National Indian Health Board

Regulation Review and Impact Analysis Report v. 8.01

PURPOSE:

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), if any, and indicates the extent to which the recommendations made by NIHB were incorporated into any subsequent CMS actions.

I. Regulations with pending due dates for public comments-

- Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for Potential CMS Innovation – Comments due 9/24/2018 (Ref. #1)
- Dear Tribal Leader Letter on behalf of the Acting Director pertaining to Tribal Leaders and Urban Indian Organization Leaders to provide an update on Indian Health Service regulatory reform activities – Comment period forthcoming (Ref. #9)
- The Substance Abuse and Mental Health Services Administration (SAMHSA) invites you to participate in a virtual Tribal Consultation session regarding implementation of the Confidentiality of Substance Use Disorder Patient Records regulations (42 CFR Part 2 or Part 2). The purpose for this Tribal Consultation is to elicit your input concerning the effect of 42 CFR Part 2 on patient care, health outcomes, and patient privacy – Comments due 9/14/2018 directly to SAMHSA at tribalconsultation@samsha.hhs.gov
- The Acting Director writes to Tribal Leaders to initiate Tribal Consultation on proposed updates to the Sanitation Deficiency System – A Guide for Reporting Sanitation Deficiencies for American Indian and Alaska Native Homes and Communities – Comment period extended 9/14/2018 (Ref #10)

II. Comments recently submitted by NIHB, TTAG, and/or other Tribal organizations-

- Medicare Program; Request for Information Regarding the Physician Self-Referral Law – Submitted 8/24/2018 (Ref. #3)
- Dear Tribal Leader Letter Initiating Tribal Consultation on the funding mechanism to distribute behavioral health initiatives that are currently distributed through grants – Submitted 8/17/2018 (Ref #7)
- Comments on Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (CMS-10401/OMB control number (CMS-10401/OMB control number 0938-1155) – Submitted 3/9/2018. (Ref #17)
- Comment on proposed rulemaking - Department of Health and Human Services, Office for Civil Rights RIN 0945–ZA03 – Submitted 3/27/2018. (Ref #16)
- Executive Office of the President of the United States Delivering Government Solutions in the 21st Century Reform Plan and Reorganization Proposals – Submitted to MMPC 8/13/2018 (Ref #6)
- Comments on DTLL - Tribal Consultation on SDPI Funding Distribution for FY 2019—Submitted 5/18/2018 (Ref #14)
- Comments 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, RIN 0906-AB18—Submitted 5/22/2018 (Ref #13)
- Comments on Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Systems and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of claims (CMS-1694-P)—Submitted on 6/25/2018 (Ref #1)
- Comments on DTLL - PRC Chapter Update Tribal Consultation—Submitted 7/6/2017 (Ref #11)

- Comments on Request for information regarding the Patient Protection and Affordable Care Act: Reducing Regulatory Burdens and Improving Health Care Choices to Empower Patients (CMS-9928-NC)—Submitted on 7/12/17 (Ref #27)
- Comments on Wisconsin Badger Care Reform Application—Submitted on 7/15/2017 (Ref #26)
- Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (0991-ZA49)—Submitted on 7/16/2018 (Ref #5)
- Comments on Notice of Request for Information Regarding Health Care Access Standards—Submitted on 7/30/2018 (Ref #4)
- Comments on Medicare Program: CY 2018 Updates to the Quality Payment Program Proposed Rule (CMS-5522-P)—Submitted on 8/21/2017 (Ref #25)
- Comments on RPMS from NIHB—Submitted 8/30/2017
- Comments on "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program" (CMS-1676-P)—Submitted on 9/11/2017 (Ref #23)
- Comments on Department of Health & Human Services Draft Strategic Plan for FY 2018-2022—Submitted 10/26/2017 (Ref #22)
- Comments on IHS Strategic Plan 2018-2022—Submitted 10/31/2017 (Ref #21)
- Comments on RFI: Centers for Medicare & Medicaid Services: Innovation Center New Direction—Submitted 11/20/2017 (Ref #20)
- Comments on U.S. Food and Drug Administration: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments, Docket No. FDA-2017-N-5608—Submitted on 12/21/2017 (Ref #19)

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

- Employee Benefits Security Administration (EBSA) Definition of "Employer" Under Section 3(5) of ERISA-Association Health Plans – Comments due 8/20/2018
- Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program – Comments due 9/10/2018 (Ref. #2)

IV. Recent final rules issued-

- Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) – Effective 10/1/2018 (Ref. #1).
- 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, RIN 0906-AB18 – Further delay of Effective date 7/1/2019 (Ref. #13)

RRIAR TABLE: Listing, Summary, and Analysis Report on Regulations Reviewed (July 2017-September 2018)

Ref. #	Short Title/Current Status of Regulation/Agency/File Code	Dates (Issued, Due, Action)	Brief Summary of Proposed Agency Action	Summary of NIHB and/or TTAG Recommendations	NIHB Analysis
1.	**Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs)** ACTION: Final Rule AGENCY: CMS FILE CODE: CMS 1694-F	Published: 8/17/2018 Effective: 10/1/2018	• The final rule is effective October 1, 2018 and revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from continuing experiences with these systems for FY 2019. • These revisions also reflect changes to Medicare graduate medical education (GME) affiliation agreements for new urban teaching hospitals. • Effective January 1, 2019, CMS will update its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate. • Additionally, CMS is updating policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.	• NIHB provided comments on the proposed rule: CMS 1694-P on June 25, 2018. • In terms of the Hospital Acquired Conditions (HAC) measures, NIHB recommends that CMS establish an exclusion for low volume hospitals, or further refine the methodology to achieve the desired result and accurately depict performance of rural hospitals. Patient Safety and Adverse Events (PSI-90). NIHB asserts that the PSI-90 is a deeply flawed measure and should be reviewed as a whole. • Moreover, NIHB recommend that Indian Health Service and Tribal Hospitals should be made eligible to receive Medicare funding for residence programs in regards to the GME section of the proposed rule. • It is critically important to note that beneficiaries of the Indian health system do not have to pay for care that they receive from IHS, Tribal, and urban Indian health programs. Since IHS and Tribal hospitals do not charge its patients for services it would be extremely difficult for Indian health providers to develop fee for service schedules that private hospitals maintain in the course of their day to day operations. Therefore it would not be appropriate to require Indian health providers to comply with the price transparency requirements. It would also be very confusing to beneficiaries of the Indian health system to see such	• Upon review and subsequent analyses of CMS 1694-F (effective 10/1/18); in relation to the HAC measures, CMS is not finalizing their proposals to remove any of the six patient safety measures, with PSI-90 being one of those measures. CMS further stated they are not finalizing their proposal to remove the Safety domain from the Hospital Value-Based Purchasing (VBP) Program, as they are not finalizing their proposals to remove all of the measures in that domain, therefore CMS is not finalizing changes to the domain weighting. • CMS agreed that small sample sizes may have negative implications for hospital quality measures (e.g. HACs) due to limited sample sizes and ultimately limit the statistical reliability of reporting by race or other sociodemographic measures and that they are not consistently captured in claims.

				information since our patients are accustomed to not pay for services when they go to an IHS or Tribally-operated hospital. NIHB recommended that the proposed rule exempt Indian health providers from any of the price transparency requirements included at section X. (*Requirements for Hospitals to Make a List of Their Standard Changes via the Internet*)	Therefore, CMS will continue to examine how best to improve the collection of such data. • In regards to GME, this item was addressed in the final rules' ***Out of Scope Public Comments section:*** • "Indian Health Service and Tribal Hospitals be made eligible to receive Medicare funding for residency training programs; CMS felt comments related to the aforementioned item were out of scope for the proposal included in the FY'19 IPPS/LTCH PPS proposed rule." • According to CMS, the prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. As stated within CMS 1694-F, "*There were 29 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment*

					methodology for these hospitals."
2.	**Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: CMS-1693-P RIN: 0938-AT31	Published: 7/27/2017 Due Date: 9/10/2018	• The CY 2019 Medicare Physician Fee Schedule Proposed Rule with comment period was placed on display at the Federal Register on July 27, 2018. This proposed rule updates payment policies, payment rates, and other provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after Jan. 1, 2019. • This proposed rule proposes potentially mis-valued codes, adds procedures to the telehealth list and other policies affecting the calculation of payment rates. This proposed rule includes a number of new proposals, including a proposal to change documentation, coding and payment to reduce administrative burden and improve payment accuracy for office/outpatient Evaluation and Management visits, and a proposal to pay separately for two newly defined physicians' services furnished using communication technology		
3.	**Medicare Program; Request for Information Regarding the Physician Self-Referral Law** ACTION: Request for Information AGENCY: CMS, HHS FILE CODE: CMS-1720-NC RIN: 0938-AT64	Published: 6/25/2018 Due Date: 8/24/2018	• The Department of Health and Human Services (HHS) is working to transform the healthcare system into one that pays for value. Care coordination is a key aspect of systems that deliver value. Removing unnecessary government obstacles to care coordination is a key priority for HHS. To help accelerate the transformation to a value-based system that includes care coordination, HHS has launched a Regulatory Sprint to Coordinated Care, led by the Deputy Secretary. This Regulatory Sprint is focused on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care. • The Centers for Medicare & Medicaid Services (CMS) has made facilitating coordinated care a top priority and seeks to identify ways in which its regulations may impose undue burdens on the healthcare industry and serve as obstacles to coordinated care and its efforts to deliver better value and care for patients. Through internal discussion and input from external stakeholders, CMS has	-NIHB has stated the physician self-referral law, commonly known as the "Stark law," and its accompanying regulations pose unique challenges and direct barriers to the delivery of quality care to American Indians and Alaska Natives. As a result, NIHB strongly encourages CMS to create new exceptions that are consisted with the United States' trust responsibility to Tribes and take into account the uniqueness of the Indian Health Care system. On February 27, 2012, the TTAG submitted comments on the Office of Inspector General's (OIG) annual solicitation for proposals to develop or modify safe harbor provisions under the anti-kickback statute (OIG–120–N) in which the TTAG suggested a number of new Tribal safe harbors. -NIHB deemed those recommendations submitted on 2/27/2012 to	

