| Lead Agency: SHORT TITLE **Reference Number; Title of Reg/Agency Action** | **Agency release date; due date for comments** | | **Agency’s Summary of Action** | **Notes:** |
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| **-- Priority Roster Items --** | | | | |
| **Extension for States Under Medicaid Home and Community-Based Settings Criteria**  **AGENCY: CMS**  <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-05-09.html> | Issued: 5/9/2017 | | CMS announced a three-year extension for state Medicaid programs to meet the Home and Community Based Services (HCBS) settings requirements for settings operating before March 17, 2014. This extension is in response to states’ request for more time to demonstrate compliance with the regulatory requirements and ensure compliance activities are collaborative, transparent, and timely. States now have until March 17, 2022 to demonstrate compliance with the final rule. |  |
| **IHS Update on Efforts to Combat the Opioid Epidemic facing AI/AN Communities**  **AGENCY: IHS**  **Dear Tribal Leader Letter**  <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2017_Letters/DTLL_DUIOLL_OpioidEpidemic_050717.pdf> | Issued:  5/2/2017 | | In March 2017, the IHS established the IHS National Committee on Heroin, Opioid, and Pain Efforts (HOPE Committee) through an official charter. The HOPE Committee is comprised of multidisciplinary members with professional backgrounds in pharmacy, medicine, nursing, and behavioral health.  The HOPE Committee will work from a framework based on six elements: 1) Establishing IHS policies; 2) Training Health Care Providers; 3) Ensuring Effective Pain Management; 4) Increasing Access to Naloxone; 5) Expanding Medication Assisted Treatment (MAT); and 6) Reducing the Inappropriate Use of Methadone. Policy work includes updating the Indian Health Manual (IHM) Chapter 30 "Chronic NonCancer Pain," implemented in 2013, to align with the Centers for Disease Control and Prevention "Guideline for Prescribing Opioids for Chronic Pain." In 2016, IHS implemented IHM Chapter 32 "State Prescription Drug Monitoring Programs" (PDMP). In 2016, the IHS implemented a mandatory training course, entitled "IHS Essential Training on Pain and Addiction." In December 2015, the IHS signed a memorandum of agreement with the Bureau of Indian Affairs (BIA) to increase access to naloxone, a medication that reverses the effects of heroin or prescription opioid overdose and saves lives.  The IHS is working to increase access to MAT, the use of medications with counseling and behavioral therapies, to treat opioid use disorders, and also to increase the number of primary care providers who have been trained to prescribe MAT. Additionally, IHS is actively working to reduce the use of methadone for pain management. |  |
| **Seeks Comment and Data on Actions to Accelerate Adoption and Accessibility of Broadband-Enabled Health Care Solutions and Advanced Technologies**  **AGENCY: FCC**  **Public Notice**  <http://transition.fcc.gov/Daily_Releases/Daily_Business/2017/db0424/FCC-17-46A1.pdf> | Issued:  4/24/2017  **Due Date:**  **6/24/2017** | | The Federal Communications Commission (FCC or Commission) seeks information on how it can help enable the adoption and accessibility of broadband-enabled health care solutions, especially in rural and other underserved areas of the country. In order to perform these and other important roles in the health technology space, the Commission should continue to evaluate the nation’s broadband health infrastructure and to understand the ongoing technology-based transformation in health care delivery. This will better assure that consumers—from major cities to rural and remote areas, Tribal lands, and underserved regions—can access potentially lifesaving health technologies and services, like telehealth and telemedicine. Leading this effort on behalf of the agency is its Connect2HealthFCC Task Force. This Public Notice seeks comment, data, and information on a broad range of regulatory, policy, technical, and infrastructure issues related to the emerging broadband-enabled health and care ecosystem. Commenters should address the agency’s authority on all issues raised in this Notice.  There are a growing number of broadband-enabled solutions that can play an important role in improving population health; addressing health needs beyond the hospital; expanding access to primary, acute, preventive and specialist care, especially for those Americans living in rural and underserved areas; providing more cost-effective solutions; improving the quality of care; and better engaging consumers in their health. Put simply, health care is being transformed by the availability and accessibility of broadband-enabled services and technologies and the development of life-saving wireless medical devices. Indeed, we are already realizing some of the tremendous benefits that broadband-enabled health technologies and innovative wireless medical devices have to offer:  Electronic Health Record (EHR) systems can track and transmit vast amounts of patient clinical data.  X-rays, MRIs, and CAT scans can be transmitted seamlessly to specialists at a distant hospital.  Telemedicine and telehealth programs and services provide opportunities to close access to care gaps and facilitate specialized training.  Medical providers are able to prescribe medications electronically, saving time and money. Surgeons are able to perform operations miles away from patients via robotics.  