7.ddd. (29), 50.e. (90), 89.i. (127)	
Navigators and non-Navigator assistance personnel	7.a. (18/16)	7.o. (26/3), 7.p. (27)	7.oo. (44)	7.q. (15), 7.v. (18), 7.kk. (19)	
Out-of-pocket costs				7.ccc. (25)	
Outreach	7.a. (18/16), 7.g. (29/76)	67.b. (163)	7.pp. (46)		
Program integrity		7.s. (30/11)			

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Quality	100.a. (144)		100.b. (271)		
Special enrollment periods		31.h. (105)	6.h. (22), 7.ii. (38), 7.jj. (38), 29.i. (108)	7.yy. (23), 7.aaa. (24), 29.r. (60)	
Stand-alone dental plans		7.u. (32/12)		7.l. (15)	
Web portal	7.g. (29/76)		65. (199/36)		
State-based					
General		7.dd. (40), 50.u. (150)	50.o. (172), 50.s. (175)	7.t. (17)	
Shared responsibility payment exemptions				50.cc. (95)	
State alternative applications		50.k. (143/73), 50.l. (144)			
Federal Employees Health Benefits Program (FEHBP)		174.a. (323), 174.b. (325)	174.c. (315), 174.d. (317), 174.e. (318)	174.f. (185)	
Health insurance market rules					
Regulations					
90-day waiting period	91.a. (138)		91.b. (231), 91.c. (231)		
Age curves		92.c. (205)			
Appeals and external review	90. (138)	128.a. (259), 128.b. (261), 128.c. (261), 128.d. (262)		128.e. (166), 128.f. (166)	
Contraceptive services		31.i. (107)	31.y. (136),	31.dd. (61),	

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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.06)	
			31.ee. (144), 31.ff. (145)	31.gg. (63), 31.ll. (65), 31.nn. (69), 31.xx. (80)	
Cost-sharing limitations				89.j. (128)	
Employer-sponsored insurance verification				54. (103)	
General		92.a. (202/91)	92.u. (242/49), 92.dd. (257/52) 92.ff. (260)		
Geographic rating areas		92.c. (205)			
Grandfathered health plans		92.e. (206)	92.h. (234), 92.n. (237)		
Information reporting		31.k. (108), 31.l. (110), 92.b. (203), 92.c. (205)	31.aa. (138), 31.cc. (142), 31.ii. (147), 92.g. (232), 145.b. (302),	31.kk. (65), 31.yy. (83), 92.pp. (138), 92.qq. (138), 92.rr. (139), 92.uu. (141)	
Mental health services	31.a. (74/115)		92.t. (241)		
Network/provider issues			92.w. (249/51), 92.cc. (255), 145.a. (301)	89.j. (128), 92.ll. (134/26) 145.c. (175), 145.d. (176)	
Preventive services (**see Essential health benefits**)					
Product modification/withdrawal				92.vv. (142)	
Rate review		92.o. (213)	92.g. (232),	92.mm. (135),	

RRIAR Index: Health Reform[1]					
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			92.s. (240)	92.nn. (136), 92.ss. (140)	
Reference pricing			92.gg. (261)		
Same-sex spouses			92.z. (252)		
Stop-loss insurance	56. (106)				
Student insurance	51. (101)				
Transitional policy			92.x. (250), 92.aa. (253)		
Unique plan identifiers	77.a. (125)			77.e. (119)	
Notices					
Annual/lifetime limits		92.d. (205), 92.j. (210)			
Coverage (Summary of Benefits and Coverage)		122.c. (254)		31.pp. (71/10), 31.tt. (78), 31.uu. (79), 92.kk. (133)	
Enrollment opportunity		92.j. (210)		92.v. (131)	
Market discontinuation/renewal		92.f. (207)	92.y. (251)	92.ww. (144)	
Patient protection		92.d. (205), 92.j. (210)	92.k. (236), 92.r. (238)		
Pre-existing condition exclusion		122.b. (254)			
Rescission		92.d. (205), 92.j. (210)	92.i. (235), 92.q. (237)		
Special enrollment rights		122.a. (253)			
Transition		92.p. (214)			