			identified some aspects of the physician self-referral (aka Stark Law) law as a potential barrier to coordinated care therefore addressing unnecessary obstacles to coordinated care, whether they be real or perceived, caused by the physician self-referral law is one of CMS's goals in this Regulatory Sprint. For CMS to inform their efforts to assess and address the impact and burden of the physician self-referral law, including whether and, if so, how it may prevent or inhibit care coordination.	be in line with the current RFI. They include: - **42 C.F.R. § 1001.952(k). Waiver of beneficiary coinsurance and deductible amounts.** There is currently a safe harbor for reduction or waiver of Medicare or State health care program beneficiary's obligation to pay coinsurance or deductibles. Such a safe harbor encourages access to health care that an individual might otherwise forego. We believe this safe harbor should be extended to AI/ANs eligible for IHS services. - **42 C.F.R. § 1001.952(z). New Safe Harbor for Indian health care providers.** Four new safe harbors are provided for under this new paragraph. - **New 42 C.F.R. § 1001.952(z)(1) Exchanges among Indian health care providers.** The first safe harbor directed at Indian health care providers is aimed at authorizing exchanges or transfer of value among Indian health care providers. - **New 42 C.F.R. § 1001.952(z)(2). Transfers from an Indian health care provider to an Indian eligible for or receiving the services of that provider.** - **New 42 C.F.R. § 1001.952(z)(3). Sharing Arrangements.** The proposed safe harbor regarding sharing arrangements is intended to ensure that sharing medical care facilities and resources among Indian health care providers and other health care providers is encouraged. - **New 42 C.F.R. § 1001.952(z)(4). Support of Indian health care providers.** This safe harbor, which is fleshed out in the greatest detail, is modeled after the safe harbor provided to Federally	

				Qualified Health Centers ("FQHCs") in 42 C.F.R. § 1001.952(w). The Indian health system is a real-world embodiment of the FQHC mission as articulated by the OIG. Of particular concern: - *Patient freedom of choice among health care providers.* - *Competition among health care providers.* - *The potential overutilization of health care services. (Even with the flexibility afforded by a safe harbor, I/T/Us will still face dramatic financial shortfalls and will not suddenly begin authorizing or performing frivolous or unnecessary procedures upon receiving a safe harbor.)* - *The existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account their decisions whether to (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider.*	
4.	**Notice of Request for Information Regarding Health Care Access Standards** ACTION: Request for Information (RFI) AGENCY: VA	Published: 6/29/2018 Due Date: 7/30/2018	• The Department of Veterans Affairs (VA) is requesting information to assist in implementing section 1703B of title 38, United States Code (U.S.C.), as added by section 104(a) of the John S. McCain III, Daniel K. Akaka, and	• NIHB submitted comments on 2018-13952 on July 30, 2018. • NIHB also provided context to discern the	One item looked for is reimbursement for PRC and is not in new agreement and a cause for concern. How do we address

	FILE CODE: 2018-13952		Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 (the VA MISSION Act) which directs VA to establish access standards for furnishing hospital care, medical services, and extended care services to covered veterans for purposes of the Veterans Community Care Program. • In establishing these access standards, VA is required to consult with all pertinent Federal, private sector, and non-governmental entities. VA requests information from the public regarding the development of these access standards, including but not limited to information with regard to health plans on the use of access standards for the design of health plan provider networks, referrals from network providers to out-of-network providers, the appeals process for exemptions from benefit limits to out-of-network providers, and the measurement of performance against federal or state regulatory standards. • With regard to health systems, VA requests information from the public including but not limited to the existence of standards for appointment wait times, the use of travel distance for establishing service areas, the development or use of guidelines to refer patients to out of system providers, and the measurement of performance against federal or state regulatory standards. Responses to this notice will support industry research and VA's evaluation of access standards.	differences between the IHS and VA. • It is critical that AI/ANs Veterans not be unintentionally neglected and that they have access to the best care possible, whether that is through the Indian health care system or through the VA. Unfortunately, many AI/AN Veterans do not have faith and trust in the VA after past experiences and delays in enrollment, denial of care, or lack of access to VA services. As a result, Tribal memoranda of agreements (MOAs) and engagement with the Tribal health system, including the Indian Health Service, Tribes, and Tribal organizations, as well as urban Indian organizations (I/T/Us), provides a method for the federal government and agencies to preserve and build on the existing relationships that the VA has with IHS and Tribal Health Programs (THPs). • NIHB made note that care coordination issues could arise for AI/AN Veterans. One such instance is that the VA currently reimburses IHS and THPs for primary care under the IHS/VA Memorandum of Understanding (MOU), but the VA has not provided reimbursement for specialty and referral care provided by IHS/THPs. • NIHB recommends that Section 405(c) of the Indian Health Care Improvement Act be fully implemented and that the VA provide reimbursement for specialty care provided through referrals from IHS and THPs. • Further, the Veterans' Administration should similarly exempt AI/AN Veterans from copays and deductibles in the VA system in recognition of	since there is lack of tertiary and specialty care throughout Indian Country? (I/T/U's) Expansion of caregivers outside VA and look into better care coordination through networks in the MISSION Act.

				the federal trust responsibility. • NIHB recommends that the VA provide additional outreach and advocacy resources to ensure that AI/AN Veterans are aware of various health care benefits available in their community. NIHB supports VA efforts to expand access to medical care in Indian Country and for other rural areas using telehealth.	
5.	**HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs** ACTION: Policy Statement/RFI AGENCY: CMS FILE CODE: 0991-ZA49	Published: 5/16/2018 Due Date: 7/16/2018	Through this request for information (RFI), HHS seeks comment from interested parties to help shape future policy development and agency action. As part of President Trump's bold plan to put American patients first, the Department of Health and Human Services has developed a comprehensive blueprint that addresses many of the challenges and opportunities impacting American patients and consumers. The blueprint covers multiple areas including, but not limited to: • Improving competition and ending the gaming of the regulatory process, • Supporting better negotiation of drug discounts in government-funded insurance programs, • Creating incentives for pharmaceutical companies to lower list prices, and, • Reducing out-of-pocket spending for patients at the pharmacy and other sites of care. HHS also recognizes that achieving the goal of putting American patients first will require interagency collaboration on pharmaceutical trade policies that promote innovation, and are transparent, nondiscriminatory, and increase fair market access for American innovators. Furthermore, HHS seeks to identify when developed nations are paying less for drugs than the prices paid by Federal health programs, and correct these inequities through better negotiation.	-NIHB addressed their comments on the Policy Statement/RFI based on four key strategies in the blueprint: -**Improved Competition** In a scenario where a patient has Part D Coverage and is only covered by one specific drug by their Part D plan, we believe there would actually be a decrease in competition, not an increase. -The Blueprint calls for developing proposals to stop Medicaid and Affordable Care Act programs from raising prices in the private market. According to our constituents, the Affordable Care Act required an increase in rebates paid to Medicaid and extended this to Medicaid Managed Care Organizations. This could have caused drug manufacturers to increase the Average Wholesale Price (AWP), which also increased prices across the board. NIHB recommends looking into this cause-and-effect. -**Better negotiation** In relation to Value-based purchasing in federal programs not all EHRs are able to perform the attachment of a diagnosis code to a prescription. This may lead to increased Prior Authorizations that will cause an admin burden on providers/pharmacists. PBMs may not be a good	