Self-service health kiosks are becoming increasingly available at pharmacies and grocery chains, providing additional access points for primary care and disease screenings.  Remote patient monitoring applications and services are reducing hospital readmissions as well as travel and associated expenses for patients.  Mobile devices like smartphones and personal data assistants are transforming the way physicians manage patient care; they are also empowering and engaging consumers to take a more active role in managing their own health.  Implant or body-worn monitoring, therapeutic, and treatment technologies include wireless blood glucose monitors and automated insulin pumps.  "Ingestibles" and “smart pills” (broadband-enabled digital tools that are swallowed by the patient) use wireless technology to monitor internal reactions in real-time, dispense medication, and provide other granular health data. | NCAI and NIHB will be submitting a joint comment and send out a template comment in the coming weeks.  Description of need in Indian Country  Lack of broadband infrastructure  Health disparities in Indian Country  Lack of telemedicine  Possibilities with telemedicine for Indian country  Behavioral Health  Indigenous healing?  Existing programs  Data on Telemedicine in IC  What is happening already at IHS  Use Connect2 health for infrastructure, allow for IHS IT funding to go to equipment. Efficient use of federal funds.  Behavioral Health program  USDA RUS programs  Tribes using Connect 2 health already    Policy Recommendations  IHS-FCC MOU on Telemedicine in Indian Country  Tribal Set aside in Connect2 Health Funding  Tribal Priority for funding application  Establish advisory council for tribal participation or working group |
| **Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and LTC Hospital Prospective Payment System and Proposed Policy Changes and FY18 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid EHR Incentive Program Requirements for Eligible Hospitals, CAHs, and Eligible Professionals; Provider-Based Status of IHS and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices**  **AGENCY: CMS**  **Proposed Rule**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-28/pdf/2017-07800.pdf> | Issued:  4/14/2017  Published:  4/28/2017  **Due Date:**  **6/13/2017** | | Proposing 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 2018. Some of these proposed changes would implement certain statutory provisions contained in the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Medicare Access and CHIP Reauthorization Act of 2015, the 21st Century Cures Act, and other legislation. We also are making proposals relating to the provider-based status of Indian Health Service (IHS) and Tribal facilities and organizations and to the low-volume hospital payment adjustment for hospitals operated by the IHS or a Tribe. In addition, we are providing the proposed estimated 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 2018. 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 2018.  Proposing to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities). We also are proposing 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. We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.  Provider-based Status Proposed Rule: Takes away the arbitrary date of 2000 for the provision of services. | Comments Recommended    Provider-based Status Questions:   1. Does a standalone Tribal facility can bill up through a Tribal or IHS hospital with their consent without jeopardizing the hospital conditions of participation? 2. There are IHS/Tribal provisions on exclusions from IPPS, as well as what hospitals count and don’t count for the low volume hospital payment adjustment. |
| **Patient Protection and Affordable Care Act (ACA); Market Stabilization**  **AGENCY: CMS**  **Final Rule**  <https://www.whitehouse.gov/reorganizing-the-executive-branch> | Published:  4/18/2017  **Effective:**  **6/19/2017** | | This final rule amends standards relating to special enrollment periods, guaranteed availability, and the timing of the annual open enrollment period in the individual market for the 2018 plan year; standards related to network adequacy and essential community providers for qualified health plans; and the rules around actuarial value requirements.  Prior coverage will not be required for American Indians to meet special enrollment period (SEP) eligibility if an American Indian marries or permanently moves. AI/ANs still qualify for a SEP on a monthly basis. AI/ANs are also exempt from the open enrollment period alignment with employer-based coverage.  The final rule does not require additional pre-enrollment supporting documentation other than tribal membership documentation.  Requires qualified health plans (QHP) issuers to maintain an adequate network of providers to ensure that all types of medical services will be accessible to beneficiaries without unreasonable delay.  CMS has also released a QHP Certification Guidance for States, which will require plans to include only 20 percent of Essential Community Providers (ECPs), a reduction from the previous 30 percent. This could affect Indian Health Service Centers serving as an Essential Community Provider (ECP). A write-in process will be implemented to identify ECPs that are not included on the HHS list.  Change their approach to reviewing network adequacy in states in which an FFE (Federally-facilitated Exchange) is operating, provided the state has a sufficient adequate review process. |  |
