

Regulation Review and Impact Analysis Report v. 6.02

as of February 29, 2016

Attachments

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

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

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

In addition to this cover page, the report consists of three tables as well as 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 -

- > 4.n. CORF Eligibility and Survey Forms (CMS-359/360; comments due 3/4/2016)
- 206. Measures of Quality Improvement Activities (AHRQ/no ref. #; comments due 3/4/2016)
- 153.m. CMS/SSA Computer Matching Program (CMS/no ref. #; comments due approx. 3/10/2016)
- > 134.e. Home Health Agency Cost Report (CMS-1728-94; comments due 3/11/2016)
- 126.a. Emergency Fund (HRSA/OMB 0915-0363; comments due 3/17/2016)
- > 153.n.CMS/Homeland Security Computer Matching Program (CMS/no ref. #; comments due approx. 3/18/2016)
- > 153.o.CMS/IRS Computer Matching Program (CMS/no ref. #; comments due approx. 3/18/2016)
- > 92.d. Patient Protection Notices and Disclosure Requirements (CMS-10330; comments due 3/19/2016)
- > 92.e. Disclosure and Recordkeeping for Grandfathered Health Plans (CMS-10325; comments due 3/19/2016)
- > 121.o. Medicare Rural Hospital Flexibility Grant Program (CMS-359/360; comments due approx. 3/21/2016)
- > 95. IHS Forms to Implement the Privacy Rule (IHS-810, -912-1, -912-2, -913, and -917; comments due 3/22/2016)
- 31.tt. Summary of Benefits and Coverage and Uniform Glossary (DoL/OMB1210-0147; comments due 3/28/2016)
- 92.kk. Summary of Benefits and Coverage and Uniform Glossary (CMS-10407; comments due 3/28/2016)
- ➤ 60.I. Expanding Uses of Medicare Data by Qualified Entities (CMS-5061-P; comments due 3/29/2016)
- > 175.b.New Use for System of Records (Part A Enrollment Data) (CMS/no ref. #; comments due 3/29/2016)
- > 112.I. Expanded Access to Non-VA Care Through Veterans Choice (VA/RIN 2900-AP60; comments due 3/30/2016)

1

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.

- 43. Medicaid Reimbursement for Outpatient Drugs (CMS-2345-FC; comments due 4/1/2016)
- 25.dd. Emergency and Foreign Hospital Services (CMS-1771; comments due 4/5/2016)
- 52.r. Prior Authorization of Home Health Services Demonstration (CMS-10599; comments due 4/5/2016)
- 60.c. Health Insurance Common Claims Form (CMS-1500 (02/12)/CMS-1500 (08/05)/CMS-1490S; comments due 4/5/2016)
- 60.m. Reapplication Submission for Qualified Entities (CMS-10596; comments due 4/5/2016)
- 79. Fiscal Soundness Reporting Requirements (CMS-906; comments due 4/5/2016)
- 208. Medicare Probable Fraud Measurement Pilot (CMS-10406; comments due 4/5/2016)
- > 52.s. Evaluation of the Medicare Patient IVIG Demonstration (CMS-10600; comments due 4/11/2016)
- 112.n. Catastrophic Health Emergency Fund (CMS-359/360; comments due 4/11/2016)
- 134.a. Prepaid Health Plan Cost Report (CMS-276; comments due 4/11/2016)
- 140. Social Security Office Report of State Buy-in Problem (CMS-1957; comments due 4/11/2016)
- 207. Confidentiality of Substance Use Disorder Patient Records (SAMHSA-4162-20; comments due 4/11/2016)
- 3.c. Durable Medical Equipment Certificate of Medical Necessity (CMS-846-849, -10125, and -10126; comments due 4/19/2016)
- 3.d. Certification of Medical Necessity for Home Oxygen Therapy (CMS-484; comments due 4/19/2016)
- 48.b. Medical Loss Ratio Rebate Calculation Report and Notices (CMS-10418; comments due 4/19/2016)
- 92.s. Rate Increase Disclosure and Review Reporting Requirements (CMS-10379; comments due 4/19/2016)
- > 172.a. Medicare Current Beneficiary Survey (CMS-0015A; comments due 4/25/2016)

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

- > 7.III. 2017 Letter to Issuers in FFMs (CCIIO/no ref. #; comments submitted 1/17/2016 by TSGAC)
- 136.e. Requirements for Reporting Quality Measures (CMS-3323-NC; comments submitted 2/1/2016)
- > 14.c. Waivers for State Innovation (CMS-9936-N; comments submitted 2/23/2016 by TSGAC)

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

- > 54. ESI Coverage Verification (CMS/RIN 0938-ZB09; approved by OMB 4/26/2012 but not yet published)
- 16.b. Medicaid HCBS Waivers (CMS-2249-F2; approved by OMB 1/14/2014 but not yet published)
- 180. Flu Vaccination Standard for Certain Providers and Suppliers (CMS-3213-F; approved by OMB 4/18/2014 but not yet published)
- 164.b. Medicare Secondary Payer and "Future Medicals" (CMS-6047-P; approved by OMB 10/9/2014 but not yet published)
- 6.i. Pre-Existing Health Insurance Plan Program Updates (CMS-9995-IFC4; sent to OMB 2/3/2015)
- 188a. Emergency Preparedness Requirements (CMS-3178-F; sent to OMB 11/3/2015)
- > 188.b. Fire Safety Requirements for Certain Health Care Facilities (CMS-3277-F; sent to OMB 11/3/2015)
- > 112.d.I/T/U Payment for Physician and Non-Hospital-Based Services (IHS/RIN 0917-AA12; sent to OMB 12/14/2015)
- 25.ii. Hospital Changes to Promote Innovation, etc. (CMS-3295-P; sent to OMB 1/4/2016)
- 1.p. Health IT Certification Program: Enhanced Oversight (HHS ONC/RIN 0955-AA00; sent to OMB 1/25/2016)
- > 5.d. PACE Update (CMS-4168-P; sent to OMB 1/25/2016)
- 10.g. Medicare Shared Savings Program: ACO Benchmarking (CMS-1644-P; approved by OMB 1/27/2016)
- 154.b.Medicaid/CHIP Managed Care (CMS-2390-F; sent to OMB 2/18/2016)
- 112.o.IHS Reimbursement Rates for CY 2016 (IHS/RIN 0917-ZA30; approved by OMB 2/19/2016)
- > 70.f. Part B Drug Model (CMS-1670-P; sent to OMB 2/25/2016)

Recent (final) rules issued -

31.ddd. 2017 Actuarial Value Calculator (CCIIO/no ref. #; issued 1/21/2016)

- > 26. Medicaid Home Health (CMS-2348-F; issued 2/2/2016)
- ➤ 49.a. Reporting and Returns of Medicare Overpayments (CMS-6037-F; issued 2/12/2016)
- ➤ 204. Medicaid Services "Received Through" an IHS/Tribal Facility (SHO #16-002; issued 2/26/2016)
- > 39.f. Basic Health Program: Federal Funding Methodology for 2017 (CMS-2396-FN; issued 2/29/2016)

Contacts: Devin Delrow at DDelrow@nihb.org.

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

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 2/29/2016

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
			SECTION I: MEDICAID (AND DUAL MEDICAID AND MEDICARE)	Beginning on page 1 of 40	
			Section II: Medicare	Beginning on page 8 of 40	
			SECTION III: HEALTH REFORM	Beginning on page 24 of 40	
			SECTION IV: OTHER	Beginning on page 37 of 40	
			SECTION I: MEDICAID (AND DUAL MEDICAID AND MEDICARE)		
1.p.	Health IT Certification Program: Enhanced Oversight ACTION: Proposed Rule NOTICE: ONC Health IT Certification Program: Enhanced Oversight and Accountability AGENCY: HHS ONC	HHS ONC RIN 0955- AA00	Issue Date: [Pending at OMB as of 1/25/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

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

: regulation review complete

: regulation currently under review

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?
1.q.	2015 Test Tools and Procedures for Health IT Certification ACTION: Notice NOTICE: Notice of Availability: 2015 Edition Test Tools and Test Procedures Approved by the National Coordinator for the ONC Health IT Certification Program AGENCY: HHS ONC	HHS ONC (no reference number)	Issue Date: 2/4/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
16.b.	Medicaid HCBS Waivers ACTION: Proposed-Final Rule NOTICE: Medicaid; State Plan Home and Community-Based Services, 5- Year Period for Waivers, Provider Payment Reassignment; Setting Requirements AGENCY: CMS	CMS-2249- P2 F2	Issue Date: 5/3/2012 Due Date: 6/4/2012 7/2/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension 5/3/2012; Final Rule approved by OMB 1/13/2014	 Summary of Agency action: √ NIHB analysis of action: None. 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
20.a.	Assuring Access to Services ACTION: Proposed-Final Rule NOTICE: Medicaid Program; Methods for Assuring Access to Covered Medicaid Services AGENCY: CMS	CMS-2328-PFC	Issue Date: 5/6/2011 Due Date: 7/5/2011 ANTHC File Date: 7/5/2011 Date of Subsequent Agency Action, if any: Issued Final Rule 11/2/2015 Due Date: 1/4/2016	 Summary of Agency action: √ ANTHC analysis of action: √ Summary of subsequent Agency action: √ 	 ANTHC recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
20.b.	Data Metrics and Alternative Processes for Access to Care ACTION: Request for Information NOTICE: Medicaid Program; Request for Information (RFI)Data Metrics and Alternative Processes for Access to Care in the Medicaid Program AGENCY: CMS	CMS-2328-NC	Issue Date: 11/2/2015 <u>Due Date:</u> 1/4/2016 <u>NIHB File Date:</u> None <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
23.b.	MACPro: New Online System for State Plan Amendments, Waivers, etc. ACTION: Request for Comment NOTICE: Medicaid and CHIP Program (MACPro) AGENCY: CMS	CMS-10434	Issue Date: 1/2/21/2012 Due Date: 1/22/2013 TSGAC File Date: 1/22/2013 Date of Subsequent Agency Action, if any: Issued revision 11/9/2015 Due Date: 1/8/2016	 Summary of Agency action: √ TSGAC analysis of action: √ Summary of subsequent Agency action: √ 	 TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action:
26.	Medicaid Home Health ACTION: Proposed Final Rule NOTICE: Medicaid Program; Face- to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health AGENCY: CMS	CMS-2348-PF	Issue Date: 7/12/2011 Due Date: 9/12/2011 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Rule 2/2/2016	 Summary of Agency action: √ 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

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?
41.f.	New Safe Harbors ACTION: Notice NOTICE: Solicitation of New Safe Harbors and Special Fraud Alerts AGENCY: HHS OIG	OIG-124-N	Issue Date: 12/23/2015 Due Date: 2/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
43.	Medicaid Reimbursement for Outpatient Drugs ACTION: Proposed-Final Rule NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS	CMS-2345- PFC	Issue Date: 2/2/2012 Due Date: 4/2/2012 NIHB File Date: 4/2/2012 Date of Subsequent Agency Action, if any: Issued Final Rule 2/1/2016 Due Date: 4/1/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
46.e.	Final FY 2013 and Preliminary FY 2015 DSH Allotments ACTION: Notice NOTICE: Medicaid Program; Final FY 2013 and Preliminary FY 2015 Disproportionate Share Hospital Allotments, and Final FY 2013 and Preliminary FY 2015 Institutions for Mental Diseases Disproportionate Share Hospital Limits AGENCY: CMS	CMS-2398-N	Issue Date: 2/2/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 2/29/2016

63.a. Si A N In Tr	Medicaid/Transformed-Medicaid Statistical Information Systems ACTION: Request for Comment MOTICE: Medicaid Statistical Information System (MSIS) and Transformed-Medicaid Statistical	CMS-R-284	<u>Issue Date:</u> 8/15/2012 <u>Due Date:</u> 10/15/2012 <u>NIHB File Date:</u> None	Summary of Agency action: √	NIHB recommendations included:Subsequent Agency action:
A	nformation System (T-MSIS) AGENCY: CMS		Date of Subsequent Agency Action, if any: Issued extension 10/19/2012; issued revision 12/3/2012, 12/31/2015 Due Date: 11/19/2012; 1/2/2013; 2/29/2016	 NIHB analysis of action: None Summary of subsequent Agency action: √ 	Analysis of Agency action:
SI A N R	Social Security Office Report of State Buy-in Problem ACTION: Request for Comment NOTICE: Social Security Office Report of State Buy-in Problem AGENCY: CMS	CMS-1957	Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 5/10/2013, 2/10/2016 Due Date: 6/10/2013; 4/11/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

National Indian Health Board, Regulation Review and Impact Analysis Report

Page 5 of 40

2/29/2016

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
154.b.	Medicaid/CHIP Managed Care ACTION: Proposed Final Rule NOTICE: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability AGENCY: CMS	CMS-2390- P F	Issue Date: 6/1/2015 Due Date: 7/27/2015 NIHB File Date: 7/27/2015; TTAG also filed comments 7/27/2015 Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 2/18/2016	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action
175.b.	Medicaid Drug Use Review Program ACTION: Request for Comment NOTICE: Medicaid Drug Use Review Program AGENCY: CMS	CMS-R-153	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/17/2014, 1/29/2016 Due Date: 4/16/2014; 3/29/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
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:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
188.a.	Emergency Preparedness Requirements ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS	CMS-3178- P F	Issue Date: 12/27/2013 Due Date: 2/25/2014 3/31/2014 TTAG File Date: 3/31/2014 Date of Subsequent Agency Action, if any: Issued due date extension 2/21/2014; sent Final Rule to OMB 11/3/2015	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action:
188.b.	Fire Safety Requirements for Certain Health Care Facilities ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities AGENCY: CMS	CMS-3277- P F	Issue Date: 4/16/2014 Due Date: 6/16/2014 TTAG File Date: 6/16/2014 Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 11/3/2015	 Summary of Agency action: √ NIHB analysis of action: √ 	 TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action:
204.	Medicaid Services "Received Through" an IHS/Tribal Facility ACTION: Request for Information Final Policy NOTICE: Medicaid Services "Received Through" an Indian Health Service/Tribal Facility: A Request for Comment AGENCY: CMS	CMS (no reference number) SHO #16-002	Issue Date: 10/27/2015 Due Date: 11/17/2015 TTAG File Date: 11/17/2015; TSGAC also filed comments 11/17/2015 Date of Subsequent Agency Action, if any: Issued Final Policy 2/26/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 TTAG recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
			Section II: Medicare		
3.c.	Durable Medical Equipment Certificate of Medical Necessity ACTION: Request for Comment NOTICE: DME Medicare Administrative Contractor CMN and Supporting Documentation Requirements AGENCY: CMS	CMS-846-849, -10125, and -10126	Issue Date: 9/24/2012 Due Date: 11/23/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/8/2013, issued revision 2/19/2016 Due Date: 4/8/2013; 4/19/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
3.d.	Certification of Medical Necessity for Home Oxygen Therapy ACTION: Request for Comment NOTICE: Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Documentation Requirements AGENCY: CMS	CMS-484	Issue Date: 3/14/2013 Due Date: 4/15/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/19/2016 Due Date: 4/19/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
4.n.	CORF Eligibility and Survey Forms ACTION: Request for Comment NOTICE: Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations AGENCY: CMS	CMS-359/360	Issue Date: 1/4/2016 Due Date: 3/4/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
5.a.	PACE Information Request ACTION: Request for Comment NOTICE: Medicare and Medicaid; Programs of All-Inclusive Care for the Elderly (PACE) AGENCY: CMS	CMS-R-244	Issue Date: 7/30/2010 Due Date: 9/28/2010 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/8/2010, 10/4/2013, 12/20/2013, 12/8/2015 Due Date: 11/8/2010; 12/3/2013; 1/21/2014; 2/8/2016	 Summary of Agency action: √ NIHB analysis of action: None. Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
5.d.	PACE Update ACTION: Proposed Rule NOTICE: Programs of All-Inclusive Care for the Elderly (PACE) Update AGENCY: CMS	CMS-4168-P	Issue Date: [Pending at OMB as of 1/25/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
10.g.	Medicare Shared Savings Program: ACO Benchmarking ACTION: Proposed Rule NOTICE: Medicare Shared Savings Program; Accountable Care OrganizationsRevised Benchmarking Methodology AGENCY: CMS	CMS-1644-P	Issue Date: [Approved by OMB 1/27/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	 In Table B Is the summary of Agency action included? Is the NIHB analysis included? 	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
11.d.	Bid Pricing Tool ACTION: Request for Comment NOTICE: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs) AGENCY: CMS	CMS-10142	Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 10/4/2013, 12/20/2013, 9/26/2014, 12/24/2014, 9/24/2015, 12/18/2015 Due Date: 2/19/2013; 12/3/2013; 1/21/2014; 11/25/2014; 1/23/2015; 11/23/2015; 1/19/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
11.f.	Plan Benefit Package and Formulary Submission ACTION: Request for Comment NOTICE: PBP and Formulary Submission for Medicare Advantage and Prescription Drug Plans AGENCY: CMS	CMS-R-262	Issue Date: 10/5/2012 Due Date: 12/4/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 11/1/2013, 1/17/2014, 9/26/2014, 12/19/2014, 9/24/2015, 12/18/2015 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 1/20/2015; 11/23/2015; 1/19/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
11.i.	Medicare Advantage Appeals and Grievance Data Disclosure ACTION: Request for Comment NOTICE: Medicare Advantage Appeals and Grievance Data Disclosure Requirements AGENCY: CMS	CMS-R-282	Issue Date: 2/22/2013 Due Date: 4/23/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 5/3/2013, 12/14/2015 Due Date: 6/3/2013; 2/12/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.cc.	Revisions to Requirements for Discharge Planning for Hospitals ACTION: Proposed Rule NOTICE: Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies AGENCY: CMS	CMS-3317-P	Issue Date: 11/3/2015 Due Date: 1/4/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.dd.	Emergency and Foreign Hospital Services ACTION: Request for Comment NOTICE: Emergency and Foreign Hospital Services AGENCY: CMS	CMS-1771	Issue Date: 9/21/2015 Due Date: 11/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 11/9/2015, 2/5/2016 Due Date: 12/9/2015, 4/5/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
25.ee.	Design of Survey on Patient Experiences with Care in LTCHs ACTION: Request for Information NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in LTCHs AGENCY: CMS	CMS-3327-NC	Issue Date: 11/20/2015 Due Date: 1/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.ff.	Design of Survey on Patient Experiences with Care in IRFs ACTION: Request for Information NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Inpatient Rehabilitation Facilities AGENCY: CMS	CMS-3328-NC	Issue Date: 11/20/2015 Due Date: 1/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 2/29/2016

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
25.gg.	Inpatient Prospective Payment Systems0.2 Percent Reduction ACTION: Notice NOTICE: Medicare Program; Inpatient Prospective Payment Systems; 0.2 Percent Reduction AGENCY: CMS	CMS-1658-NC	Issue Date: 12/1/2015 Due Date: 2/2/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.hh.	Explanation of FY 2004 Outlier Fixed-Loss Threshold ACTION: Notice NOTICE: Medicare Program; Explanation of FY 2004 Outlier Fixed-Loss Threshold as Required by Court Rulings AGENCY: CMS	CMS-1659-N	Issue Date: 1/22/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
25.ii.	Hospital Changes to Promote Innovation, etc. ACTION: Request for Comment NOTICE: Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care AGENCY: CMS	CMS-3295-P	Issue Date: [Pending at OMB as of 1/4/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
49.a.	Reporting and Returns of Medicare Overpayments ACTION: Proposed Final Rule NOTICE: Medicare Program; Reporting and Returning of Overpayments AGENCY: CMS	CMS-6037- P F	Issue Date: 2/16/2012 Due Date: 4/16/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension notice 2/17/2015; issued Final Rule 2/12/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
52.j.	Moratoria on Enrollment of Ambulances and HHAs ACTION: Notice NOTICE: Medicare, Medicaid, and CHIP: Announcement of New and Extended Temporary Moratoria on Enrollment of Ambulances and Home Health Agencies in Designated Geographic Locations AGENCY: CMS	CMS-6046-N CMS-6047-N CMS-6059-N2 CMS-6059-N3 CMS-6059-N4	Issue Date: 2/4/2014 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u> Issued extension notice 8/1/2014, 2/2/2015, 7/27/2015, 2/2/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
52.q.	Home Health Face-to-Face Encounter Clinical Templates ACTION: Request for Comment NOTICE: Home Health Face-to- Face Encounter Clinical Templates AGENCY: CMS	CMS-10564	Issue Date: 8/12/2015 Due Date: 10/13/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 2/29/2016

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
52.r.	Prior Authorization of Home Health Services Demonstration ACTION: Request for Comment NOTICE: Medicare Prior Authorization of Home Health Services Demonstration AGENCY: CMS	CMS-10599	Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
52.s.	Evaluation of the Medicare Patient IVIG Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration AGENCY: CMS	CMS-10600 See also 52.k.	Issue Date: 2/10/2016 Due Date: 4/11/2016 NIHB File Date: Date 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.c.	Health Insurance Common Claims Form ACTION: Request for Comment NOTICE: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR Part 424, Subpart C AGENCY: CMS	CMS-1500 (02/12) CMS-1500 (08/05) CMS-1490S	Issue Date: 9/21/2012 Due Date: 10/22/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/15/2015, 2/5/2016 Due Date: 12/16/2015; 4/5/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
60.1.	Expanding Uses of Medicare Data by Qualified Entities ACTION: Proposed Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities AGENCY: CMS	CMS-5061-P	Issue Date: 2/2/2016 Due Date: 3/29/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
60.m.	Reapplication Submission for Qualified Entities ACTION: Request for Comment NOTICE: Reapplication Submission Requirement for Qualified Entities Under ACA Section 10332 AGENCY: CMS	CMS-10596	Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
70.f.	Part B Drug Model ACTION: Proposed Rule NOTICE: Part B Drug Model AGENCY: CMS	CMS-1670-P	Issue Date: [Pending at OMB as of 2/25/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
71.n.	Medicare ESRD PPS and Quality Incentive Program ACTION: Proposed Final Rule NOTICE: Medicare Program; End- Stage Renal Disease Prospective Payment System, and Quality Incentive Program AGENCY: CMS	CMS-1628- P F	Issue Date: 7/1/2015 Due Date: 8/25/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 9/2/2015; issued Final Rule 11/6/2015; issued correction 12/31/2015	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
71.0.	ESRD Application and Survey and Certification Report ACTION: Request for Comment NOTICE: End Stage Renal Disease Application and Survey and Certification Report AGENCY: CMS	CMS-3427	Issue Date: 11/16/2015 Due Date: 1/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
79.	Fiscal Soundness Reporting Requirements ACTION: Request for Comment NOTICE: Fiscal Soundness Reporting Requirements AGENCY: CMS	CMS-906	Issue Date: 9/4/2012 Due Date: 11/5/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/21/2012; issued extension 10/2/2015; 11/9/2015, 2/5/2016 Due Date: 1/22/2013; 12/1/2015; 12/9/2015, 4/5/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
80.b.	Advanced Beneficiary Notice of Noncoverage ACTION: Request for Comment NOTICE: Advance Beneficiary Notice of Noncoverage AGENCY: CMS	CMS-R-131	Issue Date: 12/12/2012 Due Date: 2/11/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2013; issued extension 11/9/2015 Due Date: 3/28/2013; 1/8/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
118.	Hospital Wage Index Occupational Mix Survey ACTION: Request for Comment NOTICE: Hospital Wage Index Occupational Mix Survey and Supporting Regulations AGENCY: CMS	CMS-10079	Issue Date: 12/7/2012 Due Date: 2/5/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/28/2013; issued extension 10/9/2015, 12/28/2015 Due Date: 4/1/2013; 12/8/2015; 1/27/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
121.m.	Medicare Enrollment Application DMEPOS Suppliers ACTION: Request for Comment NOTICE: Medicare Enrollment ApplicationDurable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers AGENCY: CMS	CMS-855S	Issue Date: 9/11/2015 Due Date: 11/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/18/2015 Due Date: 1/19/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
121.n.	Medicare Registration Application ACTION: Request for Comment NOTICE: Medicare Registration Application AGENCY: CMS	CMS-855O	Issue Date: 12/11/2015 Due Date: 2/9/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
121.0.	New Use for System of Records (Part A Enrollment Data) ACTION: Notice NOTICE: Privacy Act of 1974; Report of a New Routine Use for a CMS System of Records AGENCY: CMS	CMS (no reference number)	Issue Date: 2/18/2016 Due Date: 30 days (approx. 3/21/2016) NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
126.a.	Medicare Rural Hospital Flexibility Grant Program ACTION: Request for Comment NOTICE: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination AGENCY: HRSA	HRSA (OMB 0915-0363)	Issue Date: 12/28/2012 Due Date: 60 days (approx. 3/1/2013) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/26/2013; issued revision 5/27/2015, 2/12/2016 Due Date: 30 days (approx. 5/28/2013); 7/27/2015; 3/17/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: reg

: regulation review complete

: regulation currently under review



RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
129.b.	Awarding and Administration of MAC Contracts ACTION: Notice NOTICE: Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts AGENCY: CMS	CMS-1653-NC	Issue Date: 12/21/2015 Due Date: 2/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
134.a.	Prepaid Health Plan Cost Report ACTION: Request for Comment NOTICE: Prepaid Health Plan Cost Report AGENCY: CMS	CMS-276	Issue Date: 1/30/2013 Due Date: 4/1/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 5/3/2013; issued revision 2/10/2016 Due Date: 6/3/2013; 4/11/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
134.e.	Home Health Agency Cost Report ACTION: Request for Comment NOTICE: Home Health Agency Cost Report AGENCY: CMS	CMS-1728-94	Issue Date: 6/28/2013 Due Date: 8/27/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 9/17/2013; issued revision 9/4/2015, 2/10/2016 Due Date: 10/17/2013; 11/3/2015; 3/11/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
136.c.	PQRS and the eRx Incentive Program Data Assessment ACTION: Request for Comment NOTICE: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support AGENCY: CMS	CMS-10519	Issue Date: 3/17/2014 <u>Due Date</u> : 5/16/2014 <u>NIHB File Date</u> : None <u>Date of Subsequent Agency</u> <u>Action, if any</u> : Issued new request 9/8/2014; issued revision 9/25/2015, 1/29/2016 <u>Due Date</u> : 10/6/2014; 11/24/2015; 2/29/2016	subsequent Agency action: √	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
136.e.	Requirements for Reporting Quality Measures ACTION: Request for Information NOTICE: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs AGENCY: CMS	CMS-3323-NC	Issue Date: 12/31/2016 Due Date: 2/1/2016 2/16/2016 NIHB File Date: 2/1/2016 Date of Subsequent Agency Action, if any: Issued due date extension 2/2/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
137.d.	Data Collection for Beneficiaries Receiving Beta Amyloid PET ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease AGENCY: CMS	CMS-10583	Issue Date: 9/25/2015 Due Date: 11/24/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/8/2015 Due Date: 1/7/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
142.a.	Detailed Notice of Discharge ACTION: Request for Comment NOTICE: Detailed Notice of Discharge (DND) AGENCY: CMS	CMS-10066	Issue Date: 3/6/2013 Due Date: 5/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 11/27/2015 Due Date: 6/17/2013; 1/26/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
142.b.	Important Message from Medicare ACTION: Request for Comment NOTICE: Important Message from Medicare (IM) AGENCY: CMS	CMS-R-193	Issue Date: 3/6/2013 Due Date: 5/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 12/8/2015 Due Date: 6/17/2013; 2/8/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
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
172.a.	Medicare Current Beneficiary Survey ACTION: Request for Comment NOTICE: Medicare Current Beneficiary Survey AGENCY: CMS	CMS-0015A	Issue Date: 7/26/2013 Due Date: 9/24/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 10/4/2013; issued revision 2/24/2016 Due Date: 11/4/2013; 4/25/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
195.c.	Collection of Customer Satisfaction Surveys ACTION: Request for Comment NOTICE: Generic Clearance for the Collection of Customer Satisfaction Surveys AGENCY: CMS	CMS-10415	Issue Date: 10/30/2015 Due Date: 12/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/30/2015 Due Date: 1/29/2015	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
208.	Medicare Probable Fraud Measurement Pilot ACTION: Request for Comment NOTICE: Medicare Probable Fraud Measurement Pilot AGENCY: CMS	CMS-10406	Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
			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.jjj.	Establishment of QHPs and Exchanges ACTION: Request for Comment NOTICE: Establishment of Qualified Health Plans and American Health Benefit Exchanges AGENCY: CMS	CMS-10400	Issue Date: 11/23/2015 Due Date: 1/22/2015 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:
7.kkk.	ECP Petition for 2017 ACTION: Notice NOTICE: Essential Community Provider Petition for the 2017 Benefit Year AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 12/9/2015 Due Date: 1/8/2016 1/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension	 Summary of Agency action: √ TSGAC analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
7.111.	2017 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft 2017 Letter to Issuers in the Federally-Facilitated Marketplaces AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 12/23/2015 Due Date: 1/17/2016 TSGAC File Date: 1/17/2016 Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
7.mmm.	Establishment of an Exchange by a State and QHPs ACTION: Request for Comment NOTICE: Establishment of an Exchange by a State and Qualified Health Plans AGENCY: CMS	CMS-10593	Issue Date: 12/2/2015 Due Date: 2/1/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
7.nnn.	Establishment of Exchanges and QHPsStandards for Employers ACTION: Request for Comment NOTICE: Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers AGENCY: CMS	CMS-10592	Issue Date: 12/2/2015 Due Date: 2/1/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
7.000.	CMS Healthcare.gov Site Wide Online Survey ACTION: Request for Comment NOTICE: CMS Healthcare.gov Site Wide Online Survey AGENCY: CMS	CMS-10597	Issue Date: 12/14/2015 Due Date: 2/12/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
12.f.	FAQs on the CO-OP Program ACTION: Guidance NOTICE: Frequently Asked Questions on the Consumer Operated and Oriented Plan (CO-OP) Program AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/27/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
14.c.	Waivers for State Innovation ACTION: Notice NOTICE: Waivers for State Innovation AGENCY: CMS/Treasury	CMS-9936-N	Issue Date: 12/16/2015 Due Date: Open TSGAC File Date: 2/23/2016 Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 TSGAC recommendations included: √ Subsequent Agency action: Analysis of Agency action:
27.u.	Transitional Reinsurance Program Collections for 2015 ACTION: Guidance NOTICE: The Transitional Reinsurance Program's Contribution Collections for the 2015 Benefit Year AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/12/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
29.d.	Minimum Value of Eligible Employer-Sponsored Plans ACTION: Proposed Final Rule NOTICE: Minimum Value of Eligible Employer-Sponsored Plans and Other Rules Regarding the Health Insurance Premium Tax Credit AGENCY: IRS	REG 125398- 12 REG 143800- 14 TD 9745	Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued supplement to Proposed Rule 9/1/2015; issued Final Rule 12/18/2015; issued correction 1/15/2016 Due Date: 11/2/2015	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
31.tt.	Summary of Benefits and Coverage and Uniform Glossary ACTION: Request for Comment NOTICE: Summary of Benefits and Coverage and Uniform Glossary Required Under the Affordable Care Act AGENCY: DoL	DoL (OMB 1210-0147) See also 92.kk.	Issue Date: 2/27/2015 Due Date: 3/30/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2016 Due Date: 3/28/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
31.ddd.	2017 Actuarial Value Calculator ACTION: Guidance NOTICE: Draft-2017 Actuarial Value Calculator AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 11/20/2015 Due Date: 12/7/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Guidance 1/21/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
39.f.	Basic Health Program: Federal Funding Methodology for 2017 ACTION: Proposed Final Methodology NOTICE: Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018 AGENCY: CMS	CMS-2396- ₽FN	Issue Date: 10/22/2015 Due Date: 11/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued Final Methodology 2/29/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
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; issued extension 2/19/2016 Due Date: 3/25/2013; 1/21/2014; 3/5/2014; 3/31/2015; 5/26/2015; 4/19/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
50.f.	Eligibility and Enrollment for Employees in SHOP ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Employees in SHOP AGENCY: CMS	CMS-10438 See also 50.m.	Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: Issued revision 12/11/2015 Due Date: 2/9/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √

: regulation review complete

: regulation currently under review

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 2/29/2016

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
50.g.	Eligibility and Enrollment for Small Businesses in SHOP ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in SHOP AGENCY: CMS	CMS-10439 See also 50.m.	Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: Issued revision 12/11/2015 Due Date: 2/9/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
50.h.	Eligibility for Insurance Affordability Programs and Enrollment ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment Through Affordable Insurance Exchanges, Medicaid and CHIP Agencies AGENCY: CMS	CMS-10440	Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: 4/30/2013; issued extension 12/2/2015 Due Date: 2/1/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: √ Analysis of Agency action: √
50.aa.	SHOP Effective Date and Termination Notice Requirements ACTION: Request for Comment NOTICE: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements AGENCY: CMS	CMS-10555	Issue Date: 3/9/2015 Due Date: 5/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/14/2015 Due Date: 1/13/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
51.c.	Application of Market Reforms to Student Health Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin SeriesINFORMATION: Application of the Market Reforms and Other Provisions of the Affordable Care Act to Student Health Coverage AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/5/2016 <u>Due Date:</u> None <u>NIHB File Date:</u> <u>Date of Subsequent Agency</u> <u>Action, if any:</u>	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
54.	ESI Coverage Verification ACTION: Notice NOTICE: Employer-Sponsored Coverage Verification: Preliminary Informational Statement AGENCY: CMS	CMS RIN 0938- ZB09	Issue Date: [Approved by OMB 4/26/2012] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	Summary of Agency action:NIHB analysis of action:	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
67.a.	State Consumer Assistance Grants ACTION: Request for Comment NOTICE: Consumer Assistance Program Grants AGENCY: CMS	CMS-10333	Issue Date: 7/27/2012 Due Date: 9/25/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/7/2012; issued extension 11/2/2015, 1/20/2016 Due Date: 2/7/2013; 1/4/2016; 2/19/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
89.g.	Cost Sharing Reduction Reconciliation ACTION: Request for Comment NOTICE: Cost Sharing Reduction Reconciliation AGENCY: CMS	CMS-10526	Issue Date: 6/27/2014 Due Date: 8/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/26/2014; issued revision 9/14/2015, 1/20/2016 Due Date: 10/27/2014; 11/13/2015; 2/19/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
89.m.	Notice of Benefit and Payment Parameters for 2017 ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 AGENCY: CMS	CMS-9937- P F	Issue Date: 12/2/2015 Due Date: 12/21/2015 TTAG File Date: 12/21/2015; TSGAC also filed comments 12/21/2015 Date of Subsequent Agency Action, if any: Final Rule approved by OMB 2/25/2016	 Summary of Agency action: √ NIHB analysis of action: √ 	 TTAG recommendations included: √ Subsequent Agency action: Analysis of Agency action:
89.n.	Manual for Reconciliation of Advance Payment of CSRs ACTION: Guidance NOTICE: Draft Manual for Reconciliation of Advance Payment of Cost-Sharing Reductions for Benefit Years 2014 and 2015 AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/15/2016 Due Date: 2/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
92.b.	Compliance with Individual and Group Market Reforms ACTION: Request for Comment NOTICE: Information Collection Requirements for Compliance with Individual and Group Market Reforms AGENCY: CMS	CMS-10430	Issue Date: 11/21/2012 Due Date: 1/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 2/22/2013; issued revision 12/2/2015 Due Date: 3/25/2013; 2/1/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.d.	Patient Protection Notices and Disclosure Requirements ACTION: Request for Comment NOTICE: Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection Under the Affordable Care Act AGENCY: CMS	CMS-10330	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.e.	Disclosure and Recordkeeping for Grandfathered Health Plans ACTION: Request for Comment NOTICE: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care Act AGENCY: CMS	CMS-10325	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
92.s.	Rate Increase Disclosure and Review Reporting Requirements ACTION: Request for Comment NOTICE: Rate Increase Disclosure and Review Reporting Requirements AGENCY: CMS	CMS-10379	Issue Date: 12/27/2013 Due Date: 2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 4/2/2014; issued revision 2/19/2016 Due Date: 5/2/2014; 4/19/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.kk.	Summary of Benefits and Coverage and Uniform Glossary ACTION: Request for Comment NOTICE: Summary of Benefits and Coverage and Uniform Glossary AGENCY: CMS	CMS-10407 See also 31.tt.	Issue Date: 11/24/2014 Due Date: 1/23/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 2/24/2015; issued revision 2/26/2016 Due Date: 3/26/2015; 3/28/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
92.ccc.	Rate Filing Justifications for 2016 for Single Risk Pool Coverage ACTION: Guidance NOTICE: DRAFT Bulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage Effective on or after January 1, 2017 AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/22/2015 Due Date: 1/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation

: regulation review complete

: regulation currently under review

National Indian Health Board TABLE A: REGULATIONS INCLUDED TO DATE IN RRIAR TABLES B AND C UPDATED THROUGH 2/29/2016

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
92.ddd.	Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data BulletinINFORMATION: Evaluation of EDGE Data Submissions for 2015 Benefit Year for Interim Reinsurance Payments and Interim Risk Adjustment Summary Report AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
111.f.	Mental Health Parity Rules: External Review for MSPP ACTION: Request for Comment NOTICE: Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008: Technical Amendment to External Review for MSPP AGENCY: IRS	TD 9640 (OMB 1545-2165)	Issue Date: 11/27/2015 Due Date: 1/26/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
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 NIHB File Date: 2/4/2015 Date of Subsequent Agency Action, if any: Issued due date extension 1/14/2015; sent Final Rule to OMB 12/14/2015	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: √ Subsequent Agency action: Analysis of Agency action:
112.l.	Expanded Access to Non-VA Care Through Veterans Choice ACTION: Interim Final Rule NOTICE: Expanded Access to Non-VA Care Through the Veterans Choice Program AGENCY: VA	VA RIN 2900- AP60	Issue Date: 12/1/2015 Due Date: 3/30/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
112.m.	Dear Tribal Leader Letter (Contract Support Costs Policy) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS	IHS (no reference number)	Issue Date: 1/7/2016 Due Date: Open NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
112.n.	Catastrophic Health Emergency Fund ACTION: Proposed Rule NOTICE: Catastrophic Health Emergency Fund AGENCY: IHS	IHS RIN 0905- AC97	Issue Date: 1/26/2016 Due Date: 3/11/2016 4/11/2016 NIHB File Date: Date of Subsequent Agency Action, if any: Issued due date extension 2/25/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
112.0.	IHS Reimbursement Rates for CY 2016 ACTION: Notice NOTICE: Reimbursement Rates for Calendar Year 2016 AGENCY: IHS	IHS RIN 0917- ZA30	Issue Date: [Approved by OMB on 2/19/2019] 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:
149.	Evaluation of the Graduate Nurse Education Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Graduate Nurse Education Demonstration Program AGENCY: CMS	CMS-10467	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/28/2013; issued revision 10/16/2015, 1/19/2016 Due Date: 7/29/2013; 12/15/2015; 2/28/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
82.j.	Complaint Forms for Health Information Privacy Issues ACTION: Request for Comment NOTICE: Complaint Forms for Discrimination; Health Information Privacy Complaints AGENCY: HHS OCR	HHS-OS-0945- 0002-60D HHS-OS-0945- 0002-30D	SECTION IV: OTHER Issue Date: 10/20/2015 Due Date: 12/21/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
95.	IHS Forms to Implement the Privacy Rule ACTION: Request for Comment NOTICE: IHS Forms to Implement Privacy Rule (45 CFR Parts 160; 164) AGENCY: IHS	IHS-810, -912- 1, -912-2, -913, and -917	Issue Date: 10/2/2012 Due Date: 60 days (approx. 11/30/2012) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 1/22/2016 Due Date: 3/22/2016	 Summary of Agency action: √ NIHB analysis of action: √ Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
125.	Interest Rate on Overdue Debts ACTION: Notice NOTICE: Notice of Interest Rate on Overdue Debts AGENCY: HHS	HHS (no reference number)	Issue Date: 12/28/2012 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revision 3/5/2013, 4/23/2013, 7/23/2013, 11/12/2013, 9/2/2014, 10/27/2014, 1/27/2015, 8/17/2015, 11/3/2015, 1/27/2016	 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

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
153.m.	CMS/SSA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974: CMS Computer Match No. 2016-12; HHS Computer Match No. 1604; SSA Computer Match No. 1097-1899 AGENCY: CMS	CMS (no reference number)	Issue Date: 2/9/2016 Due Date: 30 days (approx. 3/10/2016) NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
153.n.	CMS/Homeland Security Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-10; HHS Computer Match No. 1607 AGENCY: CMS	CMS (no reference number)	Issue Date: 2/17/2016 <u>Due Date</u> : 30 days (approx. 3/18/2016) NIHB File Date: <u>Date of Subsequent Agency Action, if any</u> :	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
153.o.	CMS/IRS Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-08; HHS Computer Match No. 1606 AGENCY: CMS	CMS (no reference number)	Issue Date: 2/17/2016 <u>Due Date</u> : 30 days (approx. 3/18/2016) NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
189.c.	Annual Update of the HHS Poverty Guidelines ACTION: Notice NOTICE: Annual Update of the HHS Poverty Guidelines AGENCY: HHS	HHS (no reference number)	Issue Date: 1/25/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
194.f.	340B Drug Pricing Program Reporting Requirements ACTION: Request for Comment NOTICE: 340B Drug Pricing Program Reporting Requirements AGENCY: HRSA	HRSA (OMB 0915-0176)	Issue Date: 12/23/2015 Due Date: 2/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
199.b.	CLAS County Data ACTION: Guidance NOTICE: CLAS County Data AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 12/12/2014 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 1/7/2015, 2/9/2015, 1/27/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

RRIAR Ref. #	Short Title/ Current Status of Regulation/ Title/ Agency	File Code	Dates (Issue, Due, File, Subsequent Action) ¹	In Table B Is the summary of Agency action included? Is the NIHB analysis included?	 In Table C Is the list of NIHB recommendations included? Has the Agency taken subsequent action? Is an analysis of subsequent Agency action included?
205.	Sharing What WorksBPPPLE Form ACTION: Request for Comment NOTICE: IHS Sharing What WorksBest Practice, Promising Practice, and Local Effort (BPPPLE) Form AGENCY: IHS	IHS (OMB 0917-0034)	Issue Date: 10/9/2015 Due Date: 12/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 11/17/2015; issued due date extension 12/15/2015 Due Date: 12/17/2015 1/9/2016	 Summary of Agency action: √ NIHB analysis of action: Summary of subsequent Agency action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
206.	Measures of Quality Improvement Activities ACTION: Request for Information NOTICE: Request for Measures Assessing Health Care Organization Quality Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self- Management AGENCY: AHRQ	AHRQ (no reference number)	Issue Date: 2/10/2016 Due Date: 3/4/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:
207.	Confidentiality of Substance Use Disorder Patient Records ACTION: Proposed Rule NOTICE: Confidentiality of Substance Use Disorder Patient Records AGENCY: SAMHSA	SAMHSA- 4162-20	Issue Date: 2/9/2016 Due Date: 4/11/2016 NIHB File Date: Date of Subsequent Agency Action, if any:	 Summary of Agency action: √ NIHB analysis of action: √ 	 NIHB recommendations included: Subsequent Agency action: Analysis of Agency action:

: regulation review complete

: regulation currently under review

National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
1.p.	Health IT Certification Program: Enhanced Oversight ACTION: Proposed Rule NOTICE: ONC Health IT Certification Program: Enhanced Oversight and Accountability AGENCY: HHS ONC	HHS ONC RIN 0955- AA00	Issue Date: [Pending at OMB as of 1/25/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS:	
1.q.	2015 Test Tools and Procedures for Health IT Certification ACTION: Notice NOTICE: Notice of Availability: 2015 Edition Test Tools and Test Procedures Approved by the National Coordinator for the ONC Health IT Certification Program AGENCY: HHS ONC	HHS ONC (no reference number)	Issue Date: 2/4/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; Use: The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where a vulnerability to the Medicare program might exist. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those which bill for the items) complete the administrative information (e.g., patient name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinician (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the medical condition of the beneficiary and signs the CMN. The physician or other clinician returns the CMN to the supplier, which then submits the CMN (paper or electronic) to CMS with a claim for reimbursement. SUMMARY OF NIHB ANALYSIS: CMS requires submission of DME CMNs and Informational Forms to ensure the integrity of the Medicare program. The information	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					collection in this PRA request will impose no changes to the current burden on suppliers and providers. SUMMARY OF AGENCY ACTION: CMS on 3/8/2013 issued a restatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-03-08/pdf/2013-05388.pdf	
3.c.	Durable Medical Equipment Certificate of Medical Necessity ACTION: Request for Comment NOTICE: DME Medicare Administrative Contractor CMN and Supporting Documentation Requirements AGENCY: CMS	CMS-846- 849, -10125, and -10126	Issue Date: 9/24/2012 Due Date: 11/23/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 3/8/2013, issued revision 2/19/2016 Due Date: 4/8/2013; 4/19/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; Use: The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where a vulnerability to the Medicare program might exist. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those which bill for the items) complete the administrative information (e.g., patient name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinician (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the medical condition of the beneficiary and signs the CMN. The physician or other clinician returns the CMN to the supplier, which then submits the CMN (paper or electronic) to CMS with a claim for reimbursement. SUMMARY OF NIHB ANALYSIS: CMS requires submission of DME CMNs and Informational Forms to ensure the integrity of the Medicare program. The information collection in this PRA request will impose no changes to the current burden on suppliers and providers. SUMMARY OF AGENCY ACTION: CMS on 3/8/2013 issued a restatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-03-08/pdf/2013-05388.pdf CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03474.pdf	



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



Ref.	Short Title/Current Status of Regulation/Title/ 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.n.	CORF Eligibility and Survey Forms ACTION: Request for Comment NOTICE: Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations AGENCY: CMS	CMS- 359/360	Issue Date: 1/4/2016 Due Date: 3/4/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Supporting Regulations; Use: CMS-359 serves as the application for health care providers seeking to participate in the Medicare program as a Comprehensive Outpatient Rehabilitation Facility (CORF). This form initiates the process for facilities to become certified as a CORF and provides the CMS Regional Office State Survey Agency staff identifying information regarding the applicant that is stored in the Automated Survey Processing Environment (ASPEN) system. CMS-360 serves as a survey tool used by the State Survey Agencies to record information to determine provider compliance with the CORF Conditions of Participation (CoPs) and to report this information to the federal government. This form includes basic information on the CoP requirements, check boxes to indicate the level of compliance, and a section for recording notes. CMS has the responsibility and authority for certification decisions based on provider compliance with the CoPs, and this form supports that process. https://www.gpo.gov/fdsys/pkg/FR-2016-01-04/pdf/2015-32965.pdf SUMMARY OF NIHB ANALYSIS:	
5.a.	PACE Information Request ACTION: Request for Comment NOTICE: Medicare and Medicaid; Programs of All- Inclusive Care for the Elderly (PACE) AGENCY: CMS	CMS-R-244	Issue Date: 7/30/2010 Due Date: 9/28/2010 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Programs for All-inclusive Care of the Elderly (PACE) and Supporting Regulations; <i>Use</i> : The PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their state nursing home eligibility standards using capitated payments from Medicare and the state. The model of care includes as core services the provision of adult day health care and multidisciplinary team case management, with controlled access to and allocation of all health services. Participants receive physician, therapeutic, ancillary, and social support services in their residence or onsite at the adult day health center. The PACE programs must provide all Medicare and Medicaid covered services, including hospital, nursing home, home health, and other specialized services. Financing of this model occurs through prospective capitation of both Medicare and Medicaid payments. The information collection requirements ensure that only appropriate organizations become PACE organizations and that CMS has the information necessary to monitor the care	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			extension 10/8/2010, 10/4/2013, 12/20/2013, 12/8/2015 <u>Due Date:</u> 11/8/2010; 12/3/2013; 1/21/2014; 2/8/2016		provided to the frail, vulnerable population served. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/8/2010 issued an extension of this PRA request. CMS on 10/4/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf CMS on 12/20/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf CMS on 12/8/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-08/pdf/2015-30891.pdf No comments recommended.	
5.d.	PACE Update ACTION: Proposed Rule NOTICE: Programs of All- Inclusive Care for the Elderly (PACE) Update AGENCY: CMS	CMS-4168-P	Issue Date: [Pending at OMB as of 1/25/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would update the PACE regulations published on 12/8/2006. This proposed rule would improve the quality of the existing regulations, provide operational flexibility and modifications, and remove redundancies and outdated information. These updates seek to ensure the health and safety of PACE participants. SUMMARY OF NIHB ANALYSIS:	
6.i.	Pre-Existing Health Insurance Plan Program	CMS-9995- IFC4	Issue Date: [Pending at		SUMMARY OF AGENCY ACTION:	



Ref. #	Short Title/Current Status of Regulation/Title/Agency Updates ACTION: Interim Final Rule NOTICE: Pre-Existing Condition Insurance Plan Program Updates AGENCY: CMS	File Code	Issue Date; Due Date & File Date OMB as of 2/3/2015] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF NIHB ANALYSIS:	NIHB Recs.
7.jjj.	Establishment of QHPs and Exchanges ACTION: Request for Comment NOTICE: Establishment of Qualified Health Plans and American Health Benefit Exchanges AGENCY: CCIIO	CMS-10400	Issue Date: 11/23/2015 Due Date: 1/22/2015 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Establishment of Qualified Health Plans and American Health Benefit Exchanges; Use: ACA expands access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). As directed by the rule titled "Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers" (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of qualified health plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of essential community providers (ECPs), and non-discrimination. The Exchange must ensure that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on ACA, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State-Based or Federally-Facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of ACA.	



Ref.	Short Title/Current Status of Regulation/Title/ 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-2015-11-23/pdf/2015-29725.pdf SUMMARY OF NIHB ANALYSIS:	
7.kkk.	ECP Petition for 2017 ACTION: Notice NOTICE: Essential Community Provider Petition for the 2017 Benefit Year AGENCY: CCIIO	CCIIO (no reference number)	Due Date: 1/8/2016 1/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued due date extension		SUMMARY OF AGENCY ACTION: In accordance with section 1311(c)(1)(C) of the ACA, qualified health plan (OHP), including stand-alone dental plan (SADP) issuers must include within their network essential community providers (ECPs), where available, that serve predominantly low-income, medically-underserved individuals. Under this same section of ACA, the HHS Secretary must establish criteria for certification of health plans as QHPs, including criteria for issuer satisfaction of the ECP inclusion requirement. Under 45 CFR 156.235, the HHS Secretary has established criteria for inclusion of a sufficient number and geographic distribution of ECPs, where available, in the networks of issuers to ensure reasonable and timely access to a broad range of such providers for low-income, medically-underserved individuals in their service areas. To satisfy this ECP requirement, QHP and SADP issuers must submit an ECP template as part of their QHP application, in which they must list the ECPs with which they have contracted to provide health care services to low-income, medically-underserved individuals in their service areas. HHS has compiled a non-exhaustive list of available ECPs, based on data it and other federal agencies maintain, that has served as an initial source of ECP information. The non-exhaustive HHS ECP list for the 2016 benefit year is available at https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/ahp.html . HHS updates this ECP list annually to assist issuers with identifying providers that qualify for inclusion in issuer networks toward satisfaction of the ECP standard under 45 CFR 156.235. That regulation defines ECPs as health care providers benefit defined in section 340B(a)(4) of the Public Health Service Act (PHS Act) and described in section 1927(c)(1)(D)(IV) of the Social Security Act (Act). Interested parties should submit their petition by no later than 11:59 p.m. ET	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					https://data.healthcare.gov/cciio/ecp_petition More information on QHPs is available on the CCIIO Web site at https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/qhp.html. SUMMARY OF TSGAC ANALYSIS: A TSGAC briefing memo on the petition is embedded below. TSGAC-Memo-Action -Needed-to-Retain-St A TSGAC briefing memo that includes the steps to submitting the petition and the final HHS ECP List for 2017 is embedded below. TSGAC Memo-Steps to Update-or	
7.111.	2017 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft 2017 Letter to Issuers in the Federally-Facilitated Marketplaces AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 12/23/2015 Due Date: 1/17/2016 TSGAC File Date: 1/17/2016 Date of Subsequent Agency Action, if any:	TSGAC response:	SUMMARY OF AGENCY ACTION: This draft 2017 Letter to Issuers in the Federally-Facilitated Marketplaces (Letter) provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-Facilitated Marketplaces (FFMs) or the Federally-Facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in those Marketplaces in 2017. Unless otherwise specified, references to the FFMs include the FF-SHOPs. Throughout this Letter, CMS identifies the areas in which states performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS also describes how parts of this Letter apply to issuers in State-Based Marketplaces on the Federal Platform (SBM-FPs). CMS notes that the policies articulated in this Letter apply to the certification process for plan years beginning in 2017. Previously published rules concerning market-wide and QHP certification standards,	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		FIIE Date		eligibility and enrollment procedures, and other Marketplace-related topics appear in 45 CFR Subtitle A, Subchapter B. CMS proposed additional standards in a proposed rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017" (2017 Payment Notice Proposed Rule, CMS 9937-P), which appeared in the 12/2/2015 FR. CMS expects issuers to consult all applicable regulations, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of ACA. Throughout the plan year, QHP issuers might have to correct deficiencies identified in CMS post-certification activities, as a result of the investigation of consumer cases, oversight by State regulators or by CMS, or an industry-standard internal compliance and risk management program of the issuer. QHP issuers in the FFMs also might have to meet other requirements for plan years beginning in 2017, as indicated in future rulemaking. CMS welcomes comments on this proposed guidance. To the extent that this guidance summarizes policies proposed through other rulemaking processes not yet finalized, such as the rulemaking process for the 2017 Payment Notice Proposed Rule, stakeholders should comment on those underlying policies through the ongoing rulemaking processes and not through the comment process for this Letter. Please send comments on other aspects of this Letter to FFEcomments@cms.hhs.gov by 1/17/2016. Interested parties should submit comments organized by subsections of this Letter. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-2017-Letter-to-Issuers-12-23-2015 508.pdf SUMMARY OF NIHB ANALYSIS: A related multi-year analysis of the provisions in this annual Letter is embedded below.	
7 mmm		0110 12722				
7.mmm.	Establishment of an Exchange by a State and QHPs	CMS-10593	<u>Issue Date:</u> 12/2/2015		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Establishment of an Exchange by a State and Qualified Health Plans; Use: ACA expands access to health insurance for individuals and	



Ref.	Short Title/Current Status of Regulation/Title/ 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: Establishment of an Exchange by a State and Qualified Health Plans AGENCY: CMS		Due Date: 2/1/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). As directed by the rule Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of qualified health plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of essential community providers (ECPs), and nondiscrimination. The Exchange must ensure that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR parts 155 and 156, based on ACA, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State-Based or Federally-Facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of ACA. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf SUMMARY OF NIHB ANALYSIS: This PRA notice might include issues on which tribal organizations want to comment.	
7.nnn.	Establishment of Exchanges and QHPs Standards for Employers ACTION: Request for Comment NOTICE: Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers AGENCY: CMS	CMS-10592	Issue Date: 12/2/2015 Due Date: 2/1/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; <i>Use</i> : Section 1321(a) requires HHS to issue regulations setting standards for meeting the requirements under Title I of ACA, including the offering of qualified health plans (QHPs) through the Marketplaces. On 3/27/2012, HHS published the rule CMS-9989-F, Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (Exchange rule). The Exchange rule contains provisions that mandate reporting and data collections necessary to ensure that health insurance issuers meet the requirements of ACA. These information collection requirements appear in 45 CFR part 156. The data collection and reporting requirements will assist HHS in creating a seamless and coordinated system of eligibility and enrollment. The data collected by health insurance issuers will help to inform HHS, Marketplaces, and health insurance issuers as to the participation of individuals,	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date		employers, and employees in the individual Exchange. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf SUMMARY OF NIHB ANALYSIS: CMS-10592 seeks OMB approval of the regulatory PRA requirements associated with the minimum requirements that health insurance issuers must meet with respect to participation in the Marketplaces, specifically the following sections of 45 CFR part 156: OHP issuer notice of effective date (§156.260(b)); OHP issuer reconciliation of enrollment files with Exchange (§156.265(f)); OHP issuer notice of enrollee nonpayment of premium (§156.270(b)); OHP issuer notice to providers of the possibility for denied claims(§156.270(d)(3)); OHP issuer notice of payment delinquency to an enrollee (§156.270(e)); OHP issuers maintenance of records of terminations of coverage (§156.270(h)); and OHP issuer notification of plan non-renewal (§156.290). This PRA request does not have any associated forms or templates. A Supporting Statement for this PRA request is available at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10592.html .	
7.000.	CMS Healthcare.gov Site Wide Online Survey ACTION: Request for Comment NOTICE: CMS Healthcare.gov Site Wide Online Survey AGENCY: CMS	CMS-10597	Issue Date: 12/14/2015 Due Date: 2/12/2016 NIHB File Date: Date of Subsequent		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: CMS Healthcare.gov Site Wide Online Survey; Use: This survey seeks to gain an understanding of user experience, comprehension, and satisfaction with using the federal Health Insurance Marketplace Web site established by ACA. The Marketplace provides coverage to uninsured U.S. residents, as well as those already enrolled in Marketplace health insurance. One of the ways to purchase Marketplace insurance involves the use of the online tools on HealthCare.gov. CMS has developed a survey for consumers to take while using the Web site. This survey represents part of a continuing data collection program mandated by ACA. It seeks to support the program goal to provide tools and information to help consumers successfully find health insurance for which they might not otherwise qualify for or might not find. Monitoring usability and the	



				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.
			Agency Action, if any:		user experience through this ongoing survey provides the Web site developers with valuable information for use in continuous improvement of the Web site. https://www.gpo.gov/fdsys/pkg/FR-2015-12-14/pdf/2015-31399.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
10.g.	Medicare Shared Savings Program: ACO Benchmarking ACTION: Proposed Rule NOTICE: Medicare Shared Savings Program; Accountable Care OrganizationsRevised Benchmarking Methodology AGENCY: CMS	CMS-1644-P	Issue Date: [Approved by OMB 1/27/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would address changes to the Medicare Shared Savings Program, specifically a revised benchmarking methodology, which affects Medicare payments to providers of services and suppliers participating in accountable care organizations (ACOs) under the Medicare Shared Savings Program. These changes would apply to existing ACOs and approved ACO applicants participating in the program beginning 1/1/2017. 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, if any: Issued		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); <i>Use</i> : Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) must submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by the Centers for Medicare & Medicaid Services (CMS). MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid, with the information provided in the BPT used as the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development, administrative expenses, profit levels, and projected plan enrollment information. CMS reviews and analyzes the information provided in the BPT and decides whether to approve the plan pricing proposed by each organization. CMS is requesting to continue its use of the BPT for the collection of information for CY 2014 through CY 2016.	



Ref.	Short Title/Current Status of Regulation/Title/ 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 1/17/2013, 10/4/2013, 12/20/2014, 12/24/2014, 9/24/2015, 12/18/2015 Due Date: 2/19/2013; 1/21/2014; 11/25/2014; 11/23/2015; 11/19/2016		SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 1/17/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2013-00858.pdf CMS on 10/4/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24250.pdf CMS on 12/20/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-12-20/pdf/2013-30334.pdf CMS on 9/26/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-22990.pdf CMS on 12/24/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-12-24/pdf/2014-30026.pdf CMS on 9/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-24/pdf/2015-24263.pdf No comments recommended. CMS on 12/18/2015 issued a revision of this PRA request. CMS has revised this package subsequent to the publication of the 60-day notice in the 9/24/2015 FR (80 FR 57619). https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31887.pdf No comments recommended.	
11.f.	Plan Benefit Package and Formulary Submission ACTION: Request for Comment	CMS-R-262	<u>Issue Date:</u> 10/5/2012 <u>Due Date:</u> 12/4/2012		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); Use: Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations must submit plan benefit packages—which consist of the Plan Benefit Package (PBP)	



		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.
	NOTICE: PBP and Formulary Submission for Medicare Advantage and Prescription Drug Plans AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 1/17/2013, 11/1/2014, 9/26/2014, 12/19/2015, 12/18/2015 Due Date: 2/19/2013; 12/31/2013; 2/18/2014; 11/25/2014; 11/25/2014; 11/20/2015; 11/23/2015; 11/9/2016		software, formulary file, and supporting documentation, as necessary—for all Medicare beneficiaries residing in their service area. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits, as well as generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. In addition, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization. SUMMARY OF NIHB ANALYSIS: A link to a detailed list of changes to the PBP software appears below. In addition, if issues with the current formulary development process or the use of the formulary have occurred, this PRA request might provide an opportunity to comment on them. The changes proposed are to be implemented and effective by CY 2014. http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html SUMMARY OF SUBSEQUENT AGENCY ACTION: Based on operational changes and policy clarifications to Medicare and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2013-00858.pdf CMS on 11/17/2013 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-11-01/pdf/2013-26107.pdf CMS on 9/26/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-09915.pdf CMS on 9/26/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-09915.pdf CMS on 12/19/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-09915.pdf CMS on 12/19/2014 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-01-17/pdf/2014-09915.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 CMS on 9/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-24/pdf/2015-24263.pdf No comments recommended. CMS on 12/18/2015 issued a revision of this PRA request. CMS has revised this package subsequent to the publication of the 60-day notice in the 9/24/2015 FR (80 FR 57619). https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31887.pdf No comments recommended.	NIHB Recs.
11.i.	Medicare Advantage Appeals and Grievance Data Disclosure ACTION: Request for Comment NOTICE: Medicare Advantage Appeals and Grievance Data Disclosure Requirements AGENCY: CMS	CMS-R-282	Issue Date: 2/22/2013 Due Date: 4/23/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 5/3/2013, 12/14/2015 Due Date: 6/3/2013; 2/12/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare Advantage Appeals and Grievance Data Disclosure Requirements (42 CFR 422.111); Use: Section 1852(c)(2)(C) of the Social Security Act and 42 CFR 422.111(c)(3) require that Medicare Advantage (MA) organizations and demonstrations disclose information pertaining to the number of disputes, as well as their disposition in the aggregate, with the categories of grievances and appeals to any individual eligible to elect an MA organization who requests this information. MA organizations and demonstrations remain under a requirement to collect and provide this information to individuals eligible to elect an MA organization, and CMS continues to need the same format and form for reporting. http://www.gpo.gov/fdsys/pkg/FR-2013-02-22/pdf/2013-04120.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/3/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10530.pdf Instructions for information disclosure, a model disclosure form, and a Supporting Statement are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1205062.html .	

National Indian Health Board

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis The Instructions do not require identification of specific categories of appeals (other than expedited appeals). CMS on 12/14/2015 issued an extension of this PRA request.	NIHB Recs.
					https://www.gpo.gov/fdsys/pkg/FR-2015-12-14/pdf/2015-31399.pdf No comments recommended.	
12.f.	FAQs on the CO-OP Program ACTION: Guidance NOTICE: Frequently Asked Questions on the Consumer Operated and Oriented Plan (CO-OP) Program AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/27/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This guidance answers several frequently asked questions regarding the Consumer Operated and Oriented Plan (CO-OP) Program. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CO-OP-Questions-Final-1-27-16.pdf SUMMARY OF NIHB ANALYSIS:	
14.c.	Waivers for State Innovation ACTION: Notice NOTICE: Waivers for State Innovation AGENCY: CMS/Treasury	CMS-9936-N	Issue Date: 12/16/2015 Due Date: Open TSGAC File Date: 2/23/2016 Date of Subsequent Agency	TSGAC response:	SUMMARY OF AGENCY ACTION: This guidance relates to Section 1332 of ACA and its implementing regulations. Section 1332 provides the HHS and Treasury Secretaries with the discretion to approve a state proposal to waive specific provisions of the ACA (a State Innovation Waiver), provided the proposal meets certain requirements. In particular, the Secretaries can only exercise their discretion to approve a waiver if they find that the waiver would provide coverage to a comparable number of residents of the state as would occur absent the waiver, would provide coverage at least as comprehensive and affordable as would occur absent the waiver, and would not increase the federal deficit. If approved for the waiver, the state can receive funding equal to the amount of forgone federal financial assistance that would have occurred pursuant to specified ACA programs, known as pass-through funding. States can obtain State Innovation Waivers for effective dates beginning on or after 1/1/2017, with approvals for periods of as long as 5 years and with the possibility of renewal. HHS and Treasury	See Table C.



				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.
	-		Action, if any:		promulgated implementing regulations in 2012.	
					This document provides additional information about the requirements for State Innovation Waivers, the application review procedures, the amount of pass-through funding, certain analytical requirements, and operational considerations.	
					The Departments welcome comments on this guidance and will consider issuing additional guidance in the future if additional clarifications are necessary.	
					https://www.gpo.gov/fdsys/pkg/FR-2015-12-16/pdf/2015-31563.pdf	
					SUMMARY OF NIHB ANALYSIS: Tribal organizations might want to submit comments asking CMS to address the specific impact of State Innovation Waivers on AI/ANs, as recommended in prior comments. An analysis of this guidance appears below.	
					Coverage: The guidance calls for: "Assessment of whether the proposal covers a comparable number of individuals also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues." No explicit mention of Al/AN has a distinct group of residents, whereby the state's proposal would be evaluated to ensure no reduction in coverage.	
					Affordability: The guidance states: "Increasing the number of state residents with large health care spending burdens would cause a waiver to fail the affordability requirement, even if the waiver would increase affordability for many other state residents. Assessment of whether the proposal meets the affordability requirement also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues. Reducing affordability for these types of vulnerable groups would cause a waiver to fail this requirement, even if the waiver maintained affordability in the aggregate." But no explicit mention of Al/ANs is included in the guidance.	
					<u>Coverage</u> : "The waiver must not decrease the number of individuals with coverage that satisfies EHB requirements, the number of individuals with coverage of any particular category of EHB, or the number of individuals with coverage that includes the services	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date		covered under the state's Medicaid and/or CHIP programs Assessment of whether the proposal meets the comprehensiveness requirement also takes into account the effects across different groups of state residents, and, in particular, vulnerable residents, including low-income individuals, elderly individuals, and those with serious health issues or who have a greater risk of developing serious health issues." Deficit Neutrality: "Under the deficit neutrality requirement, the projected Federal spending net of Federal revenues under the State Innovation Waiver must be equal to or lower than projected Federal spending net of Federal revenues in the absence of the waiver. The effect on Federal spending includes all changes in Exchange financial assistance and other direct spending, such as changes in Medicaid spending (while holding the state's Medicaid policies constant) that result from the changes made through	
					the State Innovation Waiver. Projected Federal spending under the waiver proposal also includes all administrative costs to the Federal government, including any changes in Internal Revenue Service administrative costs, Federal Exchange administrative costs, or other administrative costs associated with the waiver. Waivers must not increase the Federal deficit over the period of the waiver (which may not exceed 5 years unless renewed) or in total over the ten-year budget plan The ten-year budget plan must describe for both the period of the waiver and for the ten-year budget the projected Federal spending net of Federal revenues under the State Innovation Waiver and the projected Federal spending net of Federal revenues in the absence of the waiver."	
					The assessment does not consider the impact of policy changes that are contingent on further state action, such as state legislation that is proposed but not yet enacted. It also does not include the impact of changes contingent on other Federal determinations, including approval of Federal waivers pursuant to statutory provisions other than Section 1332. Therefore, the assessment would not take into account changes to Medicaid or CHIP that require separate Federal approval, such as changes in coverage or Federal Medicaid or CHIP spending that would result from a proposed Section 1115 demonstration, regardless of whether the Section 1115 demonstration proposal is submitted as part of a coordinated waiver application with a State Innovation Waiver The assessment does take into account changes in Medicaid and/or CHIP coverage or in Federal spending on Medicaid and/or CHIP that would result directly from the proposed waiver of provisions pursuant to Section 1332, holding state Medicaid and CHIP policies constant A state may submit a coordinated waiver application as provided in 31 CFR 33.102 and 45 CFR 155.1302; in such a case, each waiver will be evaluated independently according to applicable Federal laws."	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Internal Revenue Service: "Certain changes that affect Internal Revenue Service (IRS) administrative processes may make a waiver proposal not feasible to implement. At this time, the IRS is not generally able to administer different sets of rules in different states. As a result, while a state may propose to entirely waive the application of one or more of the tax provisions listed in Section 1332 to taxpayers in the state, it is generally not feasible to design a waiver that would require the IRS to administer an alteration to these provisions for taxpayers in the state. For example, it is generally not feasible to have the IRS administer a different set of eligibility rules for the premium tax credit for residents of a particular state." Public Input on Waiver Proposals: "Consistent with the statutory provisions of Section 1332, regulations at 31 CFR 33.112 and 45 CFR 155.1312 require states to provide a public notice and comment period for a waiver application sufficient to ensure a meaningful level of public input prior to submitting an application. As part of the public notice and comment period, a state with one or more Federally-recognized tribes must conduct a separate process for meaningful consultation with such tribes Section 1332 and its implementing regulations also require the Federal Government to provide a public notice and comment period, once the Secretaries receive an application."	
16.b.	Medicaid HCBS Waivers ACTION: Proposed-Final Rule NOTICE: Medicaid; State Plan Home and Community- Based Services, 5-Year Period for Waivers, Provider Payment Reassignment; Setting Requirements 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		SUMMARY OF AGENCY ACTION: This proposed rule would revise Medicaid regulations to define and describe State plan home and community-based services (HCBS) under the Social Security Act (the Act) as added by the Deficit Reduction Act of 2005 and amended by ACA. This rule would offer States new flexibility in providing necessary and appropriate services to elderly and disabled populations. In particular, this rule would not require the eligibility link between HCBS and institutional care that exists under the Medicaid HCBS waiver program. This rule would describe Medicaid coverage of the optional State plan benefit to furnish HCBS and receive Federal matching funds. This proposed rule also would amend Medicaid regulations consistent with the requirements of ACA, which amended the Act to provide authority for a 5-year duration for certain demonstration projects or waivers, at the discretion of the HHS Secretary, when they involve individuals dually eligible for Medicaid and Medicare benefits. In addition, this rule would provide an additional limited exception to the general requirement that payment for services under a State plan go directly to the individual	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date date extension	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis 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	NIHB Recs.
			5/3/2012; Final Rule approved by OMB 1/13/2014		payments to other parties to benefit the providers by ensuring health, welfare, and training. Finally, this rule would amend Medicaid regulations to provide home and community-based setting requirements of ACA for the Community First Choice State plan option.	
					SUMMARY OF NIHB ANALYSIS:	
20.a.	Assuring Access to Services ACTION: Proposed-Final Rule NOTICE: Medicaid Program; Methods for Assuring Access to Covered Medicaid Services AGENCY: CMS	CMS-2328- PFC	Issue Date: 5/6/2011 Due Date: 7/5/2011 ANTHC File Date: 7/5/2011 Date of Subsequent Agency Action, if any: Issued Final Rule 11/2/2015 Due Date: 1/4/2016		SUMMARY OF AGENCY ACTION: This proposed rule would create a standardized, transparent process for states to follow as part of their broader efforts to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area" as required by section 1902(a)(30)(A) of the Social Security Act (Act). This proposed rule also would recognize, as states have requested, electronic publication as an optional means of communicating proposed rate-setting policy changes in state plan amendments (SPAs) to the public. SUMMARY OF ANTHC ANALYSIS: Although this proposed rule serves as an excellent first step in efforts to provide clearer standards and more actively monitor compliance with sufficiency and access requirements in section 1902(a)(30)(A), additional attention is needed for areas where access currently is inadequate. ANTHC generally approves of the MACPAC-recommended three-part framework for determining service access data elements: 1) information on enrollee needs, 2) availability of care and providers, and 3) utilization of services. In general, the Indian health system serves a patient population very different from that of the mainstream United States. As a result, if consideration was given to the availability of culturally competent care (and not just "care"), this would help ensure that states consider the unique position of Indian health programs and their patients when evaluating their Medicaid programs. ANTHC supports the proposed requirement that states submit Medicaid access data collected during the prior year in support of state plan amendments that reduce payment rates or restructure provider payments in circumstances when the resulting changes could create access issues, but Medicaid access data could vary tremendously from year to year, resulting in skewed statistics. The propose	