				idea to have as oversight of diagnosis codes. -NIHB agrees with allowing more substitution in Medicare Part D to address price increases for single source generics. -The Blueprint proposes to send a report to the President on whether lower prices on some Medicare Part B drugs could be negotiated for by Part D plans. NIHB believes this would probably increase collections. It would also change the workflow of how Part B drugs are dispensed and billed versus how Part D drugs are dispensed and billed. -**Incentives for Lower List Prices** -The Blueprint proposes reforms to the 340B drug discount program. NIHB strongly urges caution on any changes to the 340B program. The 340B program is hugely important to Tribal health programs, which are severely underfunded and face with enormous need. Both the 340B and the VA prime vendor discount program are the two primary ways that Tribes and Tribal organizations purchase prescription drugs at a discount -NIHB and Tribes promote collaboration with HHS to develop this comprehensive blueprint that addresses many of the challenges and opportunities impacting American patients and consumers.	
6.	**Executive Office of the President of the United States Delivering Government Solutions in the 21st Century Reform Plan and Reorganization Proposals** ACTION: Notice, Report AGENCY: Executive Office of the President	Notice: 6/21/2018 Published: 8/13/2018 by NIHB	• Executive Order (EO) 13781, entitled "Comprehensive Plan for Reorganizing the Executive Branch," highlights the need to evaluate the organizational constructs that support today's mission delivery objectives. Building on a history of bipartisan Government reform initiatives, the EO focuses specifically on the role of organizational alignment in reducing "duplication and redundancy," and improving "efficiency, effectiveness, and accountability of the executive branch.	The Federal and Congressional Departments at NIHB recommended the Government Reform and Reorganization document and the accompanying sections be delegated to various members of the aforementioned departments with the intent of summarizing and contextualizing.	-NIHB only focused on the areas that would have direct impact on Tribal health. Areas that directly impact Tribal Health: -Consolidate Non-Commodity Nutrition Assistance Programs into HHS, Rename HHS the Department of Health and Public

					Welfare, and Establish the Council on Public Assistance - Reorganize Federal Food Safety Functions into a Single Agency, the Federal Food Safety Agency - U.S. Public Health Service Commission Corps - Strengthening Federal Evaluation (Government Wide) - Reorganizing Economic Statistical Agencies **Areas that tangentially affect Tribal health** -Moving USDA Housing Programs to HUD: Tribes get funding from the USDA's Rural Development Block Grant (RDBG), which would be moved to HUD. RDBG also funds non-housing projects for Tribes, so HUD may not be the best-suited to handle those projects. - Government-wide transition to electronic government: National Archives and Records Administration (NARA) has the authority to set record-keeping practices for federal agencies. Through the Federal Records Act, NARA is setting a deadline to stop accepting paper records by December 31, 2022. While IHS is not mentioned in the proposal, its Health IT Modernization effort will most likely be impacted by this transition.

					-Merging the National Marine Fisheries Service (NMFS) with the U.S. Fish and Wildlife Service (FWS) has a direct impact on Indian Country due to historical issues regarding fishing rights for various Tribes, but does not directly relate to Tribal health. The merger would combine fishing and wildlife management into one part of the Bureau of Indian Affairs (BIA), which could potentially free up some money in the Bureau's budget. **Conclusion** NIHB will continue to monitor these efforts and keep Tribes apprised of changes that occur through the Executive Branch or if they evolve through Congress.
7.	**Dear Tribal Leader Letter Initiating Tribal Consultation on the funding mechanism to distribute behavioral health initiatives that are currently distributed through grants** ACTION: Notice of Extension of Comment Period AGENCY: IHS	Published: 5/18/2018 Due Date: 8/17/2018	• The Consolidated Appropriations Act, 2018 Explanatory Statement encourages the Indian Health Service (IHS) to transfer behavioral health initiative funding through Indian Self-Determination and Education Assistance Act (ISDEAA) contracts and compacts rather than through grants. Currently, the total funding amount appropriated for all Agency behavioral health initiatives is $59.2 million. Of this total amount, the IHS funds approximately $51.9 million through grants and Federal awards that includes $5.9 million for Urban Indian Organizations. The remaining $7.3 million supports IHS National Management. The IHS Division of Behavioral Health will host a series of virtual learning sessions to further explain how the behavioral health initiative funding is distributed through grants, including a devoted session on IHS National Management. I encourage you to participate in this learning series that occurs prior to the formal Tribal Consultation and Urban	-NIHB provided comments in response to the DTLL in relation to IHS Behavioral Health Funding Resolution 18-15 "Support for National Behavioral Health Technical Assistance and Supportive Services" and was subsequently certified and adopted by the Board with quorum present on August 15, 2018 by an affirmative vote of 5 FOR and 1 AGAINST (Nashville Area).	-Concerns arose with the way in which the DTLL was written, more specifically the topic: "Advocacy and raising national awareness and visibility (National Indian Health Board, National Council of Urban Indian Health Cooperative agreement funding and support)." This description does not adequately describe NIHB's cooperative agreement with the agency and is effectually misleading. -NIHB also receives funding through the

			Confer sessions. Please see the enclosed schedule for additional information on the virtual learning series. • During the formal Tribal Consultation and Urban Confer sessions, I invite you to provide feedback on all topics related to our behavioral health grants. However, there are few topics that I ask for your specific input on and those are listed here: • Distribution methodologies (e.g., national funding formula that is used as a standard; national formula and Area formulas that vary depending on the input of Tribes for that region; base funding for all Tribes, Tribal Organizations, or Urban Indian Organizations; funding for only those Tribes, Tribal Organizations, or Urban Indian Organizations that currently receive funding and add Tribes with new funding/increases); • Funding formulas (e.g., Tribal Size Adjustment, User Population, Disease Burden, Poverty, etc.); • Funding for Urban Indian Organizations; • Impact on current grantees • Funding mechanism (grants, cooperative agreements, ISDEAA contracts, or compacts). • Demonstrating effectiveness (e.g., data collection, evaluation, establishing national outcomes; Tribal Epidemiology Center funding for technical assistance, evaluation; etc.); and • Advocacy and raising national awareness and visibility (National Indian Health Board, National Council of Urban Indian Health cooperative agreement funding and support).		National Indian Health Outreach and Education (NIHOE) Cooperative Agreement with IHS to provide training and technical assistance services and resources to Tribes addressing behavioral health challenges in addition to hosting national behavioral health conferences. NIHB also provides technical assistance to Tribal leaders appointed to the HIS National Tribal Advisory Committee on Behavioral Health. The aforementioned funding provisions are vital to fulfilling the advocacy and raising national awareness through the cooperative agreement, therefore its importance is paramount in achieving a collective voice on behalf of the 573 Tribes recognized in Indian Country.
8.	**Medicaid/CHIP Program; Medicaid Program and Children's Health Insurance Program (CHIP); Changes to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs in Response to the Affordable Care Act; Correction** ACTION: Notice AGENCY: CMS FILE CODE: CMS-6068-F2 RIN: 0938-AS74	Published: 5/3/2018 Effective Date: 8/04/2018	• Technical error that is identified and corrected in this correcting document. Inadvertently omitted the removal of § 431.802, discussed on page 31161 of the final rule.		
9.	**Dear Tribal Leader Letter on behalf of the Acting Director pertaining to Tribal Leaders and Urban Indian Organization Leaders to provide an update on Indian Health Service regulatory reform activities.**	Published: 7/23/2018 Due Date: TBD	• In 2017, President Donald Trump issued two Executive Orders directing Federal departments and agencies to manage costs associated with Federal regulations and establish regulatory reform task forces to evaluate existing regulations and identify those that		

			should be repealed, replaced, or modified: • Executive Order 13771 – Reducing Regulation and Controlling Regulatory Costs • Executive Order 13777 – Enforcing the Regulatory Reform Agenda While the IHS is not seeking to consult or confer on a specific regulatory matter at this time, the IHS has developed a Stakeholder Engagement Plan as a tool to promote participation, coordination, and transparency among stakeholders regarding regulatory reform activities. The Stakeholder Engagement Plan outlines the requirements of the communications efforts to reach and inform all stakeholders.		
10.	**The Acting Director writes to Tribal Leaders to initiate Tribal Consultation on proposed updates to the Sanitation Deficiency System – A Guide for Reporting Sanitation Deficiencies for American Indian and Alaska Native Homes and Communities** ACTION: Notice of Extension of Comment Period AGENCY: IHS – Office of Environmental Health and Engineering, Division of Sanitation Facilities Contruction	Published: 7/2/2018 Due Date: 9/14/2018	• Tribal Consultation on proposed updates to the attached Indian Health Service (IHS) Sanitation Deficiency System (SDS) - A Guide for Reporting Sanitation Deficiencies for American Indian and Alaska Native Homes and Communities (commonly known as the "SDS Guide"). • June 2018 Final Draft for Tribal Consultation*The Secretary shall submit a report which sets forth the level of sanitation deficiency for each sanitation facilities project of each Indian tribe or community, and the amount of funds necessary to raise all Indian tribes and communities to a level I sanitation deficiency or to zero sanitation deficiency. --from Public Law 94-437, Section 302(g)* • A business day comment period has been extended, beginning July 2, 2018 through September 14, 2018.	An e-mail blast was sent to members of the MMPC Workgroup on 8/2/2018 indicating the extension of the deadline.	
11.	**Dear Tribal Leader Letter (DTLL) initiating Tribal consultation on changes to the Indian Health Manual (the "Manual"), Part 2, Chapter 3 "Services to Indians and Others" (also known as "Purchased/Referred Care" or "PRC") (the "PRC Chapter")** ACTION: Notice AGENCY: IHS	Published: 5/18/2018 Submitted: 7/6/2018	Tribal Consultation on the Indian Health Service (IHS) Indian Health Manual (IHM), Part 2 – "Services to Indians and Others, Chapter 3 – Purchased/Referred Care" at the request of Tribes. Tribal Consultation on the Purchased/Referred Care Chapter Update will consist of the following: • A 30-business day Comment Period, through July 6, 2018; Notice of Extension (7/6) of Deadline changed to August 6, 2018. • Two All Tribes Conference Calls; and • A face-to-face, in-person Tribal Consultation to gather input and recommendations from you on updates or revisions you would recommend for the Purchased/Referred Care Chapter Update.	-A redline draft of the Draft PRC Chapter has been provided at: https://www.ihs.gov/prc/draft-prc-chapter-of-the-ihm/ This redline document highlights the recommendations made on behalf of NIHB.	NIHB encourages the IHS to meet with Tribal Workgroups and technical advisors to hear and incorporate their recommendations before issuing a DTLL, particularly on detailed matters such as this. In addition, NIHB request that IHS utilize the PRC Workgroup to review the comments submitted during this consultation to develop a revised draft PRC chapter