| **Presidential Executive Order 13781 on a Comprehensive Plan for Reorganizing the Executive Branch**  <https://www.gpo.gov/fdsys/pkg/FR-2017-03-16/pdf/2017-05399.pdf> | Issued:  3/13/2017 | | * OMB, within 180 days after public comment, is to propose a plan to reorganize government functions and eliminate unnecessary agencies and agency programs * Each agency must submit a plan to the OMB director to reorganize the agency, if appropriate, in order to improve the efficiency, effectiveness, and accountability of that agency * OMB will publish a notice in the federal register inviting public comment to suggest improvements in the reorganization and functioning of the executive branch. * In developing OMB’s plan, things that should be taken into consideration include:    (i)    whether some or all of the functions of an agency, a component, or a program are appropriate for the Federal Government or would be better left to State or local governments or to the private sector through free enterprise;  (ii)   whether some or all of the functions of an agency, a component, or a program are redundant, including with those of another agency, component, or program;  (iii)  whether certain administrative capabilities necessary for operating an agency, a component, or a program are redundant with those of another agency, component, or program;  (iv)   whether the costs of continuing to operate an agency, a component, or a program are justified by the public benefits it provides; and  (v)    the costs of shutting down or merging agencies, components, or programs, including the costs of addressing the equities of affected agency staff.  **Recommendations:**  Obviously our first concern is keeping IHS.  Once the comment period happens, it’s important to get notice out to Tribes quickly and get template comments out there asking for preservation of IHS.  However we need to be careful about any other suggestions we might make to make the agency more accountable.  The other thing to take into consideration is that IHS already has a plan to reorganize the agency to do just what this EO is proposing to do that was started under Mary Smith.  It might be prudent to ask IHS to share that plan with Tribes so that they can support it in their recommendations and comments. | Comments Recommended  <https://www.whitehouse.gov/reorganizing-the-executive-branch>  NIHB will provide a template comment for public comment.  Importance to head agencies with office of tribal affairs  OMB Memo: provides agencies guidance to begin immediate actions to reduce the workforce and cost sayings (President’s Budget); **submit an agency reform plan to OMB in September 2017.** |
| **340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date**  **AGENCY: HRSA**  **Interim Final Rule; Delay of Effective Date**  <https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf> | Published:  3/6/2017  **Effective:**  **~~3/21/2017~~**  **5/22/2017** | | The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), referred to as the ‘‘340B Drug Pricing Program’’ or the ‘‘340B Program.’’ This final rule will apply to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. This final rule sets forth the calculation of the 340B ceiling price and application of civil monetary penalties (CMPs). |  |
| **Presidential Executive Order on Enforcing the Regulatory Reform Agenda**  **Executive Order**  <https://www.gpo.gov/fdsys/pkg/FR-2017-03-01/pdf/2017-04107.pdf> | Issued:  2/24/2017  **Published:**  3/1/2017 | | The purpose of the Executive Order is to lower regulatory burdens on the American people by implementing and enforcing regulatory reform. Sec.2. Within 60 days of the date of this order the head of each agency, shall designate an agency official as its Regulatory Reform Officer (RRO) to oversee implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms (EO 13771; EO 12866; EO 13563). Sec.3. Each agency shall establish a Regulatory Reform Task Force to evaluate existing regulations and make recommendations to the agency head regarding their repeal, replacement, or modification. Sec.4. Consistent with the policy, each agency should measures its progress in performing the tasks in Section 3.Sec.5. Upon the request of an agency head, the Director may waive compliance with this order if the Director determines that the agency generally issues very few or no regulations. | -Carl Mitchell, IHS Director of Division of Regulatory Affairs and in charge of FOIA requests. |
| **Reducing Regulation and Controlling Regulatory Costs**  **Presidential Executive Order 13771**  <https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling> | Published:  1/30/2017 | | Purpose: It is important that for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.  Sec. 2.  Regulatory Cap for Fiscal Year 2017.  (a)  Unless prohibited by law, whenever an executive department or agency (agency) publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed.  (b)  For fiscal year 2017, which is in progress, the heads of all agencies are directed that the total incremental cost of all new regulations, including repealed regulations, to be finalized this year shall be no greater than zero, unless otherwise required by law or consistent with advice provided in writing by the Director of the Office of Management and Budget (Director). | Question for OMB: How will it be determined which two existing regulations can be repealed for a new regulation to be in place? |