RRIAR Index: Health Reform[1]					
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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.06)	
High-risk pools (see Pre-Existing Condition Insurance Plan)					
Issuer Letters (CCIIO)					
2014 Issuer Letter		7.n. (23/1)			
2015 Issuer Letter			7.ee. (29/4)		
2016 Issuer Letter				7.vv. (20/6)	
Marketplaces (see Exchanges)					
Medical loss ratio					
General requirements	48.a. (96)	48.d. (131), 48.g. (133), 89.a. (194/79)	48.e. (169)	27.n. (56), 48.b. (87), 48.h. (89)	
Medicare Parts C and D		48.c. (131), 48.f. (132)			
Medicaid/CHIP					
Application of essential health benefits	31.a. (74/115)				
Community First Choice Option	16.a. (49/100)				
Eligibility/enrollment under ACA	7.a. (18/16), 7.c. (24/67), 7.g. (29/76)	28.a. (82/24), 28.c. (84/30)	28.e. (104)		
Federal Medical Assistance Percentage rates		28.d. (85/38)			
Medicare					
Accountable Care Organization standards	10.b. (138/82)				
Federally Qualified Health Center payments			159.b. (310/60)		
Minimum essential coverage		31.e. (94/40),	29.m. (113),	31.rr. (76)	

RRIAR Index: Health Reform[1]

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		31.q. (114/47), 31.s. (117)	31.p. (130), 31.x. (135/16), 92.aa. (253)		
Multi-State Plan Program		111.a. (237/94), 111.b. (238/96), 111.c. (240/102), 111.d. (241)		111.e. (149)	
Nondiscrimination		99.b. (221/94), 111.b. (238/96)			
Notice of Benefit and Payment Parameters					
2014		89.a. (194/79), 89.b. (195/87)	7.bb.(28)		
2015			89.e. (225)		
2016				89.h. (124/16)	
Patient-Centered Outcomes Research Trust Fund	116. (154)				
Pre-Existing Condition Insurance Plan	6.a. (16/15), 6.b. (17)	6.c., (17), 6.d. (18), 6.e. (18), 6.f. (19)	6.g. (22), 6.h. (22)	6.i. (13)	
Premium tax credits					
General	29.a. (70/112)	29.b. (86), 29.c. (87), 29.d. (88), 29.f. (89), 50.d. (136/61), 50.h. (140/68),	29.g. (107/12), 29.h. (108), 29.j. (109), 29.k. (110), 29.l. (113), 29.m. (113),	29.q. (59), 92.uu. (141)	

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Relation to cost-sharing reduction eligibility		50.n. (146)	29.n. (115), 50.w. (178) 89.a. (/43)		
Prescription drug fee			198.a. (347), 198.b. (347)	198.c. (193)	
Qualified health plans					
Accreditation	50.b. (98)	31.d. (93), 50.j. (142)		7.bbb. (25)	
Actuarial value	45. (87)	31.d. (93), 89.a. (194/79), 89.b. (195/87)	31.hh. (147), 92.aa. (253), 92.ii. (264)	31.mm. (67)	
Enrollee satisfaction				168. (181/39)	
Essential community providers	7.a. (18/16), 7.b. (21/22)	7.i. (19), 7.n. (23/1), 50.c. (135/54), 111.b. (238/96)	7.ee. (29/4), 92.cc. (255)	7.ddd. (29), 50.e. (90)	
General	7.b. (21/22)	50.p. (147), 89.c. (198/89)	7.b. (3)		
Guaranteed availability			92.aa. (253)		
Quality improvement/rating system			50.t. (176/29)	92.tt. (141)	
State evaluation		50.i. (142)			
Third-party payments	7.a. (18/16), 7.b. (21/22), 7.g. (29/76), 29.a. (70/112)		50.q. (173), 50.x. (179/30), 50.y. (182)		