					that will go out for Tribal consultation before being finalized. NIHB released comments in relation to the following areas within the PRC manual: -Definitions related to legal vs. Agency definitions. -Payor of Last Resort Requirements -PRCDAs and the Process for Re-designation -Eligibility Requirements -Tribal Appeals Process -Notification of a Claim -NIHB also provided recommendations for the clarification of "Referrals" and "Authorizations". -Other issues include: In Section 2-3.9(3), Authorization for PRC, the IHS appears to place a mandate on the Centers for Medicare and Medicaid Services (CMS). The IHS cannot govern the activities of the CMS. If there is an agreement between the IHS and the CMS recognizing that the CMS will take these actions, the IHS should reference it in this section.

12.	**Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates, et al., CMS-1694-P** Action: Proposed Rule Agency: CMS,HHS FILE CODE: CMS-1694-P	Published: 5/7/2018 Due Date: 6/25/2018	CMS proposed to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2019. Some of these proposed changes implement certain statutory provisions contained in the 21st Century Cures Act and the Bipartisan Budget Act of 2018, and other legislation. We also are proposing to make changes relating to Medicare graduate medical education (GME) affiliation agreements for new urban teaching hospitals. In addition, CMS proposed to provide the market basket update that would apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2019. We are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2019. In addition, we are proposing to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs). CMS proposed to establish new requirements or revise existing requirements for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (now referred to as the Promoting Interoperability Programs). In addition, we are proposing changes to the requirements that apply to States operating Medicaid Promoting Interoperability Programs. CMS proposed to update policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. CMS also proposed to make changes relating to the required supporting documentation for an acceptable Medicare cost report submission and the supporting information for physician certification and recertification of claims.	-NIHB provided comments to CMS on June 25, 2018 submitted recommendations in relation to the following topics in the proposed rule: -***Hospital Acquired Conditions Measures:*** NIHB expressed concerns over the potential impact of proposed alternative scoring methodologies for calculating total Hospital Acquired Conditions scores. Small rural, hospitals have scores that are low because they had less than 1.0 predicted infections for all other measures which resulted in 85% of their HAC score and a two year penalty. In the rule, CMS proposes to either, remove the domains and weight all measures equally, or to limit the maximum Domain 2 weight from 85% to 60% when only one Domain 2 measure is scored. However, rural hospitals will still be penalized. Therefore, NIHB recommends the review of the PSI-90 measure as a whole and its presence in any kind of payment reform. -In light of this, NIHB recommend that CMS establish an exclusion for low volume hospitals, or further refine the methodology to achieve the desired result and accurately depict performance of rural hospitals. -***Graduate Medical Education:*** -NIHB recommends that Medicare funding be eligible for IHS and Tribal hospitals so there is a funding stream for residency programs and could boast to be a more powerful recruitment and retention tool which is needed in Indian Country.	

				-Requirements for Hospitals to Make Public List of Standard Charges: -Effective January 1, 2019, CMS will update its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate. To address this, CMS is considering ways to improve the accessibility and usability of the charge information that hospitals are required to disclose under section 2718(e) of the Public Health Service Act. -NIHB feels it is critically important to note that beneficiaries of the Indian health system do not have to pay for care that they receive from IHS, Tribal, and urban Indian health programs. Since IHS and Tribal hospitals do not charge its patients for services it would be extremely difficult for Indian health providers to develop fee for service schedules that private hospitals maintain in the course of their day to day operations.	
13.	**340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation** ACTION: Final Rule AGENCY: HRSA, HHS	Published: 6/5/2018 Due Date: Effective Date: 7/1/2019	• The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), known as the "340B Drug Pricing Program" or the "340B Program." HRSA published a final rule on January 5, 2017, that set forth the calculation of the ceiling price and application of civil monetary penalties. The final rule applied to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. • On May 7, 2018, HHS solicited comments on further delaying the effective date of the January 5, 2017, final rule to July 1, 2019. HHS proposed this action to allow a more deliberate process of considering	-NIHB provided comments on the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation in May 2018. -NIHB reminded Health Resources and Services Administration (HRSA) that in terms of the 340B program, an FQHC is defined as including "an outpatient health program or facility operated by a Tribe or Tribal organization under the Indian Self-Determination and Education Assistance Act … or by an urban Indian	

			alternative and supplemental regulatory provisions and to allow for sufficient time for any additional rulemaking. After consideration of the comments received on the proposed rule, HHS is delaying the effective date of the January 5, 2017, final rule, to July 1, 2019.	organization receiving funds under title V of the Indian Health Care Improvement Act … for the provision of primary health services." 42 U.S.C. § 1396d (l) (2) (B) (iv). -NIHB reminded HRSA that access to the 340B program is critically important for AI/ANs and if there are instances where manufacturers are shorting Tribal health programs funds, there must be adequate civil monetary penalties in place to ensure that every monetary amount that is due to the Tribal health program is paid. -Additionally, NIHB provided comments relating to are concerning any regulatory action that could affect the purposes of the 340B program and reduce the ability of Tribes and Tribal organizations to provide much-needed care to their patients. Therefore, before any final rule is implemented, we request Tribal consultation per Executive Order 13175.	
14.	**The Acting Director writes to Tribal Leaders to initiate a Tribal Consultation on the distribution of funding for the Special Diabetes Program for Indians in Fiscal year 2019.** ACTION: Notice AGENCY: IHS	Published: 4/13/2018 Due Date: 5/14/2018	RADM Weahkee initiated a Tribal Consultation on the distribution of funding for the Special Diabetes Program for Indians (SDPI) in fiscal year (FY) 2019. The SDPI has been funding diabetes treatment and prevention activities in Tribal, Urban Indian, and Indian Health Service (IHS) health programs since FY 1998. The Tribal Leaders Diabetes Committee (TLDC) recommended that Tribal Consultation on the distribution of SDPI funding for FY 2019 be conducted in all 12 IHS Areas. Tribal Leader input is welcome on any aspect of the SDPI, but would be especially helpful in response to the following questions: 1. Should there be any changes in the SDPI national funding distribution? If so, in what way? Currently, the SDPI funding distribution is as follows: • Community-Directed grant program $130.2 million	-NIHB provided comments on the DTLL on May 18, 2018. -NIHB communicated they are disappointed in the President's FY 2019 Budget Request to Congress proposed to move SDPI out of mandatory funding and into a discretionary funding, could lessen SDPI as a priority compared to other IHS programs leading to decreased funding and program instability (NIHB Resolution 18-07) -NIHB recommended that IHS hold an in-person consultation session(s) to provide for effective participation and meaningful dialogue.	