						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.
					and tribal organizations. In soliciting comments on whether to delete the word "significant" from §447.205(a) on notice requirements, CMS correctly recognizes that it is extraordinarily difficult to determine a uniform threshold as to what constitutes a "significant" proposed change in the methods and standards for setting state payment rates for services. The proposed rule did not ask for comments on the exceptions to notice requirements contained in §447.205(b), but the exception for "changes made to conform to Medicare methods or levels of reimbursement" could exempt actions extremely disruptive to access. CMS proposes to allow states to substitute publication on a Web site for publication in print media. Although the additional notice avenue is useful, substituting it for other forms of notice could raise concerns unless some additional protections are added and conditions are satisfied. Given the significant challenges facing tribal health programs, as well as the critical role of third-party reimbursement to the very solvency of the tribal health system, virtually any change in state reimbursement rates will have a "direct effect" on tribal health programs. SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule with comment period provides for a transparent data-driven process for states to document whether they have sufficient Medicaid payments to enlist providers to assure beneficiary access to covered care and services consistent with section 1902(a)(30)(A) of the Social Security Act (Act) and to address issues raised by that process. This final rule with comment period also recognizes electronic publication as an optional means of providing public notice of proposed changes in rates or rate-setting methodologies that the state intends to include in a Medicaid state plan amendment (SPA). CMS has provided an opportunity for comment on whether it should make future adjustments to the provisions setting forth requirements for ongoing state reviews of beneficiary access. http://www.gpo.gov/fdsys/pkg/FR-201	
20.1-	Data Matrico sud	CMC 2220	Janua Data		CHAMADY OF ACTION ACTION. In this was weet for information (DEI), CARO and I	
20.b.	Data Metrics and Alternative Processes for Access to Care	CMS-2328- NC	Issue Date: 11/2/2015 Due Date:		SUMMARY OF AGENCY ACTION: In this request for information (RFI), CMS seeks public input to inform the potential development of standards with regard to access to covered services for beneficiaries under the Medicaid program. Specifically, CMS requests information on core access to care measures and metrics that it could use to	
	ACTION: Request for Information		1/4/2016 NIHB File		measure access to care for beneficiaries in the Medicaid program (including in fee-for- service and managed care delivery systems) and to develop local, state, and national thresholds and goals to inform and improve access in the program. CMS also seeks	
	NOTICE: Medicaid Program;		<u>Date:</u> None		feedback on approaches to using the metrics, possibly including setting access goals	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency Request for Information (RFI)Data Metrics and Alternative Processes for Access to Care in the Medicaid Program AGENCY: CMS	File Code	Issue Date; Due Date & File Date Date of Subsequent Agency Action, if any:	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis and thresholds and creating formal processes for beneficiaries to raise access concerns. http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27696.pdf SUMMARY OF NIHB ANALYSIS:	NIHB Recs.
23.b.	MACPro: New Online System for State Plan Amendments, Waivers, etc. ACTION: Request for Comment NOTICE: Medicaid and CHIP Program (MACPro) AGENCY: CMS	CMS-10434	Issue Date: 12/21/2012 Due Date: 1/22/2013 TSGAC File Date: 1/22/2013 Date of Subsequent Agency Action, if any: Issued revision 11/9/2015 Due Date: 1/8/2016	TSGAC resposne:	SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection: Title: Medicaid and CHIP Program (MACPro); Use: Medicaid, authorized by Title XIX of the Social Security Act and, CHIP, reauthorized by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), play an important role in financing health care for approximately 48 million people throughout the country. By 2014, it is expected that an additional 16 million people will become eligible for Medicaid and CHIP as a result of the Affordable Care Act (Pub. L. 111–148). In order to implement the statute, CMS must provide a mechanism to ensure timely approval of Medicaid and CHIP state plans, waivers and demonstrations, and provide a repository for all Medicaid and CHIP program data that supplies data to populate Healthcare.gov and other required reports. Additionally, 42 CFR 430.12 sets forth the authority for the submittal and collection of state plans and plan amendment information. Pursuant to this requirement, CMS has created the MACPro system. Generally, MACPro will be used by both state and CMS officials to: Improve the state application and federal review processes, improve federal program management of Medicaid programs and CHIP, and standardize Medicaid program data. More specifically, it will be used by state agencies to (among other things): (1) Submit and amend Medicaid state plans, CHIP state plans, and Information System Advanced Planning Documents, and (2) submit applications and amendments for state waivers, demonstration, and benchmark and grant programs. It will be used by CMS to (among other things): (1) Provide for the review and disposition of applications, and (2) monitor and track application activity. A paper-based version of the MACPro instrument would be sizable and time consuming for interested parties to follow as a paper-based instrument. In our effort to provide the public with the most efficient means to make sense of the MACPro.	See Table C.



				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.
					SUMMARY OF TSCAG ANALYSIS: MACPro requires the State to submit information on both general and Tribal consultation processes in the "initial application," which the State completes at the outset of any submission. With regard to Tribal consultation, the application first asks whether "one or more Indian Health Programs or Urban Indian Organizations furnish health care services in this State." If the State answers "yes," the application asks whether "this state plan amendment is likely to have a direct effect on Indians, Indian health care programs, or urban Indian organizations." If the State answers "yes," the application asks whether "the State has solicited advice from Tribal governments prior to submission of this SPA application." If the State answers "yes," the application asks for the name of any Indian Tribe, Tribal organization, or urban Indian organization (I/T/U) consulted, the consultation date, and the method/location of the consultation. The State also must upload any copies of the consultation notices sent to I/T/Us. The State does not have to provide any summary of the Tribal comments received and/or its response (if any). After completion of the initial application, MACPro provides the State with a specific submission form that, unlike the general application, is specifically tailored to the exact action or amendments that the State proposes. MACPro also will send the State a notification reminding it to complete this form. After the State submits its final package to CMS, MACPro will assign a CMS point of contact and review team to the SPA. The package is then "dispositioned" for approval, disapproval, and post-approval. Alternatively, if CMS reviews the package and determines a need for additional information, the review team will notify the State, which must resubmit the package to CMS. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 11/9/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-11-09/pdf/2015-28449.pdf	
25.cc.	Revisions to Requirements for Discharge Planning for Hospitals	CMS-3317-P	Issue Date: 11/3/2015 <u>Due Date:</u> 1/4/2016		SUMMARY OF AGENCY ACTION: This proposed rule would revise the discharge planning requirements that hospitals, including long-term care hospitals and inpatient rehabilitation facilities, critical access hospitals, and home health agencies must meet to participate in the Medicare and Medicaid programs. This proposed rule also would implement the discharge planning requirements of the Improving Medicare Post-Acute	



Ref.	Short Title/Current Status of Regulation/Title/ 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; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any:		Care Transformation Act of 2014. SUMMARY OF NIHB ANALYSIS:	
25.dd.	Emergency and Foreign Hospital Services ACTION: Request for Comment NOTICE: Emergency and Foreign Hospital Services AGENCY: CMS	CMS-1771	Issue Date: 9/21/2015 Due Date: 11/20/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 11/9/2015, 2/5/2016 Due Date: 12/9/2015, 4/5/2016		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Reinstatement without change of a previously approved collection; <i>Title</i> : Emergency and Foreign Hospital Services; <i>Use</i> : Section 1866 of the Social Security Act (Act) states that any provider of services must qualify to participate in the Medicare program and qualify for payments under Medicare if it files an agreement with the HHS Secretary to meet the conditions outlined in this section of the Act. Section 1814(d)(1) of the Act and 42 CFR 424.100 allow payment of Medicare benefits for a Medicare beneficiary to a nonparticipating hospital that does not have an agreement in effect with CMS. These payments can occur if such services were emergency services and if CMS would have to make the payment if the hospital had an agreement in effect and met the conditions of payment. This form is used in connection with claims for emergency hospital services provided by hospitals that do not have an agreement in effect under Section 1866 of the Act. As specified in 42 CFR 424.103(b), before a non-participating hospital can receive payment for emergency services rendered to a Medicare beneficiary, it must submit a statement sufficiently comprehensive to support that an emergency existed. Form CMS-1771 contains a series of questions relating to the medical necessity of the emergency. The attending physician must attest to the need for the hospitalization under the regulatory emergency definition and give clinical documentation to support the claim. http://www.gpo.gov/fdsys/pkg/FR-2015-09-21/pdf/2015-23528.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					reinstatement of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2015-11-09/pdf/2015-28448.pdf No comments recommended. CMS on 2/5/2016 issued a reinstatement of this PRA request with no changes. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02278.pdf No comments recommended.	
25.ee.	Design of Survey on Patient Experiences with Care in LTCHs ACTION: Request for Information NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Long-Term Care Hospitals AGENCY: CMS	CMS-3327- NC	Issue Date: 11/20/2015 Due Date: 1/19/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This request for information will aid in the design and development of a survey regarding patient and family member experiences with the care received in long-term care hospitals (LTCHs). http://www.gpo.gov/fdsys/pkg/FR-2015-11-20/pdf/2015-29622.pdf SUMMARY OF NIHB ANALYSIS:	
25.ff.	Design of Survey on Patient Experiences with Care in IRFs ACTION: Request for Information	CMS-3328- NC	Issue Date: 11/20/2015 <u>Due Date:</u> 1/19/2016		SUMMARY OF AGENCY ACTION: This request for information will aid in the design and development of a survey regarding patient and family member experiences with the care received in inpatient rehabilitation facilities (IRFs). http://www.gpo.gov/fdsys/pkg/FR-2015-11-20/pdf/2015-29623.pdf	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/Agency NOTICE: Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Inpatient Rehabilitation Facilities AGENCY: CMS	File Code	Issue Date; Due Date & File Date NIHB File Date: None Date of Subsequent Agency Action, if any:	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF NIHB ANALYSIS:	NIHB Recs.
25.gg.	Inpatient Prospective Payment Systems0.2 Percent Reduction ACTION: Notice NOTICE: Medicare Program; Inpatient Prospective Payment Systems; 0.2 Percent Reduction AGENCY: CMS	CMS-1658- NC	Issue Date: 12/1/2015 Due Date: 2/2/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In accordance with the 10/6/2015 court order in Shands Jacksonville Medical Center, Inc., et al. v. Burwell, No. 14-263 (D.D.C.) and consolidated cases that challenge the 0.2 percent reduction in inpatient prospective payment systems (IPPS) rates to account for the estimated \$220 million in additional FY 2014 expenditures resulting from the 2-midnight policy, this notice discusses the basis for the 0.2 percent reduction and its underlying assumptions and invites comments on the same to facilitate further CMS consideration of the FY 2014 reduction. CMS will consider and respond to the comments received in response to this notice, and to comments already received on this issue in a final notice, which the agency will publish by 3/18/2016. http://www.gpo.gov/fdsys/pkg/FR-2015-12-01/pdf/2015-30486.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
25.hh.	Explanation of FY 2004 Outlier Fixed-Loss Threshold ACTION: Notice NOTICE: Medicare	CMS-1659-N	Issue Date: 1/22/2016 Due Date: None NIHB File		SUMMARY OF AGENCY ACTION: In accordance with court rulings in cases that challenge the federal fiscal year (FY) 2004 outlier fixed-loss threshold rulemaking, this document provides further explanation of certain methodological choices made in the FY 2004 fixed-loss threshold determination. https://www.gpo.gov/fdsys/pkg/FR-2016-01-22/pdf/2016-01309.pdf	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency Program; Explanation of FY 2004 Outlier Fixed-Loss Threshold as Required by Court Rulings AGENCY: CMS	File Code	Issue Date; Due Date & File Date Date: Date of Subsequent Agency Action, if any:	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF NIHB ANALYSIS:	NIHB Recs.
25.ii.	Hospital Changes to Promote Innovation, etc. ACTION: Proposed Rule NOTICE: Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care AGENCY: CMS	CMS-3295-P	Issue Date: [Pending at OMB as of 1/4/2016] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would update the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. This proposed rule would change the requirements to meet current standards of practice, as well as support improvements in quality of care, reduce barriers to care, and reduce some issues that might exacerbate workforce shortage concerns. SUMMARY OF NIHB ANALYSIS:	
26.	Medicaid Home Health ACTION: Proposed Final Rule NOTICE: Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health AGENCY: CMS	CMS-2348- PF	Issue Date: 7/12/2011 Due Date: 9/12/2011 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule would revise the Medicaid home health service definition as required by section 6407 of ACA to add a requirement that physicians document the existence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible individual within reasonable timeframes. This proposal would align the timeframes with similar regulatory requirements for Medicare home health services in accordance with section 6407 of ACA and would reflect the commitment of CMS to the general principles of Executive Order 13563, released on 1/18/2011 and titled "Improving Regulation and Regulatory Review." In addition, this rule proposes to amend home health services regulations to clarify the definitions of included medical supplies, equipment, and appliances, as well as clarify that States cannot limit home health services to services delivered in the home, or to services furnished to individuals who are homebound.	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date Issued Final Rule 2/2/2016		SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule revises the Medicaid home health service definition consistent with section 6407 of ACA and section 504 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to add requirements that, for home health services, physicians document and, for certain medical equipment, physicians or certain authorized non-physician practitioners (NPP) document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes. This final rule also aligns the timeframes for the face-to-face encounter with similar regulatory requirements for Medicare home health services. In addition, this final rule amends the definitions of medical supplies, equipment, and appliances. CMS expects minimal impact with the implementation of section 6407 of ACA and section 504 of MACRA. CMS recognizes that states might have budgetary implications as a result of the amended definitions of medical supplies, equipment, and appliances. Specifically, this final rule might expand coverage of medical supplies, equipment, and appliances under the home health benefit. Under this final rule, items previously covered only under certain sections of the Social Security Act now will fall under the home health benefit.	
27.u.	Transitional Reinsurance Program Collections for 2015 ACTION: Guidance NOTICE: The Transitional Reinsurance Program's Contribution Collections for the 2015 Benefit Year AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/12/2015 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Section 1341 of ACA established a transitional reinsurance program to help stabilize premiums in the individual market inside and outside of the Marketplaces. The transitional reinsurance program collects contributions from health insurance issuers and certain self-insured group health plans (collectively, "contributing entities") at an annual per capita contribution rate to fund reinsurance payments to issuers of non-grandfathered reinsurance-eligible individual market plans, the administrative costs of operating the reinsurance program, and the general fund of the U.S. Treasury for the 2014, 2015, and 2016 benefit years. To meet the targets for the 2015 benefit year, HHS established an annual per capita contribution rate of \$44.00 in the HHS Notice of Benefit and Payment Parameters for 2015 Final Rule. Contributing entities had the option to pay the 2015 benefit year contribution: (1) in one payment remitted no later than 1/15/2016, reflecting \$44.00 per covered life; or (2) in two separate payments, with the first payment due by 1/15/2016, reflecting \$33.00 per covered life, and the second payment due by 1/15/2016, reflecting	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					\$11.00 per covered life. For the 2015 benefit year, HHS anticipates that it will have \$7.7 billion in reinsurance contributions for use as reinsurance payments. Based on submissions from contributing entities for the 2015 benefit year as of 2/3/2016, HHS estimates that it will collect a total of \$6.5 billion. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RIC_2015ContributionsGuidance.pdf SUMMARY OF NIHB ANALYSIS:	
29.d.	Minimum Value of Eligible Employer-Sponsored Plans ACTION: Proposed Final Rule NOTICE: Minimum Value of Eligible Employer-Sponsored Plans and Other Rules Regarding the Health Insurance Premium Tax Credit AGENCY: IRS	REG- 125398 12 REG- 143800 14 TD 9745	Issue Date: 5/3/2013 Due Date: 7/2/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued supplement to Proposed Rule 9/1/2015; issued Final Rule 12/18/2015; issued correction 1/15/2016		SUMMARY OF AGENCY ACTION: This document contains proposed regulations relating to the health insurance premium tax credit enacted by ACA, as amended by the Medicare and Medicaid Extenders Act of 2010, the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011, and the Department of Defense and Full-Year Continuing Appropriations Act, 2011. These proposed regulations affect individuals who enroll in qualified health plans through Affordable Insurance Exchanges (Exchanges) and claim the premium tax credit and Exchanges that make qualified health plans available to individuals and employers. These proposed regulations also provide guidance on determining whether health coverage under an eligible employer-sponsored plan provides minimum value and affect employers that offer health coverage and their employees. http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10463.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule includes a number of clarifying amendments to the premium tax credit in addition to the proposed regulations for determining acceptable minimum value for employer-sponsored coverage. No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: IRS on 9/1/2015 issued a document that withdraws, in part, a notice of proposed rulemaking published on 5/3/2013 relating to the health insurance premium tax credit enacted by ACA (including guidance on determining whether health coverage under an eligible employer-sponsored plan provides minimum value) and replaces the withdrawn portion with new proposed	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.	
	rigency		<u>Due Date:</u> 11/2/2015		regulations providing guidance on determining whether health coverage under an eligible employer-sponsored plan provides minimum value. These proposed regulations affect participants in eligible employer-sponsored health plans and employers that sponsor these plans. http://www.gpo.gov/fdsys/pkg/FR-2015-09-01/pdf/2015-21427.pdf This supplemental notice of proposed rulemaking reviews the IRS-imposed requirement to define "minimum value" of employer-sponsored coverage to include both (1) a requirement to cover at least 60 percent of the average costs of the covered services and (2) a requirement to include hospitalization and physician services, effective pursuant to the dates provided in the proposed rule. IRS on 12/18/2015 issued a document that contains final regulations on the health insurance premium tax credit enacted by ACA, as amended by the Medicare and Medicaid Extenders Act of 2010, the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011, and the Department of Defense and Full-Year Continuing Appropriations Act, 2011. These final regulations affect individuals who enroll in qualified health plans (OHPs) through Affordable Insurance Exchanges (Exchanges, or Marketplaces) and claim the health insurance premium tax credit and Exchanges that make QHPs available to individuals and employers. https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31866.pdf IRS on 1/15/2016 issued a document that contains corrections to final regulations (TD 9745) published in the 12/18/2015 FR (80 FR 78971). As published, the final regulations contain an error that might prove misleading and needs clarification. Accordingly, this document amends 26 CFR part 1.		
					https://www.gpo.gov/fdsys/pkg/FR-2016-01-15/pdf/2016-00701.pdf		
31.tt.	Summary of Benefits and Coverage and Uniform Glossary ACTION: Request for	DoL (OMB 1210-0147) See also 92.kk.	<u>Issue Date:</u> 2/27/2015 <u>Due Date:</u> 3/30/2015		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		

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency Comment NOTICE: Summary of Benefits and Coverage and Uniform Glossary Required Under the Affordable Care Act AGENCY: DoL		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2016 Due Date: 3/28/2016		working group comprised of stakeholders, to develop standards for use by a group health plan and a health insurance issuer in compiling and providing to applicants, enrollees, and policyholders and certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. The subject information collection relates to the provision of the following: A summary of benefits and coverage, which includes coverage examples; a uniform glossary of health coverage and medical terms; and notice of modifications. Group health plans and health insurance issuers must use the Summary of Benefits and Coverage template and instructions for completing the template, as authorized by the Departments, to satisfy the section 2715 disclosure requirements. ACA section 2715 authorizes this information collection. http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04094.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF NIHB ANALYSIS: SUMMARY OF OF SUBSEQUENT AGENCY ACTION: DoL on 2/26/2016 issued a revision of this PRA request. According to DoL, as required by section 2715, the Departments consulted NAIC to provide further input before finalizing revisions to the SBC template and associated documents. The Departments now plan to finalize the templates and glossary and seek OMB approval for the revised information collection, so that plans and issuers can begin using the revised forms for making the disclosures under PHS Act section 2715 and the implementing regulations. https://www.gpo.gov/fdsys/pkg/FR-2016-02-26/pdf/2016-04318.pdf	
31.ddd.	2017 Actuarial Value Calculator ACTION: Guidance NOTICE: Draft 2017 Actuarial Value Calculator AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 11/20/2015 Due Date: 12/7/2015 NIHB File Date: None Date of Subsequent		SUMMARY OF AGENCY ACTION: Under the Essential Health Benefits, Actuarial Value, and Accreditation final rule (EHB Final Rule) published in the 2/25/2013 FR (78 FR 12834), HHS requires use of an Actuarial Value (AV) Calculator by issuers of nongrandfathered health insurance plans offered in the individual and small group markets, both inside and outside of the Affordable Insurance Exchanges (or Marketplaces) for the purposes of determining levels of coverage. Section 1302(d)(2)(A) of ACA stipulates calculation of AV based on the provision of essential health benefits (EHB) to a standard population. The statute groups health plans into four tiers: bronze, with an AV of 60 percent; silver, with an AV of 70 percent; gold, with an AV of 80 percent; and platinum, with an AV of 90 percent. The EHB Final Rule allows a <i>de minimis</i> variation of +/- 2 percentage points of AV for each tier.	



	T = 1 = 1 = 1		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.
			Agency Action, if any: Issued Final Guidance 1/21/2016		The AV Calculator represents an empirical estimate of the AV calculated in a manner that provides a close approximation to the actual average spending by a wide range of consumers in a standard population. This document details the specific methodologies used in the AV calculation.	
					The first part of this document provides background that includes an overview of the regulation allowing HHS to make updates to the AV Calculator, as well as the updates incorporated into the draft 2017 AV Calculator. In the second part of this document, CCIIO provides a detailed description of the development of the standard population and the AV Calculator methodology. The first section details the data and methods used in constructing the continuance tables used to calculate AV in combination with the user inputs. The second section describes the AV Calculator interface and the calculation of actuarial value based on the interface and the continuance tables. The draft 2017 AV Calculator is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-2017-AV-Calculator-111615xlsm.xlsm .	
					CCIIO will accepting comments on the draft 2017 AV Calculator, as well as the draft 2017 AV Calculator User Guide and the draft 2017 AV Calculator Methodology, until 5 p.m. on 12/7/2015. Interested parties should submit comments to the CMS Actuarial Value email at actuarialvalue@cms.hhs.gov .	
					https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft- 2017-AVC-Methodology-111915.pdf	
					SUMMARY OF NIHB ANALYSIS:	
					SUMMARY OF SUBSEQUENT AGENCY ACTION: Under the Essential Health Benefits, Actuarial Value, and Accreditation final rule (EHB Final Rule) published in the February 25, 2013, Federal Register (78 FR 12834), HHS requires use of an Actuarial Value (AV) Calculator by issuers of non-grandfathered health insurance plans offered in the individual and small group markets, both inside and outside of the Affordable Insurance Exchanges (or Marketplaces) for the purposes of determining levels of coverage. Section 1302(d)(2)(A) of ACA stipulates calculation of AV based on the provision of essential health benefits (EHB) to a standard population. The statute groups health plans into four	
					tiers: bronze, with an AV of 60 percent; silver, with an AV of 70 percent; gold, with an AV of 80 percent; and platinum, with an AV of 90 percent. The EHB Final Rule allows a de	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					minimis variation of +/- 2 percentage points of AV for each tier. The AV Calculator represents an empirical estimate of the AV calculated in a manner that provides a close approximation to the actual average spending by a wide range of consumers in a standard population. This document details the specific methodologies used in the AV calculation. CCIIO has revised this document from the 2016 version to incorporate updates in the final 2017 version, released on January 21, 2016. The first part of this document provides background that includes an overview of the regulation allowing HHS to make updates to the AV Calculator, as well as the updates incorporated into the 2017 AV Calculator. For the second part of the document, CCIIO provides a detailed description of the development of the standard population and the AV Calculator methodology. The first section details the data and methods used in constructing the continuance tables used to calculate AV in combination with the user inputs. The second section describes the AV Calculator interface and the calculation of actuarial value based on the interface and the continuance tables. The final 2017 AV Calculator is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-AV-Calculator-2017.xlsm . CCIIO notes that the final 2017 AV Calculator does not affect any 2016 plans and will only apply for 2017 plans. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-AV-C-Methodology-012016.pdf	
39.f.	Basic Health Program: Federal Funding Methodology for 2017 ACTION: Proposed Final Methodology NOTICE: Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018	CMS-2396- PFN	Issue Date: 10/22/2015 Due Date: 11/23/2015 NIHB File Date: None Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: This document provides the methodology and data sources necessary to determine federal payment amounts made in program years 2017 and 2018 to states that elect to establish a Basic Health Program under ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Marketplaces. http://www.gpo.gov/fdsys/pkg/FR-2015-10-22/pdf/2015-26907.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: This document provides the methodology and data sources necessary to determine federal payment amounts made	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency AGENCY: CMS	File Code	Issue Date; Due Date & File Date Action, if any: Issued Final Methodology 2/29/2016	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis in program years 2017 and 2018 to states that elect to establish a Basic Health Program under ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges (Exchanges).	NIHB Recs.
					https://www.gpo.gov/fdsys/pkg/FR-2016-02-29/pdf/2016-03902.pdf	
41.f.	New Safe Harbors ACTION: Notice NOTICE: Solicitation of New Safe Harbors and Special Fraud Alerts AGENCY: HHS OIG	OIG-124-N	Issue Date: 12/23/2015 Due Date: 2/22/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In accordance with section 205 of HIPAA, this annual document solicits proposals and recommendations for developing new, and modifying existing, safe harbor provisions under the federal anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new HHS OIG Special Fraud Alerts. https://www.gpo.gov/fdsys/pkg/FR-2015-12-23/pdf/2015-32267.pdf SUMMARY OF NIHB ANALYSIS:	
43.	Medicaid Reimbursement for Outpatient Drugs ACTION: Proposed-Final Rule NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS	CMS-2345- ₽FC	Issue Date: 2/2/2012 Due Date: 4/2/2012 NIHB File Date: 4/2/2012 Date of Subsequent Agency Action, if any: Issued Final	NIHB response:	SUMMARY OF AGENCY ACTION: This proposed rule would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of ACA. This proposed rule also would revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program. http://www.gpo.gov/fdsys/pkg/FR-2012-02-02/pdf/2012-2014.pdf SUMMARY OF NIHB ANALYSIS: As the Proposed Rule notes, I/T/U pharmacies can purchase drugs through the Federal Supply Source (FSS) or the 340B programs. The Proposed Rule also notes that these I/T/U pharmacies are then reimbursed under Medicaid State Plans. In the Proposed Rule, CMS indicates that it considered alternative methodologies but chose instead to propose no specific methodologies for the I/T/U programs and instead "to invite public comment on Medicaid payment levels for these facilities." The Proposed Rule goes on to state, however, that CMS is proposing "that"	See Table C.



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date Rule 2/1/2016 Due Date: 4/1/2016		States that do not have specific methodologies develop such methodologies for these providers consistent with [CMS'] proposed shift from [estimated acquisition cost (EAC)] to [actual acquisition cost (AAC)]." In addition, the Proposed Rule would require States to submit a State Plan Amendment through the formal review process (including all consultation requirements) when submitting plans to change how dispensing is reimbursed. The Proposed Rule notes that States still would have to substantiate "how their dispensing fee reimbursement to pharmacy providers reasonably reflects the cost of dispensing a drug and will ensure access for these drugs to Medicaid beneficiaries." Most importantly, with regard to dispensing fees, the Proposed Rule would require that, "[w]here the professional dispensing fee might differ because of unique circumstances for 340B covered entities or IHS and tribal pharmacies, the State should look at these circumstances to determine if a different professional dispensing fee is warranted for these entities." SUMMARY OF SUBSEQUENT AGENCY ACTION: This final rule implements provisions of ACA pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). This final rule also revises other requirements related to CODs, including key aspects of their Medicaid coverage and payment and the Medicaid drug rebate program. CMS will accept comments on the following subject areas discussed in this final rule: the definition and identification of "line extension drug" at § 447.502. https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf A summary memo-covered Outpatien	
46.e.	Final FY 2013 and Preliminary FY 2015 DSH Allotments ACTION: Notice	CMS-2398-N	Issue Date: 2/2/2016 Due Date: None		SUMMARY OF AGENCY ACTION: This notice announces the final federal share disproportionate share hospital (DSH) allotments for federal FY 2013 and the preliminary federal share DSH allotments for FY 2015. This notice also announces the final FY 2013 and the preliminary FY 2015 limitations on aggregate DSH payments that states can make to institutions for mental disease and other mental health facilities. In addition, this	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Medicaid Program; Final FY 2013 and Preliminary FY 2015 Disproportionate Share Hospital Allotments, and Final FY 2013 and Preliminary FY 2015 Institutions for Mental Diseases Disproportionate Share Hospital Limits		NIHB File Date: Date of Subsequent Agency Action, if any:		notice includes background information describing the methodology for determining the amounts of state FY DSH allotments. https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01836.pdf SUMMARY OF NIHB ANALYSIS:	
48.b.	Medical Loss Ratio Rebate Calculation Report and Notices 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, 11/31/2014, 1/30/2015, 4/24/2015; issued extension 2/19/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Annual MLR and Rebate Calculation Report and MLR Rebate Notices; Use: Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, federal and state taxes and licensing and regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding federal and states taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/22/2013 issued a revision of this PRA request. The 60-day Federal Register notice published on 12/4/2012 (77 FR 71801), pertained to the 2012 MLR Annual Reporting Form and Instructions, and the comment period closed on 2/4/2013. CMS received a total of 4 public comments on 25 specific issues regarding the notice of the revised MLR PRA package. Most of the 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	



Ref. # Short Title/Current Status of Regulation/Title/ Agency File Code File Date & File Date Title Date Status Of Regulation Agency Action Agency Action File Date Status Date & File Date Date & File Date Date & File Date Date Status Date Date & File Date Date Date & File Date Date Date & File Date Date Date Date & File Date Date Date Date Date Date Date Dat	NIHB Recs.
Due Date: 3/25/2013: 1/21/2014: 3/5/2014: 3/5/2014: 3/5/2015: 5/5/2015: 5/5/2015: 5/5/2015: 5/5/2016: 6/19/2016 MILR 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 as one reflect changes for the 2012 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 anationwide 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 plans in burden. However, the requirement to report diag on student health plans on a nationwide basis, smillar to expatriate plans in burden. However, the requirement to report diag on student health plans on a nationwide basis, smillar to expatriate plans in burden. However, the requirement to report diag on student health plans will increase burden for some issuers. CMS estimates a net reduction in total information collection burden. http://www.gpa.gov/fidsys/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) portained to the 2013 MLR Annual Reporting form and Instructions, with comments closing on 12/12/014. 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 carifying 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 CMs has considered all of the proposed suggestions and has revisions and has revisions, reaches, and rebate notices. In addition, CMS has updated its annual burden hour estimates to reflect the additional burde	



Ref.	Short Title/Current Status of Regulation/Title/ 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 2014 MLR Reporting Form and instructions reflect changes for the 2014 reporting year and beyond set forth in the March 2013 update to 45 CFR part 158 regarding the MLR reporting and rebate distribution deadlines and the accounting for the transitional reinsurance, risk adjustment, and risk corridors. CMS also has revised the 2014 MLR Reporting Form and instructions to include the reporting elements required under the risk corridors data submission requirements in 45 CFR 153.530. In 2015, issuers likely will send fewer notices and rebate checks to policyholders and subscribers, reducing burden for QHP issuers. However, the requirement to report the risk corridors data will increase burden for QHP issuers. CMS estimates a net reduction in total burden from 294,911 to 271,600. http://www.gpo.gov/fdsys/pkg/FR-2015-01-30/pdf/2015-01790.pdf CMS on 4/24/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-04-24/pdf/2015-09591.pdf No comments recommended. CMS on 2/19/2016 issued an extension of this PRA request. According to CMS, the 2015 MLR Reporting Form and instructions reflect changes for the 2015 reporting/benefit year and beyond. In 2016, issuers likely will submit fewer reports and send fewer notices to policyholders and subscribers, reducing burden on issuers. Conversely, issuers likely will send more rebate checks in the mail to individual market policyholders, increasing burden for some issuers. CMS estimates a net reduction in total burden from 271,600 to 235,148. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03474.pdf No comments recommended.	
49.a.	Reporting and Returns of Medicare Overpayments ACTION: Proposed Final Rule NOTICE: Medicare	CMS-6037- PF	<u>Issue Date:</u> 2/16/2012 <u>Due Date:</u> 4/16/2012 <u>NIHB File</u>		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:	



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

Ref.	Short Title/Current Status of Regulation/Title/Agency Program; Reporting and Returning of Overpayments AGENCY: CMS	File Code	Issue Date; Due Date & File Date Date: None Date of Subsequent Agency Action, if any: Issued extension notice 2/17/2015; issued Final Rule 2/12/2016	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/17/2015 issued a document (CMS-6037-RCN) to announce the extension of the timeline for publication of the "Medicare Program; Reporting and Returning of Overpayments" final rule. CMS has issued this notice in accordance with the Social Security Act (the Act), which requires provision of notice in the FR if exceptional circumstances cause the agency to publish a final rule more than 3 years after the publication date of the proposed rule. In this case, the complexity of the rule and scope of comments warrants the extension of the timeline for publication. http://www.gpo.gov/fdsys/pkg/FR-2015-02-17/pdf/2015-03072.pdf CMS on 2/2/2016 issued a final rule that requires providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date 60 days after the date on which identification of the overpayment occurred or the due date of any corresponding cost report, if applicable. The requirements in this rule seek to ensure compliance with applicable statutes, promote the furnishing of high quality care, and protect the Medicare Trust Funds against fraud and improper payments. This final rule provides needed clarity and consistency in the reporting and returning of self-identified overpayments. https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02789.pdf A Modern Healthcare article on this final rule is available at	NIHB Recs.
					A Modern Healthcare article on this final rule is available at http://www.modernhealthcare.com/article/20160211/NEWS/160219982?utm . A summary of this final rule is embedded below. Repayment of Overpayments - CMS	
50.f.	Eligibility and Enrollment for Employees in SHOP ACTION: Request for Comment NOTICE: Data Collection to	CMS-10438 See also 50.m.	<u>Issue Date:</u> 1/29/2012 <u>Due Date:</u> 2/28/2013 <u>NIHB File</u>		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Data Collection to Support Eligibility Determinations and Enrollment for Employees in the Small Business Health Options Program; <i>Use</i> : Section 1311(b)(1)(B) of ACA requires that the Small Business health Option Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health programs (QHPs) offered in the small group market. Section 1311(c)(1)(F) of ACA requires HHS to establish criteria for certification of health plans as QHPs and that these	See Table C.