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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.06)	
Reinsurance, risk corridors, and risk adjustment	7.a. (18/16), 27.a. (65/104)	27.b. (77), 27.d. (79), 27.e. (80)	27.c. (100), 27.f. (101), 27.g. (102), 27.h. (102), 27.j. (104)	27.i. (52), 27.k. (53), 27.l. (54), 27.m. (55), 27.n. (56)	
Shared responsibility payments					
Employers		31.k. (108)	31.f. (120)		
Exemptions		31.e. (94/40), 31.h. (105), 31.q. (114/47)	7.jj. (38), 7.ll. (41), 7.mm. (42), 7.nn. (43), 7.tt. (51), 29.m. (113), 31.v. (133/13), 31.bb. (139/18),	50.cc. (95)	
Individuals		31.g. (103/44), 31.r. (116)	31.x. (135/16)		
Small Business Health Options Program (SHOP)					
Aggregation of premiums			50.z. (183)		
Direct Enrollment				50.bb. (94)	
General	7.c. (24/67)	7.s. (30/11), 7.dd. (40), 50.f. (138/64), 50.g. (139/66), 89.c. (198/89)	7.ee. (29/4), 50.z. (183)	7.vv. (20/6), 50.aa. (94)	

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	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.06)	
State alternative applications		50.m. (145)			
Waivers for state innovation	14. (49/98)				
Wellness programs		99.a. (220)	99.c. (269)	99.d. (144), 99.e. (146)	

AR NUMBER REFERENCE GUIDE: HEALTH REFORM
UPDATED THROUGH 7/31/2015

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

sRRIAR Number	Action	Short Title	Agency
7.aa.	Guidance	Federally Facilitated Marketplace Enrollment Operational Policy	CCIIO
7.bb.	Final Rule	Program Integrity; Amendments to the HHS Notice of Benefit and Payment Parameters	CMS
7.cc.	Guidance	Using Account Transfer Flat Files to Enroll Individuals	CCIIO
7.dd.	Final Rule	Maximizing Coverage Under ACA	CMS
7.ee.	Guidance	2015 Letter to Issuers in FFMs	CCIIO
7.ff.	Guidance	Enrollment and Termination Policies for Marketplace Issuers	CCIIO
7.gg.	Guidance	Casework Guidance for Issuers in FFMs	CCIIO
7.hh.	Guidance	Guidance on Individuals "In Line" for FFM	CCIIO
7.ii.	Guidance	Guidance on Special Enrollment Periods for Complex Cases	CCIIO
7.jj.	Guidance	SEPs and Hardship Exemptions for Certain Individuals	CCIIO
7.kk.	Request for Comment	Standards for Navigators and Non-Navigator Personnel	CMS
7.ll.	Guidance	Filing Threshold Hardship Exemption	CCIIO
7.mm.	Guidance	Exemption for Individuals Eligible for Indian Provider Services	CCIIO
7.nn.	Guidance	Hardship Exemptions, Age Offs, and Catastrophic Coverage	CCIIO
7.oo.	Guidance	Information and Tips for Assisters: Working with AI/ANs	CCIIO
7.pp.	Guidance	Effort to Help Marketplace Enrollees Stay Covered	CCIIO
7.qq.	Guidance	Options for Paper-Based Marketplace Eligibility Appeals	CCIIO
7.rr.	Guidance	Termination of Enrollment in FFM Due to Death	CCIIO
7.ss.	Notice	Health Insurance Marketplace Public Use Files	CCIIO
7.tt.	Guidance	Hardship Exemptions for Persons Meeting Certain Criteria	CCIIO
7.uu.	Guidance	Guidance for Issuers on 2015 Reenrollment in the FFM	CCIIO
7.vv.	Guidance	2016 Letter to Issuers in FFMs	CCIIO
7.ww.	Guidance	Special Protections for AI/ANs	CMS
7.xx.	Guidance	AI/AN Trust Income and MAGI	CMS
7.yy.	Notice	Special Enrollment Period for Tax Season	CMS
7.zz.	Guidance	Hardship Exemptions for Persons Meeting Certain Criteria	CCIIO
7.aaa.	Guidance	Ending Special Enrollment Periods for Coverage in 2014	CCIIO
7.bbb.	Guidance	Key Dates in 2015: QHP Certification in the FFM, et al.	CCIIO
7.ccc.	Notice	Out-of-Pocket Cost Comparison Tool for FFMs	CCIIO
7.ddd.	Request for Comment	ECP Data Collection to Support QHP Certification for PY 2017	CMS
10.b.	Final Rule	ACO Standards	CMS
12.a.	Request for Comment	Co-Op Plans (Section 1322 of ACA)	CCIIO (OCIIO)
12.b.	Final Rule	Co-Op Plans (Section 1322 of ACA)	CMS
12.c.	Guidance	CO-OP Program Contingency Fund	CCIIO