| **Hiring Freeze**  **Memorandum for the Heads of Executive Departments and Agencies**  **Presidential Memorandum**  <https://www.gpo.gov/fdsys/pkg/FR-2017-01-25/pdf/2017-01842.pdf> | Published:  1/25/2017 | | The President ordered a freeze on the hiring of Federal civilian employees to be applied across the board in the executive branch. As part of this freeze, no vacant positions existing at noon on January 22, 2017, may be filled and no new positions may be created, except in limited circumstances. This order does not include or apply to military personnel. The head of any executive department or agency may exempt from the hiring freeze any positions that it deems necessary to meet national security or public safety responsibilities. In addition, the Director of the Office of Personnel Management (OPM) may grant exemptions from this freeze where those exemptions are otherwise necessary.  Within 90 days of the date of this memorandum, the Director of the Office of Management and Budget (OMB), in consultation with the Director of OPM, shall recommend a long-term plan to reduce the size of the Federal Government’s workforce through attrition. This order shall expire upon implementation of the OMB plan. | [IHS DTLL 2/10/2017](https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2017_Letters/DTLL_UIOLL-HiringFreeze_02102017.pdf)  [HHS Exemptions Memorandum](http://www.raps.org/uploadedFiles/Site_Setup/Regulatory_Focus/News/2017/02/2017%20HHS%20Hiring%20Freeze%20Exemptions%20-%20signed%20(002).pdf)  [Memorandum from OMB Acting Director](https://www.chcoc.gov/content/federal-civilian-hiring-freeze-guidance)  [OMB Memorandum for Reforming the Federal Government and Reducing Federal Civilian Workforce](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-22.pdf) |
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| **Full Roster** | | | | |  |  |  |
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| **Agency Information Collection; Proposed Project- Re-Engineered Visit for Primary Care**  **AGENCY: AHRQ**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-05-05/pdf/2017-09097.pdf> | Published:  5/5/2017  Due Date:  6/5/2017 | | The Re-engineered Visit for Primary Care, directly addresses the agency’s goal to conduct research to enhance the quality of health care and reduce avoidable readmissions, which are a major indicator of poor quality and patient safety. Research from AHRQ’s Healthcare Cost and Utilization Project (HCUP) indicates that in 2011 there were approximately 3.3 million adult hospital readmissions in the United States. Adults covered by Medicare have the highest readmission rate (17.2 per 100 admissions), followed by adults covered by Medicaid (14.6 per 100 admissions) and privately insured adults (8.7 per 100 admissions). High rates of readmissions are a major patient safety problem and are associated with a range of adverse events, such as prescribing errors and misdiagnoses of conditions in the hospital and ambulatory care settings. Collectively these readmissions are associated with $41.3 billion in annual hospital costs, many of which potentially could be avoided. In recent years, payer and provider efforts to reduce readmissions have proliferated. Many of these national programs have been informed or guided by evidence-based research, toolkits and guides, such as AHRQ’s RED (ReEngineered Discharge), STAAR (STate Action on Avoidable Readmission), AHRQ’s Project BOOST (Better Outcomes by Optimizing Safe Transitions), the Hospital Guide to Reducing Medicaid Readmissions, and Eric Coleman’s Care Transitions Intervention. These efforts have largely focused on enhancing practices occurring within the hospital setting, including the discharge process transitions among providers and between settings of care. While many of these efforts have recognized the critical role of primary care in managing care transitions, they have not had an explicit focus on enhancing primary care with the aim of reducing avoidable readmissions. |  |
| **Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2018, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, Survey Team Composition, and Proposal to Correct the Performance Period for the NHSN HCP Influenza Vaccination Immunization Reporting Measure in the ESRD QIP for PY 2020**  **AGENCY: CMS**  **Proposed Rule**  <https://www.gpo.gov/fdsys/pkg/FR-2017-05-04/pdf/2017-08521.pdf> | Published:  5/4/2017  **Due Date:**  **6/26/2017** | | This proposed rule would update the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2018. It also proposes to revise and rebase the market basket index by updating the base year from 2010 to 2014, and by adding a new cost category for Installation, Maintenance, and Repair Services. The rule also includes proposed revisions to the SNF Quality Reporting Program (QRP), including measure and standardized patient assessment data proposals and proposals related to public display. In addition, it includes proposals for the Skilled Nursing Facility Value-Based Purchasing Program that will affect Medicare payment to SNFs beginning in FY 2019 and clarification on the requirements regarding the composition of professionals for the survey team. The proposed rule also seeks to clarify the regulatory requirements for team composition for surveys conducted for investigating a complaint and to align regulatory provisions for investigation of complaints with the statutory requirements. The proposed rule also includes one proposal related to the performance period for the National Healthcare Safety Network (NHSN) Healthcare Personnel (HCP) Influenza Vaccination Reporting Measure included in the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP). |  |