Ref. # Short Title/Current Status of Regulation/Title/ Agency File Code	NIMB Recs.
Support Eligibility Determinations and Enrollment for Employees in SHOP AGENCY: CMS AGENCY: AGENCY AGENCY: AGENCY AGENCY: AGENCY AGENCY: AGENCY AGENCY: AGENCY AGENCY: AGENCY AGENC	o a model application of qualify to participate in oyees will use apply to 810) provides more detail apployee eligibility. cation, with subsequent of or updating information and initial open enrollment ellection of applications ements of § 155.725 of somit an application for call center operated by or, per § 155.730(f) of the elderstanding of the olication. The employer's 2061), CMS received ers raised concerns to the employee ed document submission CMS has considered all ection of information, availability of other ating whether 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.
					SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/11/2015 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-11/pdf/2015-31302.pdf	
					No comments recommended.	
50.g.	Eligibility and Enrollment for Small Businesses in SHOP ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in SHOP AGENCY: CMS	CMS-10439 See also 50.m.	Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: Issued revision 12/11/2015 Due Date: 2/9/2016		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection: <i>Title</i> : Data Collection to Support Eligibility Determinations and Enrollment for Small Businesses in the Small Business Health Options Program; <i>Use</i> : Section 1311(b)(1)(B) of ACA requires that the Small Business health Option Program (SHOP) assist qualified small employers in facilitating the enrollment of their employees in qualified health programs (QHPs) offered in the small group market. Section 1311(c)(1)(F) of ACA mandates that HHS establish criteria for certification of health plans as QHPs and that these criteria require plans to utilize a uniform enrollment form for qualified employers. Further, section 1311(c)(5)(B) requires HHS to develop a model application and web site that assists employers in determining whether they qualify to participate in SHOP. HHS has developed a single, streamlined form that employers will use apply to SHOP. Section 155.730 of the Exchanges Final Rule provides more detail about this "single employer application," which will determine employer eligibility. Employers will have to provide the information upon initial application, with subsequent information collections for the purposes of confirming accuracy of or updating information from previous submissions. Information collection will begin during initial open enrollment in October 2013, per § 155.410 of the Exchanges Final Rule. Collection of applications for SHOP will occur year round, per the rolling enrollment requirements of § 155.725 of the Exchanges Final Rule. Employers will have the ability to submit an applications for SHOP online, via a paper application, over the phone through a call center operated by an Exchange, or in person through an agent, broker, or Navigator, per § 155.730(f) of the Exchanges Final Rule. Applicants also will have to verify their understanding of the application and sign attestations regarding information in the application. The employer's state will receive completed applications.	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.			
					streamline and reduce duplication, especially in future years. CMS has considered all of the proposed suggestions and has made changes to this collection of information, such as adding a privacy statement, including information on "doing business as" and information on employer type, and making electronic notices the default option. CMS also has removed some information related to the employer choice of plan offerings and contribution because it is not necessary for an eligibility determination. http://www.gpo.gov/fdsys/pkg/FR-2013-01-29/pdf/2013-01770.pdf CMS-10439 is available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10439.html. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/11/2015 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-11/pdf/2015-31302.pdf No comments recommended.				
					No confinence reconfinenced.				
50.h.	Eligibility for Insurance Affordability Programs and Enrollment ACTION: Request for Comment NOTICE: Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment Through Affordable Insurance Exchanges, Medicaid and CHIP Agencies	CMS-10440	Issue Date: 1/29/2012 Due Date: 2/28/2013 NIHB File Date: 2/28/2013 Date of Subsequent Agency Action, if any: 4/30/2013;		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Affordable Insurance Exchanges, Medicaid and Children's Health Insurance Program Agencies; <i>Use</i> : Section 1413 of ACA directs the Secretary of HHS to develop and provide to each State a single, streamlined form for applying for coverage through the Exchange and Insurance Affordability Programs, including Medicaid, CHIP, and the Basic Health Program, as applicable. The application must maximize the ability of applicants to complete the form satisfactorily, taking into account the characteristics of individuals who qualify for the programs. A State may develop and use its own single streamlined application if approved by the Secretary, in accordance with section 1413, and if it meets the standards established by the Secretary. Section 155.405(a) of the Exchange Final Rule (77 FR 18310) provides more detail about the application that the Exchange must use to determine eligibility and to collect	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.
#				Response	information necessary for enrollment. The regulations in § 435.907 and § 457.330 establish the requirements for State Medicaid and CHIP agencies related to the use of the single, streamlined application. CMS has designed the single, streamlined application as a dynamic online application that will tailor the amount of data required from applicants based on their circumstances and responses to particular questions. CMS has designed a paper version of the application to collect only the data required to determine eligibility. Individuals will have the ability to submit an application online, through the mail, over the phone through a call center, or in person, per § 155.405(c)(2) of the Exchange Final Rule, as well as through other commonly available electronic means as noted in § 435.907(a) and § 457.330 of the Medicaid Final Rule. Individuals can submit the application to an Exchange, Medicaid, or CHIP agency. In response to the notice published in the July 6, 2012, FR (77 FR 40061), CMS received approximately 65 public comments. In response, CMS has made significant changes to the application materials, such as moving from categories of data elements to completed draft applications, among others. http://www.gpo.gov/fdsys/pkg/FR-2013-01-29/pdf/2013-01770.pdf CMS-10440 is available at http://www.gpo.gov/fdsys/pkg/FR-2013-01-29/pdf/2013-01770.pdf CMS-10440 html. Video demonstrations of the online application are available at http://www.youtube.com/user/CMSHHSgov/ . SUMMARY OF NIHB ANALYSIS: CMS-10440 contains two Exchange-related paper applications. One of the paper applications is for persons applying for financial	
					applications. One of the paper applications is for persons applying for financial assistance (FA). The other paper application is for persons who do not want to apply for financial assistance (non-FA) / do not want to provide information on their finances. There is also a comprehensive list of all questions asked through the online and paper applications. The primary Al/AN-related questions are in Step 4 (page 17) of the FA application and Step 3 (page 5) of the non-FA application.	
					On pages 38 and 41 of the comprehensive list of questions ("508_CMS-10440_Appendix_A_ Individual_Questionnaire"), there are questions pertaining to the identification of persons eligible for Indian-specific benefits. On page 19, there is a question on documenting citizenship status, with the identification of "Document"	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis indicating member of a federally-recognized Indian tribe" as one of the options. On page 22, there is a question on race. On page 24, there is question (Q. 6) on who is AI/AN. On page 31, there are questions on Indian-specific income to be excluded from income calculations for Medicaid and CHIP. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/2/2015 issued an extension of this PRA request.	NIHB Recs.
					http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf No comments recommended.	
50.aa.	SHOP Effective Date and Termination Notice Requirements ACTION: Request for Comment NOTICE: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements AGENCY: CMS	CMS-10555	Issue Date: 3/9/2015 Due Date: 5/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/14/2015 Due Date: 1/13/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements; Use: CMS requires that, for plan years beginning on or after 1/1/2017, the Small Business Health Options Program (SHOP) must ensure that a qualified health plan (QHP) issuer notifies qualified employees, enrollees, and new enrollees in a QHP through the SHOP of the effective date of coverage. As required by the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameter for 2016 (CMS-9944-F), published on 2/27/2015, if any enrollee has his or her coverage terminated through the SHOP due to non-payment of premiums or a loss of eligibility to participate in the SHOP, the SHOP must notify the enrollee or the qualified employer of the termination of such coverage. In the termination of coverage, the SHOP must include the termination date and reason for termination to the enrollee or qualified employer. http://www.gpo.gov/fdsys/pkg/FR-2015-03-09/pdf/2015-05420.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/14/2015 issued a new version of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-14/pdf/2015-31398.pdf No comments recommended.	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
51.c.	Application of Market Reforms to Student Health Coverage ACTION: Guidance NOTICE: Insurance Standards Bulletin Series INFORMATION: Application of the Market Reforms and Other Provisions of the Affordable Care Act to Student Health Coverage AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 2/5/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This Bulletin provides guidance on the application of certain provisions of the ACA to premium reduction arrangements offered in connection with student health plans and provides temporary transition relief from enforcement by HHS and the Department of Labor (DoL) of the Department of the Treasury (Treasury) (collectively, the Departments) in certain circumstances. On 9/13/2013, DoL published Technical Release 2013-03, addressing the application of the market reforms to health reimbursement arrangements and employer payment plans under the ACA. Treasury and IRS contemporaneously published parallel guidance in Notice 2013-54, and HHS issued guidance stating that it concurs in the application of the laws under its jurisdiction as set forth in the guidance issued by DoL and Treasury and IRS. Subsequent guidance reiterated and clarified the application of the market reforms to employer payment plans. This Bulletin provides a transition period for the application of certain market reforms to certain arrangements offered by an institution of higher education to its students designed to reduce the cost of student health coverage (whether insured or self-insured) through a credit, offset, reimbursement, stipend, or similar arrangement (a premium reduction arrangement). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/student-health-bulletin.pdf	
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	CMS-6046-N CMS-6047-N CMS-6059- N2 CMS-6059- N3 CMS-6059- N4	Issue Date: 2/4/2014 Due Date: None NIHB File Date: Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: This document announces the imposition of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies in designated geographic locations to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2014-02-04/pdf/2014-02166.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 8/1/2014 issued a document (CMS-6047-N) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies (HHAs) in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas,	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Designated Geographic Locations AGENCY: CMS		Action, if any: Issued extension notice 8/1/2014, 2/2/2015, 7/27/2016		Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2014-08-01/pdf/2014-18174.pdf CMS on 2/2/2015 issued a document (CMS-6059-N2) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies (HHAs) in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2015-02-02/pdf/2015-01696.pdf CMS on 7/27/2015 issued a document (CMS-6059-N3) to announce the extension of temporary moratoria on the enrollment of new ambulance suppliers and home health agencies, subunits, and branch locations in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. http://www.gpo.gov/fdsys/pkg/FR-2015-07-28/pdf/2015-18327.pdf CMS on 2/2/2016 issued a document (CMS-6059-N4) to announce the extension of temporary moratoria on the enrollment of new Medicare Part B ground ambulance suppliers and Medicare home health agencies, subunits, and branch locations in specific locations within designated metropolitan areas in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to prevent and combat fraud, waste, and abuse. These moratoria also apply to the enrollment of home health agencies and ground ambulance suppliers in Medicaid and CHIP. https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01835.pdf	
52.q.	Home Health Face-to-Face Encounter Clinical Templates ACTION: Request for Comment NOTICE: Home Health Face-to-Face Encounter Clinical Templates	CMS-10564	Issue Date: 8/12/2015 Due Date: 10/13/2015 NIHB File Date: None Date of		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Home Health Face-to-Face Encounter Clinical Templates; Use: CMS requires this collection of data to support the eligibility of Medicare home health services. Home health services are covered under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services consist of part-time, medically necessary skilled care (nursing, physical therapy, occupational therapy, and speech-language therapy) ordered by a physician. CMS has developed a list of clinical elements within a suggested electronic clinical template that would allow electronic health record vendors to create prompts to assist physicians when documenting the home health face-to-face encounter for Medicare purposes. Once	



	Chart Title/Commant Ct-to-		Janua 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: CMS		Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016		completed by the physician, the resulting progress note or clinic note would become part of the medical record. The primary users of these new clinical templates will include physicians and/or allowed non-physician practitioners (NPPs). The templates will help users to capture the necessary information needed to complete the face-to-face encounter documentation. This will help physicians and/or allowed NPPs comply with Medicare policy requirements, thereby reducing the possibility of non-payment of a home health claim because of failure to meet Medicare requirements. http://www.gpo.gov/fdsys/pkg/FR-2015-08-12/pdf/2015-19818.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/28/2015 issued an extension of this PRA request. CMS has revised this information collection request with non-substantive changes since the publication of the 60-day notice in the 8/12/2015 FR (80 FR 48320). https://www.gpo.gov/fdsys/pkg/FR-2015-12-28/pdf/2015-32435.pdf No comments recommended.	
52.r.	Prior Authorization of Home Health Services Demonstration ACTION: Request for Comment NOTICE: Medicare Prior Authorization of Home Health Services Demonstration AGENCY: CMS	CMS-10599	Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Medicare Prior Authorization of Home Health Services Demonstration; <i>Use</i> : Section 402(a)(1)(J) of the Social Security Amendments of 1967 authorizes the HHS Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." In accordance with this authority, CMS seeks to develop and implement a Medicare demonstration project to help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among home health agencies (HHAs) providing services to Medicare beneficiaries. This demonstration will help assure that payments for home health services are appropriate before payment of claims, thereby preventing fraud, waste, and abuse. As part of this demonstration, CMS proposes performing prior authorization before processing claims for home health services in: Florida, Texas, Illinois, Michigan, and Massachusetts. CMS will establish a prior authorization procedure similar to the Prior	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Authorization of Power Mobility Device (PMD) Demonstration, implemented by CMS the agency in 2012. This demonstration also will follow and adopt prior authorization processes that currently exist in other health care programs, such as TRICARE, certain state Medicaid programs, and in private insurance. The information required under this collection is requested by Medicare contractors to determine proper payment or suspicion of fraud. Medicare contractors will request the information from HHA providers submitting claims for payment from the Medicare program in advance to determine appropriate payment. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02277.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
52.s.	Evaluation of the Medicare Patient IVIG Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration AGENCY: CMS	CMS-10600 See also 52.k.	Issue Date: 2/10/2016 Due Date: 4/11/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration; <i>Use</i> : Primary Immune Deficiency Diseases (PIDDs) result from genetic defects that cause a lack of and/or impaired antibody function. Without antibodies, the immune system cannot function effectively. Immunoglobulin (IG) therapy temporarily replaces some of the missing or improperly working antibodies (immunoglobulins) in individuals with PIDD. By special statutory provision, Medicare Part B covers intravenous immunoglobulin (IVIG) for individuals with PIDD who wish to receive the drug in-home, but does not allow for Medicare to cover any of the items and services needed to administer the drug unless the individual is homebound or otherwise receiving services under a Medicare home health episode of care. Therefore, most beneficiaries with PIDD receive treatment at hospital outpatient departments, physician offices, and other outpatient settings. A current alternative to IVIG is subcutaneous immunoglobulin (SCIG), a product that permits some beneficiaries to self-administer the immunoglobulin safely at home without an attending healthcare professional. SCIG at home is reimbursed by Medicare, with limitations. Under the Medicare Patient IVIG Access Demonstration project, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option most	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis appropriate for the beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (e.g., drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration. https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02686.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	NIHB Recs.
54.	ESI Coverage Verification ACTION: Notice NOTICE: Employer- Sponsored Coverage Verification: Preliminary Informational Statement AGENCY: CMS	CMS RIN 0938- ZB09	Issue Date: [Approved by OMB 4/26/2012 but not yet published] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS:	
60.1.	Expanding Uses of Medicare Data by Qualified Entities ACTION: Proposed Rule NOTICE: Medicare Program; Expanding Uses of Medicare Data by Qualified Entities	CMS-5061-P	Issue Date: 2/2/2016 Due Date: 3/29/2016 NIHB File Date: Date of		SUMMARY OF AGENCY ACTION: This proposed rule would implement new statutory requirements that would expand how qualified entities can use and disclose data under the qualified entity program to the extent consistent with applicable program requirements and other applicable laws, including information, privacy, security, and disclosure laws. In doing so, this proposed rule would explain how qualified entities can create non-public analyses and provide or sell such analyses to authorized users, as well as how qualified entities can provide or sell combined data, or provide Medicare claims data alone at no cost, to certain authorized users. This proposed rule also would implement certain privacy and security requirements and impose assessments on qualified entities if the qualified entity or the authorized user violates the terms of a data	



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	AGENCY: CMS		Subsequent Agency Action, if any:		use agreement (DUA) required by the qualified entity program. https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01790.pdf Background Section 10332 of ACA established the Qualified Entity program, requiring the program to make available standardized extracts of Medicare claims data under parts A, B, and D to "qualified entities" for the evaluation of the performance of providers and suppliers. Qualified entities can use the information for the purpose of evaluating the performance of providers and suppliers, as well as to generate public reports regarding such performance. To become a qualified entity, an organization must submit an application that includes, among other things, a description of the methodologies that the applicant proposes to use to evaluate the performance of providers and suppliers in the geographic area(s) selected. A list of the 13 existing qualified entities is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/OEMedicareData/index.html?redirect=/OEMedicareData. Impact on Medicaid According to CMCS, this proposed rule has relevance to Medicaid in two areas: • State Medicaid Agencies as Qualifies Entities: This proposed rule includes a policy to include state Medicaid agencies under the definition of a qualified entity, a change that would allow state Medicaid agencies to access Medicare data from CMS for research purposes (CMCS encourages states to submit comments as to whether or not they agree with this policy). • Access to Medicaid/CHIP Data: This proposed rule also includes a policy under which qualified entities (possibly including states) could not access Medicaid/CHIP data via CMS and would have to turn directly to state agencies for this data (CMCS encourages states to submit comments as to whether or not they agree with this policy). SUMMARY OF NIHB ANALYSIS:	
60.m.	Reapplication Submission for Qualified Entities	CMS-10596	<u>Issue Date</u> : 2/5/2016		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : New collection; <i>Title</i> : Reapplication Submission Requirement for Qualified Entities Under ACA Section 10332; <i>Use</i> : Section 10332 of ACA requires the HHS Secretary to make	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Request for Comment NOTICE: Reapplication Submission Requirement for Qualified Entities Under ACA Section 10332 AGENCY: CMS		Due Date: 4/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		standardized extracts of Medicare claims data under Parts A, B, and D available to "qualified entities" for the evaluation of the performance of providers of services and suppliers. The statute provides the HHS Secretary with discretion to establish criteria to determine whether an entity qualifies to use claims data to evaluate the performance of providers of services and suppliers. After consideration of comments from a wide variety of stakeholders during the public comment period, CMS established "Medicare Program; Availability of Medicare Data for Performance Measurement" (Final Rule). To implement the requirements outlined in the legislation, the CMS established the Qualified Entity Certification Program (QECP). The Final Rule requires qualified entities to reapply for certification six months prior to the end of their 3-year certification period to remain in good standing. This form serves as the official reapplication that qualified entities must complete to reapply to QECP. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02278.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
67.a.	State Consumer Assistance Grants ACTION: Request for Comment NOTICE: Consumer Assistance Program Grants AGENCY: CMS	CMS-10333	Issue Date: 7/27/2012 Due Date: 9/25/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/7/2012; issued extension 11/2/2015, 1/20/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Consumer Assistance Program Grants; Use: Section 1002 of ACA provides for the establishment of consumer assistance (or ombudsman) programs (CAPs), starting in FY 2010. Federal grants will support CAPs, which will assist consumers with filing complaints and appeals; assist consumers with enrollment into health coverage, collect data on consumer inquiries and complaints to identify problems in the marketplace; educate consumers on their rights and responsibilities; and with the establishment of the new Exchange marketplaces, resolve problems with premium credits for Exchange coverage. ACA requires CAPs to report data to the HHS Secretary "on the types of problems and inquiries encountered by consumers" (section 2793 (d)). Analysis of this data reporting will help identify patterns of practice in the insurance marketplaces and uncover suspected patterns of noncompliance. HHS must share program data reports with the Departments of Labor and Treasury and state regulators. Program data also can offer CMS one indication of the effectiveness of state enforcement, affording opportunities to provide technical assistance and support to state insurance regulators and, in extreme cases, inform the need to trigger federal enforcement.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			<u>Due Date:</u> 2/7/2013; 1/4/2016; 2/19/2016		http://www.healthcare.gov/news/factsheets/2010/10/capgrants_states.html. Awards are made to States, and to qualify to receive a grant, a State must designate an independent office of health insurance consumer assistance, or an ombudsman, that, directly or in coordination with State health insurance regulators and consumer assistance organizations to collect and report data to the HHS Secretary on the types of problems and inquiries encountered by consumers. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/7/2012 issued a revision of this PRA request. CMS received 21 comments in response to the 60-day notice on this information collection published in the 7/27/2012 FR. The majority of these comments, which CMS has addressed in this notice, involved feedback on providing CAPs with more flexibility in collecting and reporting data. http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29626.pdf CMS on 11/2/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-11-02/pdf/2015-27859.pdf CMS on 1/20/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-20/pdf/2016-00994.pdf No comments recommended.	
70.f.	Part B Drug Model ACTION: Proposed Rule NOTICE: Part B Drug Model AGENCY: CMS	CMS-1670-P	Issue Date: [Pending at OMB as of 2/25/2016] Due Date: NIHB File Date:		SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS:	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			Date of Subsequent Agency Action, if any:			
71.n.	Medicare ESRD PPS and Quality Incentive Program ACTION: Proposed Final Rule NOTICE: Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program AGENCY: CMS	CMS-1628- PF	Issue Date: 7/1/2015 Due Date: 8/25/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued correction 9/2/2015; issued Final Rule 11/6/2015; issued correction 12/31/2015		SUMMARY OF AGENCY ACTION: This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2016. The proposals in this rule would ensure that ESRD facilities receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during CY 2016. This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP) for CY 2016. In an effort to incentivize ongoing quality improvement among eligible providers, the ESRD QIP proposes to establish and revise requirements for quality reporting and measurement, including the inclusion of new quality measures for payment year (PY) 2019 and beyond and updates to programmatic policies for the PY 2017 and PY 2018 ESRD QIP. http://www.gpo.gov/fdsys/pkg/FR-2015-07-01/pdf/2015-16074.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule would implement an incentive payment adjustment for ESRD services. SUMMARY OF AGENCY ACTION: CMS on 9/2/2015 issued a document (CMS-1628-CN) to correct a technical error that appeared in the proposed rule titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program" and published in the 7/1/2015 FR (80 FR 37808). This document makes the following correction: on page 37814, second column, second full paragraph, in line 16, the reference to "13A" is corrected to read "11A". http://www.gpo.gov/fdsys/pkg/FR-2015-09-02/pdf/2015-21783.pdf CMS on 11/6/2015 issued a final rule that updates and makes revisions to the end-stage renal disease (ESRD) prospective payment system (PPS) for CY 2016. This final rule will ensure that ESRD facilities receive accurate Medicare payment amounts for furnishing outpatient maintenance dialysis treatments during CY 2016. This final rule also will set forth requirements for the ESRD Quality Incentive Program (QIP), including for PYs 2017 through 2019.	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					http://www.gpo.gov/fdsys/pkg/FR-2015-11-06/pdf/2015-27928.pdf CMS on 12/31/2015 issued a document (CMS-1628-CN2) to correct technical and typographical errors that appeared in the final rule published in the 11/6/2015 FR and titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program." https://www.gpo.gov/fdsys/pkg/FR-2015-12-31/pdf/2015-32967.pdf	
71.0.	ESRD Application and Survey and Certification Report ACTION: Request for Comment NOTICE: End Stage Renal Disease Application and Survey and Certification Report AGENCY: CMS	CMS-3427	Issue Date: 11/16/2015 Due Date: 1/15/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: End Stage Renal Disease Application and Survey and Certification Report; Use: Part I of this form serves as a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. The Medicare/Medicaid State survey agency completes Part II of this form to determine facility compliance with ESRD conditions for coverage. http://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-29160.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
79.	Fiscal Soundness Reporting Requirements ACTION: Request for Comment NOTICE: Fiscal Soundness Reporting Requirements AGENCY: CMS	CMS-906	Issue Date: 9/4/2012 Due Date: 11/5/2012 NIHB File Date: None Date of Subsequent		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Fiscal Soundness Reporting Requirements; <i>Use</i> : CMS has responsibility for overseeing the ongoing financial performance for all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors, and Program of All-Inclusive Care for the Elderly (PACE) organizations. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. The revised fiscal soundness reporting form combines MAO, PDP, 1876 Cost Plans, Demonstration Plans, and PACE organizations. Entities contracting in these programs currently submit all documentation requested. Specifically, all contracting organizations must submit annual independently audited financial statements one time per year. The MAOs with a net loss, a negative net	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	rigonoj		Agency Action, if any: Issued revision 12/21/2012; issued extension 10/2/2015; 11/9/2016 Due Date: 1/22/2013; 12/1/2015; 12/9/2016 Algency Action, if any: Issued revision 10/2/2015; 11/9/2016		worth, or both must file three quarterly statements. Currently, approximately 44 MAOs file quarterly financial statements. The PDPs also must file three unaudited quarterly financial statements. The PACE organizations must file 3 quarterly financial statements for the first three years in the program. Additionally, PACE organizations with a net loss, a negative net worth, or both must file statements. The revised information request includes one additional data element for PACE organizations, Total Subordinated Liabilities. http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/21/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30749.pdf CMS on 10/2/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-25108.pdf CMS on 11/9/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-10-02/pdf/2015-25108.pdf No comments recommended. CMS on 2/5/2016 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02278.pdf No comments recommended.	
80.b.	Advanced Beneficiary Notice of Noncoverage ACTION: Request for Comment	CMS-R-131	Issue Date: 12/12/2012 Due Date: 2/11/2013		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Advance Beneficiary Notice of Noncoverage (ABN); Use: Certain Medicare providers and suppliers use the Advanced Beneficiary Notice of Noncoverage (ABN) (CMS-R-131) to inform fee-for-service (FFS) beneficiaries of potential liability for certain items/services billed to the program. Under section 1879 of the Social Security Act, Medicare beneficiaries can have financially responsibility for	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	NOTICE: Advance Beneficiary Notice of Noncoverage AGENCY: CMS		NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 2/26/2013; issued extension 11/9/2015 Due Date: 3/28/2013; 1/8/2016		items or services usually covered under the program, but denied in an individual case under specific statutory exclusions, if beneficiaries are informed that Medicare likely will deny payment prior to furnishing the items or services. When required, Part B paid physicians, providers (including institutional providers, such as outpatient hospitals), practitioners (such as chiropractors), and suppliers, as well as hospice providers and Religious Non-Medical Health Care Institutions paid under Part A, deliver ABN. The revised ABN in this information collection request incorporates expanded use by Home Health Agencies (HHAs), with no substantive changes to the form or changes that will affect existing ABN users. http://www.gpo.gov/fdsys/pkg/FR-2012-12-12/pdf/2012-29951.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/26/2013 issued a revision of this PRA request. The revised ABN in this information collection request incorporates expanded use by HHAs, with no substantive changes to the form and no changes that will affect existing ABN users. http://www.gpo.gov/fdsys/pkg/FR-2013-02-26/pdf/2013-04313.pdf CMS on 11/9/2015 issued an extension of this PRA request. With this PRA submission, CMS has made minimal formatting changes to the ABN form, including the addition of language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (section 504) by alerting the beneficiary to CMS nondiscrimination practices and the availability of alternate forms of this notice, if needed. Additionally, CMS has made minor language and grammatical changes to the instructions to improve provider/supplier comprehension and decrease the probability of errors in completing the ABN. CMS has made no substantive changes to the form or to the instructions. http://www.gpo.gov/fdsys/pkg/FR-2015-11-09/pdf/2015-28449.pdf No comments recommended.	
82.j.	Complaint Forms for Health Information Privacy Issues	HHS-OS- 0945-0002- 60D	<u>Issue Date</u> : 10/20/2015		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Complaint Forms for Discrimination; Health Information Privacy Complaints; Use: Individuals can file written complaints with the HHS	



	T					
Ref.	Short Title/Current Status of Regulation/Title/ 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: Complaint Forms for Discrimination; Health Information Privacy Complaints AGENCY: HHS OCR	HHS-OS- 0945-0002- 30D	Due Date: 12/21/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/28/2015 Due Date: 1/27/2016		Office for Civil Rights (OCR) when they believe programs or entities that receive federal financial assistance from HHS have discriminated against them or violated their right to the privacy of protected health information. http://www.gpo.gov/fdsys/pkg/FR-2015-10-20/pdf/2015-26604.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/28/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-28/pdf/2015-32551.pdf No comments recommended.	
83.a.	Medicaid/Transformed-Medicaid Statistical Information System ACTION: Request for Comment NOTICE: Medicaid Statistical Information System (MSIS) and Transformed-Medicaid Statistical Information System (T-MSIS) AGENCY: CMS	CMS-R-284	Issue Date: 8/15/2012 Due Date: 10/15/2012 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 10/19/2012; issued revision 12/3/2012, 12/31/2015		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of a currently approved collection; Title: Medicaid Statistical Information System (MSIS); Use: States and other jurisdictions use MSIS to report fundamental statistical data on the operation of their Medicaid program. The data provides the only national-level information available on enrollees, beneficiaries, and expenditures. It also provides the only national-level information available on Medicaid utilization. This information serves as the basis for analyses and for cost savings estimates for HHS cost-sharing legislative initiatives to Congress. The data also plays a crucial role in CMS and HHS actuarial forecasts. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/31/2015 issued a revision of this PRA request. CMS has added the Transformed-Medicaid Statistical Information System (T-MSIS) to this information collection. https://www.gpo.gov/fdsys/pkg/FR-2015-12-31/pdf/2015-32880.pdf T-MSIS has the capacity to capture the status of an individual as an IHS beneficiary,	