sRRIAR Number	Action	Short Title	Agency
12.d.	Request for Comment	Consumer Operated and Oriented Program	CMS
12.e.	Guidance	CO-OP Program Guidance Manual	CCIIO
14.	Final Rule	ACA Waivers for State Innovation	Treasury/CMS
16.a.	Final Rule	New Medicaid Community First Choice Option	CMS
27.a.	Final Rule	Risk Adjustment Standards in ACA	CMS
27.b.	Guidance	HHS Risk Adjustment Model Algorithm	CCIIO
27.c.	Request for Comment	Reinsurance, Risk Corridors, and Risk Adjustment Standards	CMS
27.d.	Guidance	HHS-Developed Risk Adjustment Model Algorithm	CCIIO
27.e.	Guidance	Reinsurance Enrollment Count	CCIIO
27.f.	Guidance	Risk Corridors and Budget Neutrality	CCIIO
27.g.	Guidance	Reinsurance Contributions Process	CCIIO
27.h.	Guidance	HHS-Developed Risk Adjustment Model Algorithm	CMS
27.i.	Request for Comment	Risk Corridors Transitional Policy	CMS
27.j.	Guidance	Transitional Reinsurance Program Annual Form	CCIIO
27.k.	Guidance	Transitional Reinsurance Program Collections for 2014	CCIIO
27.l.	Guidance	Transitional Reinsurance Program--Timing of Refunds	CCIIO
27.m.	Guidance	Transitional Adjustment for 2014 Risk Corridors Program	CCIIO
27.n.	Guidance	CSR Amounts in Risk Corridors and MLR Reporting	CCIIO
28.a.	Final Rule	Medicaid Eligibility Under ACA	CMS
28.c.	Final Rule	Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, etc.	CMS
28.d.	Final Rule	Increased FMAP Changes Under ACA	CMS
28.e.	Request for Comment	Medicaid Implementation Advanced Planning Document	CMS
29.a.	Final Rule	Premium Subsidies and Tax Credits	IRS
29.b.	Final Rule	Health Insurance Premium Tax Credit	Treasury
29.c.	Request for Comment	Health Insurance Premium Tax Credit	IRS
29.d.	Proposed Rule	Minimum Value of Eligible Employer-Sponsored Plans	IRS
29.e.	Final Rule	Information Reporting for Exchanges	IRS
29.f.	Guidance	IRS Ruling 2013-17 and Advance Premium Tax Credits	CCIIO
29.g.	Request for Comment	Payment Collections Operations Contingency Plan	CMS
29.h.	Guidance	Verification of Income for Tax Credits and Cost Sharing	HHS
29.i.	Guidance	Victims of Domestic Abuse	CCIIO
29.j.	Final/Temporary Rule	Rules Regarding the Health Insurance Premium Tax Credit	IRS
29.k.	Proposed Rule	Rules Regarding the Health Insurance Premium Tax Credit	IRS
29.l.	Guidance	Determining the Deduction for the Premium Tax Credit	IRS