			• Urban Indian Health Programs $ 8.5 million • SDPI Support $6.1 million • Data Infrastructure Improvement $5.2 million 2. The SDPI Data Infrastructure Improvement funds provide important support for SDPI at the national, Area, and local levels. The funding supports diabetes data collection, validation, and analytics, as well as associated training and support systems. Should there be any changes in the SDPI Data Infrastructure Improvement funding allocation? If so, how could SDPI Data Infrastructure Improvement funds be allocated to better support local grant related data and infrastructure needs by SDPI grantees?	- NIHB recommended that no changes be made to the Community-Directed grant program or the Urban Indian Health Program for FY2019. NIHB does recommend that IHS increase transparency and accountability for Data Infrastructure Improvement Funds. While NIHB acknowledges that the infrastructure to support high-quality diabetes data must be met through a variety of agreements, licenses and contracts, - NIHB recommended that IHS establish and require performance and accountability measures for entities supporting local, regional and national data related to SDPI programs. This includes regular Area level performance measures and reporting. This will ensure transparency, accountability, and assist Tribes in determining how to best use funds to support their Diabetes program. -NIHB further recommends that annual reports be provided to the Tribal Leaders Diabetes Committee (TLDC) to ensure Tribal Leaders are informed of the return on investment of important data infrastructure improvement dollars. -In order to use data infrastructure funds efficiently and effectively, NIHB recommended that a portion of the FY19 data infrastructure improvement funds be allocated to conduct a program-level, Area level and national level data infrastructure needs assessment.	
15.	**Request for Modifications to Marketplace Application Process to Prevent Loss of Comprehensive Indian-Specific Cost-Sharing Protections for AI/ANs**	Published: 4/18/2018 Effective: 4/18/2018	• TTAG provided a letter to the Director of the Center for Consumer Information and Insurance Oversight at the Centers for Medicare and Medicaid Services after the TTAG quarterly meeting between TTAG	-TTAG raised concerns regarding the cost-sharing reductions (CSRs) afforded to them under the ACA while enrolling in health	The IHS TSGAC letter outlined the following: - TSGAC believes that more effective

	ACTION: Notice AGENCY: CCIIO, CMS		representatives and CMS staff held February 21-22, 2018.	plans through the Marketplace. -In response, TTAG supplemented their letter with recommendations provided by the IHS Tribal Self-Governance Advisory Committee (TSGAC). The TSGAC letter was dated 4/10/2018.	communication is needed to prevent enrollment of AI/ANs who are eligible for the comprehensive Indian-specific CSRs into the same Marketplace plan as family members who are not eligible, as this would block access to these protections for AI/ANs. - TSGAC urges the Tribal Technical Advisory Group (TTAG) to work with CMS to modify notification script(s) that appear during the Marketplace (HealthCare.gov) application process to provide improved notice of the special rule for family policies to AI/AN Marketplace enrollees. Specifically, this notice should explain the rationale for providing AI/AN Marketplace applicants with the option to enroll family members in the same or different plans and should clearly indicate the impact of enrolling family members in the same plan (*i.e.*, the loss of eligibility for the comprehensive CSRs for all AI/AN family members). -TSGAC requests TTAG to work with CMS to encourage Marketplaces that do not use the HealthCare.gov platform to include a similar notice in their application processes.

16.	**Department of Health and Human Services, Office for Civil Rights RIN 0945–ZA03** ACTION: Proposed Rule AGENCY: OCR, HHS FILE CODE: 2018-01226	Published: 1/26/2018 Due Date: 3/27/2018	• In the regulation of health care, the United States has a long history of providing conscience-based protections for individuals and entities with objections to certain activities based on religious belief and moral convictions. Multiple such statutory protections apply to the Department of Health and Human Services (HHS, or the Department) and the programs or activities it funds or administers. The Department proposes to revise regulations previously promulgated to ensure that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate, in violation of such Federal laws. • Through this rulemaking, the Department proposes to grant overall responsibility to its Office for Civil Rights (OCR) for ensuring that the Department, its components, HHS programs and activities, and those who participate in HHS programs or activities comply with Federal laws protecting the rights of conscience and prohibiting associated discriminatory policies and practices in such programs and activities. • In addition to conducting outreach and providing technical assistance, OCR will have the authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by the Department and its components, and use enforcement tools otherwise available in civil rights law to address violations and resolve complaints. • In order to ensure that recipients of Federal financial assistance and other Department funds comply with their legal obligations, the Department will require certain recipients to maintain records; cooperate with OCR's investigations, reviews, or other enforcement actions; submit written assurances and certifications of compliance to the Department; and provide notice to individuals and entities about their conscience and associated anti-discrimination rights, as applicable.	-NIHB provided comments to OCR, the Office of the Secretary at HHS on March 27, 2018. -NIHB applauded the efforts taken on behalf of the Department in terms of the rulemaking process and how there is no substitute for direct Tribal Consultation. -NIHB recommended that OCR remain in compliance with EO 13175 in the formulation and implementation of policies and to defer to Tribes when establishing standards.	As with any other Executive Department Agency, HHS has a duty and responsibility to ensure that the laws it administers are implemented in a manner that respects Congress' authority to enact Indian-specific legislation that fulfills its unique trust responsibility to Indian Tribes and Indian people. As the Supreme Court has recognized, Congress' authority to authorize Indian specific programs in furtherance of the trust relationship is subject to rational basis review, and will not be subject to claims of discrimination under strict scrutiny under Title VI of the Civil Rights Act or otherwise.
17.	**Agency Information Collection Activities: Proposed Collection; Comment Request** ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-10401	Published: 1/8/2018 Due Date: 3/9/2018	This notice sets out a summary of the use and burden associated with the following information collections. *CMS–10401 Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment* Type of Information Collection Request: Revision of a previously approved collection; Title of Information	NIHB commented on two issues related to the Indian-specific cost-sharing protections available to certain American Indians and Alaska Natives (AI/ANs) enrolled through a Marketplace.	

			Collection*: Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment*; Use: The data collection and reporting requirements described below will be used by HHS to run the permanent risk adjustment program, including validation of data submitted by issuers, on behalf of States that requested HHS to run it for them. Risk adjustment is one of three (3) market stability programs established by the Patient Protection and Affordable Care Act and is intended to mitigate the impact of adverse selection in the individual and small group health insurance markets inside and outside of the Health Insurance Exchanges. HHS will also use this data to adjust the payment transfer formula for risk associated with high-cost enrollees. State regulators can use the reporting requirements outlined in this collection to request a reduction to the statewide average premium factor of the risk adjustment transfer formula, beginning for the 2019 benefit year, and thereby avoid having to establish their own programs. Issuers and providers can use the alternative reporting requirements for mental and behavioral health records described herein to comply with State privacy laws.	-First, NIHB commented on health insurance reporting of enrollee-level data related to the permanent risk adjustment program, particularly, in determining the adjustment for the receipt of cost-sharing reductions (CSRs) in the Federal risk adjustment model (referred to as the "induced utilization factor"). -Second, NIHB highlighted the potential for the costs of the Indian-specific cost-sharing protections to be shifted to Marketplace enrollees—including eligible AI/ANs themselves—due to the elimination of direct Federal funding of the CSRs and proposes modifying the Federal risk adjustment model to help address this concern. NIHB requests that CMS continue to require Qualified Health Plan (QHP) issuers to submit individual, enrollee-level data on the usage of CSRs. The NIHB further asks that CMS make any future adjustments to the induced utilization factor based on enrollee-level data to capture the great variation in the degree to which some AI/ANs access the Indian specific CSRs. In addition, the NIHB urges CMS to consider modifying the Federal risk adjustment model, either through the induced utilization factor or through some other mechanism, to account for the loss of CSR payments to issuers for the Indian-specific CSRs for AI/AN enrollees.	
18.	**Dear Tribal Leader Letter (DTLL) on the recently released Dear State Medicaid Director (SMD: 18-002) letter, entitled RE: Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries** ACTION: Notice AGENCY: IHS	Published: 1/17/2018 Due Date: 2/14/2018	-Within this DTLL, former CMS Director Brian Neale stated that CMS could not approve exempting IHS beneficiaries from Section 1115 Demonstration waivers that impose mandatory Medicaid work and community engagement requirements because of civil rights concerns. In addition, on that same day on January 17th, in a meeting with the Department of Health and Human Services' Secretary's Tribal	-NIHB/TTAG reminded CMS on February 14, 2018why Tribes have been opposed to Medicaid Work Requirements and disagree with OCRs interpretation thereof. NIHB attached a memo drafted by Hobbs-Strauss to better illustrate this point. These include why CMS has the	

			Advisory Committee (STAC), former CMS Director Neale indicated that the Office of Civil Rights objected to such an exemption because of their interpretation that an exemption could not be given on the basis of "race."	authoritative stance to issue an exemption for IHS beneficiaries that does not raise OCR concerns. -The supplemental memo outlined the following points: I. Indian Tribes are political, sovereign entities to which the federal government owes a trust responsibility II. The Federal Government May Lawfully Carry Out Its Trust Responsibility By Singling Out Indians and Indian Tribes for Special Treatment III. The Civil Rights Act and the Affordable Care Act do not prohibit the federal government from carrying out its trust responsibility to provide Indians and Indian tribes with healthcare IV. Congress and the Department of Health and Human Services May Lawfully Create Indian Specific Programs to Help Fulfill the United States' Trust Responsibility to Provide for the Health Care of Indians V. CMS and HHS Have A Duty to Accommodate Indian Interests in Administering Federal Statutes VI. Exempting Indians from Work and Community Engagement Requirements is Lawful and Necessary In conclusion, CMS has a duty to ensure that AI/ANs are not subjected to State-imposed work requirements that would present a barrier to their participation in the Medicaid program. CMS should withdraw those provisions in Director Neale's January 17, 2018 letter that assert that CMS lacks the authority to make such accommodations for IHS beneficiaries. CMS not only has ample legal	