Ref.	Short Title/Current Status of Regulation/Title/ 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		Due Date: 11/19/2012; 1/2/2013; 2/29/2016		which is important for purposes of ensuring that Al/ANs receive cost-sharing and other Indian-specific protections. Tribal organizations might want to submit comments on this issue. Analysis From Joan O'Connell: This is what I know about T-MSIS and the December notice in the Federal Register. First, we have been asking Kitty/Jim for information on Al/AN Medicaid enrollees and I/T/U providers from T-MSIS for months. I feel it is extremely important to obtain data to see if the new variables are being used correctly. Jim Lyon told us that he is trying to reach out to CMS' Jeff Silverman for information. We asked Jim if Jeff could participate in the January TTAG Data Subcommittee call or Data Subcommittee meeting in February, or if we could schedule a call with Jeff. We have had no word yet on that. In addition, I contacted by phone and by email CMS' Camiel Rowe, who is listed on the T-MSIS December notice in the Federal Register. She told me she would try to obtain information for me on the "changes in collection of information," other than changing state reporting data to CMS monthly with T-MSIS instead of quarterly, and on Al/AN and I/T/Us in T-MSIS by this past Tuesday. I followed up with her again since I have had no word back yet I think lack of our having T-MSIS data is an important issue to raise in a response to the notice in the Federal Register-even though the types of T-MSIS measures in not directly addressed in the notice is to report hours to be spent on the proposed change for states to report data more frequently to CMS, I think a response to this notice could: Support state Medicaid programs' monthly submissions of data to CMS in order to have timely data on Medicaid enrollees and providers; Describe Al/AN disparities and key Medicaid Al/AN and I/T provider provision; State the importance of having T-MSIS data for Al/AN and I/T/Us to monitor implementation of Al/AN protections and I/T payments to ensure "the proper performance of CMS functions"; T-MSIS is a national database and source	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					 Request that regular reports be available on a quarterly basis to monitor use of measures, AI/AN protections, and I/T payments from T-MSIS to ensure the "quality, utility, and clarity of the information to be collected." 	
89.g.	Cost Sharing Reduction Reconciliation ACTION: Request for Comment NOTICE: Cost Sharing Reduction Reconciliation AGENCY: CMS	CMS-10526	Issue Date: 6/27/2014 Due Date: 8/26/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/26/2014; issued revision 9/14/2015, 1/20/2016 Due Date: 10/27/2014; 11/13/2015; 2/19/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Cost Sharing Reduction Reconciliation; Use: Under established HHS regulations, qualified health plan (QHP) issuers will receive estimated advance payments of cost-sharing reductions throughout the year. Each issuer will then undergo a reconciliation process at the end of the benefit year to ensure that HHS reimburses each issuer only for actual cost sharing. This information collection establishes the data elements that a QHP issuer would have to report to HHS to establish the cost-sharing reductions provided on behalf of enrollees for the benefit year. http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15075.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. ACA provides for cost-sharing reductions (CSRs) for eligible individuals who purchase health insurance from a qualified health plan (QHP) through an Exchange. On 3/11/2013, CMS issued a final rule (CMS-9964-F, Payment Notice) that detailed a plan in which HHS would advance monthly payments to issuers for estimated CSRs and then reconcile the advanced amounts against actual CSRs provided by issuers to eligible enrollees during the benefit year. The Payment Notice detailed a methodology for issuers to use when calculating and submitting to HHS the actual CSR amounts provided to enrollees in a benefit year. In response to concerns about the complexity of the methodology, CMS on 10/30/2013 issued a final rule (CMS-9957-F2/CMS-9964-F3) that allows QHP issuers to elect to use a simplified formula during the first three years of the program, from 2014 through 2016, to estimate CSRs provided to enrollees. Under this PRA request, CMS proposes to collect data for both the standard and simplified methodologies through the CSR Reconciliation Data Template. This information collection would allow HHS to gather data necessary to reconcile dollar amounts advanced to QHP issuers by HHS with dollar amounts paid (either actual or reestimated) by the issuer on behalf of an enrol	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date		payments made by issuers for the cost-sharing protections provided to Al/ANs under the limited and zero cost-sharing variations and propose to transition to an alternative payment mechanism only after demonstrating such an alternative would not create counter-productive financial incentives." This recommendation sought to diminish opportunities for health plans to receive payments from CMS for cost-sharing reductions and not actually provide the cost-sharing reductions due to enrollees. In response, CMS indicated that issuers will have to use the standard methodology, which relies on actual cost-sharing reduction payments, after 2016. However, CMS stated that CMS "will continue to consider alternative approaches for reimbursing OHP issuers for the future, including a capitated payment system" (See 89.b. and 7.bb. for additional details). TTAG also recommended that CMS ensure the collection of a robust amount of data on the actual payments made by issuers under the Indian-specific cost-sharing variations and ensure the collection of data represents the experiences of all health plans, with consideration to factors such as the service areas of plans, the degree of I/T/U penetration in the service areas, the percentage of Al/ANs enrolled in a plan, plan size and market concentration, and whether plans provided protections under the limited or zero cost-sharing variations. Again, this recommendation sought to ensure any estimated or capitated systems reflect actual payment made on behalf of Al/ANs and not inadvertently create incentives for health plans to deny the cost-sharing protections due to Al/ANs. This PRA request is consistent with the TTAG recommendations in that it is for the purpose of gathering data from health plans to permit CMS to reconcile advance payments made with actual (and re-estimated) payments made and potentially to develop alternative payment approaches for future periods based on a robust set of data. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/26/2014 issued a new version of this PRA	
					version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-26/pdf/2014-22980.pdf	
					CMS on 9/14/2015 issued a revision of this PRA request. This revised collection eliminates some data elements and requires summary plan level reporting and reporting in the 2016 reconciliation cycle on the dollar amount of 2014 cost-sharing reductions used in calculations for medical loss ratio and risk corridors programs reporting. http://www.gpo.gov/fdsys/pkg/FR-2015-09-14/pdf/2015-22959.pdf	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date	'	The revised CSR Reconciliation Data Elements form and a Supporting Statement for this PRA request are available at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10526html . On 4/30/2013, tribal organizations submitted comments in response to CMS-9964-IFC (see 89.b.), which included an alternative, optional methodology for calculating the value of cost-sharing reductions provided for the purpose of reconciliation of advance payments of cost-sharing reductions and created a transition period permitting the use of this alternative. CMS on 1/20/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-20/pdf/2016-00994.pdf No comments recommended.	
89.m.	Notice of Benefit and Payment Parameters for 2017 ACTION: Proposed Final Rule NOTICE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 AGENCY: CMS	CMS-9937- ₽F	Issue Date: 12/2/2015 Due Date: 12/21/2015 TTAG File Date: 12/21/2015; TSGAC also filed comments 12/21/2015 Date of Subsequent Agency Action, if any: Final Rule approved by	TTAG response: TSGAC response:	SUMMARY OF AGENCY ACTION: This proposed rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost sharing reductions; and user fees for Federally-Facilitated Exchanges. It also provides additional standards for the annual open enrollment period for the individual market for the 2017 benefit year; essential health benefits; cost-sharing requirements; qualified health plans; updated standards for Exchange consumer assistance programs; network adequacy; patient safety standards; the Small Business Health Options Program; stand-alone dental plans; acceptance of third-party payments by qualified health plans; the definitions of large employer and small employer; fair health insurance premiums; guaranteed availability; student health insurance coverage; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions and appeals; and other related topics. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-29884.pdf A fact sheet on this proposed rule is available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CMS-9937-P-Fact-Sheet-final-112015.pdf. SUMMARY OF NIHB ANALYSIS:	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.
			OMB 2/25/2016			
89.n.	Manual for Reconciliation of Advance Payment of CSRs ACTION: Guidance NOTICE: Draft Manual for Reconciliation of Advance Payment of Cost-Sharing Reductions for Benefit Years 2014 and 2015 AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/15/2016 Due Date: 2/15/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This draft manual for all issuers offering a qualified health plan (QHP) through a health insurance Marketplace provides information on the process for reconciling advance payment of cost-sharing reduction amounts that QHP issuers have received to reflect the cost-sharing reduction amounts those issuers provided to eligible Marketplace enrollees. This draft manual provides QHP issuers with general instructions on using the standard, simplified, and actuarial value methodologies described at 45 CFR § 156.430 for the purpose of determining the value of cost-sharing reduction amounts provided to eligible Marketplace enrollees and further describes the data elements issuers must submit when the annual cost-sharing reduction reconciliation process begins in spring 2016. CMS requests comment on this draft manual. Please submit comments to CSRreview@cms.hhs.gov by 5 p.m. on 2/15/2016. When submitting comments, please indicate the section of the draft manual to which the comment pertains. After carefully considering comments received, CMS intends to publish a final version of this manual prior to data submission. Collection of these data elements has approval under OMB control number 0938-1266. Technical guidance on actual submission of data will appear in separate documents posted with this manual (see below). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CMS-Guidance-on-CSR-Reconciliation.pdf The document titled "CSR Reconciliation: Issuer to MIDAS Attestation Inbound Specification-DRAFT.pdf. The document titled "CSR Reconciliation: Issuer to MIDAS Inbound Specification DRAFT.pdf. The document titled "CSR Reconciliation: Sample Pipe Delimited Format" is available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CSR-Recon-Issuer-to-MIDAS-Inbound-Specification_DRAFT.pdf.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					Reconcilation-Sample-Pipe-Delimited-Format-DRAFT-01-13-2016.pdf. SUMMARY OF NIHB ANALYSIS:	
92.b.	Compliance with Individual and Group Market Reforms ACTION: Request for Comment NOTICE: Information Collection Requirements for Compliance with Individual and Group Market Reforms AGENCY: CMS	CMS-10430	Issue Date: 11/21/2012 Due Date: 1/22/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 2/22/2013; issued revision 12/2/2015 Due Date: 3/25/2013; 2/1/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement of a previously approved collection; Title: Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; Use: The provisions of title XXVII of the Public Health Service Act (PHS Act) promote access to health insurance and reduce allowable limitations on coverage. Sections 2723 and 2761 of the PHS Act direct CMS to enforce title XXVII with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the individual and group market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. This collection also pertains to notices issued by individual and group health insurance issuers and self-funded non-Federal governmental plans. This collection includes the issuance of certificates of creditable coverage; notification of preexisting condition exclusions; notification of special enrollment rights; and review of issuer filings of individual and group market products or similar Federal review in cases in which a state is not enforcing a title XXVII individual or group market provision. SUMMARY OF NIHB ANALYSIS: The underlying policies pertaining to individual and group market reforms under ACA (and prior law) are presented in various proposed rules by CMS, with the most recent being CMS-972: Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review; Proposed Rule. This Paperwork Reduction Act comment request merely identifies the applicable provisions of title XXVII of the PHSA and the estimated number of hours for insurers to file the information that may be requested by CMS. CMS-10430 is instructive, though, in identifying the sections of the PHSA for which they will evaluate state enforcement efforts and und	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					plans. For purposes of title XXVII of the PHS Act, all other health insurance is sold in the individual market. The topics contained in the applicable provisions identified in CMS-10430 include: Certificates and disclosure of prior coverage; Notice of preexisting condition exclusion; Notice of preexisting condition exclusion; Notice of impaired financial capability; Federal review of policy forms to ensure guaranteed availability; Federal review of policy forms to ensure guaranteed renewability; Full disclosure by issuers to all small employers of materials on all products and other information; Federal review of policy forms to ensure coverage for the essential health benefits package; Notice to Federal government of self-funded, non-Federal government plan optout; and Notice to non-Federal government plan enrollees of opt-out. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/22/2013 issued a restatement of this PRA request. This information collection includes minimal changes to reflect laws passed since the approval of the previous collection document, which expired 9/30/2012. The OMB control number for this proposed collection will remain the same, but it will receive a new CMS Form Number. http://www.gpo.gov/fdsys/pkg/FR-2013-02-22/pdf/2013-04135.pdf CMS on 12/2/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-30534.pdf No comments recommended.	
92.d.	Patient Protection Notices and Disclosure Requirements	CMS-10330	<u>Issue Date:</u> 4/4/2013		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of	



Ref.	Short Title/Current Status of Regulation/Title/ 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: Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection Under the Affordable Care Act AGENCY: CMS		Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016		Coverage; and Disclosure Requirements for Patient Protection under the Affordable Care Act; <i>Use</i> : Under section 2711 of the Public Health Service Act (PHS Act) as amended by ACA, health plans used the enrollment opportunity notice to notify certain individuals of their right to re-enroll in their plan. The affected individuals included those whose coverage ended because of reaching a lifetime limit on the dollar value of all benefits for any individual. Use of this notice, a one-time requirement, will not continue. Under section 2712 of the PHS Act as amended by ACA, health plans will use the rescission notice to provide advance notice to certain individuals who might have their coverage rescinded. The affected individuals include those at risk of rescission on their health coverage. Under section 2719A of the PHS Act as amended by ACA, health plans will use the patient protection notification to inform certain individuals of their right to choose a primary care provider or pediatrician and to use obstetrical/gynecological services without prior authorization. http://www.gpo.gov/fdsys/pkg/FR-2013-04-04/pdf/2013-07798.pdf SUMMARY OF NIHB ANALYSIS: The ability to identify an I/T/U provider as the primary care provider for an enrollee under an Exchange-facilitated plan is important. This planissued notice will inform enrollees of the ability to select a primary care provider of choice. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15539.pdf CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03473.pdf No comments recommended.	
92.e.	Disclosure and Recordkeeping for Grandfathered Health	CMS-10325	<u>Issue Date:</u> 4/4/2013		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Plans ACTION: Request for Comment NOTICE: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans Under the Affordable Care Act AGENCY: CMS		Due Date: 6/3/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 6/28/2013; issued revision 2/19/2016 Due Date: 7/29/2013; 3/19/2016		Act; Use: Section 1251 of ACA provides that certain health plans in existence as of March 23, 2010grandfathered health plansdo not have to comply with certain statutory provisions in the law. To maintain grandfathered health plan status, the Interim Final Rule titled "Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act" requires a plan to maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents needed to verify, explain, or clarify its status. The plan must make these records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official. The recordkeeping requirement will allow verification of the grandfathered health plan status of the plan. A plan also must include a statement in any plan materials provided to participants or beneficiaries (in the individual market, primary subscribers) describing the benefits provided under the plan and indicating its grandfathered health plan status. The disclosure requirement will provide participants and beneficiaries with important information, such as that grandfathered health plans do not have to comply with certain consumer protection provisions contained in ACA, as well as contact information that they can use to determine which protections apply and the circumstances under which a plan might lose grandfathered health plan status. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15539.pdf CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03473.pdf	
92.s.	Rate Increase Disclosure and Review Reporting	CMS-10379	<u>Issue Date:</u> 12/27/2013		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved information collection; Title: Rate	



Red. # Short Title/ Agency Requirements ACTION: Request for Comment NOTICE: Rate Increase Disclosure and Review Reporting Requirements AGENCY: CMS # AGENCY: CMS Due Date: 275/2014								
ACTION: Request for Comment NOTICE: Rate Increase Disclosure and Review Reporting Requirements AGENCY: CMS AGENCY: CMS Date of Subsequent 4/2/2014; issued revision 2794 directs the HHS Secretary, in conjunction with states, to establish a process for the annual review of "unreasonable increases in premiums for health insurance coverage." The statute provides that health insurance issuer must suffill to the HHS Secretary and the applicable state justification of the implementation of the increases. Section 2794 also specifies that, beginning with plan years starting in 2014, the HHS Secretary, in conjunction with states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. Section 2794 directs the HHS Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. The regulation therefore develops a process to ensure the public disclosure of information and justification relating to unreasonable rate increases submit justification for an unreasonable rate increases effective in 2014 (submitted for review in 2013). To those ends, the regulation establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for any rate increases effective in 2014 (submitted for review in 2013). To those ends, the regulation establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increases, a Final Justification requirement for unreasonable rate increases that the issuer will not implement. On 11/14/2013, CMS issued a letter to State Insurance Commissioners outlining transitional policy for non-grandfathered coverage in the small group and individual health insurance soverage in the media coverage in the individual or small group market renewed for a policy year starting between 11/2014 and 10/1/2014 will remain in compliance with certain market reforms if it meets certain specific conditio	of Regulation/Title/ Agency	File Code	Due Date &		and Summary of NIHB Analysis	NIHB Recs.		
essential health benefits). In addition, because the single risk pool (1311(e)) depends on all of the aforementioned sections (2701, 2702, 2704, 2705, and 2707), the transitional	ACTION: Request for Comment NOTICE: Rate Increase Disclosure and Review Reporting Requirements		2/25/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued reinstatement 4/2/2014; issued revision 2/19/2016 Due Date: 5/2/2014;		adds a new section 2794 of the Public Health Service Act (PHS Act) directing the HHS Secretary, in conjunction with states, to establish a process for the annual review of "unreasonable increases in premiums for health insurance coverage." The statute provides that health insurance issuers must submit to the HHS Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 also specifies that, beginning with plan years starting in 2014, the HHS Secretary, in conjunction with states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. Section 2794 directs the HHS Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. The regulation therefore develops a process to ensure the public disclosure of all such information and justification. Section 2794 requires that health insurance issuers submit justification for an unreasonable rate increase to both CMS and the relevant state prior to its implementation. Additionally, section 2794 requires the HHS Secretary, in conjunction with states, to monitor rate increases effective in 2014 (submitted for review in 2013). To those ends, the regulation establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined unreasonable by a state or CMS, and a notification requirement for unreasonable rate increases that the issuer will not implement. On 11/14/2013, CMS issued a letter to State Insurance Commissioners outlining transitional policy for non-grandfathered coverage in the small group and individual health insurance markets. If permitted by applicable state authorities, health insurance issuers can continue coverage that would otherwise get terminated or cancelled, and affected individuals and small businesses can re-enroll in such covera			



Ref.	Short Title/Current Status		Issue Date;	NIHB	Brief Summary of Proposed Agency Action	
#	of Regulation/Title/ Agency	File Code	Due Date & File Date	Response	and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date		plans remain exempt from the single risk pool. CMS designed the Unified Rate Review Template and system exclusively for use with the single risk pool plan, and any attempt to include non-single risk pool plans in the Unified Rate Review template or system will create errors, inaccuracies, and limitations that would prevent the effectiveness of reviews of both sets of non-grandfathered plans (single risk pool and transitional). For these many reasons, CMS requires issuers with transitional plans experiencing rate increases subject to review to use the Rate Review Justification system and templates required and utilized prior to 4/1/2013. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30994.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 4/2/2014 issued a reinstatement of this PRA request with changes. http://www.gpo.gov/fdsys/pkg/FR-2014-04-02/pdf/2014-07402.pdf No comments recommended. This PRA request establishes reporting requirements for 1) insurance products in the "single-risk pool" and 2) non-grandfathered plans in the individual and small-group markets operating under the "transitional policy" for plans that otherwise would get canceled. CMS on 2/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-19/pdf/2016-03474.pdf No comments recommended.	
92.kk.	Summary of Benefits and Coverage and Uniform Glossary ACTION: Request for	CMS-10407 See also 31.tt.	Issue Date: 11/24/2014 <u>Due Date:</u> 1/23/2015		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 Department of Labor (DoL), and the Department of the Treasury (collectively, the Departments), in consultation with the National Association of Insurance Commissioners	
	NOTICE: Summary of Benefits and Coverage and		NIHB File Date: None		(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	
	Uniform Glossary		Date of		applicable plan or coverage." To implement these disclosure requirements, collection of	



	Chart Title/Comment Chat		Janua 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: CMS		Subsequent Agency Action, if any: Issued extension 2/24/2015; issued revision 2/26/2016 Due Date: 3/26/2015; 3/28/2016		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 OHPs to provide for Indian-specific cost-sharing variations, are available at http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1251222.html. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/24/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-02-24/pdf/2015-03650.pdf No comments recommended. CMS on 2/26/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-26/pdf/2016-04318.pdf The proposed revised SBC template, uniform glossary, and other related forms are available at the links below. • Proposed SBC Blank Template: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Uniform-Glossary.pdf • Proposed SBC Sample Completed Template: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SBC-Sample-Completed.pdf	
					Proposed Why This Matters language for SBC "No" Answers:	



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/No-Answers.pdf Proposed Why This Matters language for SBC "Yes" Answers: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Yes-Answers.pdf Proposed Instructions for Completing the SBCIndividual Health Insurance Coverage: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/cciio-Individual-Instructions.PDF Proposed Instructions for Completing the SBCGroup Health Plan Coverage" https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Group-Instructions.pdf Proposed Guide for Coverage Examples CalculationsMaternity Scenario, Diabetes Scenario, and Foot Fracture: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Coverage_examples_calculator.pdf Proposed Coverage Examples NarrativeMaternity Scenario: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/maternity-narrative-pdf Proposed Coverage Examples NarrativeDiabetes Scenario: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/diabetes-narrative.pdf Proposed Coverage Examples NarrativeFoot Fracture: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/diabetes-narrative.pdf Proposed Coverage Examples NarrativeFoot Fracture: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/diabetes-narrative.pdf This PRA request contains revised versions of the SBC documents. The SBC documentswhich each QHP issuer must release for each plan "variation" offered on a Marketplaceare critical for enrollees to understand how the Indian-specific cost-sharing protections apply (a QHP plan "variation" is a plan with a set of distinct cost-sharing protections, such as the "zero" and "limited" cost-sharing variations (CSVs)). Once the template is finalized, CCIIO has agreed to populate the templates to create sample "zero-CSV (Z-CSV)" and "limited-CSV (L-CSV)" versions. CCIIO will share these samples with QHP issuers for use in their development of Z	
92.ccc.	Rate Filing Justifications for	CCIIO (no	Issue Date:		SUMMARY OF AGENCY ACTION: This draft bulletin seeks comment on the proposed	



Rel. of Pegulation/Title/ File Code Due Date & NIHB Brief Summary of Proposed Agency Action MIHI							
# Agency File Date Response and Summary of Ninb Analysis	#	Agency	File Code I	Due Date & File Date	NIHB Response	and Summary of NIHB Analysis	NIHB Recs.
2016 for Single Risk Pool Coverage ACTION: Guidance ACTION: Guidance NOTICE: DRAFT Bulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage Effective on or after January 1, 2017 AGENCY: CCIIO AGENCY: CCIIO AGENCY: CCIIO Light State		Coverage nu ACTION: Guidance NOTICE: DRAFT Bulletin: Timing of Submission and Posting of Rate Filing Justifications for the 2016 Filing Year for Single Risk Pool Coverage Effective on or after January 1, 2017	number) D 1 N D S A	Due Date: 1/22/2016 NIHB File Date: None Date of Subsequent Agency		coverage, consistent with the proposed amendments to the rate review regulations at 45 CFR Part 154 in the 2017 Payment Notice Proposed Rule. Specifically, this bulletin proposes guidance for purposes of establishing the uniform dealline under 45 CFR 154.20(b) for health insurance issuers to submit the Unified Rate Review Template for proposed rates in the individual and small group markets. It also proposes guidance for purposes of establishing the uniform posting deadline under 45 CFR 154.301(b)(1)(i) for a state with an effective rate review program to provide public access to information regarding proposed rate increases subject to review. The bulletin also identifies the deadline for posting of final rate increases (including those not subject to review) and the CMS Web address for use by states with an effective rate review program that elect to provide public access from their website through a link to the rate information made available on the CMS Web site. The timelines specified in this bulletin would apply to rates filed in 2016 (2016 filling year) for single risk pool coverage (including both qualified health plans (QHPs) and non-QHPs) effective on or after 1/1/2017. In addition, 45 CFR 154.301(b)(3) requires states with an effective rate review program to post the required information on proposed rate increases subject to review and final rate increases (including those not subject to review) at a uniform time and not on a rolling basis. That requirement applies to rate increase information for single risk pool coverage, including both QHP and non-QHPs, both inside and outside of Marketplaces. The timelines in this bulletin reflect that policy. CMS seeks comments from states, issuers, and other interested parties on how to implement that requirement consistent with state legislative and regulatory requirements. CMS understands that some states that operate a State-Based Marketplace, as well as certain states that utilize the Federally-Facilitated Marketplace platform, faced significant challenge	



		_				
Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Timeline-Bulletin-12-23-15-FINAL.pdf SUMMARY OF NIHB ANALYSIS:	
92.ddd.	Evaluation of EDGE Data Submissions for 2015 ACTION: Guidance NOTICE: EDGE Server Data BulletinINFORMATION: Evaluation of EDGE Data Submissions for 2015 Benefit Year for Interim Reinsurance Payments and Interim Risk Adjustment Summary Report AGENCY: CCIIO	CCIIO (no reference number)	Issue Date: 1/21/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This bulletin provides guidance on the operational processes that CMS will use to evaluate issuer EDGE server data for the 2015 benefit year for the release of interim reinsurance payments and interim risk adjustment summary reports. This analysis will help CMS determine whether an issuer has provided sufficient access to EDGE server data for CMS to calculate interim reinsurance payments and release an interim risk adjustment summary report in a specific state and market. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Evaluation_of_EDGE_Data_Submissions_for_2015_Benefit_Year_for_Interim_Reinsurance_Payments_and_Interim_Risk_Adjustment_S.pdf SUMMARY OF NIHB ANALYSIS:	
95.	IHS Forms to Implement the Privacy Rule ACTION: Request for Comment NOTICE: IHS Forms to Implement Privacy Rule (45 CFR Parts 160 & 164) AGENCY: IHS	IHS-810, - 912-1, -912- 2, -913, and - 917	Issue Date: 10/2/2012 Due Date: 60 days (approx. 11/30/2012) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension without change of currently approved collection; Title: IHS Forms to Implement the Privacy Rule (45 CFR Parts 160 & 164); Use: The HHS rule titled "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule), which implements the privacy requirements of the Administrative Simplification subtitle of HIPAA, requires this information collection. This rule creates national standards to protect personal health information and gives patients increased access to their medical records. This rule requires the collection of information to implement these protection standards and access requirements. SUMMARY OF NIHB ANALYSIS: This PRA request includes no changes to the current forms that IHS uses to implement the Privacy Rule. IHS will use the following data collection instruments to meet the information collection requirements contained in the Privacy Rule:	



Ref. short Title(corrent Status of Regulation/Title/ Agency ### Agency ### Brie Code ### Response ### III- Date ### addition ### addition ### Agency ### Agency ### addition ### Agency ###	Cl T!!! - /O		I		
authorization for its use or disclosure of protected health information of the than for treatment, payment, and health care operations. This form, "Authorization for Use or Disclosure of Protected Health Information," is used to document an individual's authorization to use or disclose their protected health information. 1 Hs-912-1: The rule regards a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information, and the covered entity may or may not agree to the restriction. This form, "Request for Restrictions(s)," is used to document an individual's request for restriction of their protected health information and whether HS agreed or disagreed with the restriction. 1 Hs-912-2: The rule permits a covered entity to terminate its agreement to a restriction if the individual request to terminate a formetry agreed to restriction regarding the use and disclosure of protected health information. 1 Hs-913: The rule requires covered entities to permit individuals to request that the covered entity provide accounting of disclosures of protected health information made by the covered entity provide accounting of disclosures of their protected health information and the agency shandling of the request. 1 Hs-917: The rule requires covered entities to permit an individual to request that the covered entity manual and the agency shandling of the request. 1 Hs-917: The rule requires covered entities to permit an individual to request that the covered entity manual manual to the individual that meantdenner is accepted. If the covered entity must inform the individual that meantdenner is accepted. If the covered entity must inform the individual that meantdenner is accepted. If the covered entity must inform the individual that meantdenner is accepted. If the covered entity must inform the individual that meantdenner is accepted. If the covered entity must inform the individual that meantdenner is accepted. If the covered entity manual the p	of Regulation/Title/	File Code	Due Date &		NIHB Recs.
			1/22/2016 <u>Due Date</u> :	authorization for its use or disclosure of protected health information other than for treatment, payment, and health care operations. This form, "Authorization for Use or Disclosure of Protected Health Information," is used to document an individual's authorization to use or disclose their protected health information. • IHS-912-1: The rule requires a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information, and the covered entity may or may not agree to the restriction. This form, "Request for Restrictions(s)," is used to document an individual's request for restriction of their protected health information and whether IHS agreed or disagreed with the restriction. • IHS-912-2: The rule permits a covered entity to terminate its agreement to a restriction if the individual agrees to or requests the termination in writing. This form, "Request for Revocation of Restriction(s)," is used to document the agency or individual request to terminate a formerly agreed to restriction regarding the use and disclosure of protected health information. • IHS-913: The rule requires covered entities to permit individuals to request that the covered entity provide an accounting of disclosures of protected health information made by the covered entity. This form, "Request for an accounting of disclosures of their protected health information and the agency's handling of the request. • IHS-917: The rule requires covered entities to permit an individual to request that the covered entity amend protected health information. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must inform the individual that the amendment is accepted. If the covered entity denies the requested amendment, in whole or in part, the covered entity must inform the individual that the amendment is accepted. If the covered entity denies the requested amendment, in whole or in part, the covered entity denies the requested amendme	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
111.f.	Mental Health Parity Rules: External Review for MSPP ACTION: Request for Comment NOTICE: Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008: Technical Amendment to External Review for MSPP AGENCY: IRS	TD 9640 (OMB 1545- 2165)	Issue Date: 11/27/2015 Due Date: 1/26/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008: Technical Amendment to External Review for Multi-State Plan Program; <i>Use</i> : The final regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), which requires parity between mental health or substance use disorder benefits and medical/surgical benefits with respect to financial requirements and treatment limitations under group health plans and group and individual health insurance coverage, includes disclosure provisions for group health plans and health insurance coverage offered in connection with a group health plan, included an amendment to the interim final regulations implementing Public Health Service Act (PHS Act) section 2719 to specify that the federal external review process under PHS Act section 2719(b)(2) and paragraph (d) of the internal claims and appeals and external review regulations apply to the Multi-State Plan Program (MSPP) administered by OPM. Section 2719 of the PHS Act and its implementing regulations provide that group health plans and health insurance issuers must comply with either a state external review process or the federal external review process. This information collection request addresses this requirement. http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-30101.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
112.d.	I/T/U Payment for Physician and Non- Hospital-Based Services ACTION: Proposed 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	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	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,	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: IHS		Agency Action, if any: Issued due date extension 1/14/2015; sent Final Rule to OMB 12/14/2015		and enables IHS to expand beneficiary access to medical care. http://www.gpo.gov/fdsys/pkg/FR-2014-12-05/pdf/2014-28508.pdf SUMMARY OF NIHB ANALYSIS: NIHB strongly supports expanding Medicare-Like Rates beyond hospital-based providers and believes this proposed rule serves as a good step toward achieving that goal. However, as drafted, this proposed rule does not provide the flexibility necessary to ensure continued access to care for Al/ANs through the Purchased/Referred Care (PRC) programs. Without a mechanism to ensure such flexibility, this proposed rule could operate to deny many Al/ANs access to critically important and life-saving services. This proposed rule requires revisions to provide the flexibility needed to ensure continued access to care while still lowering costs. 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.I.	Expanded Access to Non-VA Care Through Veterans Choice ACTION: Interim Final Rule NOTICE: Expanded Access to Non-VA Care Through the Veterans Choice Program AGENCY: VA	VA RIN 2900- AP60	Issue Date: 12/1/2015 Due Date: 3/30/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: VA revises its medical regulations that implement section 101 of the Veterans Access, Choice, and Accountability Act of 2014 (Choice Act), which requires VA to establish a program to furnish hospital care and medical services through eligible non-VA health care providers to eligible veterans who either cannot receive care within the wait-time goals of the Veterans Health Administration (VHA) or who qualify based on their place of residence (Veterans Choice Program or Program). The most recent amendments to the Choice Act made by the Construction Authorization and Choice Improvement Act of 2014 and by the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 require these regulatory revisions. The Construction Authorization and Choice Improvement Act of 2014 amended the Choice Act to define additional criteria that VA can use to determine that travel to a VA medical facility constitutes an "unusual or excessive burden," and the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 amended the Choice Act to cover all veterans enrolled in the VA health care system, remove the 60-day limit on an	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					episode of care, modify the wait-time and 40-mile distance eligibility criteria, and expand provider eligibility based on criteria as determined by VA. This interim final rule revises VA regulations consistent with the changes made to the Choice Act as described above. http://www.gpo.gov/fdsys/pkg/FR-2015-12-01/pdf/2015-29865.pdf SUMMARY OF NIHB ANALYSIS: This interim final rule includes no Indian-specific provisions and does not address a previous tribal recommendation that VA use existing sharing agreements with I/T/U facilities, rather than requiring these facilities to negotiate new agreements, when implementing section 101 of the Choice Act. Previously, VA has indicated that it remains "committed to using existing agreements and partnerships where possible."	
112.m.	Dear Tribal Leader Letter (Contract Support Costs Policy) ACTION: Notice NOTICE: Dear Tribal Leader Letter AGENCY: IHS	IHS (no reference number)	Issue Date: 1/7/2016 Due Date: Open NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This letter seeks to initiate a consultation on the IHS Contract Support Costs (CSC) policy. IHS plans to update and implement a new policy in 2016. The policy, developed in 1992 and revised several times since then through coordination and consultation with Al/AN Tribes and tribal organizations, aims to provide uniform and equitable guidance on the preparation and negotiation of requests for CSC funds for new and existing awards authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA). The new policy comes in response to a June 2012 Supreme Court decision on CSC claims against the Department of the Interior in the case Salazar v. Ramah Navajo Chapter (Ramah). The impact of this decision generated additional review for IHS, although not a party to the Ramah case, and its CSC policy. The current CSC policy appears in the Indian Health Manual at Part 6, Chapter 3 (2007), available online at https://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p6c3 . IHS last initiated consultation on this policy in October 2011. As IHS updates this policy, please send written input or feedback to Robert G. McSwain by mail at the address below or by e-mail at consultation@ihs.gov . Robert G. McSwain Principal Deputy Director Indian Health Service 5600 Fishers Lane Mail stop: 08E86	



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
112.n.	Catastrophic Health	IHS	Issue Date:		http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/ 2016_Letters/54891-1_DTLL_CSC_Consultation_to_OD_1-7-16.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF AGENCY ACTION: IHS administers the Catastrophic Health Emergency	
	Emergency Fund ACTION: Proposed Rule NOTICE: Catastrophic Health Emergency Fund AGENCY: IHS	RIN 0905- AC97	1/26/2016 Due Date: 3/11/2016 4/11/2016 NIHB File Date: Date of Subsequent Agency Action, if any: Issued due date extension 2/25/2016		Fund (CHEF), which serves to meet the extraordinary medical costs associated with the treatment of victims of disasters or catastrophic illnesses within the responsibility of the agency. This proposed rule would establish: definitions governing CHEF; a requirement that a Service Unit shall not qualify for reimbursement for the cost of treatment until the cost of the episode of care has reached a certain threshold; a procedure for reimbursement for certain services exceeding a threshold cost; a procedure for payment for certain cases; and a procedure to ensure payment will occur from CHEF if other sources of payment (federal, state, local, or private) are available. https://www.gpo.gov/fdsys/pkg/FR-2016-01-26/pdf/2016-01138.pdf An IHS press release on this proposed rule is available at https://www.ihs.gov/newsroom/index.cfm/pressreleases/2016pressreleases/ihs-seeks-comment-on-new-regulation-for-catastrophic-health-emergency-fund/. SUMMARY OF NIHB ANALYSIS: A summary of this proposed rule is embedded below. IHS CHEF Proposed Rule analysis 2016-0 SUMMARY OF SUBSEQUENT AGENCY ACTION: IHS on 2/25/20136 issued a	
					document that extends the due date to submit comments regarding this proposed rule from March 11, 2016, to February 11, 2016.	
112.0.	IHS Reimbursement Rates for CY 2016	IHS RIN 0917- ZA30	Issue Date: [Approved by OMB on		SUMMARY OF AGENCY ACTION: SUMMARY OF NIHB ANALYSIS:	



Ref.	Short Title/Current Status		Issue Date;	NIHB	Brief Summary of Proposed Agency Action	
#	of Regulation/Title/	File Code	Due Date &	Response	and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date	тооролоо	una cummary or runal year	
	ACTION: Notice		2/19/2019]			
	NOTICE: Reimbursement		Due Date:			
	Rates for Calendar Year		Due Date.			
	2016		NIHB File			
			Date:			
	AGENCY: IHS					
			Date of			
			Subsequent			
			Agency Action, if any:			
			ACTION, II arry.			
118.	Hospital Wage Index	CMS-10079	Issue Date:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of	
	Occupational Mix Survey		12/7/2012		a currently approved collection; <i>Title</i> : Hospital Wage Index Occupational Mix Survey and	
	ACTION: Request for		<u>Due Date</u> :		Supporting Regulations in 42 CFR, Section 412.64; <i>Use</i> : Section 304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to	
	Comment		2/5/2013		collect data every 3 years on the occupational mix of employees for each short-term,	
	Comment		2/3/2013		acute care hospital participating in Medicare to construct an occupational mix adjustment	
	NOTICE: Hospital Wage		NIHB File		to the wage index for application beginning 10/1/2004 (the FY 2005 wage index). The	
	Index Occupational Mix		Date: None		occupational mix adjustment seeks to control for the effect of hospital employment	
	Survey and Supporting				choices on the wage index.	
	Regulations		Date of		LII. II	
	AGENCY: CMS		Subsequent Agency		http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29627.pdf	
	AGLINGT. CIVIS		Action, if any:		SUMMARY OF NIHB ANALYSIS:	
			Issued		Solumnar of this private role.	
			revision		SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/28/2013 issued a revision	
			2/28/2013;		of this PRA request.	
			issued		http://www.gpo.gov/fdsys/pkg/FR-2013-02-28/pdf/2013-04548.pdf	
			extension		CMC on 10/0/2015 issued on outonsion of this DDA request. The EV 2017	
			10/9/2015, 12/28/2015		CMS on 10/9/2015 issued an extension of this PRA request. The FY 2016 survey will provide for the collection of hospital-specific wages and hours data for calendar year	
			12/20/2013		2016 (i.e., payroll periods ending between 1/1/2016 and 12/31/2016). The 2016 Medicare	
			Due Date:		occupational mix survey will apply beginning with the FY 2019 wage index.	
			4/1/2013;		http://www.gpo.gov/fdsys/pkg/FR-2015-10-09/pdf/2015-25809.pdf	
			12/8/2015;			



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.
		1/27/2016		No comments recommended. CMS on 12/28/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-28/pdf/2015-32435.pdf No comments recommended.	
121.m. Medicare Enrollment ApplicationDMEPOS Suppliers ACTION: Request for Comment NOTICE: Medicare Enrollment Application Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers AGENCY: CMS	CMS-855S	Issue Date: 9/11/2015 Due Date: 11/10/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 12/18/2015 Due Date: 1/19/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Enrollment ApplicationDurable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers; Use: The CMS-855S Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier enrollment application gathers from a supplier information that tells CMS its name, whether it meets certain qualifications of a health care supplier, where it renders its services or supplies, the identity of the owners of the enrolling entity, and information necessary to establish correct claims payment. This revision of CMS-855S seeks to simplify and clarify the current data collection and to remove obsolete and/or redundant questions. CMS has corrected grammar and spelling errors and has added limited informational text within the application form and instructions in conjunction with links to Web sites when greater detail is needed by the supplier. To clarify current data collection differentiations and to comport with accreditation coding, CMS has updated Section 3D ("Products and Services Furnished by This Supplier"). This revision does not offer any new material data collection. http://www.gpo.gov/fdsys/pkg/FR-2015-09-11/pdf/2015-22944.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/18/2015 issued a revision of this PRA request. CMS received one comment in response to the 60-day notice. https://www.gpo.gov/fdsys/pkg/FR-2015-12-18/pdf/2015-31887.pdf No comments recommended.	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
121.n.	Agency Medicare Registration Application ACTION: Request for Comment NOTICE: Medicare Registration Application AGENCY: CMS	CMS-855O	Issue Date: 12/11/2015 Due Date: 2/9/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Revision of a currently approved collection; <i>Title</i> : Medicare Registration Application; <i>Use</i> : CMS-8550 serves to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications for enrollment in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services and/or prescribing Medicare Part D drugs for Medicare beneficiaries. The application allows a physician or other eligible professional to enroll in Medicare without approval for billing privileges. Applicants submit the required information is submitted when requesting enrollment in Medicare for the sole purpose of ordering and certifying certain Medicare items and services or for prescribing Medicare Part D drugs. Medicare contractors use the application to collect data to help ensure that the applicant has the necessary credentials to order and certify certain Medicare items and services or to prescribe Medicare Part D drugs. This includes ensuring that the physician is not excluded from the Medicare program. https://www.gpo.gov/fdsys/pkg/FR-2015-12-11/pdf/2015-31302.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
121.0.	New Use for System of Records (Part A Enrollment Data) ACTION: Notice NOTICE: Privacy Act of 1974; Report of a New Routine Use for a CMS System of Records AGENCY: CMS	CMS (no reference number)	Issue Date: 2/18/2016 Due Date: 30 days (approx. 3/21/2016) NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, this notice announces a new routine use to the existing system of records titled Enrollment Data Base (EDB), System No. 09-70-0502, last modified in the 2/26/2008 FR (73 FR 10249), to assist with transmitting data to IRS for 10958 processing. The new routine use will authorize CMS to disclose information maintained in the system "to the IRS for the purposes of reporting Medicare Part A enrollment information and to provide statements to the individual enrollees with respect to whom information is reported to the IRS." Disclosures made pursuant to the routine use will be coordinated through the CMS Division of Medicare Enrollment Coordination, Medicare Enrollment and Appeals Group, Center for Medicare. SUMMARY OF NIHB ANALYSIS: No comments recommended.	