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

sRRIAR Number	Action	Short Title	Agency
31.cc.	Request for Comment	Application for Filing ACA Information Returns	IRS
31.dd.	Final Rule	Coverage of Certain Preventive Services Under ACA	IRS/DoL/CMS
31.ee.	Interim Final Rule	Coverage of Certain Preventive Services Under ACA	IRS/DoL/CMS
31.ff.	Proposed Rule	Coverage of Certain Preventive Services Under ACA	IRS
31.gg.	Request for Comment	EBSA Form 700--Certification	DoL
31.hh.	Guidance	State-Specific Data for the Actuarial Value Calculator	CCIIO
31.ii.	Request for Comment	Reporting of Minimum Essential Coverage	IRS
31.jj.	Request for Comment	Information Reporting by Employers on Health Coverage	IRS
31.kk.	Request for Comment	ACA Uniform Explanation of Coverage Documents	IRS
31.ll.	Request for Comment	Data Submission for the FFE User Fee Adjustment	CMS
31.mm.	Guidance	2016 Actuarial Value Calculator	CCIIO
31.nn.	Request for Comment	Notification of Objection to Covering Contraceptive Services	CMS
31.oo.	Final Rule	Amendments to Excepted Benefits	IRS/DoL/CMS
31.pp.	Final Rule	Summary of Benefits and Coverage and Uniform Glossary	IRS/DoL/CMS
31.qq.	Guidance	FAQ About Excepted Benefits	CCIIO
31.rr.	Guidance	Minimum Essential Coverage Application Review Process	CCIIO
31.ss.	Guidance	Excise Tax on High Cost Employer Health Coverage	IRS
31.tt.	Request for Comment	ACA Section 2715 Summary Disclosures	DoL
31.uu.	Guidance	ACA Implementation FAQs (SBC)	CCIIO
31.vv.	Guidance	EHBs: List of the Largest Three Small Group Products by State	CCIIO
31.xx.	Guidance	ACA Implementation FAQs (Preventive Services)	CCIIO
31.yy.	Guidance	ACA Information Returns Reference Guide	IRS
39.a.	Request for Information	Basic Health Program	CMS
39.b.	Final Rule	Basic Health Program	CMS
39.c.	Final Methodology	Basic Health Program: Federal Funding Methodology for 2015	CMS
39.d.	Request for Comment	Basic Health Program Report for Exchange Premium	CMS
39.e.	Final Methodology	Basic Health Program: Federal Funding Methodology for 2016	CMS
45.	Guidance	Actuarial Value and Cost-Sharing	CMS
48.a.	Final Rule	Medical Loss Ratio Requirements	CMS
48.b.	Request for Comment	Medical Loss Ratio Rebate Calculation Report and Notices	CMS
48.c.	Final Rule	MLR Requirements for Medicare Part C and Part D	CMS
48.d.	Guidance	Medical Loss Ratio Reporting and Rebate Requirements	CCIIO
48.e.	Final Rule	Computation of MLR	IRS
48.f.	Request for Comment	Medical Loss Ratio Report for MA Plans and PDPs	CMS

sRRIAR Number	Action	Short Title	Agency
48.g.	Guidance	Medical Loss Ratio Reporting and Rebate Requirements	CCIIO
48.h.	Guidance	Q&A on MLR Reporting and Rebate Requirements	CCIIO
50.b.	Final Rule	EHB and QHP Standards	CMS
50.c.	Guidance	Model Qualified Health Plan Addendum (Indian Addendum)	CMS/IHS
50.d.	Request for Comment	Data Elements for Exchange Application	CMS
50.e.	Request for Comment	Initial Plan Data Collection to Support QHP Certification	CMS
50.f.	Request for Comment	Eligibility and Enrollment for Employees in SHOP	CMS
50.g.	Request for Comment	Eligibility and Enrollment for Small Businesses in SHOP	CMS
50.h.	Request for Comment	Eligibility for Insurance Affordability Programs and Enrollment	CMS
50.i.	Guidance	State Evaluation of Plan Management Activities	CCIIO
50.j.	Request for Comment	Recognized Accrediting Entities Data Collection	CMS
50.k.	Guidance	Model Eligibility Application	CCIIO
50.l.	Guidance	State Alternative Applications for Health Coverage	CCIIO
50.m.	Guidance	State Alternative Applications for Health Coverage Through SHOP	CCIIO
50.n.	Final Rule	Disclosures for Health Insurance Affordability Program Eligibility	Treasury
50.o.	Request for Comment	State Health Insurance Exchange Incident Report	CMS
50.p.	Guidance	QHP Webinar Series FAQs	CMS
50.q.	Guidance	Third Party Payments of Premiums for QHPs	CCIIO
50.r.	Guidance	Implementation of Section 402 of IHCIA	IHS
50.s.	Request for Comment	State-Based Marketplace Annual Report	CMS
50.t.	Request for Comment	QHP Quality Rating System Measures and Methodology	CMS
50.u.	Guidance	State-Based Marketplace Annual Reporting Tool	CCIIO
50.w.	Guidance	Retroactive Advance Payments of PTCs and CSRs Due to Exceptional Circumstances	CCIIO
50.x.	Interim Final Rule	Third Party Payment of QHP Premiums	CMS
50.y.	Final Rule	Tax Treatment of Retirement Plan Payment of Premiums	IRS
50.z.	Guidance	Implementation of Employee Choice in SHOP in 2015	CCIIO
50.aa.	Request for Comment	SHOP Effective Date and Termination Notice Requirements	CMS
50.bb.	Guidance	FAQs on Flexibilities for State-Based SHOP Direct Enrollment	CCIIO
50.cc.	Guidance	FAQs on SBM Options for Shared Responsibility Exemptions	CCIIO
51.	Final Rule	Student Insurance Coverage	CMS
54.	Notice	ESI Coverage Verification	CMS
56.	Request for Information	Stop-Loss Insurance	IRS/DoL/CMS
63.a.	Interim Final Rule	Health Care EFT Standards	HHS
63.b.	Request for Comment	Electronic Funds Transfers Authorization Agreement	CMS