				authority to make such accommodations, it has a duty to require them.	
19.	**U.S. Food and Drug Administration: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments** ACTION: Notice, Request for Comments AGENCY: FDA, HHS FILE CODE: FDA-2017-N-5608	Published: 9/29/2017 Due Date: 12/28/2017	• The FDA established a public docket to solicit suggestions, recommendations, and comments from interested parties, including patients and patient representatives, health care professionals, academic institutions, regulated industry, and other interested organizations, on questions relevant to FDA's newly established Opioid Policy Steering Committee (OPSC). • FDA is especially interested in hearing from interested parties in three key areas: What more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions; what steps can FDA take with respect to dispensing and packaging (*e.g.,* unit of use) to facilitate consistency of and promote appropriate prescribing practice; and should FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?	-NIHB provided background contextualization December 21, 2017 regarding the detrimental effects of the opioid epidemic. Toward that end, the following recommendations were outlined: -Assessing Benefit and Risk in the Opioids Setting -Steps to Promote Proper Prescribing and Dispensing -Requirements for Prescriber Education -Request for Further Tribal Consultation as outlined in EO 13175 which requires all federal agencies to engage in meaningful, robust consultation with Tribes and Tribal organizations prior to enacting policies that may have implications for Indian Country.	- On May 23, 2017, the Food and Drug Administration (FDA) Opioid Policy Steering Committee (OPSC) was established to explore and develop additional approaches or strategies FDA can use to combat the opioid crisis. The Committee is comprised of senior FDA leaders as designated by the Commissioner and resides in the Office of Medical Products and Tobacco (OMPT) in the Office of the Commissioner.
20.	**Centers for Medicare & Medicaid Services: Innovation Center New Direction** ACTION: Request for Information (RFI) AGENCY: CMS FILE CODE: CMS-1676-P	Published: 11/20/2017 Due Date: 9/20/2017	In September 2017, CMS released a Request for Information (RFI) to collect ideas on a new direction for the Innovation Center to promote patient-centered care and test market driven reforms that: • Empower beneficiaries as consumers, • Provide price transparency, • Increase choices and competition to drive quality, • Reduce costs, and • Improve outcomes. The Innovation Center is a central focus of the Administration's efforts to accelerate the move from a healthcare system that pays for volume to one that pays for value and encourages provider innovation. The Innovation Center received a robust response with approximately 1,000 responses from the public, including consumers and consumer groups, physicians and other healthcare providers, health systems, health plans, national and state associations, community-based providers, foundations, faith-based organizations,	-Within the body of this comment letter submitted by NIHB on November 20, 2017, NIHB reiterated the Federal government's trust responsibility that provides the legal justification and moral foundation for Indian specific health policymaking. It was recommended that: CMS shall: -Encourage Indian Tribes to develop their own policies to achieve program objectives; -Where possible, defer to Indian Tribes to establish standards; -In determining whether to establish federal standards, consult with Tribal officials as to the need for federal standards and any alternatives that would limit the scope of federal standards or otherwise preserve the prerogatives	

			states and technology firms. The responses focused on a number of areas that are critical to improving the quality of care for beneficiaries and decreasing unnecessary cost, such as increased physician accountability for patient outcomes, improved patient choice and transparency, realigned incentives for the benefit of the patient, and a focus on chronically ill patients. In addition to the themes that emerged around the RFI's guiding principles and eight model focus areas, the comments received in response to the RFI also reflected broad support for reducing burdensome requirements and unnecessary regulations.	and authority of Indian Tribes.	
21.	**IHS Strategic Plan 2018-2022** ACTION: Request for Comments AGENCY: IHS	Published: 10/31/2017 Due Date: Oct 2017	• IHS sought comments and recommendations on the initial IHS Strategic Plan framework. Do the IHS Mission, Vision, Goals, and Objectives reflect the direction and priorities you feel the IHS should pursue over the next 5 years?	-NIHB provided comments on October 31, 2017 which reflected the following highlights: -***Expand and Strengthen Goal 3, Objective 3: Modernize information technology and information systems to support data-driven decisions.*** The Resource and Patient Management System (RPMS) serves as the IHS electronic health record (EHR), but it has struggled to support the modern health information technology needs and mandates. This system is outdated. While IHS has begun exploring whether to update or replace the system, this process will be a multi-year endeavor. Including modernization of the Health Information system for IHS as a clear objective and goal sends a clear message that this is a priority and is responsive to requests from Tribes. We recommend that Goal 3, Objective 3 be strengthened to reflect that the modernization will be a multiyear endeavor and require specific funding so as not to affect the delivery of critical health services to American Indians and Alaska Natives.	During the initial framework comment period (9/15/17-10/31/17), the IHS held listening sessions, presented at Tribal meetings, and held conference calls with Tribal and Urban Indian Organization leaders. Comment review was composed of over 150 Tribes, Tribal Organizations, Urban Indian Organizations and IHS staff. A summary of comments for the time period 10/30/17-11/3/17 was developed and the following NIHB recommendations were taken into account: "Expand and strengthen this objective to reflect that the modernization of the IHS electronic health record system will be a multi-year endeavor and require specific funding as to not affect the delivery of critical health services to AI AN."

				-Specifically include objectives to promote the health care workforce for IHS -It was noted that IHS has been unable to meet the workforce needs with the current strategy and IHS must improve its ability to address workforce challenges if the care needs of AI/ANs are going to be met. The current IHS workforce development relies primarily on recruiting non-Indians through the loan repayment program, but those dollars are limited. An objective to recruit more AI/AN into the medical profession needs to be included in the Strategic Plan.	Another notable item that was heavily considered was the following: "Invest in and mentor Native youth to obtain health science degrees. Current IHS scholarship program is not adequate." And, "Include innovative recruitment and retention strategies that make tribal communities a sought after job/placement for health care providers." Collectively, the initial framework comment period formed the basis for the Draft Strategic Plan 2018-2022 in which NIHB submitted additional comments to IHS in regards to the political relationship and trust responsibility afforded to Tribes with the United States.
22.	**Request for Comments on the Draft Department Strategic Plan for FY 2018–2022** ACTION: Request for Comments AGENCY: HHS - Office of the Secretary, Office of the Assistant Secretary for Planning and Evaluation FILE CODE: 2017-20613	Published: 9/27/2017 Due Date: 10/26/2017	• The draft Department of Health and Human Services Strategic Plan FY 2018-2022 is provided as part of the strategic planning process under the Government Performance and Results Modernization Act of 2010 (GPRA-MA) (Pub. L. 111-352) to ensure that Agency stakeholders are given an opportunity to comment on this plan. • This document articulates how the Department will achieve its mission through five strategic goals. These five strategic goals are (1) Reform, Strengthen, and Modernize the Nation's Health Care System, (2) Protect the Health of Americans Where They Live, Learn, Work, and Play, (3) Strengthen the Economic and Social Well-Being of Americans across the Lifespan, (4) Foster Sound, Sustained Advances in Sciences, and (5) Promote Effective and Efficient Management and Stewardship. Each	-NIHB submitted comments on October 26, 2017 and outlined the following components within the comment letter: -Need for Meaningful Tribal Consultation -The Strategic Plan needs to have Stronger Language around its Trust Obligation to Tribes -Raise the level of IHS engagement across the Strategic Plan -Include modernization of the Health Information System and Telehealth infrastructure serving the Indian health care system as a clear Goal and Objective	The Office of Inspector General (OIG) annually identifies top management and performance challenges facing the Department as it strives to fulfill its mission. OIG notes that challenges can arise in the Department's responsibilities and functions, such as delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity.

			goal is supported by objectives and strategies.	-Specifically include objectives to promote the health care workforce for IHS -Include the Tribal Impact in any Change to Centralized Business Practices	Efforts to strengthen these functions are described in *Strategic Goal 5: Promote Effective and Efficient Management and Stewardship*. OIG also identified challenges that exist in programs, including Medicare, Medicaid, the Public Health Service, and the ***Indian Health Service.*** The HHS workforce comprises more than 91,000 permanent and temporary employees, serving in every region of the United States, including Tribal communities and the U.S. territories, and 66 countries around the world. To achieve its mission, ***HHS will need to recruit, hire, and retain a qualified, talented, diverse, and inclusive workforce.*** As the majority of HHS staff nears retirement eligibility, human resources offices throughout the Department help HHS components to hire the best talent from all segments of society and strengthen succession planning, to ensure the Department can continue to support mission-critical functions. Within Strategic Objective 3.2: Safeguard the public against preventable injuries

					and violence or their results, one of the performance goals is to "Increase intimate partner (domestic) violence screening among American Indian and Alaska Native females". -AIAN were mentioned in the health equity, more specifically, ***Strategic Objective 1.3: Improve Americans' access to healthcare and expand choices of care and service options and HHS provided and HHS exemplified this point by stating: "American Indians and Alaska Natives born today have a life expectancy that is 4.4 years less than that of the average U.S. population".*** One of the performance goals explicitly states: "Increase tele-behavioral health encounters nationally among American Indians and Alaska Natives". -The document eludes to the IHS as a division working to achieve some of the strategic plan goals, but does not necessarily address the trust obligation to Tribes nor the need for Tribal consultation. In all, advocacy for robust language that is tribal and IHS specific needs to be further incorporated within the goals and objectives.
23.	**Tribal Technical Advisory Group Request for Current American**	Published: 10/17/2017	• In summary, TTAG provided Mr., Randy Pate, who serves as Deputy	-TTAG expressed their gratitude for data that was	It was reiterated that being able to