Ref.	Short Title/Current Status		Issue Date;	NIHB	Brief Summary of Proposed Agency Action	
#	of Regulation/Title/ Agency	File Code	Due Date & File Date	Response	and Summary of NIHB Analysis	NIHB Recs.
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, 10/27/2015, 8/17/2015, 11/3/2015, 11/3/2015, 1/27/2016		SUMMARY OF AGENCY ACTION: Section 30.18 of HHS claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that HHS becomes entitled to recovery. The rate must equal or exceed the current value of funds rate set by the Department of Treasury or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities," unless the HHS Secretary waives interest in whole or part or a statute, contract, or repayment agreement prescribes a different rate. The Secretary of the Treasury may revise this rate quarterly. HHS publishes this rate in the Fed Reg. The current rate of 10 38%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2012. This interest rate is effective until the Secretary of the Treasury notifies the HHS of any change. SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: Under the 3/5/2013 revision, the current rate of 105/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2012. This interest rate will remain effective until the Secretary of the Treasury notifies HHS of any change. http://www.gpo.gov/fidsys/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/fidsys/pkg/FR-2013-04-23/pdf/2013-0758.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, "Nation	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
#	•	File Code		Response	Under the 11/12/2013 revision, the current rate of 101/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2013. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2013-11-12/pdf/2013-26994.pdf Under the 9/2/2014 revision, the current rate of 103/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2014-09-02/pdf/2014-20773.pdf Under the 10/27/2014 revision, the current rate of 10 3/4%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 9/30/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2014-10-27/pdf/2014-25443.pdf	NIND RECS.
					Under the 1/27/2015 revision, the current rate of 10 1/2%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2014. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2015-01-27/pdf/2015-01429.pdf Under the 8/17/2015 revision, the current rate of 9 3/4%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 6/30/2015. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-20217.pdf Under the 11/3/2015 revision, the current rate of 10.0%, as fixed by the Secretary of the	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis Treasury, is certified for the quarter ended 9/30/2015. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision. http://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-20217.pdf Under the 1/27/2016 revision, the current rate of 9 3/4%, as fixed by the Secretary of the Treasury, is certified for the quarter ended 12/31/2015. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program" and "National Research Service Award Program." This interest rate will apply to overdue debt until HHS publishes a revision.	NIHB Recs.
126.a.	Medicare Rural Hospital Flexibility Grant Program ACTION: Request for Comment NOTICE: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination AGENCY: HRSA	HRSA (OMB 0915-0363)	Issue Date: 12/28/2012 Due Date: 60 days (approx. 3/1/2013) NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 4/26/2013; issued revision 5/27/2015, 2/12/2016 Due Date: 30 days (approx.		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) quality improvement interventions; (c) financial and operational improvement initiatives; and (d) multi-hospital patient safety initiatives. http://www.gpo.gov/fdsys/pkg/FR-2012-12-31/pdf/2012-31399.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: HRSA on 4/26/2013 issued a new version of this PRA request. In response to comments on the original request, ORHP adjusted the burden estimate based on new calculations.	

National Indian Health Board

Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date 5/28/2013); 7/27/2015; 3/17/2016	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis http://www.gpo.gov/fdsys/pkg/FR-2013-04-26/pdf/2013-09946.pdf HRSA on 5/27/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-05-27/pdf/2015-12700.pdf No comments recommended. HRSA on 2/12/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-16/pdf/2016-03014.pdf	NIHB Recs.
					No comments recommended, but some tribal organizations might have an interest in the CAH-related proposed revised measures.	
129.b.	Awarding and Administration of MAC Contracts ACTION: Notice NOTICE: Medicare Program; Request for Information Regarding the Awarding and the Administration of Medicare Administrative Contractor Contracts AGENCY: CMS	CMS-1653- NC	Issue Date: 12/21/2015 Due Date: 2/19/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This request for information solicits public comment on the processes and procedures that CMS could use to leverage new legal authorities to incentivize and reward exceptional Medicare Administrative Contractor (MAC) contract performance; publish performance information on each MAC, to the extent permitted by law; and make MAC jurisdictional changes. https://www.gpo.gov/fdsys/pkg/FR-2015-12-21/pdf/2015-32027.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
	AGENCT. CIVIS					
134.a.	Prepaid Health Plan Cost Report ACTION: Request for Comment	CMS-276	<u>Issue Date</u> : 1/30/2013 <u>Due Date</u> : 4/1/2013		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title: Prepaid Health Plan Cost Report; Use: HMOs and Competitive Medical Plans contracting with the HHS Secretary under Section 1876 of the Social Security Act (the Act) must submit a budget and enrollment forecast, semi-annual interim report, interim final cost report, and a final certified cost report in accordance with 42 CFR 417.572-417.576. Health Care	

National Indian Health Board

	Short Title/Current Status		Issue Date;			
Ref.	of Regulation/Title/	File Code	Due Date &	NIHB	Brief Summary of Proposed Agency Action	NIHB Recs.
#	Agency	The Code	File Date	Response	and Summary of NIHB Analysis	MILID KCC3.
	NOTICE: Prepaid Health		NIHB File		Prepayment Plans contracting with the HHS Secretary under Section 1833 of the Act	
	Plan Cost Report		Date:		must submit a budget and enrollment forecast, semi-annual interim report, and final cost	
	l Tan Cost Report		<u>Date</u> .		report in accordance with 42 CFR 417.808 and 42 CFR 417.810. CMS seeks approval	
	AGENCY: CMS		Date of		for the reinstatement with change of form CMS-276. The Cost Report outlines the	
	AGENCT. CIVIS		Subsequent		provisions for implementing Section 1876(h) and Section 1833(a)(1)(A) of the Act. The	
			Agency		revisions will implement some changes in response to ACA, clarify certain instructions,	
			Action, if any:		and update outdated issues within the Cost Report.	
			Issued		and apadic oditation issues within the cost report.	
			reinstatement		http://www.gpo.gov/fdsys/pkg/FR-2013-01-30/pdf/2013-01849.pdf	
			5/3/2013;		mip.nww.gpo.govitasys.pikgr it 2015 of 50/pan2015 of 617/pan	
			issued		SUMMARY OF NIHB ANALYSIS:	
			revision		Community of Miller Minder Color	
			2/10/2016		SUMMARY OF AGENCY ACTION: CMS on 5/3/2013 issued a reinstatement of this	
			2,10,2010		PRA request with changes. CMS has made revisions to implement certain changes	
			Due Date:		associated with ACA, clarify instructions, and update outdated issues within the Cost	
			6/3/2013;		Report and the Budget Report.	
			4/11/2016		http://www.gpo.gov/fdsys/pkg/FR-2013-05-03/pdf/2013-10530.pdf	
					The state of the s	
					CMS on 2/10/2016 issued a revision of this PRA request.	
					https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02686.pdf	
					No comments recommended.	
134.e.	, ,	CMS-1728-	Issue Date:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension	
	Report	94	6/28/2013		without change of a currently approved collection; Title: Home Health Agency Cost	
					Report; Use: In accordance with sections 1815(a), 1833(e) and 1861(v)(1)(A) of the	
	ACTION: Request for		<u>Due Date</u> :		Social Security Act, providers of service in the Medicare program must submit annual	
	Comment		8/27/2013		information to achieve reimbursement for health care services rendered to Medicare	
					beneficiaries. In addition, they must submit cost reports to their Medicare contractor on	
	NOTICE: Home Health		NIHB File		an annual basis. The Medicare contractor uses the cost report to make settlement with	
	Agency Cost Report		<u>Date</u> : None		the provider for the fiscal period covered by the cost report and to decide whether to	
					audit the records of the provider. Section 413.24(a) requires providers receiving payment	
	AGENCY: CMS		Date of		on the basis of reimbursable cost to provide adequate cost data based on their financial	
			Subsequent		and statistical records that qualified auditors can verify. Besides determining program	
			Agency		reimbursement, the data submitted on the cost reports supports the management of	
			Action, if any:		federal programs.	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date Issued extension	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis http://www.gpo.gov/fdsys/pkg/FR-2013-06-28/pdf/2013-15558.pdf	NIHB Recs.
			9/17/2013; issued revision 9/4/2015, 2/10/2016 <u>Date:</u> 10/17/2013; 11/3/2015; 3/11/2016		SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/17/2013 issued an extension of this PRA request with no changes. http://www.gpo.gov/fdsys/pkg/FR-2013-09-17/pdf/2013-22515.pdf CMS on 9/4/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-04/pdf/2015-22033.pdf No comments recommended. CMS on 2/10/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02685.pdf	
					No comments recommended.	
136.c.	PQRS and the eRx Incentive Program Data Assessment ACTION: Request for Comment NOTICE: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support AGENCY: CMS	CMS-10519	Issue Date: 3/17/2014 Due Date: 5/16/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 9/8/2014; issued revision		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support; Use: PQRS and the eRx Incentive Program have data integrity issues, such as rejected and improper payments. This four-year project will evaluate incentive payment information for accuracy and identify improper payments, with the goal of recovering these payments. Additionally, the results of the project will contribute to recommendations to avoid future data integrity issues. CMS will analyze data submission, processing, and reporting for potential errors, inconsistencies, and gaps related to data handling, program requirements, and clinical quality measure specifications of PQRS and the eRx Incentive Program. CMS will conduct surveys of Group Practices, Registries, and Data Submission Vendors (DSVs) to evaluate PQRS and the eRx Incentive Program. Follow-up interviews will occur with a small number of respondents. http://www.gpo.gov/fdsys/pkg/FR-2014-03-17/pdf/2014-05845.pdf	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
			9/25/2015, 1/29/2016 <u>Due Date</u> : 10/6/2014; 11/24/2015; 2/29/2016		SUMMARY OF NIHB ANALYSIS: No comments recommended, given that this PRA request focuses on PQRS data integrity issues. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 9/8/2014 issued a new version of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2014-09-05/pdf/2014-21179.pdf CMS on 9/25/2015 issued a revision of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-24474.pdf No comments recommended. CMS on 1/29/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-29/pdf/2016-01689.pdf This PRA request raises concerns that CMS might use its analysis to request repayment of funds paid as much as five years earlier.	
136.e.	Requirements for Reporting Quality Measures ACTION: Request for Information NOTICE: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs AGENCY: CMS	CMS-3323- NC	Issue Date: 12/31/2016 Due Date: 2/1/2016 2/16/2016 NIHB File Date: 2/1/2016 Date of Subsequent Agency Action, if any: Issued due date extension	NIHB response:	SUMMARY OF AGENCY ACTION: This request for information seeks public comment regarding several items related to the certification of health information technology (IT), including electronic health records (EHR) products used for reporting to certain CMS quality reporting programs such as, but not limited to, the Hospital Inpatient Quality Reporting (IQR) Program and the Physician Quality Reporting System (PQRS). In addition, CMS seeks feedback on how often to require recertification, the number of clinical quality measures (CQMs) to which a certified Health IT Module should have to certify, and testing of certified Health IT Module(s). Specifically, CMS seeks public input on the following areas of certification and testing of health IT, particularly relating to how often to require recertification, the number of CQMs a certified Health IT Module should have to certify to, and the testing of certified Health IT Module(s) to reduce the burden and further streamline the process for providers and health IT developers while ensuring such products are certified and tested appropriately for effectiveness. The feedback will inform CMS and HHS ONC of elements that might need consideration for future rules relating to the reporting of quality measures under CMS programs. This request for information serves as part of the effort of CMS to streamline/reduce EP, eligible hospital, CAH, and health IT developer burden.	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.
			2/2/2016		https://www.gpo.gov/fdsys/pkg/FR-2015-12-31/pdf/2015-32931.pdf SUMMARY OF NIHB ANALYSIS: Tribal representatives might want to provide comments specific to EHR technologies used by I/Ts.	
137.d.	Data Collection for Beneficiaries Receiving Beta Amyloid PET ACTION: Request for Comment NOTICE: Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease AGENCY: CMS	CMS-10583	Issue Date: 9/25/2015 Due Date: 11/24/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 12/8/2015 Due Date: 1/7/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease; Use: In the Decision Memorandum #CAG-00431N issued on 9/27/2013, CMS determined sufficient evidence exists to support the use of beta amyloid PET in 2 scenarios: (1) to exclude Alzheimer's disease (AD) in narrowly defined and clinically difficult differential diagnoses; and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD. CMS will cover one beta amyloid PET scan per patient through Coverage with Evidence Development under section 1862(a)(1)(E) of the Social Security Act (Act) in clinical studies that meet specific criteria established by CMS. Clinical studies must have EMS approval, involve subjects from appropriate populations, and use comparative and longitudinal methods. Radiopharmaceuticals used in the scan must have FDA approval. Approved studies must address defined research questions established by CMS. Clinical studies in this National Coverage Determination (NCD) must adhere to the designated timeframe and meet standards established by CMS in the NCD. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines to meet specifically identified requirements and research questions. To qualify for payment, providers must prescribe beta amyloid PET for beneficiaries with a set of clinical criteria specific to each cancer. Providers must transmit data elements to CMS for evaluation of the short and long-term benefits of beta amyloid PET to beneficiaries and for use in future clinical decision making. http://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-24474.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/8/2015 issued a new version of this PRA request. http://www.qpo.gov/fdsys/pkg/FR-2015-015-12-08/pdf/2015-30892.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.	
140.	Social Security Office Report of State Buy-in Problem ACTION: Request for Comment NOTICE: Social Security Office Report of State Buy-in Problem AGENCY: CMS	CMS-1957	Issue Date: 2/28/2013 Due Date: 4/29/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued reinstatement 5/10/2013, 2/10/2016 Due Date: 6/10/2013; 4/11/2016		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Reinstatement of a previously approved collection; <i>Title</i> : Social Security Office (SSO) Report of State Buy-in Problem; <i>Use</i> : Under Section 1843 of the Social Security Act, states can enter into an agreement with HHS to enroll eligible individuals in Medicare and pay their premiums. The program seeks to ensure that Medicaid serves as the payer of last resort by permitting a state to provide Medicare protection to certain groups of needy individuals, as part of its total assistance plan. The program also transfers some medical costs for this population from Medicaid, a program partially funded by the state, to Medicare, a program funded by the federal government and individual premiums. Generally, states include in the program individuals who meet the eligibility requirements for Medicare and are cash recipients or are deemed cash recipients or categorically needy under Medicaid. In some cases, states might include individuals who are not cash assistance recipients under the Medical Assistance Only group. The day-to-day operations of the program are accomplished through an automated data exchange process that exchanges Medicare and Buy-in entitlement information between the Social Security district offices, Medicaid state agencies, and CMS. When problems arise that the normal data exchange process cannot resolve, clerical actions are required. CMS-1957 is used to report Buy-in problems cases and serves as the only standardized form available for communications between the aforementioned agencies for the resolution of beneficiary complaints and inquiries regarding State Buy-in eligibility. http://www.gpo.gov/fdsys/pkg/FR-2013-02-28/pdf/2013-04551.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/10/2013 issued a reinstatement of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-10/pdf/2016-02686.pdf	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	<u> </u>				No comments recommended.	
142.a.	Detailed Notice of Discharge ACTION: Request for Comment NOTICE: Detailed Notice of Discharge (DND) AGENCY: CMS	CMS-10066	Issue Date: 3/6/2013 Due Date: 5/6/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 5/17/2013, 11/27/2015 Due Date: 6/17/2013; 1/26/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Detailed Notice of Discharge (DND); Use: When a Medicare beneficiary requests a Quality Improvement Organization review of his/her inpatient hospital discharge, hospitals and Medicare plans have used DND to provide the beneficiary with a detailed explanation regarding the reason for discharge. http://www.gpo.gov/fdsys/pkg/FR-2013-03-06/pdf/2013-05176.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/17/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 11/27/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-30070.pdf No comments recommended.	
142.b.	Important Message from Medicare ACTION: Request for Comment NOTICE: Important Message from Medicare (IM) AGENCY: CMS	CMS-R-193	Issue Date: 3/6/2013 Due Date: 5/6/2013 NIHB File Date: None Date of Subsequent Agency		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Important Message from Medicare (IM); Use: Hospitals have used IM to inform original Medicare, Medicare Advantage, and other Medicare plan beneficiaries who are hospital inpatients about their hospital rights and discharge rights. In particular, IM provides information about when a beneficiary will and will not have liability for charges for a continued stay in a hospital and offers a detailed description of the Quality Improvement Organization review process. http://www.gpo.gov/fdsys/pkg/FR-2013-03-06/pdf/2013-05176.pdf SUMMARY OF NIHB ANALYSIS:	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date Action, if any: Issued extension 5/17/2013, 12/8/2015 Due Date: 6/17/2013;	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 5/17/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-05-17/pdf/2013-11811.pdf CMS on 12/8/2015 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2015-12-08/pdf/2015-30891.pdf No comments recommended.	NIHB Recs.
			2/8/2016		NO COMMENS RECOMMENDED.	
149.	Evaluation of the Graduate Nurse Education Demonstration ACTION: Request for Comment NOTICE: Evaluation of the Graduate Nurse Education Demonstration Program AGENCY: CMS	CMS-10467	Issue Date: 4/4/2013 Due Date: 6/3/2013 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued new request 6/28/2013; issued revision 10/16/2015, 1/19/2016 Due Date: 7/29/2013; 12/15/2015; 2/28/2016		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: New collection; Title: Evaluation of the Graduate Nurse Education Demonstration Program; Use: Section 5509 of ACA, under title XVIII of the Social Security Act, requires the Graduate Nurse Education (GNE) Demonstration Under section 5509, the five selected demonstration sites receive "payment for the hospital's reasonable costs for the provision of qualified clinical training to advance practice registered nurses." Section 5509 also requires completion of an evaluation of the GNE Demonstration by October 17, 2017. This evaluation includes analysis of the following: (1) growth in the number of advanced practice registered nurses (APRNs) with respect to a specific base year as a result of the demonstration; (2) growth for each of the following specialties: clinical nurse specialist, nurse practitioner, certified nurse anesthetist, and certified nurse midwife; and (3) costs to the Medicare program as result of the demonstration. For this evaluation, CMS will collect primary data through site visits, key stakeholder interviews, small discussion groups and focus groups, telephone interviews, electronic templates for quantitative data submission, and quarterly demonstration site reports. CMS will collect secondary data from mandatory hospital cost reports and several other existing data sources, such as the American Association of Colleges of Nursing (AACN). http://www.gpo.gov/fidsys/pkg/FR-2013-04-04/pdf/2013-07798.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 6/28/2013 issued a new version of this PRA request. http://www.gpo.gov/fidsys/pkg/FR-2013-06-28/pdf/2013-15539.pdf	



Ref. #	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis CMS on 10/16/2015 issued a revision of this PRA request. http://www.qpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-26390.pdf	NIHB Recs.
					No comments recommended. CMS on 1/19/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-19/pdf/2016-00844.pdf	
153.m.	CMS/SSA Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974: CMS Computer Match No. 2016-12; HHS Computer Match No. 1604; SSA Computer Match No. 1097- 1899 AGENCY: CMS	CMS (no reference number)	Issue Date: 2/9/2016 Due Date: 30 days (approx. 3/10/2016) NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a computer matching program (CMP) that CMS plans to conduct with the Social Security Administration (SSA). Under this CMP, titled "Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services and the Social Security Administration for Determining Enrollment or Eligibility for Insurance Affordability Programs Under the Patient Protection and Affordable Care Act," SSA will disclose information to CMS in connection with the administration of state health subsidy programs under ACA and its implementing regulations. SSA will provide data to CMS, and CMS will use SSA data needed to make initial eligibility determinations, eligibility redeterminations and renewal decisions, including appeal determinations, for state health subsidy programs and certifications of exemption. https://www.gpo.gov/fdsys/pkg/FR-2016-02-09/pdf/2016-02527.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	
153.n.	CMS/Homeland Security Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-10; HHS Computer Match No. 1607	CMS (no reference number)	Issue Date: 2/17/2016 Due Date: 30 days (approx. 3/18/2016) NIHB File Date:		SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a computer matching program (CMP) that CMS plans to conduct with the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS). Under this CMP, titled "Computer Matching Agreement between the Centers for Medicare & Medicaid Services and the Department of Homeland Security, United States Citizenship and Immigration Services, for the Verification of United States Citizenship and Immigration Status Data for Eligibility Determinations," CMS will access USCIS data needed to make eligibility determinations in its capacity as a Federally-Facilitated Exchange, and state agencies that administer Medicaid, a Basic Health Program, CHIP, and State-Based	

National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	AGENCY: CMS		Date of Subsequent Agency Action, if any:		Exchanges will receive the results of verifications using USCIS data accessed through the CMS Data Services Hub to make eligibility determinations. https://www.gpo.gov/fdsys/pkg/FR-2016-02-17/pdf/2016-03203.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice addresses ongoing actions by federal agencies to conduct automated matching of applicant information for verification and fraud detection.	
153.o.	CMS/IRS Computer Matching Program ACTION: Notice NOTICE: Privacy Act of 1974; CMS Computer Match No. 2016-08; HHS Computer Match No. 1606 AGENCY: CMS	CMS (no reference number)	Issue Date: 2/17/2016 Due Date: 30 days (approx. 3/18/2016) NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: In accordance with the requirements of the Privacy Act of 1974, as amended, this notice announces the re-establishment of a computer matching program (CMP) that CMS plans to conduct with IRS, a bureau of the Department of the Treasury. Under this CMP, titled "Computer Matching Agreement between the Department of Health and Human Services, Centers for Medicare & Medicaid Services, and the Department of the Treasury, Internal Revenue Service, for the Verification of Household Income and Family Size for Insurance Affordability Programs and Exemptions," to support the verification of household income and family size for an applicant receiving an eligibility determination under the ACA, IRS will disclose tax return information to CMS, and CMS will disclose this information to entities administering Medicaid, CHIP, or Basic Health Programs (BHPs), as well as Exchanges (or Marketplaces) through the CMS Data Services Hub. CMS, in its capacity as the Federally-Facilitated Exchange (or Federally-Facilitated Marketplace), or an administering entity will match tax return information for the purpose of determining eligibility for state health subsidy programs (premium tax credits, cost-sharing reductions, Medicaid, CHIP, or BHPs), as well as certain certificates of exemption. https://www.gpo.gov/fdsys/pkg/FR-2016-02-17/pdf/2016-03185.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended. This notice addresses ongoing actions by federal agencies to conduct automated matching of applicant information for verification and fraud detection.	
154.b.	Medicaid/CHIP Managed Care ACTION: Proposed Final	CMS-2390- P F	<u>Issue Date:</u> 6/1/2015	NIHB 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	See Table C.



Ref. # Short Title/Current Status of Regulation/Title/ Agency File Code Response Rule File Date File Date TTAG Short Title/Current Status of Regulation/Title/ Agency File Code	NIHB Recs.
	lth
NOTICE: Medicaid and Children's Health Insurance Program (CHIP) Programs. Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategles, and Revisions Related to Third Parry Liability AGENCY: CMS AGENCY:	s of Act of O514. Act



Ref.	Short Title/Current Status		Issue Date;	NIHB	Brief Summary of Proposed Agency Action	
#	of Regulation/Title/ Agency	File Code	Due Date & File Date	Response	and Summary of NIHB Analysis	NIHB Recs.
	Agency		The Date		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].	
					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	



Ref.	Short Title/Current Status of Regulation/Title/ 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 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 Al/ANs to decline to enroll in Medicaid managed care.	
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:		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.
			Date of Subsequent Agency Action, if any:			
172.a.	Medicare Current Beneficiary Survey ACTION: Request for Comment NOTICE: Medicare Current Beneficiary Survey AGENCY: CMS	CMS-0015A	Issue Date: 7/26/2013 Due Date: 9/24/2013 NIHB File Date: Date of Subsequent Agency Action, if any: Issued extension 10/4/2013; issued revision 2/24/2016 Due Date: 11/4/2013; 4/25/2016		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Medicare Current Beneficiary Survey; <i>Use</i> : The Medicare Current Beneficiary Survey (MCBS), the most comprehensive and complete survey available on the Medicare population, captures data not otherwise collected through CMS operations. MCBSan in-person, nationally-representative, longitudinal survey of Medicare beneficiaries sponsored by CMS and directed by the Office of Information Products and Data Analytics (OIPDA) in partnership with the new Center for Medicare and Medicaid Innovation (CMMI)captures information on beneficiaries, whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. CMS enhances data produced as part of the MCBS with administrative data (e.g. fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. CMS has administered MCBS for more than 20 years (encompassing over 1 million interviews), with three annual interviews per survey participant. http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-17985.pdf SUMMARY OF NIHB ANALYSIS: This PRA request might warrant comments similar those provided on the Medicaid enrollee survey (CMS-10493). SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 10/4/2013 issued an extension of this PRA request. http://www.gpo.gov/fdsys/pkg/FR-2013-10-04/pdf/2013-24219.pdf CMS on 2/24/2016 issued a revision of this PRA request. According to CMS, the revisions to this information collection will streamline some questionnaire sections, add a few new measures, and update the wording of questions and response categories. Most of the revised questions reflect an effort to bring the MCBS questionnaire in line with other national surveys that have more current wording of questions and response categories with well-established measures. As a whole, these revisions do not change the resp	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					program change to oversample small population groups. https://www.gpo.gov/fdsys/pkg/FR-2016-02-24/pdf/2016-03908.pdf No comments recommended.	
175.b.	Medicaid Drug Use Review Program ACTION: Request for Comment NOTICE: Medicaid Drug Use Review (DUR) Program AGENCY: CMS	CMS-R-153	Issue Date: 11/29/2013 Due Date: 1/28/2014 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued revision 3/17/2014, 1/29/2016 Due Date: 4/16/2014; 3/29/2016		SUMMARY OF AGENCY ACTION: <i>Type of Information Collection Request</i> : Extension of a currently approved collection; <i>Title</i> : Medicaid Drug Use Review (DUR) Program; <i>Use</i> : This information collection serves to: establish patient profiles in pharmacies, identify problems in prescribing, dispensing, or both prescribing and dispensing; determine the ability of each program to meet minimum standards required for federal financial participation; and ensure quality pharmaceutical care for Medicaid patients. State Medicaid agencies that have prescription drug programs must perform prospective and retrospective drug use review to identify aberrations in prescribing, dispensing, and patient behavior. http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28537.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 3/17/2014 issued a revision of this PRA request. CMS has revised the information collection request subsequent to the publication of the 60-day notice in the 11/29/2013 FR. http://www.gpo.gov/fdsys/pkg/FR-2014-03-17/pdf/2014-05785.pdf Background Section 4401 of the Omnibus Budget Reconciliation Act of 1990 and section 1927(g) of the Social Security Act require states to operate a Drug Use Review (DUR) program for covered outpatient drugs under fee-for-service Medicaid. The DUR program must ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. The DUR program must consist of prospective drug use review (ProDUR), retrospective drug use review (RetroDUR), data assessment of drug use against predetermined standards, and ongoing educational outreach activities. In addition, states must submit an annual DUR program report that includes a description of the nature and scope of their DUR activities as outlined in the statute and regulations. Form CMS-R-153, a survey, serves as the collection instrument for state reporting of their DUR program. Over the years, technology has changed as has the practice of	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency		File Date	Response	pharmacy. Therefore, CMS has revised the survey to address more fully the current practices and areas of concern within the Medicaid Pharmacy Programs. Analysis The survey included in this PRA request includes no Al/AN-specific or I/T/U-specific sections, questions, or revisions. Among the most significant changes to the survey, CMS has added several questions to the ProDUR section (II) to clarify state data processing and authorization requirements. CMS also has added a question to the Generic Policy and Utilization Data section (VI) to clarify state authorization requirements for dispensation of brand-name drugs in lieu of generics. In the Fraud, Waste, and Abuse Detection section (VIII), CMS has added several new subsections that address state pain management program practices, screening and restrictions on opioid prescribing, monitoring of morphine-equivalent daily dose prescribing, and monitoring of buprenorphine prescribing. In addition to these revisions to the survey, this PRA request provides an opportunity to comment on any past problems that might have occurred regarding this information collection. According to the notice, this information collection is necessary to establish patient profiles in pharmacies, identify problems in prescribing and/or dispensing, determine the ability of each state DUR program to meet minimum standards required for federal financial participation, and ensure quality pharmaceutical care for Medicaid patients. CMS seeks to provide non-statistical information, comparisons, and trends back to states based on their reported experiences with DUR. States might benefit from this information and might fine tune their programs each year based on state-reported innovative practices and CMS-identified best practices gathered from the DUR annual reports. CMS on 1/29/2016 issued a revision of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2016-01-29/pdf/2016-01688.pdf	
180.	Flu Vaccination Standard for Certain Providers and Suppliers	CMS-3213-F	Issue Date: [Approved by OMB on		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	

National Indian Health Board

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	ACTION: Request for Comment NOTICE: Influenza Vaccination Standard for Certain Participating Providers and Suppliers AGENCY: CMS		A/18/2014] Due Date: NIHB File Date: Date of Subsequent Agency Action, if any:		surrogate declined vaccination. This final rule seeks to increase the number of patients receiving annual vaccination against seasonal influenza and decrease the morbidity and mortality rate from influenza. This final rule also requires certain providers and suppliers to develop policies and procedures that will allow them to offer vaccinations for pandemic influenza in case of a future pandemic influenza event. SUMMARY OF NIHB ANALYSIS:	
188.a.	Emergency Preparedness Requirements ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers AGENCY: CMS	CMS-3178- PF	Issue Date: 12/27/2013 Due Date: 2/25/2014 3/31/2014 TTAG File Date: 3/31/2014 Date of Subsequent Agency Action, if any: Issued due date extension 2/21/2014; sent Final Rule to OMB 11/3/2015	TTAG response:	SUMMARY OF AGENCY ACTION: This proposed rule would establish national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to ensure that they adequately plan for both natural and manmade disasters and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It also would ensure that these providers and suppliers adequately prepare to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. CMS proposes emergency preparedness requirements that 17 provider and supplier types must meet to participate in the Medicare and Medicaid programs. Since existing Medicare and Medicaid requirements vary across the types of providers and suppliers, CMS also proposes variations in these requirements. CMS has based these variations on existing statutory and regulatory policies and differing needs of each provider or supplier type and the individuals to whom they provide health care services. Despite these variations, this proposed rule would provide generally consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters. http://www.gpo.gov/fdsys/pkg/FR-2013-12-27/pdf/2013-30724.pdf SUMMARY OF NIHB ANALYSIS: This proposed rule, which seeks to ensure the availability of health care during emergencies, would impose substantial new emergency	See Table C.