sRRIAR Number	Action	Short Title	Agency
64.a.	Notice	Policy on Conferring with Urban Indian Organizations	IHS
64.b.	Notice	CMS Tribal Consultation Policy	CMS
64.c.	Notice	Tribal Consultation Policy	Treasury
65.	Request for Comment	Health Care Reform Insurance Web Portal Requirements	CMS
67.a.	Request for Comment	State Consumer Assistance Grants	CMS
67.b.	Request for Comment	Research on Outreach for Health Insurance Marketplace	CMS
67.c.	Guidance	Use of 1311 Funding for Change Orders	CCIIO
67.d.	Guidance	Use of 1311 Funds and No Cost Extensions	CCIIO
67.e.	Guidance	Consumer Assistance for Marketplace Enrollment	CCIIO
67.f.	Guidance	Use of 1311 Funds, et al.	CCIIO
67.g.	Guidance	FAQs on Use of 1311 Funds for Establishment Activities	CCIIO
68.	Request for Comment	Security of Electronic Health Information	CMS
77.a.	Final Rule	Unique Plan Identifiers	CMS
77.e.	Request for Information	Requirements for the Health Plan Identifier	CMS
88.a.	Request for Comment	Early Retiree Reinsurance Program Survey	CMS
88.b.	Notice	Early Retiree Reinsurance Program	CMS
89.a.	Final Rule	Notice of Benefit and Payment Parameters for 2014	CMS
89.b.	Interim Final Rule	Amendments to the Notice of Benefit and Payment Parameters	CMS
89.c.	Final Rule	Small Business Health Options Program	CMS
89.d.	Request for Comment	Cost-Sharing Reductions Reconciliation Methodology	CMS
89.e.	Final Rule	Notice of Benefit and Payment Parameters for 2015	CMS
89.f.	Guidance	Choice of Methodology for Cost-Sharing Reduction Reconciliation	CCIIO
89.g.	Request for Comment	Cost Sharing Reduction Reconciliation	CMS
89.h.	Final Rule	Notice of Benefit and Payment Parameters for 2016	CMS
89.i.	Request for Comment	Information Collection for Machine-Readable Data for QHPs	CMS
89.j.	Guidance	ACA Implementation FAQs (Cost-Sharing Limitations)	CCIIO
89.k.	Letter to CCIIO	Eligibility Determinations for Indian-Specific CSVs	TTAG
90.	Guidance	Adverse Benefit Determinations	CCIIO
91.a.	Guidance	Waiting Period Limitation Under Public Health Service Act	CCIIO
91.b.	Final Rule	Waiting Period Limitation and Coverage Requirements	IRS/DoL/CMS
91.c.	Final Rule	Waiting Period Limitation	IRS/DoL/CMS
92.a.	Final Rule	Health Insurance Market Rules	CMS
92.b.	Request for Comment	Compliance with Individual and Group Market Reforms	CMS
92.c.	Guidance	Age Curves, Geographical Rating Areas, and State Reporting	CMS