	Indian and Alaska Native Enrollment Data for Health Insurance Marketplaces ACTION: TTAG Request for Update on Data AGENCY: CMS, CCIIO	Due Date: 10/17/2017	Administrator for the Center for Medicare and Medicaid Services in addition to serving as the Director, Center for Consumer Information and Insurance Oversight (CCIIO) at HHS with a letter chronicling a request for an updated report on AI/ANs enrolled in health insurance coverage through the Health Insurance Marketplaces established under the ACA.	previously disseminated for 2015 and 2016 in regard to the Federally Facilitated Marketplace (FFM), therefore a similar report is requested for 2017 due to the validity of the information provided within the reports. -Additionally, TTAG requested that CMS/CCIIO provide similar data sets for enrollment in the State-Based Marketplaces (SBMs). - At a minimum, TTAG requested CMS/CCIIO provide state specific data on the number of enrollees determined eligible for the Indian-specific cost-sharing protections (i.e., zero cost-sharing variation and limited cost-sharing variation) under SBMs. These data would provide a solid indicator of the level of AI/AN enrollment in Marketplaces.	base outreach enrollment efforts, as well as policy proposals, on current and comprehensive data is critical to the effectiveness of TTAG.
24.	**Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: 2017-14639, CMS-1676-P RIN: 0938-AT02	Published: 7/21/2017 Due Date: 9/11/2017	-On April 14, 2015, the U.S. Senate passed a two-year renewal of the Special Diabetes Program for Indians (SDPI). The extension of the Special Diabetes Program for Type I Diabetes and for Indians through FY 2017 is included in Section 213 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which became Public Law No: 114-10 on April 16, 2016. - During the 17 years of the Special Diabetes Program for Indians (SDPI), the Indian Health Service (IHS), tribal, and urban (I/T/U) health programs have implemented evidence-based and community-driven strategies to prevent and treat diabetes. -The structure of the MDPP is problematic with respect to I/T/Us participation and the NIHB and Tribes recognize the state of chronic underfunding and lack of resources in Indian Country. • **Section K. of the proposed rule: Proposed Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model:** • On 11/15/2016, CMS issued a final rule to implement aspects of the Medicare Diabetes Prevention	-NIHB provided comments on September 11, 2017 in relation to Part K entitled: the Medicare Diabetes Prevention Program (MDPP) which is a structured lifestyle, evidence-based intervention. -NIHB has heard from Tribal representatives that a 1-year core maintenance session is not a realistic time period to see lifestyle behavior changes. - CMS proposes that if a beneficiary develops diabetes while participating in the MDPP program, the diabetes diagnosis would not prevent the beneficiary from continuing to receive MDPP services. NIHB and Tribes are pleased that CMS will not prevent beneficiaries who develop diabetes from receiving the MDPP services. However, the program should **NOT** be limited to individuals with prediabetes. Medicare beneficiaries who have already been diagnosed	

			Program (MDPP) expanded model (81 FR 80459 through 80475 and 80552 through 80558) as part of the CY 2017 PFS final rule. Section 1115A(c) of the Act provides the Secretary with the authority to expand, through rulemaking (including implementation on a nationwide basis), the duration and scope of a model that is being tested under section 1115A (b) of the Act if certain determinations specified in the Act are made, taking into account the evaluation of the model under section 1115A (b) (4) of the Act. The MDPP expanded model is an expansion of CMS' Center for Medicare and Medicaid Innovation's (Innovation Center) Diabetes Prevention Program (DPP) model test under the authority of section 1115A of the Act. The Secretary expanded the DPP model test in duration and scope under the authority of section 1115A(c) of the Act. • HHS has verified that expansion of the MDPP model would lead to reduced Medicare spending. The MDPP expansion is projected to improve the quality of patient care without limiting benefits or coverage. Therefore, more Medicare beneficiaries will be able to access the benefits of the MDPP. CMS is proposing to expand the Medicare Diabetes Prevention Program beginning April 1, 2018. The MDPP services will be categorized by CMS as "additional preventative services" under Medicare Part B and will be administered by a non-physician community-based organization. The primary goal of the lifestyle intervention is at least 5 percent average weight loss among participants. The clinical intervention consists of 16 core maintenance sessions of a curriculum and then less intensive monthly ongoing sessions to assist the participants in maintaining healthy behaviors. CMS is proposing to include a 2-year limit on the ongoing maintenance sessions, assuming attendance and weight loss goals are met. Therefore, the MDPP service period will include a 3-year period consisting of ***1-year of core maintenance*** sessions and 2-years of ongoing maintenance sessions. There are 16 core sessions offered at least a week apart during the first 6 months and core maintenance sessions are offered at least once per month in the remaining 6 months of the first year.	with diabetes need assistance and support as well. ***NIHB recommends*** that Medicare beneficiaries with type II diabetes be included as eligible beneficiaries and that there is collaboration with the SDPI and recipients to ensure alignment, collaboration, and consistency with program eligibility -NIHB recommends that weight loss goals be modified, that separate categories be provided for men and women, that CMS take into consideration other possible co-morbidities and finally that Tribes be granted the flexibility to determine their own diabetes prevention measures of success. - NIHB request that SDPI programs are granted grandfathered recognition, using the SDPI measurement and reporting criteria through a CDC pilot project or CMS pilot project. NIHB recommend that CMS work with IHS and Tribes through meaningful Tribal consultation to incorporate SDPI and Tribal participation in the MDPP. Additionally, NIHB recommends CMS and CDC conduct an outreach and education initiative for SDPI and Tribal health care programs to become CDC-recognized Diabetes Prevention Program organizations in order to enroll in the MDPP beginning on April 1, 2018. - NIHB again recommends that CMS conduct a pilot program for currently operating SDPI Diabetes Prevention programs to be certified as grandfathered in to provide services and receive reimbursement through the MDPP. - NIHB recommend implementation of a similar program for Medicaid. In	

				the implementation of a Medicaid Diabetes Prevention Program model, we urge that a mechanism be developed to allow Federally Qualified Health Centers (FQHC) and IHS/Memorandum of Agreement (MOA) clinic providers to receive additional reimbursement outside of their all-inclusive rate when providing these preventive services.	
25.	**Medicare Program: CY 2018 Updates to the Quality Payment Program Proposed Rule** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: CMS-5522-P, 2017-13010	Published: 6/30/2017 Due Date: 8/21/2017	• The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program for eligible clinicians. Under the Quality Payment Program, eligible clinicians can participate via one of two tracks: Advanced Alternative Payment Models (APMs); or the Merit-based Incentive Payment System (MIPS). CMS began implementing the Quality Payment Program through rulemaking for calendar year (CY) 2017. This rule provides proposed updates for the second and future years of the Quality Payment Program.	-NIHB requests Tribal consultation on the development of the proposed Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Model (APM) policies because it is of the utmost importance that the Indian Health Service (IHS) and Medicare and Medicaid within CMS conduct consultation for coordination so that the federal agencies are coordinated in implementing performance measures that are aligned. - NIHB encourages CMS to work with IHS to ensure there is some alignment with the MIPS and Advanced APMs measure requirements with the established Government Performance Results Act (GPRA) measures of which IHS is mandated to report on. Overall, however, NIHB recommends that CMS strive to make the QPP streamlined and reduce the participation burden on clinicians, particularly for providers serving patients in underserved areas such as Indian Country. -In regards to MIPS exclusions, NIHB appreciates and supports the increased low-volume threshold, which will exempt more small practices and eligible clinicians in rural and Health Professional Shortage Areas (HPSAs) from MIPS	

				participation. Moreover, NIHB is supportive of a streamlined opt-in process beginning in 2019, allowing clinicians who meet the low-volume threshold to receive positive payment adjustments -- as long as there are no negative consequences to clinicians. -To supplement the section entitled: MIPS Performance Threshold and Reporting Mechanisms, NIHB support the performance threshold of 15 points for 2018. NIHB encourages CMS to find ways to assist the lower performers, perhaps through making funds available through small awards or grants to lower performers who apply for them and have a specific area they believe could help them provide better quality care which could be demonstrated through better MIPS scores. NIHB favors this proposal because it may help ease the reporting burden for some Tribal clinicians. -For the MIPS Performance Category Scoring: - NIHB supports the proposal to keep the cost category at 0%. We continue to urge CMS to ensure that the measures and activities are appropriate for eligible Tribal clinicians who provide services to rural and under-served Medicare beneficiaries. NIHB requests that providers caring for American Indian and Alaska Native (AI/AN) patients in Indian Country be excluded from the scoring cap. - NIHB favors the proposed methodology to award improvement points based on the rate of improvement instead of improvement at the band level in the quality and cost measures.	