Ref.	Short Title/Current Status		Issue Date;	NIHB	Brief Summary of Proposed Agency Action	
#	of Regulation/Title/ Agency	File Code	Due Date & File Date	Response	and Summary of NIHB Analysis	NIHB Recs.
	ngonoy				and suppliers in an effort to safeguard human resources, ensure business continuity, and protect physical resources. Of note, this proposed rule directs providers to "comply with all applicable Federal and State emergency preparedness requirements" and requires a communications plan that complies with federal and state law, provisions potentially imposing additional emergency preparedness requirements that Tribes currently do not consider applicable. This proposed rule does not include any references to compliance with tribal law. A Health Policy Alternatives summary report on this proposed rule is available at http://www.chausa.org/docs/default-source/advocacy/010814-cha-summary-of-emergency-preparedness-rule.pdf . SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/21/2014 issued document (CMS-3178-N) that extends the comment period for this proposed rule from 2/25/2014 to 3/31/2014. CMS have received inquiries from industry organizations regarding the short time to canvass their membership for input on this proposed rule. One organization stated that it needed additional time to respond because of current regional emergencies requiring the attention of emergency management personnel who likely would have an interest in commenting on this proposed rule. Because of its scope, and because CMS specifically seeks comments to benefit from the vast experiences of emergency management and provider/supplier communities, the agency wants to allow ample time for all sections of the public to comment on this proposed rule. http://www.gpo.gov/fdsys/pkg/FR-2014-02-21/pdf/2014-03710.pdf	
188.b.	Fire Safety Requirements for Certain Health Care Facilities ACTION: Proposed Final Rule NOTICE: Medicare and Medicaid Programs; Fire Safet Requirements for Certain	CMS-3277- P F	Ssue Date: 4/16/2014 Due Date: 6/16/2014 TTAG File Date: 6/16/2014 Date: 6/1	TTAG response:	SUMMARY OF AGENCY ACTION: This proposed rule would amend the fire safety standards for Medicare and Medicaid participating hospitals, critical access hospitals (CAHs), long-term care facilities, intermediate care facilities for individuals with intellectual disabilities (ICF-IID), ambulatory surgery centers (ASCs), hospices that provide inpatient services, religious non-medical health care institutions (RNHCIs), and programs of all-inclusive care for the elderly (PACE) facilities. Further, this proposed rule would adopt the 2012 edition of the Life Safety Code (LSC) and eliminate references in CMS regulations to all earlier editions. It also would adopt the 2012 edition of the Health Care Facilities Code, with some exceptions. This proposed rule provides the LSC citation, a description of the 2012 requirement, and an explanation of its benefits for	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.
	Health Care Facilities AGENCY: CMS		Date of Subsequent Agency Action, if any: Sent Final Rule to OMB 11/3/2015		health care facilities, patients, staff, and visitors over the 2000 version in each occupancy section. http://www.gpo.gov/fdsys/pkg/FR-2014-04-16/pdf/2014-08602.pdf SUMMARY OF NIHB ANALYSIS: These proposed regulations might exceed building code requirements in some jurisdictions, as well as the current or planned fire safety standards for some THO facilities. This proposed rule does not specifically discuss applicability to Indian/tribal health care facilities. The document below includes a summary of the proposed regulations applicable to various provider types. CMS-3277-P summary 2014-04-1	
189.c.	Annual Update of the HHS Poverty Guidelines ACTION: Notice NOTICE: Annual Update of the HHS Poverty Guidelines AGENCY: HHS	HHS (no reference number)	Issue Date: 1/25/2016 Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This notice provides an update of the HHS poverty guidelines to account for the increase in prices as measured by the Consumer Price Index for the last calendar year. https://www.gpo.gov/fdsys/pkg/FR-2016-01-25/pdf/2016-01450.pdf SUMMARY OF NIHB ANALYSIS: A TSGAC memo on applicable federal poverty level (FPL) thresholds for Medicaid and Marketplace coverage is embedded below. TSGAC - 2016 and 2017 FPL Handout -	
194.f.	340B Drug Pricing Program Reporting Requirements	HRSA (OMB 0915-0176)	<u>Issue Date</u> : 12/23/2015		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Revision a currently approved collection; Title: 340B Drug Pricing Program Reporting Requirements; Use: Section 602 of the Veterans Health Care Act of 1992 enacted section 340B of the	



		_				
Ref.	Short Title/Current Status of Regulation/Title/ 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: 340B Drug Pricing Program Reporting Requirements AGENCY: HRSA		Due Date: 2/22/2016 NIHB File Date: None Date of Subsequent Agency Action, if any:		Public Health Service Act (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Under section 340B, a manufacturer that participates in Medicaid must sign a Pharmaceutical Pricing Agreement with the HHS Secretary in which the manufacturer agrees to charge enrolled covered entities a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities that choose to participate in the section 340B Drug Pricing Program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from requesting Medicaid reimbursement from a drug discounted under the 340B Program. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to an individual who is not a patient of the entity. Section 340B(a)(5)(C) of the PHS Act permits the HHS Secretary and manufacturers of a covered outpatient drug to conduct audits of covered entities in accordance with procedures established by the HHS Secretary related to the number, duration, and scope of the audits. In response to the statutory mandate of section 340B(a)(5)(C) and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) developed an informal voluntary dispute resolution process for manufacturers and covered entities, which, prior to filing a request for resolution of a dispute with OPA, should attempt in good faith to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute. In parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution process. The expected revision	
					SUMMARY OF NIHB ANALYSIS: Although this is only a PRA notice, tribal organizations might have concerns with the implementation of this policy.	



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
195.c.	Collection of Customer Satisfaction Surveys ACTION: Request for Comment NOTICE: Generic Clearance for the Collection of Customer Satisfaction Surveys AGENCY: CMS	CMS-10415	Issue Date: 10/30/2015 Due Date: 12/29/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 12/30/2015 Due Date: 1/29/2015		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Generic Clearance for the Collection Customer Satisfaction Surveys; Use: This information collection allows CMS to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with its commitment to improving service delivery. The information collected from customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with CMS programs. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations; serve as an early warning of issues with service; and focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. This collection will allow for ongoing, collaborative, and actionable communications between CMS and its customers and stakeholders. It also will allow feedback to contribute directly to the improvement of program management. Collecting voluntary customer feedback serves as the least burdensome, most effective way for CMS to determine whether its public Web sites are useful to and used by its customers. CMS needs generic clearance to ensure that it can continuously improve its Web sites though regular surveys developed from these pre-defined questions. Surveying the CMS Web sites on a regular, ongoing basis will help ensure that users have an effective, efficient, and satisfying experience, maximizing the impact of the information and resulting in optimum benefit for the public. The surveys will ensure that this communication channel meets customer and partner priorities, builds CMS brands, and contributes to the health and human services impact goals of the agency. http://www.gpo.gov/fdsys/pkg/FR-2015-10-30/pdf/2015-27619.pdf SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 12/30/2015 issued an extension of this PRA request. https://www.gpo.gov/fdsys/pkg/FR-2015-12-30/pdf/2015-32633.pdf	
199.b.	CLAS County Data	CCIIO (no reference	<u>Issue Date</u> : 12/12/2014		SUMMARY OF AGENCY ACTION: Public Health Service Act (PHS Act) section 2719 requires non-grandfathered group health plans and health insurance issuers offering	



Ref.	Short Title/Current Status of Regulation/Title/	File Code	Issue Date; Due Date &	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Agency ACTION: Guidance NOTICE: CLAS County Data AGENCY: CCIIO	number)	Due Date: None NIHB File Date: Date of Subsequent Agency Action, if any: Issued revised Guidance 1/7/2015, 2/9/2015, 1/27/2016	Nesponse	non-grandfathered health insurance coverage to provide relevant notices in a culturally and linguistically appropriate manner. The regulations implementing section 2719 require these plans and issuers to make certain accommodations for notices sent to an address in a county meeting a threshold percentage of people literate only in the same non-English language (10 percent or more of the population residing, as determined based on American Community Survey (ACS)). Section 2715 of the PHS Act requires group health plans and health insurance issuers offering group and individual coverage to provide the summary of benefits and coverage (SBC) and uniform glossary in a culturally and linguistically appropriate manner. The regulations implementing section 2715 adopt the ten percent threshold set forth in the section 2719 implementing regulations. This guidance includes all counties that meet or exceed the 10 percent threshold (rounded to the nearest percent) for the 2009-2013 ACS data and applies until the next edition. CMS will update this list annually following the release of the applicable ACS data. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data 12-05-14 clean 508.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: CCIIO on 1/7/2015 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data-01-07-15-508.pdf CCIIO on 2/9/2015 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data-pdf CCIIO on 1/27/2016 issued a revised version of this guidance. http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CO-OP-Questions-Final-1-27-16.pdf	
204.	Medicaid Services "Received Through" an IHS/Tribal Facility	CMS (no reference number)	<u>Issue Date:</u> 10/27/2015	TTAG response:	SUMMARY OF AGENCY ACTION: CMS proposes to update its policy regarding the circumstances for the availability of 100 percent federal funding for services furnished to Medicaid-eligible Al/ANs through facilities of IHS or Tribes. Through this policy change,	See Table C.



National Indian Health Board TABLE B: SUMMARY OF NOTICES & REGULATIONS UPDATED THROUGH 2/29/2016

	0		T			
Ref.	Short Title/Current Status	File Oad	Issue Date;	NIHB	Brief Summary of Proposed Agency Action	NILID D
#	of Regulation/Title/	File Code	Due Date &	Response	and Summary of NIHB Analysis	NIHB Recs.
	Agency	0110 //4 /	File Date	-	3	
		SHO #16-	Due Date:	TSGAC	which would affect all states, CMS seeks to improve access to care for Al/AN Medicaid	
	ACTION: Request for	002	11/17/2015	response:	beneficiaries. This Request for Comment paper describes the policy options under	
	Information Final Policy				consideration and seeks feedback from states, Tribes, and other stakeholders.	
			TTAG File			
	NOTICE: Medicaid Services		Date:		http://www.medicaid.gov/medicaid-chip-program-information/by-topics/indian-health-and-	
	"Received Through" an		11/17/2015;		medicaid/downloads/tribal-white-paper.pdf	
	Indian Health Service/Tribal		TSGAC also		CHAMA DV OF NILID ANALYOID ALL I	
	Facility: A Request for		filed		SUMMARY OF NIHB ANALYSIS: A background paper on this issue is embedded	
	Comment		comments		below	
			11/17/2015			
	AGENCY: CMS		D		NIHB FMAP Memo	
			Date of		2015-10-29.pdf	
			Subsequent			
			Agency		SUMMARY OF SUBSEQUENT AGENCY ACTION: CMS on 2/26/2016 issued a final	
			Action, if any:		policy via a State Health Official Letter. This letter informs state Medicaid agencies and	
			Issued Final		other state health officials about an update in payment policy affecting federal funding for	
			Policy		services received by Medicaid-eligible individuals who are Al/ANs through facilities of	
			2/26/2016		IHS, whether operated by IHS or by Tribes. As described in this letter, IHS/tribal facilities	
					can enter into care coordination agreements with non-IHS/tribal providers to furnish	
					certain services for their patients who are AI/AN Medicaid beneficiaries, and the amounts	
					paid by the state for services requested by facility practitioners in accordance with those	
					agreements would qualify for the enhanced federal matching authorized under section	
					1905(b) of the Social Security Act at a rate of 100 percent. Upon execution of a written	
					care coordination agreement, this will take effect immediately for states for the	
					expenditures for services furnished by non-IHS/tribal providers to AI/AN Medicaid	
					beneficiaries who are patients of an IHS/tribal facility acting under such agreement, as	
					described in this letter. This update in payment policy serves to help states, IHS, and	
					Tribes to improve delivery systems for Al/ANs by increasing access to care,	
					strengthening continuity of care, and improving population health.	
					https://www.medicaid.gov/federal-policy-guidance/downloads/sho022616.pdf	
205	Charing What Warls	ILIC (OMD	Jagua Data:		CHMMADY OF ACTION, Type of Information Collection Decreed Fitzgrafian	
205.	Sharing What Works	IHS (OMB	<u>Issue Date</u> : 10/9/2015		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension	
	BPPPLE Form	0917-0034)	10/9/2015		without change of a currently approved collection; <i>Title</i> : IHS Sharing What WorksBest	
	ACTION, Dogwood for		Duo Data:		Practice, Promising Practice, and Local Effort (BPPPLE) Form; <i>Use</i> : IHS seeks to raise	
	ACTION: Request for	<u> </u>	<u>Due Date</u> :		the health status of the AI/AN population to the highest possible level by providing	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Comment NOTICE: IHS Sharing What WorksBest Practice, Promising Practice, and Local Effort (BPPPLE) Form AGENCY: IHS		12/8/2015 NIHB File Date: None Date of Subsequent Agency Action, if any: Issued extension 11/17/2015, issued due date extension 12/15/2015 Due Date: 12/17/2015 1/9/2016		comprehensive health care and preventive health services. To support the IHS mission and encourage the creation and utilization of performance driven products/services by IHS, tribal, and urban Indian health (I/T/U) programs, Office of Preventive and Clinical Services program divisions (i.e., behavioral health, health promotion/disease prevention, nursing, and dental) have developed a centralized program database of best practices, promising practices, and local efforts (BPPPLE) and resources. This collection serves to further the development of a database of BPPPLE, resources, and policies available to the public on the IHS Web site. This database will serve as a resource for program evaluation and for modeling examples of various health care projects occurring in Al/AN communities. http://www.gpo.gov/fdsys/pkg/FR-2015-10-09/pdf/2015-25733.pdf SUMMARY OF NIHB ANALYSIS: SUMMARY OF SUBSEQUENT AGENCY ACTION: IHS on 11/17/2015 issued an extension of this PRA request. IHS received no comments in response to the 60-day notice on this information collection published in the 10/9/2015 FR (80 FR 61215). http://www.gpo.gov/fdsys/pkg/FR-2015-11-17/pdf/2015-29251.pdf No comments recommended. IHS on 12/15/2015 issued a document that extends the due date to submit comments regarding the 30-day notice on this information collection to 1/9/2016, as the agency issued the 30-day notice before the comment period for the 60-day notice ended on 12/8/2015. https://www.gpo.gov/fdsys/pkg/FR-2015-12-15/pdf/2015-31534.pdf	
206.	Measures of Quality	AHRQ (no	Issue Date:		SUMMARY OF AGENCY ACTION: AHRQ requests information from the public	
	Improvement Activities ACTION: Request for Information	reference number)	2/10/2016 <u>Due Date</u> : 3/4/2016		(including health care delivery organizations, health information developers, payers, quality measure developers, clinicians, and health care consumers) about quality improvement measures designed to help health care organizations monitor initiatives aimed at: improving patient understanding of health information, simplifying navigation of health care systems and facilities, and enhancing the ability of patients to manage their	
	NOTICE: Request for Measures Assessing Health		NIHB File Date:		health. Specifically, AHRQ seeks quality improvement measures in four domains:	



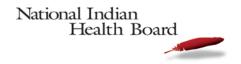
Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
	Care Organization Quality Improvement Activities to Improve Patient Understanding, Navigation, Engagement, and Self- Management AGENCY: AHRQ		Date of Subsequent Agency Action, if any:		 Communication; Ease of Navigation; Patient Engagement and Self-Management; and Organizational Structure, Policy, and Leadership. AHRQ seeks measures that do not require patient survey data and that health care organizations currently use, or have used in the past, to guide quality improvement activities designed to address these domains. AHRQ also seeks information about relevant measures under development or suggested for future development. https://www.gpo.gov/fdsys/pkg/FR-2016-02-10/pdf/2016-02679.pdf SUMMARY OF NIHB ANALYSIS: Tribal organizations might wish to communicate I/T/U-specific approaches to quality improvement activities. 	
207.	Confidentiality of Substance Use Disorder Patient Records ACTION: Proposed Rule NOTICE: Confidentiality of Substance Use Disorder Patient Records AGENCY: SAMHSA	SAMHSA- 4162-20	Issue Date: 2/9/2016 Due Date: 4/11/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: This proposed rule addresses changes to the Confidentiality of Alcohol and Drug Abuse Patient Records regulations. SAMHSA has issued this proposed rule out of a need to update and modernize the regulations, which sought to address the potential use of substance abuse information against an individual, preventing those individuals with substance use disorders from seeking needed treatment. The last substantive update to these regulations happened in 1987. Within the U.S. health care system over the last 25 years, significant changes have occurred that the current regulations did not envision, including new models of integrated care built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient information, and a new focus on performance measurement within the health care system. SAMHSA wants to ensure that patients with substance use disorders have the ability to participate in, and benefit from, new integrated health care models without fear of putting themselves at risk of adverse consequences. These new integrated models serves the triple aim of HHS: improving health care quality, improving population health, and reducing unnecessary health care costs. SAMHSA strives to facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. These concerns include: the potential for loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration. This proposed rule also seeks to make the regulations more	



Ref.	Short Title/Current Status of Regulation/Title/ Agency	File Code	Issue Date; Due Date & File Date	NIHB Response	Brief Summary of Proposed Agency Action and Summary of NIHB Analysis	NIHB Recs.
					understandable and less burdensome. https://www.gpo.gov/fdsys/pkg/FR-2016-02-09/pdf/2016-01841.pdf SUMMARY OF NIHB ANALYSIS: Tribal organizations might wish to comment on this rule on information sharing.	
208.	Medicare Probable Fraud Measurement Pilot ACTION: Request for Comment NOTICE: Medicare Probable Fraud Measurement Pilot AGENCY: CMS	CMS-10406	Issue Date: 2/5/2016 Due Date: 4/5/2016 NIHB File Date: Date of Subsequent Agency Action, if any:		SUMMARY OF AGENCY ACTION: Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare Probable Fraud Measurement Pilot; Use: CMS seeks OMB approval of the collections required for a probable fraud measurement pilot. The probable fraud measurement pilot will establish a baseline estimate of probable fraud in payments for home health care services in the fee-for-service Medicare program. CMS and its agents will collect information from home health agencies (HHAs), the referring physicians, and Medicare beneficiaries selected in a national random sample of home health claims. The pilot will rely on the information collected along with a summary of the service history of the HHA, the referring provider, and the beneficiary to estimate the percentage of total payments associated with probable fraud and the percentage of all claims associated with probable fraud for Medicare fee-for-service home health. https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02277.pdf SUMMARY OF NIHB ANALYSIS: No comments recommended.	



RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
7.111.	2017 Letter to Issuers in FFMs ACTION: Guidance NOTICE: Draft 2017 Letter to Issuers in the Federally- Facilitated Marketplaces AGENCY: CCIIO	CCIIO (no reference number) Issue Date: 12/23/2015 Due Date: 1/17/2016 TSGAC File Date: 1/17/2016 Date of Subsequent Agency Action, if any:	 Chapter 1, Section 4Standardized Options: Under the 2017 Issuer Letter, qualified health plan (QHP) issuers would have to offer "standardized options," with each option standardized in terms of in-network cost-sharingdeductible, annual limitation on cost-sharing, and copayment or coinsurance for a key set of essential health benefits (EHBs) that comprise a large percentage of total spending for the average enrollee; CCIIO should include balance billing charges and policies as an element of the standardized options to enable better plan comparisons and to facilitate selection of plans with the greatest value for QHP enrollees. Chapter 3, Section 3Out-of-Pocket Cost Comparison Tool: CCIIO has created an out-of-pocket (OOP) cost comparison tool to help improve the ability of consumers to make comparisons between QHP offerings and determine the QHP that offers the greatest value depending on a variety of factors; in designing the OOP cost comparison tool, CCIIO should incorporate the impact of the Indian-specific cost-sharing protections or, if not feasible for the 2017 coverage year, at least provide information indicating to potential AI/AN enrollees that the calculations do not include the impact of the Indian-specific cost-sharing protections. 	No subsequent Agency action taken (as of 2/29/2016).
14.C.	Waivers for State Innovation ACTION: Notice	CMS-9936-N <u>Issue Date:</u> 12/16/2015	 Indian-Specific Protections Under ACA: ACA contains a number of Indian-specific protections—some within the 	No subsequent Agency action taken (as of 2/29/2016).



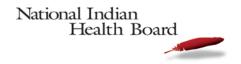
RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
	NOTICE: Waivers for State Innovation AGENCY: CMS/Treasury	Due Date: Open TSGAC File Date: 2/23/2016 Date of Subsequent Agency Action, if any:	section 1332 waiver authority of CMS and Treasury (Agencies) and some outside this authority—and a State Innovation Waiver could have a direct negative impact on Al/ANs because of changes in Indian-specific and non-Indian specific provisions of the law; to ensure that a State Innovation Waiver does not adversely affect Al/ANs, the Agencies should clarify that representations made by a state pertaining to the state satisfying the requirements for granting such a waiver must consider the specific impact on each individual Al/AN and not remain limited to the overall, or average, impact on the population as a whole. 2. Indian-Specific Protections Under the Balanced Budget Act of 1997 (BBA): BBA established section 1932(a)(2)(C) of the Social Security Act, which provides that no state can require Al/ANs to enroll in a Medicaid managed care system, except in cases in which an I/T/U operates the system; to ensure that a State Innovation Waiver does not adversely affect Al/ANs, the Agencies should emphasize the importance of maintaining the Indian-specific protections contained in section 1932 under such a waiver. 3. Indian-Specific Protections Under the American Recovery and Reinvestment Act of 2009 (ARRA): As a supplement to section 1932(a)(2)(C), ARRA section 5006 provides a number of protections for Al/ANs who elect to enroll in Medicaid managed care; to ensure that a State Innovation Waiver does not adversely affect Al/ANs, the Agencies should emphasize the importance of maintaining the Indian-specific protections contained in section 5006 under such a waiver.	



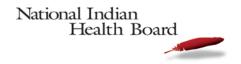
RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
43.	Medicaid Reimbursement for Outpatient Drugs ACTION: Proposed Final Rule NOTICE: Medicaid Program; Covered Outpatient Drugs AGENCY: CMS	CMS-2345- PFC Issue Date: 2/2/2012 Due Date: 4/2/2012 NIHB File Date: 4/2/2012 Date of Subsequent Agency Action, if any: Issued Final Rule 2/1/2016 Due Date: 4/1/2016	 Tribal Consultation: CMS should consider in its decisions regarding the final rule all comments received during tribal consultation, although the agency would not have received these comments until after the 4/2/2012 deadline. 	 In the 4/1/2016 Final Rule— Tribal Consultation: Rejected in part. CMS did not commit to considering comments provided through the tribal consultation process, if provided after the 4/2/2012 deadline for comments. CMS stated, "We agree that the Tribal consultation process is valuable in helping us to finalize policies and support Indian health programs. We obtained the advice and input of Tribal officials during the Tribal Technical Advisory Group (TTAG) face-to-face meeting in Washington, DC on February 23, 2012; and under Executive Order 13175 and the CMS HHS Tribal Consultation Policy (November 2011), we consulted with Tribal officials during an All Tribes' Call on March 16, 2012, and through the regulatory review process. In determining our final policies and regulations, we considered all comments received before the close of the comment period (including comments received through Tribal consultations)." [81 FR 5316-7]
			2. Payment Methodologies: Proposed § 447.518 requires the State plan to describe the payment methodology for prescription drugs, including those dispensed by I/T/U pharmacies, provided that the allowable methodologies include reimbursement on the same basis as retail pharmacies and the OMB encounter rate already approved by CMS in a number of State plans; CMS should retain this provision in the final rule but provide clarification regarding	2. Payment Methodologies: Accepted. CMS stated, "We recognize there are unique aspects of dispensing CODs to Al/ANs by I/T/U pharmacies and understand the various concerns expressed through the regulatory comment process Unlike AAC [actual acquisition cost], which is defined in § 447.502, the



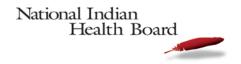
RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
			allowable methodologies to ensure that states do not mistakenly believe that current reimbursement models, such as encounter rates, are not permitted.	encounter rate is more reflective of services provided and is not granular to the extent of identifying the ingredient cost of a drug. Therefore, if a state pays I/T/Us at the encounter rate, it will satisfy the requirements in § 447.518(a)(2), which specifies that the state's payments must be in accordance with the definition of AAC. We have determined that the encounter rate is one model that states may use to reimburse I/T/U pharmacies, given that the rates are designed to address provider costs. It was not our intent in the proposed rule to change the state's authority to reimburse I/T/U pharmacies using the encounter rate, and we believe that nothing in this final rule prevents states from using the encounter rate as a model to reimburse I/T/U pharmacies. We believe that as designed, the current CMS SPA review and approval process which requires states to obtain the advice and input from I/T/Us before making changes to Medicaid reimbursements to I/T/U pharmacies, before CMS approval of the SPA, provides sufficient oversight and input regarding states establishing such pharmacy rates." [81 FR 5316]
			3. Dispensing Fee Calculations : CMS should retain in the final rule the proposed requirement that dispensing fee calculations take into account special circumstances of I/T/U pharmacies.	3. Dispensing Fee Calculations: Accepted in part. CMS stated, "We agree that there may be unique circumstances for 340B covered entities that states should consider when establishing their professional dispensing fees for these providers and that states must express the rationale for the reimbursement methodologies being proposed in their state plans. We also believe that it is important the providers are reimbursed adequately for the



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
				provision of care to beneficiaries. Therefore, we will require states to substantiate how their dispensing fee reimbursement to pharmacy providers, including 340B providers, is consistent with section 1902(a)(30)(A) of the Act. We note that states may decide to use different professional dispensing fee rates for different entities and providers. While we do not mandate any specific professional dispensing fee methodologies that states must use, states are required to provide data which indicates that the methodology is consistent with the regulation and ensures access." [81 FR 5317]
136.e.	Requirements for Reporting Quality Measures ACTION: Request for Information NOTICE: Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs AGENCY: CMS	CMS-3323-NC Issue Date: 12/31/2016 Due Date: 2/1/2016 2/16/2016 NIHB File Date: 2/1/2016 Date of Subsequent Agency Action, if any: Issued due date extension	1. Policy Option 3/Option A: Option 3 would require eligible professional (EP) health IT developers to certify health IT products to more than the current minimum number of clinical quality measures (CQMs) required for reporting, but not to all available CQMs, and within Option 3, Option A would set a minimum number of measures to which health IT developers must certify for the EP settings or eligible hospital/critical access hospital (CAH) settings, with this minimum number greater than the minimum number required for provider reporting; CMS should adopt Option 3/Option A, which provides a benefit to both providers and health IT vendors by meeting the needs of consumers and allowing vendors flexibility to provide a product to meet their targeted consumer population, and should set the minimum number of EP measures at 15 and the minimum number of eligible hospital/CAH measures at 20.	No subsequent Agency action taken (as of 2/29/2016).



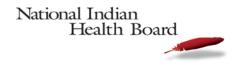
RRIAR Ref. #	Short Title/Current Status of Regulation/ Title/Agency	File Code & Dates	Summary of NIHB and/or TTAG Recommendations	Evaluation of Subsequent Rule Issued/ Action Taken by Agency
		<u>2/2/2016</u>	 Policy Option 1: Option 1 would require EP health IT developers to certify Health IT Modules to all CQMs in the EP selection list and would require eligible hospital/CAH health IT developers to certify to all CQMs in the selection list for eligible hospitals and CAHs; CMS should not adopt Option 1, which would prove impractical because not all measures apply to EPs and eligible hospitals in Indian Country and would lead to an increase in development, testing, and certification time. Policy Option 2: Option 2 would incrementally increase the number of CQMs required to have certification each year until Health IT Modules have certification for all CQMs available for reporting by EPs, eligible hospitals, and CAHs to meet their CQM reporting requirements; although Option 2 provides more time to develop all the measures in which the requirements would become effective beyond the first year, CMS should not adopt this option, as CQM measures that do not apply to the provider population would require maintenance by health IT developers. 	
204.	Medicaid Services "Received Through" an IHS/Tribal Facility ACTION: Request for Information Final Policy NOTICE: Medicaid	CMS (no reference number) SHO #16-002 Issue Date: 10/27/2015 Due Date: 11/17/2015	 TTAG/TSGAC recommendations Paragraph 1Modifying the Second Condition: CMS should a. Retain this proposal (with clarifications). b. Clarify that a service the IHS/Tribal facility can provide includes any service authorized under the Snyder Act, the Transfer Act, the Indian Health Care Improvement Act, the Indian Self-Determination and 	In the 2/26/2016 Final Policy TBE



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
T H S F	Services "Received Through" an Indian Health Service/Tribal Facility: A Request or Comment AGENCY: CMS	TTAG File Date: 11/17/2015; TSGAC also filed comments 11/17/2015 Date of Subsequent Agency Action, if any: Issued Final Policy 2/26/2016	 Education Assistance Act, or other applicable federal law. c. Clarify that services provided pursuant to section 1915 waivers and 1115 demonstrations would qualify under this proposal. d. Implement this proposal in a manner that protects the general 100 percent FMAP rule for Indians in the Medicaid Expansion population. e. Retain and highlight that services covered include "transportation services, as well as emergency transportation (EMT) services and non-emergency transportation (NEMT), including related travel expenses (such as meals, lodgings, and cost of an attendant pursuant to federal and state requirements)." 2. Comments in Response to Paragraph 2Modifying the Third Condition: CMS should a. Retain this proposal (with clarifications). b. Revise the phrase "who provides items or services not within the scope of a Medicaid "facilities services" benefit but within the IHS/tribal facility authority" to ensure that it is not susceptible to an interpretation intended to disqualify Medicaid facilities services benefits and that it expresses clearly the intention for consistency with the policy change proposed in Paragraph 1. c. Rather than requiring a written contract in all cases, allow a written referral providing that, as a condition of accepting the referral, the provider would have to 	



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
			furnish materials and records back to the referring IHS/tribal facility; exclude the phrase "[t]he IHS/Tribal facility would need to retain responsibility for the provision of services, meaning that the IHS/Tribal facility must retain control of the medical records, including updating medical records with information from care provided by contractual agents and providing care coordination for the Al/AN individual" or similar such conditions; and not require that an Al/AN is a "patient" of the IHS/tribal facility. • d. Not suggest that the IHS/tribal facility must "arrange" for the provision of services and clarify that a referral can qualify as "received through" an IHS/tribal facility even if the patient did not first obtain primary care or physical treatment within the four walls of an IHS/tribal facility for a specific referral or episode of care. • e. Clarify that a referral to a contractual agent can occur for a specific treatment, for an episode or care, or as a standing referral. • f. Adopt an approach that gives Tribes in each state the opportunity to work with their states to develop the type of referral arrangement and requirements that best suit the relationship between the IHS/tribal facilities in the state and outside providers. 3. Paragraph 3Modifying the Fourth Condition: CMS should retain this proposal. 4. Paragraph 4Application to Fee-for-Service: CMS should-	



Regulation/ Title/Agency		Action Taken by Agency
	b. Retain and highlight the language it used in its proposal to indicate that "states retain flexibility in establishing economic and efficient payment rates to sufficiently reimburse for the provision of services."	
	 Paragraph 5Application to Managed Care: CMS should- a. Retain this proposal (with clarifications). b. Clarify that the 100 percent FMAP reimbursement applies to capitation payments made for services "received through" IHS/tribal facilities in managed care systems established by state plan amendment or waiver authority. c. Allow states flexibility in ensuring that managed care plans actually pay for services by allowing them continued flexibility to give managed care plans the incentives they need to provide information back to the state to assist them in claiming 100 percent FMAP and flexibility in determining the total estimate of payments made for services "received through" IHS/tribal facilities based on aggregated data, rather than per referral or per encounter data. 	



RRIAR Index: Health Reform¹

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

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
Indian-specific ACA provisions						
Cost-sharing reductions						
Eligibility				7.ccc. (29/ <u>10</u>), 89.a. (/ <u>34</u>), 89.k. (<u>210/42</u>)		
General	7.a. (18/ <u>16</u>), 7.c. (<u>24/67</u>), 7.g. (<u>29/76</u>), 29.a. (<u>70/112</u>)	7.u. (32/12), 50.d. (136/61), 50.h. (68), 89.a. (194/79), 89.b. (195/87), 111.b. (238/96),	31.w. (133/ <u>14</u>), 31.x. (135/ <u>16</u>)	7.ww. (26), 7.xx. (27), 27.n. (97), 89.h. (203/ <u>35</u>)	50.h. (42)	

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

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

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

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



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
Referrals		111.c. (240/ <u>102</u>)		89.l. (<mark>211/<u>48</u>)</mark>		
Definition of Indian	7.a. (18/16), 7.b. (21/22), 7.c. (24/67), 7.d. (26/75)	7.u. (32/12), 31.e. (94/40), 50.d. (136/61), 50.f. (64), 50.h. (68), 89.a. (194/79), 111.b. (238/96)			50.f. (39), 50.h. (42)	
Employer mandate				31.ccc. (136/26)		
Essential community providers	7.a. (18/ <u>16</u>), 7.b. (<u>21/<u>22</u>)</u>	7.i. (19), 7.n. (23/1), 50.c. (135/54), 111.b. (238/96)	7.ee. (29/4), 92.cc. (255)	7.vv. (24/9), 7.ddd. (33), 50.e. (147), 89.h. (203/35), 92.ll. (218/54)	7.kkk. (7), 7.III. (8/ <u>1</u>)	
Exemption from tax penalty		31.e. (94/ <u>40</u>), 31.g. (103/ <u>44</u>), 31.q. (114/ <u>47</u>)	7.mm. (42), 31.v. (133/ <u>13</u>)	7.ww. (26), 89.h. (203/ <u>35</u>)		
Fees	116. (<mark>154</mark>)	89.a. (194/ <u>79</u>)		145.c. (279)		
Implementation of section 402 of IHCIA			50.q. (173), 50.r. (175), 50.x. (179/ <u>30</u>)			
Indian addendum	7.b. (21/ <u>22</u>)	50.c. (135/ <u>54</u>), 111.a. (237/ <u>94</u>), 111.b. (238/ <u>96</u>)	7.ee. (29/ <u>4</u>)	7.vv. (24/ <u>9</u>), 89.h. (203/ <u>35</u>)	7.III. (<mark>8/1</mark>)	
Issuer regulations (Indian-specific concerns)	7.a. (18/ <u>16</u>), 7.b. (21/ <u>22</u>), 7.g. (29/ <u>76</u>)	7.n. (23/ <u>1</u>), 89.a. (<u>194/<u>79</u>), 89.b. (<u>195/<u>87</u>),</u></u>	7.ee. (29/ <u>4</u>), 50.t. (176/ <u>29</u>), 65. (199/ <u>36</u>),	7.vv. (24/ <u>9</u>), 31.pp. (119/ <u>21</u>), 89.h. (203/ <u>35</u>),	7.III. (<mark>8/<u>1</u>)</mark>	



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
		111.a. (237/ <u>94</u>)	92.u. (242/ <u>49</u>), 92.cc. (255)	92.ll. (218/ <u>54</u>), 168. (287/ <u>68</u>)		
Premium sponsorship	7.a. (18/16), 7.b. (21/22), 7.g. (29/76), 29.a. (70/112)	50.d. (136/ <u>61</u>), 111.a. (237/ <u>94</u>), 111.b. (238/ <u>96</u>)	7.b. (3), 7.ee. (29/4), 50.q. (173), 50.r. (175), 50.x. (179/30), 65. (199/36)	7.vv. (24/ <u>9</u>)	7.III. (<mark>8/1</mark>)	
Tribal consultation			64.a. (196/ <u>31</u>), 64.b (198/ <u>33</u>)	64.c. (173/ <u>30</u>)		
Tribal Employer Participation in FEHBP			174.d. (317)			
Tobacco use (ceremonial)		50.d. (136/61), 50.f. (64), 50.h. (68), 92.a. (202/91)			50.f. (39), 50.h. (42)	
1311 Funding for Change orders		67.c. (164)	67.d. (<mark>202</mark>), 67.f. (<mark>203</mark>)	50.bb. (156), 67.g. (176)		
Basic Health Program	39.a. (80/ <u>123</u>)		39.b. (155/ <u>19</u>), 39.c. (157/ <u>23</u>), 39.d. (159)	39.e. (138)	39.f. (33)	
Consumer assistance grants					67.a. (51)	
Consumer Operated and Oriented Plan (CO-OP) Program	12.a. (44), 12.b. (46/ <u>94</u>)	12.c. (58)		12.d. (64), 12.e. (65)	12.f. (<mark>16</mark>)	
Cost-sharing reductions	7.a. (18/ <u>16</u>), 45. (87)	29.f. (89), 50.d. (136/ <u>61</u>), 50.h. (<u>68</u>),	29.g. (107/ <u>12</u>), 29.h. (108), 31.w. (133/ <u>14</u>),	27.n. (97), 89.k. (210/42), 89.l. (211/48),	50.h. (42), 89.g. (59), 89.n. (62)	