sRRIAR Number	Action	Short Title	Agency
92.d.	Request for Comment	Patient Protection Notices and Disclosure Requirements	CMS
92.e.	Request for Comment	Disclosure and Recordkeeping for Grandfathered Health Plans	CMS
92.f.	Guidance	Model Language for Individual Market Renewal Notices	CMS
92.g.	Request for Comment	Reporting for Grants to Support Health Insurance Rate Review	CMS
92.h.	Request for Comment	Disclosure and Recordkeeping for Grandfathered Health Plans	DoL
92.i.	Request for Comment	ACA Notice of Rescission	Treasury
92.j.	Request for Comment	Enrollment Opportunity Notice Relating to Lifetime Limits	Treasury
92.k.	Request for Comment	ACA Notice of Patient Protection	IRS
92.l.	Guidance	Application of ACA Provisions to HRAs, Health FSAs, et al.	IRS/DoL
92.m.	Guidance	Application of ACA Provisions to Certain Healthcare Arrangements	CCIIO
92.n.	Request for Comment	Rules for Group Health Plans Related to Grandfather Status	IRS
92.o.	Guidance	State Reporting for Plan or Policy Years Beginning in 2015	CCIIO
92.p.	Guidance	Standard Notices for Transition to ACA Compliant Policies	CCIIO
92.q.	Request for Comment	ACA Advance Notice of Rescission	DoL
92.r.	Request for Comment	ACA Patient Protection Notice	DoL
92.s.	Request for Comment	Rate Increase Disclosure and Review Reporting Requirements	CMS
92.t.	Guidance	ACA Implementation: Market Reform and Mental Health Parity	CCIIO
92.u.	Final Rule	Exchange and Insurance Market Standards for 2015 and Beyond	CMS
92.v.	Guidance	Q&A on Outreach by Medicaid MCOs to Former Enrollees	CCIIO
92.w.	Request for Information	Provider Non-Discrimination	CMS/IRS/DoL
92.x.	Guidance	Extension of Transitional Policy for Non-Grandfathered Coverage	CCIIO
92.y.	Guidance	Draft Notices When Discontinuing or Renewing a Product	CCIIO
92.z.	Guidance	Coverage of Same-Sex Spouses	CCIIO
92.aa.	Guidance	Health Insurance Market Reforms and Marketplace Standards	CCIIO
92.bb.	Guidance	Employer Health Care Arrangements (Q&A)	IRS
92.cc.	Guidance	FAQs on Essential Community Providers	CCIIO
92.dd.	Final Rule	Eligibility Determinations for Exchange Participation	CMS
92.ee.	Guidance	Self-Funded, Non-Federal Governmental Plans	CCIIO
92.ff.	Final Rule	Deduction Limitation for Remuneration by Insurers	IRS
92.gg.	Guidance	FAQs About ACA Implementation (Reference Pricing)	CCIIO
92.hh.	Request for Comment	Annual Eligibility Redetermination Notices, et al.	CMS
92.ii.	Guidance	Group Plans that Fail to Cover In-Patient Hospitalization Services	CCIIO
92.jj.	Guidance	ACA Implementation (Premium Reimbursement Arrangements)	CCIIO
92.kk.	Request for Comment	Summary of Benefits and Coverage and Uniform Glossary	CMS