				-Due to the need to have data from two consecutive performance periods for specific providers, NIHB is concerned that improvement scores may reward stable and high performing practices and providers while struggling practices with high turnover rates may fall further behind. NIHB suggests that accepting IHS as a qualified clinical data registry (QCDR) or Registry and allowing Tribal, Urban, and federal sites submit GPRA measures in lieu of the outlined quality measures for the quality performance category may be one way to recognize that the AI/AN population is unique and account for some of the differences in geography, social risk factors, complexity and historical trauma. - NIHB supports rewarding improvement for clinicians caring for patients with social risk factors. We encourage CMS to consider giving MIPS eligible clinicians caring for AI/AN patients in Indian Country a bonus score similar to other bonuses discussed in the proposed rule because a high percentage of our patient population have social risk factors and are complex patients. - NIHB supports the facility-based scoring option for MIPS eligible clinicians because it will assist in reducing the MIPS reporting burden on Tribal clinicians based in hospitals. - CMS is proposing to award small practices 3 points for measures in the quality performance category that do not meet data completeness requirements. NIHB supports the 3 additional points in the quality performance category that	

				do not meet data completeness requirements. CMS has proposed to add 3 points to a MIPS score by adding the Hierarchical Conditions Category (HCC) risk score to the final score. NIHB strongly supports the additional 5 point small practice bonus and the 3 point complex patient bonus. - NIHB recommends that CMS create a bonus for eligible clinicians who provide Medicare Part B services to AI/AN patients in Indian Country. We recommend that the proposed bonus for eligible clinicians should extend for the life of the program. - NIHB is appreciative and supportive of the inclusion of the 2014 Edition of Certified Electronic Health Record Technology (CEHRT), which is the most up-to-date version that IHS utilizes. For the Advancing Care Information (ACI) Performance Category, NIHB is supportive of the CMS proposal to not include a 5 year cap on clinicians' ability to claim the hardship exemption that was included under the Medicare EHR Incentive Program. NIHB suggests that CMS include a hardship exemption for clinicians who provide services in Tribal health care facilities. NIHB is concerned that clinicians may be deterred from providing services at Tribal health care facilities because they could receive a negative payment adjustment that will follow them to other facilities. - CMS's proposed rule offers virtual group participation as a way for clinicians to participate in MIPS during QPP Year 2. NIHB supports the virtual	

				group option, but we believe there should be no maximum limit on the size of the group, for clinicians who may otherwise be excluded from participating in MIPS. NIHB also recommends that CMS provide additional assistance to clinicians in rural and under-served areas, such as Indian Country, who are interested in virtual group participation, and to ensure that it is a simple and streamlined process to form a virtual group. - CMS has highlighted the advanced alternative payment model (APM) track as a vital part of bending the Medicare cost curve by encouraging the delivery of high quality, low-cost care. NIHB remains concerned with the lack of opportunities for rural and HPSA clinicians to participate in Advanced APMs due to the proposed risk requirements at a time when CMS is attempting to increase participation in APMs. CMS's proposed rule maintains that participating APM entities bear more nominal risk for monetary losses standard of 8% risk for Advanced APMs. NIHB recommends that the nominal risk standard should be lower for the 2019 and 2020 reporting years, in order to increase participation in the Advanced APM track for various eligible clinicians who provide quality services to under-served and Health Professional Shortage Areas (HPSAs).	
26.	**Wisconsin Badger Care Reform Application** **ACTION: Proposed Rule** **AGENCY: HHS, State of Wisconsin**	Published: 6/7/2017 Comments Submitted: 7/15/2017	In summary, the state of Wisconsin submitted a waiver application that if submitted in its current form would have negative implications for American Indians/Alaska Natives in the state.	NIHB asserts that while imposing such conditions may be appropriate for Wisconsin's non-Indian population, they will not work as intended for AI/ANs in Wisconsin because the	NIHB in consultation with Tribes have determined that employment incentive structures created by

			More specifically, the Badger Care Amendment seeks to encourage healthy behaviors by imposing new conditions of eligibility such as premiums and cost sharing and/or work requirements on Medicaid enrolled individuals in the new adult group.	incentives are not the same. Faced with meeting these requirements as a condition of Medicaid eligibility, AI/ANs will simply elect not enroll in Medicaid and rely on the Indian Health Service (IHS) instead. This will lead to more uncompensated care provided to otherwise Medicaid eligible individuals by the IHS, Tribes, and non-Indian healthcare providers. -Furthermore, the Badger Care Amendment will also lead to increased burdens on the Indian health system and non-Indian hospital providers. Due to inadequate funding, the Indian health system is unable to provide the full scope of medical care needed by the AI/ANs it serves. As a result, IHS operates a Purchased/Referred Care (PRC) program through which needed care is purchased from public and private providers. Funding for PRC is limited, and as a result access to outside care is severely rationed and many patient care needs go unfilled. Medicaid coverage is a critical resources needed to supplement this program. Eliminating barriers to access Medicaid eligibility helps save federal funding in the PRC program, which in turn makes additional federal funds available to cover the costs of care for non-IHS hospital providers and emergency departments that may otherwise go uncompensated. -NIHB recommends the Badger Care Amendment (if approved) include the Tribal Standard Terms and Conditions (STCs) that the CMS Tribal Technical Advisory Group (TTAG) has developed with CMS.	Medicaid work requirements do not operate in the same way for AI/AN Medicaid beneficiaries who may forgo Medicaid coverage and rely instead on IHS coverage. This, in turn, will strain the underfunded IHS system. As a practical matter, many AI/AN Medicaid beneficiaries may not be able to meet Medicaid work requirements due to high on-reservation unemployment and/or lack of connection to State employment programs. Many AI/ANs look to their Tribal governments for employment assistance rather than their state and as a result will not be able to demonstrate they are participating in State employment assistance programs. Finally, imposing work requirements on AI/AN Medicaid beneficiaries is inconsistent with the federal trust responsibility and congressional intent to increase Indian health system access to Medicaid resources.
27.	**Request for information regarding the Patient Protection and Affordable Care Act: Reducing Regulatory Burdens and**	Published: 6/12/2017 Due Date:	• The Department of Health and Human Services (HHS) is actively working to reduce regulatory burdens and	-NIHB submitted comments with their recommendations on July	The unique relationship between 3rd party insurance coverage

	Improving Health Care Choices to Empower Patients ACTION: Request for Information AGENCY: CMS, HHS FILE CODE: CMS-9928-NC, 2017-12130 RIN: 0938-ZB39	7/12/2017	improve health insurance options under Title I of the Patient Protection and Affordable Care Act. Executive Order 13765, "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal," directs the Secretary of Health and Human Services to achieve these aims. HHS seeks comment from interested parties to inform its ongoing efforts to create a more patient-centered health care system that adheres to the key principles of affordability, accessibility, quality, innovation, and empowerment.	12, 2017, and outlined the following: - Affirming the traditional regulatory authority of the States in regulating the business of health insurance -Protect existing Indian benefits and protections because they support AI/AN enrollment and Indian health provider participation. Stabilize markets by encouraging enrollment. Within the ACA, there are provisions that need to be preserved to provide quality health care services, which include: - Support the Indian Health Care Improvement Act - Safeguard Indian-specific Provisions of the Affordable Care Act - Preserve Cost-Sharing Protections for AI/ANs -Special Enrollment Periods (Section 1311) - Exemptions (Section 1501) - Payer of Last Resort (Section 2901) - Tax Exclusions for Health Benefits (Section 9021 - Elimination of Sunset for Reimbursement for all Medicare Part B Services Furnished by Certain Indian Hospitals and Clinics (Section 2902 - Quality Measures Related to Chronic Disease - Tighter Restrictions on Premium Payment Grace Periods -Advance Premium Tax Credit (APTC) and Cost Saving Reduction (CSR) Eligibility and Distribution - Consumer Health Accounts - Essential Health Benefits - 100% Federal Medical Assistance Percentage (FMAP) - Indian Health Care Provider payments exempt from Medicaid caps - Medicaid Eligibility Requirements	like Medicaid and Marketplace coverage; and the Indian health system means that the Administration has the tools it needs to allow States to design Medicaid programs that best fit non-Indian populations while simultaneously respecting Tribal sovereignty and maintaining Medicaid and the Marketplace as a critical source of funds for the Indian health system

				- Support State Flexibility While Preserving Tribal Rights ***- Definition of Indian Inconsistency:*** *- One of the legislative proposals sought by IHS in the FY 2017 IHS Congressional Budget Justification was a consistent definition of "Indian" in the ACA6. The Budget proposed to standardize ACA definitions to ensure all AI/ANs would be treated equally with respect to the Act's coverage provisions, including access to qualified health plans with no cost sharing.* The definition of "Indian: used by IHS, Medicaid, and CHIP is found in 42 CFR § 447.51. Indian means any individual defined at 25 USC 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR §136.12. This means the individual: (1) Is a member of a Federally-recognized tribe; (2) Resides in an urban center and meets one or more of the following four criteria: (i) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendent, in the first or second degree, of any such member; (ii) Is an Eskimo or Aleut or other Alaska Native; (iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or (iv) Is considered to be an Indian under regulations promulgated by the Secretary; (3) Is considered by the Secretary of the Interior to	

				be an Indian for any purpose; or (4) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.	