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
		50.n. (146), 89.a. (194/ <u>79</u>), 89.b. (195/ <u>87</u>), 89.d. (198), 89.f. (201), 111.c. (240/ <u>102</u>)	50.w (178),	92.uu. (<mark>225</mark>)		
Early retiree reinsurance program		88.a. (193), 88.b. (194)				
Electronic funds transfers	63.a. (113)	63.b. (159)				
Employer requirements (see also Shared responsibility)						
Coverage		31.i. (107), 92.l. (211), 92.m. (212)	92.bb. (254), 92.jj. (266)	31.ccc. (136/ <u>26</u>)	29.d. (29)	
Excise tax				31.ss. (124/22), 31.aaa. (132/26)		
Notices		7.x. (<mark>34</mark>), 7.z. (<mark>36</mark>)				
Reporting		31.k. (108)	31.o. (129), 31.p. (130), 31.z. (137), 31.cc. (142), 31.jj. (148)	31.yy. (130), 31.ccc. (136/ <u>26</u>), 31.eee. (137)		
Self-funded, non-federal governmental plans			92.ee. (259)			
Employer tax credits			31.m. (127), 31.n. (128)			
Essential health benefits						



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					Other Citations
Constant houseful	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
Excepted benefits		31.i. (107)	31.t. (131)	31.00. (117), 31.qq. (122)		
General				31.vv. (127), 31.zz (131)		
Preventive services	31.a. (74/ <u>115</u>), 31.b. (77)	31.c. (<mark>91</mark>), 31.j. (<mark>108</mark>)	31.y. (136), 31.ee. (144), 31.ff. (145)	31.dd. (108), 31.gg. (110), 31.ll. (112), 31.xx. (128)		
Standards	7.g. (29/ <u>76</u>), 31.a. (74/ <u>115</u>), 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		7.0. (26/ <u>3</u>), 7.u. (<u>32/<u>12</u>), 28.c. (<u>84/<u>30</u>)</u></u>	92.u. (<mark>242/<u>49</u>),</mark> 7.00. (44)			
Eligibility and enrollment	7.c. (24/ <u>67</u>), 7.g. (29/ <u>76</u>)	7.s. (30/11), 7.w. (34), 7.aa. (37), 7.cc. (39), 7.dd. (40), 50.d. (136/61), 50.h. (68), 50.k. (143/73)	7.ff. (33), 7.qq. (47), 7.rr. (48), 7.uu. (51), 67.e. (202), 92.dd. (257/ <u>52</u>)	7.eee. (35), 7.hhh. (37), 7.ppp. (45), 92.hh. (215), 92.oo. (220)	50.h. (<mark>42</mark>)	



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
Enrollee satisfaction	7.a. (18/ <u>16</u>)			168. (287 / <u>68</u>)		
Establishment					7.mmm. (<mark>9</mark>), 7.nnn. (<mark>10</mark>)	
General	7.a. (18/ <u>16</u>), 7.b. (21/ <u>22</u>), 7.e. (27)	7.i. (19), 89.c. (198/ <u>89</u>)	7.b. (<u>3</u>), 7.ss. (<u>50</u>) 92.u. (<u>242/49</u>)			
Guidance (other)						
Agent/broker		7.r. (<mark>29</mark>)				
General	7.g. (<mark>29/<u>76</u>)</mark>		31.u. (132)			
Issuer		7.n. (23/ <u>1</u>)	7.ee. (29/ <u>4</u>), 7.gg. (<u>35</u>), 7.hh. (<u>36</u>)	7.vv. (24/9), 7.bbb. (29), 7.rrr (47)	7.III. (<mark>8/1</mark>)	
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/ <u>39</u>), 68. (164)	29.0. (117), 29.p. (118), 31.cc. (142)	7.ddd. (33), 50.e. (147), 89.i. (207)	7.kkk. (7)	
Minimum acceptable risk standards				7.iii. (39)		
Navigators and non-Navigator assistance personnel	7.a. (18/ <u>16</u>)	7.o. (<mark>26/3</mark>), 7.p. (27)	7.00. (44)	7.q. (19), 7.v. (22), 7.kk. (23)		
Out-of-pocket costs				7.ccc. (29/ <u>10</u>)		
Outreach	7.a. (<mark>18/<u>16</u>),</mark>	67.b. (163)	7.pp. (46)			



RRIAR Index: Health Reform¹

Terms		Other Citations				
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
	7.g. (<mark>29/<u>76</u>)</mark>					
Policy-based payments				7.qqq. (<mark>47</mark>)		
Program integrity		7.s. (<mark>30/<u>11</u>)</mark>				
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. (27), 7.aaa. (28), 29.r. (107)		
Stand-alone dental plans		7.u. (<mark>32/<u>12</u>)</mark>		7.l. (18)		
Web portal	7.g. (<mark>29/<u>76</u>)</mark>		65. (199 / <u>36</u>)		7.000. (<mark>11</mark>)	
State-based						
General		7.dd. (40), 50.u. (150)	50.o. (172), 50.s. (175)	7.t. (20)		
Shared responsibility payment exemptions				50.cc. (157)		
State alternative applications		50.k. (143/ <u>73</u>), 50.l. (144)				
Federal Employees Health Benefits Program (FEHBP)		174.a. (323), 174.b. (325)	174.c. (315), 174.d. (317), 174.e. (318)	174.f. (290)		
Health insurance market rules						
Regulations						
90-day waiting period	91.a. (138)		91.b. (231), 91.c. (231)			
Age curves		92.c. (<mark>205</mark>)				
Appeals and external review	90. (138)	128.a. (<mark>259</mark>), 128.b. (<mark>261</mark>),		92.bbb. (232), 128.e. (263),		



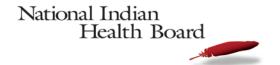
RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C						
	2012 (v.2.12)	2012 (v.2.12) 2013 (v.3.12) 2014 (v.4.12) 2015 (v.5.12) 2016 (v.6.02)					
Contraceptive services		128.c. (261), 128.d. (262) 31.i. (107)	31.y. (136), 31.ee. (144),	128.f. (263) 31.dd. (108), 31.gg. (110),			
			31.ff. (145)	31.ll. (112), 31.nn. (117), 31.xx. (128)			
Cost-sharing limitations				89.j. (207)			
Employer-sponsored insurance verification					54. (49)		
General		92.a. (<mark>202/<u>91</u>)</mark>	92.u. (242/ <u>49</u>), 92.dd. (257/ <u>52</u>) 92.ff. (260)				
Geographic rating areas		92.c. (<mark>205</mark>)					
Grandfathered health plans			92.h. (<mark>234</mark>), 92.n. (237)	92.bbb. (232)	92.e. (65)		
Information reporting		31.k. (108), 31.l. (110), 92.c. (205)	31.aa. (138), 31.cc. (142), 31.ii. (147), 92.g. (232), 145.b. (302),	31.kk. (112), 31.yy. (130), 31.eee. (137), 92.pp. (221), 92.qq. (221), 92.rr. (222), 92.uu. (225), 92.xx. (228), 92.yy. (228)	92.b. (63), 92.ddd. (72)		
Mental health services	31.a. (74 / <u>115</u>)		92.t. (241)	92.zz. (<mark>231</mark>)			
Network/provider issues			92.w. (<mark>249/51</mark>), 92.cc. (<mark>255</mark>),	89.j. (207), 92.ll. (218 / <u>54</u>)			



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C						
	2012 (v.2.12)	2013 (v.3.12)	2013 (v.3.12) 2014 (v.4.12)		2016 (v.6.02)	- Citations	
			145.a. (301)	145.c. (<mark>279</mark>), 145.d. (279)			
PACE Act				50.ee. (159), 92.aaa. (231)			
Preventive services (see Essential health benefits)							
Product modification/withdrawal				92.vv. (<mark>225</mark>)			
Rate review		92.o. (213)	92.g. (232)	92.mm. (218), 92.nn. (219), 92.ss. (223)	92.s. (67), 92.ccc. (71)		
Reference pricing			92.gg. (<mark>261</mark>)				
Same-sex spouses			92.z. (<mark>252</mark>)				
Stop-loss insurance	56. (106)						
Student insurance	51.a. (101)			51.b. (159)	51.c. (<mark>45</mark>)		
Transitional policy			92.x. (<mark>250</mark>), 92.aa. (<mark>253</mark>)				
Unique plan identifiers	77.a. (125)			77.e. (190)			
Notices							
Annual/lifetime limits		92.j. (210)		92.bbb. (232)	92.d. (<mark>64</mark>)		
Coverage (Summary of Benefits and Coverage)		122.c. (254)		31.pp. (119/ <u>21</u>), 31.uu. (126), 31.bbb. (133)	31.tt. (30), 92.kk. (68)		
Enrollment opportunity		92.j. (<mark>210</mark>)		92.v. (215)			
Market discontinuation/renewal		92.f. (207)	92.y. (<mark>251</mark>)	92.ww. (227)			
Patient protection		92.j. (210)	92.k. (236),	92.bbb. (232)	92.d. (64)		



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
			92.r. (238)			
Pre-existing condition exclusion		122.b. (254)		92.bbb. (232)		
Rescission		92.j. (<mark>210</mark>)	92.i. (235), 92.q. (237)	92.bbb. (232)	92.d. (64)	
Special enrollment rights		122.a. (<mark>253</mark>)				
Transition		92.p. (<mark>214</mark>)				
High-risk pools (see Pre-Existing Condition Insurance Plan)						
Issuer Letters (CCIIO)						
2014 Issuer Letter		7.n. (<mark>23/<u>1</u>)</mark>				
2015 Issuer Letter			7.ee. (29/ <u>4</u>)			
2016 Issuer Letter				7.vv. (<mark>24/<u>9</u>)</mark>		
2017 Issuer Letter					7.III. (<mark>8/<u>1</u>)</mark>	
Marketplaces (see Exchanges)						
Medical loss ratio						
General requirements	48.a. (96)	48.d. (131), 48.g. (133), 89.a. (194/ <u>79</u>)	48.e. (169)	27.n. (97), 48.h. (145), 48.i. (145)	48.b. (36)	
Medicare Parts C and D		48.c. (131), 48.f. (132)				
Medicaid/CHIP						
Application of essential health benefits	31.a. (74 / <u>115</u>)					
Community First Choice Option	16.a. (49/ <u>100</u>)					
Eligibility/enrollment under ACA	7.a. (<mark>18/<u>16</u>),</mark> 7.c. (<mark>24/<u>67</u>),</mark>	28.a. (82/ <u>24</u>), 28.c. (84/ <u>30</u>)	28.e. (104)			



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
	7.g. (<mark>29/<u>76</u>)</mark>					
Federal Medical Assistance Percentage rates		28.d. (<mark>85/<u>38</u>)</mark>				
Medicare						
Accountable Care Organization standards	10.b. (138/ <u>82</u>)					
Federally Qualified Health Center payments			159.b. (310/ <u>60</u>)			
Minimum essential coverage		31.e. (94/ <u>40</u>), 31.q. (<u>114/<u>47</u>), 31.s. (<u>117</u>)</u>	29.m. (113), 31.p. (130), 31.x. (135/16), 92.aa. (253)	31.rr. (123)		
Multi-State Plan Program		111.a. (237/94), 111.b. (238/96), 111.c. (240/102), 111.d. (241)		111.e. (240)	111.f. (74)	
Nondiscrimination		99.b. (221/ <u>94</u>), 111.b. (238/ <u>96</u>)		181.b. (291/ <u>72</u>)		
Notice of Benefit and Payment Parameters						
2014		89.a. (194/ <u>79</u>), 89.b. (195/ <u>87</u>)	7.bb.(28)			
2015			89.e. (225)			
2016				89.h. (203/ <u>35</u>)		
2017					89.m. (<mark>61</mark>)	
Patient-Centered Outcomes Research Trust Fund	116. (<mark>154</mark>)					
Pre-Existing Condition Insurance Plan	6.a. (16/ <u>15</u>), 6.b. (17)	6.c., (17), 6.d. (18), 6.e. (18),	6.g. (22), 6.h. (22)		6.i. (6)	



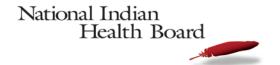
RRIAR Index: Health Reform¹

Tormo		Other				
Terms	Red = Table B Blue = Table B 2012 (v.2.12) 2013 (v.3.12) 2014 (v.4.12)			= Table C 2015 (v.5.12)	2016 (v.6.02)	Citations
	, ,	6.f. (19)	, ,	,	, ,	
Premium tax credits						
General	29.a. (70 /112)	29.b. (86), 29.c. (87), 29.f. (89), 50.d. (136/61), 50.h. (68), 50.n. (146)	29.g. (107/ <u>12</u>), 29.h. (108), 29.j. (109), 29.k. (110), 29.l. (113), 29.m. (113), 50.w. (178)	29.q. (106), 92.uu. (225)	29.d. (29), 50.h. (42),	
Relation to cost-sharing reduction eligibility				89.a. (/ <u>34</u>)		
Prescription drug fee			198.a. (347), 198.b. (347)	198.c. (306)		
Qualified health plans						
Accreditation	50.b. (98)	31.d. (93), 50.j. (142)		7.bbb. (29), 7.rrr (47)		
Actuarial value	45. (87)	31.d. (93), 89.a. (194/79), 89.b. (195/ <u>87</u>)	31.hh. (147), 92.aa. (253), 92.ii. (264)	31.mm. (114)	31.ddd. (31)	
Enrollee satisfaction				168. (287/ <u>68</u>)		
Essential community providers	7.a. (18/ <u>16</u>), 7.b. (21/ <u>22</u>)	7.i. (19), 7.n. (23/1), 50.c. (135/54), 111.b. (238/96)	7.ee. (29/4), 92.cc. (255)	7.ddd. (33), 50.e. (147)	7.kkk. (7)	
General	7.b. (<mark>21/<u>22</u>)</mark>	50.p. (147),	7.b. (<u>3</u>)			



RRIAR Index: Health Reform¹

Terms	RRIAR Entry Numbers (Page Numbers) ² Red = Table B Blue = Table C					
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
Guaranteed availability Network adequacy Quality improvement/rating system State evaluation Third-party payments	7.a. (18/16), 7.b. (21/22), 7.g. (29/76), 29.a. (70/112)	89.c. (198/ <u>89</u>) 50.i. (142)	92.aa. (253) 50.t. (176/ <u>29</u>) 50.q. (173), 50.x. (179/ <u>30</u>), 50.y. (182)	92.tt. (224)	7.jjj. (6)	
Reinsurance, risk corridors, and risk adjustment	7.a. (18/16), 27.a. (65/104)	27.b. (77), 27.d. (79), 27.e. (80)	27.c. (100), 27.f. (101), 27.g. (102), 27.h. (102), 27.j. (104)	27.i. (93), 27.k. (94), 27.l. (95), 27.m. (96), 27.n. (97), 27.o. (98), 27.p. (98), 27.q. (98), 27.r. (100), 27.s. (100), 27.t. (101)	27.u. (28)	
Shared responsibility payments Employers		31.k. (108)	31.f. (120)	31.ccc. (136/26)		
Exemptions		31.e. (106) 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),	50.cc. (157)		



RRIAR Index: Health Reform¹

Terms		Other Citations				
	2012 (v.2.12)	2013 (v.3.12)	2014 (v.4.12)	2015 (v.5.12)	2016 (v.6.02)	Citations
			31.v. (133/ <u>13</u>), 31.bb. (139/ <u>18</u>),			
Individuals		31.g. (103/ <u>44</u>), 31.r. (116)	31.x. (135/ <u>16</u>)			
Small Business Health Options Program (SHOP)						
Aggregation of premiums			50.z. (183)			
Direct Enrollment				50.bb. (156)		
General	7.c. (<mark>24/<u>67</u>)</mark>	7.s. (30/11), 7.dd. (40), 50.f. (64), 50.g. (66), 89.c. (198/89)	7.ee. (29/ <u>4</u>), 50.z. (183)	7.vv. (24/9), 7.hhh. (37), 50.dd. (159)	7.III. (8/1), 50.f. (39), 50.g. (41), 50.aa. (44)	
State alternative applications		50.m. (145)				
Waivers for state innovation	14.a. (<mark>49/<u>98</u>)</mark>			14.b. (<mark>66</mark>)	14.c. (16/ <u>1</u>)	
Wellness programs		99.a. (220)	99.c. (<mark>269</mark>)	99.d. (233), 99.e. (235)		

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

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

RRIAR			
Number	Action	Short Title	Agency
7.iii.	Guidance	FAQ on Minimum Acceptable Risk Standards for Exchanges	CCIIO
7.jjj.	Request for Comment	Establishment of QHPs and Exchanges	CMS
7.kkk.	Notice	ECP Petition for 2017	CCIIO
7.III.	Guidance	2017 Letter to Issuers in FFMs	CCIIO
7.mmm.	Request for Comment	Establishment of an Exchange by a State and QHPs	CMS
7.nnn.	Request for Comment	Establishment of Exchanges and QHPsStandards for Employers	CMS
7.000.	Request for Comment	CMS Healthcare.gov Site Wide Online Survey	CMS
7.ppp.	Guidance	Unaffiliated Issuer Enrollments and 2016 Reenrollment in FFMs	CCIIO
7.qqq.	Guidance	Policy-Based Payments: Approach for 2016	CCIIO
7.rrr.	Guidance	Key Dates for CY 2016: QHP Certification in the FFM, et al.	CCIIO
10.b.	Final Rule	ACO Standards	CMS
12.a.	Request for Comment	Co-Op Plans (Section 1322 of ACA)	CCIIO (OCIIO)
12.b.	Final Rule	Co-Op Plans (Section 1322 of ACA)	CMS
12.c.	Guidance	CO-OP Program Contingency Fund	CCIIO
12.d.	Request for Comment	Consumer Operated and Oriented Program	CMS
12.e.	Guidance	CO-OP Program Guidance Manual	CCIIO
12.f.	Guidance	FAQs on the CO-OP Program	CCIIO
14.a.	Final Rule	ACA Waivers for State Innovation	Treasury/CMS
14.b.	Guidance	Fact Sheet/FAQs on Section 1332 State Innovation Waivers	CCIIO
14.c.	Notice	Waivers for State Innovation	CMS/Treasury
16.a.	Final Rule	New Medicaid Community First Choice Option	CMS
27.a.	Final Rule	Risk Adjustment Standards in ACA	CMS
27.b.	Guidance	HHS Risk Adjustment Model Algorithm	CCIIO
27.c.	Request for Comment	Reinsurance, Risk Corridors, and Risk Adjustment Standards	CMS
27.d.	Guidance	HHS-Developed Risk Adjustment Model Algorithm	CCIIO
27.e.	Guidance	Reinsurance Enrollment Count	CCIIO
27.f.	Guidance	Risk Corridors and Budget Neutrality	CCIIO
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 ProgramTiming of Refunds	CCIIO
27.m.	Guidance	Transitional Adjustment for 2014 Risk Corridors Program	CCIIO

RRIAR			
Number	Action	Short Title	Agency
27.n.	Guidance	CSR Amounts in Risk Corridors and MLR Reporting	CCIIO
27.0.	Guidance	Risk Corridors Program Results	CCIIO
27.p.	Guidance	FY 2016 ICD-10 Crosswalk for HHS Risk Adjustment Model	CCIIO
27.q.	Guidance	Adjustment of Risk Adjustment Transfers	CCIIO
27.r.	Guidance	Early Reinsurance Payments for the 2015 Benefit Year	CCIIO
27.s.	Guidance	HHS-Developed Risk Adjustment Model Algorithm Software	CCIIO
27.t.	Guidance	Risk Corridors Payments for the 2014 Benefit Year	CCIIO
27.u.	Guidance	Transitional Reinsurance Program Collections for 2015	CCIIO
28.a.	Final Rule	Medicaid Eligibility Under ACA	CMS
28.c.	Final Rule	Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, etc.	CMS
28.d.	Final Rule	Increased FMAP Changes Under ACA	CMS
28.e.	Request for Comment	Medicaid Implementation Advanced Planning Document	CMS
29.a.	Final Rule	Premium Subsidies and Tax Credits	IRS
29.b.	Final Rule	Health Insurance Premium Tax Credit	Treasury
29.c.	Request for Comment	Health Insurance Premium Tax Credit	IRS
29.d.	Final Rule	Minimum Value of Eligible Employer-Sponsored Plans	IRS
29.e.	Final Rule	Information Reporting for Exchanges	IRS
29.f.	Guidance	IRS Ruling 2013-17 and Advance Premium Tax Credits	CCIIO
29.g.	Request for Comment	Payment Collections Operations Contingency Plan	CMS
29.h.	Guidance	Verification of Income for Tax Credits and Cost Sharing	HHS
29.i.	Guidance	Victims of Domestic Abuse	CCIIO
29.j.	Final/Temporary Rule	Rules Regarding the Health Insurance Premium Tax Credit	IRS
29.k.	Proposed Rule	Rules Regarding the Health Insurance Premium Tax Credit	IRS
29.I.	Guidance	Determining the Deduction for the Premium Tax Credit	IRS
29.m.	Guidance	Revisions to Calculating the Premium Tax Credit, et al.	IRS
29.n.	Notice	Premium Tax Credit	IRS
29.0.	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

National Indian Health Board RRIAR Number Reference Guide: Health Reform UPDATED THROUGH 2/29/2016

RRIAR			
Number	Action	Short Title	Agency
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
31.0.	Final Rule	Health Insurance Coverage Reporting by Large Employers	IRS
31.p.	Final Rule	Minimum Essential Coverage Reporting	IRS
31.q.	Request for Comment	Exchange Functions: Eligibility for Exemptions	CMS
31.r.	Guidance	Shared Responsibility Provision	CCIIO
31.s.	Guidance	Obtaining Recognition as Minimum Essential Coverage	CCIIO
31.t.	Final Rule	Amendments to Excepted Benefits	IRS/DoL/CMS
31.u.	Guidance	Options Available for Consumers with Cancelled Policies	CCIIO
31.v.	Guidance	Instructions for the Application for Indian-Specific Exemptions	CMS
31.w.	Guidance	Q&A on Cost-Sharing Reductions for Contract Health Services	CCIIO
31.x.	Final Rule	MEC and Other Rules on the Shared Responsibility Payment	IRS
31.y.	Guidance	Disclosure with Respect to Preventive Services	CCIIO
31.z.	Notice	Reporting on Employer Health Insurance Offer and Coverage	IRS
31.aa.	Notice	Reporting on Health Coverage by Insurers	IRS
31.bb.	Notice	Health Coverage Exemptions	IRS
31.cc.	Request for Comment	Application for Filing ACA Information Returns	IRS
31.dd.	Final Rule	Coverage of Certain Preventive Services Under ACA	IRS/DoL/CMS
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 700Certification	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.II.	Request for Comment	Data Submission for the FFE User Fee Adjustment	CMS

RRIAR			
Number	Action	Short Title	Agency
31.mm.	Guidance	2016 Actuarial Value Calculator	CCIIO
31.nn.	Request for Comment	Notification of Objection to Covering Contraceptive Services	CMS
31.00.	Final Rule	Amendments to Excepted Benefits	IRS/DoL/CMS
31.pp.	Final Rule	Summary of Benefits and Coverage and Uniform Glossary	IRS/DoL/CMS
31.qq.	Guidance	FAQ About Excepted Benefits	CCIIO
31.rr.	Guidance	Minimum Essential Coverage Application Review Process	CCIIO
31.ss.	Guidance	Excise Tax on High Cost Employer Health Coverage	IRS
31.tt.	Request for Comment	Summary of Benefits and Coverage and Uniform Glossary	DoL
31.uu.	Guidance	ACA Implementation FAQs (SBC)	CCIIO
31.vv.	Guidance	EHBs: List of the Largest Three Small Group Products by State	CCIIO
31.xx.	Guidance	ACA Implementation FAQs (Preventive Services)	CCIIO
31.yy.	Guidance	ACA Information Returns Reference Guide	IRS
31.zz.	Guidance	EHB Benchmark Plans for 2017 and Beyond	CCIIO
31.aaa.	Guidance	Excise Tax on High Cost Employer Health Coverage	IRS
31.bbb.	Guidance	SBC Online Posting of Documents	CCIIO
31.ccc.	Letters to IRS	Relief from ACA Employer Mandate on Tribes	TSGAC
31.ddd.	Guidance	2017 Actuarial Value Calculator	CCIIO
31.eee.	Guidance	Extension of Due Dates for 2015 Information Reporting	IRS
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
39.f.	Final Methodology	Basic Health Program: Federal Funding Methodology for 2017	CMS
45.	Guidance	Actuarial Value and Cost-Sharing	CMS
48.a.	Final Rule	Medical Loss Ratio Requirements	CMS
48.b.	Request for Comment	Medical Loss Ratio Rebate Calculation Report and Notices	CMS
48.c.	Final Rule	MLR Requirements for Medicare Part C and Part D	CMS
48.d.	Guidance	Medical Loss Ratio Reporting and Rebate Requirements	CCIIO
48.e.	Final Rule	Computation of MLR	IRS
48.f.	Request for Comment	Medical Loss Ratio Report for MA Plans and PDPs	CMS
48.g.	Guidance	Medical Loss Ratio Reporting and Rebate Requirements	CCIIO
48.h.	Guidance	Q&A on MLR Reporting and Rebate Requirements	CCIIO
48.i.	Guidance	Q&A on MLR Reporting and Rebate Requirements for 2014	CCIIO

RRIAR			
Number	Action	Short Title	Agency
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
50.0.	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
50.dd.	Guidance	FAQs on Agents and Brokers Operating in SHOP	CCIIO
50.ee.	Guidance	FAQs on the Impact of PACE Act on State Small Group Expansion	CCIIO
51.a.	Final Rule	Student Insurance Coverage	CMS
51.b.	Guidance	FAQ on Rate Review of Student Health Plans	CCIIO
51.c.	Guidance	Application of Market Reforms to Student Health Coverage	CCIIO
54.	Notice	ESI Coverage Verification	CMS
56.	Request for Information	Stop-Loss Insurance	IRS/DoL/CMS

RRIAR			
Number	Action	Short Title	Agency
63.a.	Interim Final Rule	Health Care EFT Standards	HHS
63.b.	Request for Comment	Electronic Funds Transfers Authorization Agreement	CMS
64.a.	Notice	Policy on Conferring with Urban Indian Organizations	IHS
64.b.	Notice	CMS Tribal Consultation Policy	CMS
64.c.	Notice	Tribal Consultation Policy	Treasury
65.	Request for Comment	Health Care Reform Insurance Web Portal Requirements	CMS
67.a.	Request for Comment	State Consumer Assistance Grants	CMS
67.b.	Request for Comment	Research on Outreach for Health Insurance Marketplace	CMS
67.c.	Guidance	Use of 1311 Funding for Change Orders	CCIIO
67.d.	Guidance	Use of 1311 Funds and No Cost Extensions	CCIIO
67.e.	Guidance	Consumer Assistance for Marketplace Enrollment	CCIIO
67.f.	Guidance	Use of 1311 Funds, et al.	CCIIO
67.g.	Guidance	FAQs on Use of 1311 Funds for Establishment Activities	CCIIO
68.	Request for Comment	Security of Electronic Health Information	CMS
77.a.	Final Rule	Unique Plan Identifiers	CMS
77.e.	Request for Information	Requirements for the Health Plan Identifier	CMS
88.a.	Request for Comment	Early Retiree Reinsurance Program Survey	CMS
88.b.	Notice	Early Retiree Reinsurance Program	CMS
89.a.	Final Rule	Notice of Benefit and Payment Parameters for 2014	CMS
89.b.	Interim Final Rule	Amendments to the Notice of Benefit and Payment Parameters	CMS
89.c.	Final Rule	Small Business Health Options Program	CMS
89.d.	Request for Comment	Cost-Sharing Reductions Reconciliation Methodology	CMS
89.e.	Final Rule	Notice of Benefit and Payment Parameters for 2015	CMS
89.f.	Guidance	Choice of Methodology for Cost-Sharing Reduction Reconciliation	CCIIO
89.g.	Request for Comment	Cost Sharing Reduction Reconciliation	CMS
89.h.	Final Rule	Notice of Benefit and Payment Parameters for 2016	CMS
89.i.	Request for Comment	Information Collection for Machine-Readable Data for QHPs	CMS
89.j.	Guidance	ACA Implementation FAQs (Cost-Sharing Limitations)	CCIIO
89.k.	Letter to CCIIO	Eligibility Determinations for Indian-Specific CSVs	TTAG
89.1	Request for Information	Referrals for Cost-Sharing Protections Under Limited CSVs	CMS
89.m.	Final Rule	Notice of Benefit and Payment Parameters for 2017	CMS
89.n.	Guidance	Manual for Reconciliation of Advance Payment of CSRs	CCIIO
90.	Guidance	Adverse Benefit Determinations	CCIIO
91.a.	Guidance	Waiting Period Limitation Under Public Health Service Act	CCIIO

RRIAR			
Number	Action	Short Title	Agency
91.b.	Final Rule	Waiting Period Limitation and Coverage Requirements	IRS/DoL/CMS
91.c.	Final Rule	Waiting Period Limitation	IRS/DoL/CMS
92.a.	Final Rule	Health Insurance Market Rules	CMS
92.b.	Request for Comment	Compliance with Individual and Group Market Reforms	CMS
92.c.	Guidance	Age Curves, Geographical Rating Areas, and State Reporting	CMS
92.d.	Request for Comment	Patient Protection Notices and Disclosure Requirements	CMS
92.e.	Request for Comment	Disclosure and Recordkeeping for Grandfathered Health Plans	CMS
92.f.	Guidance	Model Language for Individual Market Renewal Notices	CMS
92.g.	Request for Comment	Reporting for Grants to Support Health Insurance Rate Review	CMS
92.h.	Request for Comment	Disclosure and Recordkeeping for Grandfathered Health Plans	DoL
92.i.	Request for Comment	ACA Notice of Rescission	Treasury
92.j.	Request for Comment	Enrollment Opportunity Notice Relating to Lifetime Limits	Treasury
92.k.	Request for Comment	ACA Notice of Patient Protection	IRS
92.l.	Guidance	Application of ACA Provisions to HRAs, Health FSAs, et al.	IRS/DoL
92.m.	Guidance	Application of ACA Provisions to Certain Healthcare Arrangements	CCIIO
92.n.	Request for Comment	Rules for Group Health Plans Related to Grandfather Status	IRS
92.0.	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

National Indian Health Board RRIAR Number Reference Guide: Health Reform UPDATED THROUGH 2/29/2016

RRIAR			
Number	Action	Short Title	Agency
92.gg.	Guidance	FAQs About ACA Implementation (Reference Pricing)	CCIIO
92.hh.	Request for Comment	Annual Eligibility Redetermination Notices, et al.	CMS
92.ii.	Guidance	Group Plans that Fail to Cover In-Patient Hospitalization Services	CCIIO
92.jj.	Guidance	ACA Implementation (Premium Reimbursement Arrangements)	CCIIO
92.kk.	Request for Comment	Summary of Benefits and Coverage and Uniform Glossary	CMS
92.II.	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
92.00.	Guidance	Eligibility Redeterminations for Marketplace Coverage	CCIIO
92.pp.	Guidance	ACA Reporting Requirements for Health Coverage Providers	IRS
92.qq.	Guidance	Evaluation of EDGE Data Submissions	CCIIO
92.rr.	Guidance	EDGE Data Submission Grace Period	CCIIO
92.ss.	Guidance	Rate Review Requirements in States with SBMs	CCIIO
92.tt.	Request for Comment	QIS Implementation Plan and Progress Report	CMS
92.uu.	Guidance	Information Distribution on PTCs and CSRs for FFM Coverage	CCIIO
92.vv.	Guidance	FAQs on Uniform Modification and Plan/Product Withdrawal	CCIIO
92.ww.	Guidance	Standard Notices of Product Discontinuation and Renewal	CCIIO
92.xx.	Guidance	FAQ on Transparency Reporting for Non-QHP Coverage	CCIIO
92.yy.	Request for Comment	Transparency in Coverage Reporting by QHP Issuers	CMS
92.zz.	Guidance	FAQs on the Impact of PACE Act on State Small Group Expansion	CCIIO
92.aaa.	Guidance	FAQs on ACA and Mental Health Parity Implementation	CCIIO
92.bbb.	Final Rule	Final Rules for Grandfathered Plans, Preexisting Condition Exclusions, et al.	IRS/DoL/CMS
92.ccc.	Guidance	Rate Filing Justifications for 2016 for Single Risk Pool Coverage	CCIIO
92.ddd.	Guidance	Evaluation of EDGE Data Submissions for 2015	CCIIO
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

RRIAR			
Number	Action	Short Title	Agency
111.d.	Notice	New System of Records (MSP Program)	OPM
111.e.	Final Rule	Establishment of Multi-State Plan Program for Exchanges	OPM
111.f.	Request for Comment	Mental Health Parity Rules: External Review for MSPP	IRS
116.	Final Rule	Fees for the Patient-Centered Outcomes Research Trust Fund	Treasury
122.a.	Request for Comment	Special Enrollment Rights Under Group Health Plans	DoL
122.b.	Request for Comment	Pre-Existing Condition Exclusion Under Group Health Plans	DoL
122.c.	Request for Comment	Creditable Coverage Under Group Health Plans	DoL
128.a.	Request for Comment	ACA Internal Claims and Appeals and External Review Procedures	CMS
128.b.	Guidance	State External Review Process for Health Plans	CCIIO
128.c.	Guidance	County Level Estimates Related to CLAS Standards Under ACA	CCIIO
128.d.	Request for Comment	ACA Internal Claims and Appeals and External Review Disclosures	IRS
128.e.	Guidance	Electing a Federal External Review Process	CCIIO
128.f.	Request for Comment	ACA Internal Claims and Appeals and External Review Procedures	DoL
145.a.	Final Rule	Health Insurance Providers Fee	IRS
145.b.	Request for Comment	Report of Health Insurance Provider Information	IRS
145.c.	Proposed Rule	Health Insurance Providers Fee	IRS
145.d.	Final/Temporary Rule	Health Insurance Providers Fee	IRS
159.b.	Final Rule	Medicare PPS for Federally Qualified Health Centers, et al.	CMS
168.	Request for Comment	Enrollee Satisfaction Survey Data Collection	CMS
169.	Request for Comment	Health Care Sharing Ministries	CMS
174.a.	Final Rule	FEHBP: Members of Congress and Congressional Staff	OPM
174.b.	Final Rule	FEHBP: Coverage of Children	OPM
174.c.	Final Rule	FEHBP: Eligibility for Temporary and Seasonal Employees	OPM
174.d.	Guidance	New Flexibility for Tribal Employer Participation in FEHBP	OPM
174.e.	Final Rule	FEHBP Miscellaneous Changes: Medically Underserved Areas	OPM
174.f.	Final Rule	FEHBP: Rate Setting for Community-Rated Plans	OPM
181.b.	Final Rule	Nondiscrimination Under ACA	HHS OCR
198.a.	Final/Temporary Rule	Branded Prescription Drug Fee	IRS
198.b.	Proposed Rule	Branded Prescription Drug Fee	IRS
198.c.	Request for Comment	Branded Prescription Drug Fee	IRS