sRRIAR Number	Action	Short Title	Agency
92.ll.	Request for Comment	Health Benefit Plan Network Access and Adequacy Model Act	NAIC
92.mm.	Guidance	Rate Review Requirements	CCIIO
92.nn.	Guidance	Rate Filing Justifications for Single Risk Pool Coverage	CCIIO
92.oo.	Guidance	Eligibility Redeterminations for Marketplace Coverage	CCIIO
92.pp.	Guidance	ACA Reporting Requirements for Health Coverage Providers	IRS
92.qq.	Guidance	Evaluation of EDGE Data Submissions	CCIIO
92.rr.	Guidance	EDGE Data Submission Grace Period	CCIIO
92.ss.	Guidance	Rate Review Requirements in States with SBMs	CCIIO
92.tt.	Request for Comment	QIS Implementation Plan and Progress Report	CMS
92.uu.	Guidance	Information Distribution on PTCs and CSRs for FFM Coverage	CCIIO
92.vv.	Guidance	FAQs on Uniform Modification and Plan/Product Withdrawal	CCIIO
92.ww.	Guidance	Standard Notices of Product Discontinuation and Renewal	CCIIO
99.a.	Final Rule	Wellness Programs	IRS/DoL/CMS
99.b.	Request for Information	Nondiscrimination in Certain Health Programs or Activities	HHS OCR
99.c.	Request for Comment	Evaluation of Wellness and Prevention Programs	CMS
99.d.	Guidance	FAQs About ACA Implementation (Wellness Programs)	CCIIO
99.e.	Guidance	FAQs on Market Reforms and Wellness Programs	CCIIO
100.a.	Request for Information	Health Care Quality for Exchanges	CMS
100.b.	Request for Comment	Marketplace Quality Standards	CMS
111.a.	Request for Comment	Multi-State Plan Application	OPM
111.b.	Final Rule	Multi-State Plan Program for Exchanges	OPM
111.c.	Request for Comment	Request for External Review	OPM
111.d.	Notice	New System of Records (MSP Program)	OPM
111.e.	Final Rule	Establishment of Multi-State Plan Program for Exchanges	OPM
116.	Final Rule	Fees for the Patient-Centered Outcomes Research Trust Fund	Treasury
122.a.	Request for Comment	Special Enrollment Rights Under Group Health Plans	DoL
122.b.	Request for Comment	Pre-Existing Condition Exclusion Under Group Health Plans	DoL
122.c.	Request for Comment	Creditable Coverage Under Group Health Plans	DoL
128.a.	Request for Comment	ACA Internal Claims and Appeals and External Review Procedures	CMS
128.b.	Guidance	State External Review Process for Health Plans	CCIIO
128.c.	Guidance	County Level Estimates Related to CLAS Standards Under ACA	CCIIO
128.d.	Request for Comment	ACA Internal Claims and Appeals and External Review Disclosures	IRS
128.e.	Guidance	Electing a Federal External Review Process	CCIIO
128.f.	Request for Comment	ACA Internal Claims and Appeals and External Review Procedures	DoL

sRRIAR Number	Action	Short Title	Agency
145.a.	Final Rule	Health Insurance Providers Fee	IRS
145.b.	Request for Comment	Report of Health Insurance Provider Information	IRS
145.c.	Proposed Rule	Health Insurance Providers Fee	IRS
145.d.	Final/Temporary Rule	Health Insurance Providers Fee	IRS
159.b.	Final Rule	Medicare PPS for Federally Qualified Health Centers, et al.	CMS
168.	Request for Comment	Enrollee Satisfaction Survey Data Collection	CMS
169.	Request for Comment	Health Care Sharing Ministries	CMS
174.a.	Final Rule	FEHBP: Members of Congress and Congressional Staff	OPM
174.b.	Final Rule	FEHBP: Coverage of Children	OPM
174.c.	Final Rule	FEHBP: Eligibility for Temporary and Seasonal Employees	OPM
174.d.	Guidance	New Flexibility for Tribal Employer Participation in FEHBP	OPM
174.e.	Final Rule	FEHBP Miscellaneous Changes: Medically Underserved Areas	OPM
174.f.	Final Rule	FEHBP: Rate Setting for Community-Rated Plans	OPM
198.a.	Final/Temporary Rule	Branded Prescription Drug Fee	IRS
198.b.	Proposed Rule	Branded Prescription Drug Fee	IRS
198.c.	Request for Comment	Branded Prescription Drug Fee	IRS