| **Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities: Revisions to Case-Mix Methodology**  **AGENCY: CMS**  **Advanced Notice of Proposed Rulemaking**  <https://www.gpo.gov/fdsys/pkg/FR-2017-05-04/pdf/2017-08519.pdf> | Published:  5/4/2017  **Due Date:**  **6/26/2017** | | Solicit public comments on potential options we may consider for revising certain aspects of the existing skilled nursing facility (SNF) prospective payment system (PPS) payment methodology to improve its accuracy, based on the results of our SNF Payment Models Research (SNF PMR) project. In particular, we are seeking comments on the possibility of replacing the SNF PPS’ existing casemix classification model, the Resource Utilization Groups, Version 4 (RUG–IV), with a new model, the Resident Classification System, Version I (RCS–I). We also discuss options for how such a change could be implemented, as well as a number of other policy changes we may consider to complement implementation of RCS–I. |  |
| **Executive Order 13793 Improving Accountability and Whistleblower Protection at the Department of Veteran Affairs**  **White House**  <https://www.gpo.gov/fdsys/pkg/FR-2017-05-02/pdf/2017-08990.pdf> | Issued:  4/27/2017  Published:  5/2/2017 | | This order is intended to improve accountability and whistleblower protection at the Department of Veterans Affairs (VA) by directing the Secretary of Veterans Affairs (Secretary) to establish within the VA an Office of Accountability and Whistleblower Protection and to appoint a Special Assistant to serve as Executive Director of the Office.  Establishing a VA Office of Accountability and Whistleblower Protection. (a) Within 45 days of the date of this order, and to the extent permitted by law, the Secretary shall establish in the VA the Office of Accountability and Whistleblower Protection (Office), and shall appoint a Special Assistant, reporting directly to the Secretary, to serve as Executive Director of the Office. The VA shall provide funding and administrative support for the Office, consistent with applicable law and subject to the availability of appropriations. |  |
| **Agency Information Collection; CMS-10418 Medical Loss ratio Annual Reports, MLR Notices, and Recordkeeping Requirements**  **AGENCY: CMS**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-05-02/pdf/2017-08848.pdf> | Published: 5/2/2017  **Due Date:**  **7/3/2017** | | Revision of a currently approved collection; Title of Information Collection: Annual MLR and Rebate Calculation Report and MLR Rebate Notices; Use: Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, nonclaims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance, risk corridors, and risk adjustment programs established under sections 1341, 1342, and 1343, respectively, of the Affordable Care Act. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. |  |
| **Notice to Propose the Re-Designation of the Service Delivery Area for the Tolowa Dee-ni’ Nation, Formerly Known at Smith River Rancheria**  **AGENCY: IHS**  **Extension of Comment Period** | Published: 5/1/2017  **Due Date:**  **6/30/2017** | | Congress designated the entire state of California as a PRC Service Delivery Area, excluding certain counties, under section 810 of the Indian Healthcare Improvement Act, Public Law 94–437, as amended (25 U.S.C. 1680). The Tolowa Dee-ni’ Nation has a significant number of members who are not residents of California. According to the Tribe’s estimates, 177 enrolled Tolowa Dee-ni’ members are nonresidents who remain actively involved with the Tribe, and reside in Curry County in the State of Oregon and are not currently eligible for PRC care. 1. By expanding, the Tribe estimates the current eligible population will be increased by 177. 2. The Tribe has determined that these 177 individuals are members of the Tribe and they are socially and economically affiliated with the Tribe. 3. The expanded area including Curry County in the State of Oregon maintains a common boundary with the State of California and the statutorily created California PRC Service Delivery Area. 4. Generally, the Tribal members located in Curry County in the State of Oregon currently do not use the Indian health system for their PRC health care needs. The Tribe will use its existing Federal allocation for PRC funds to provide services to the expanded population. No additional financial resources will be allocated by IHS to the Tribe to provide services to Tribal members residing in Curry County in the State of Oregon. |  |
| **Agency Information Collection; Proposed Project- Medical Expenditure Panel Survey- Insurance Component**  **AGENCY: AHRQ**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-28/pdf/2017-08649.pdf> | Published:  4/28/2017  **Due Date:**  **6/27/2017** | | In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. Employer-sponsored health insurance is the source of coverage for 84.4 million current and former workers, plus many of their family members, and is a cornerstone of the U.S. health care system. The Medical Expenditure Panel Survey—Insurance Component (MEPS– IC) measures the extent, cost, and coverage of employer-sponsored health insurance on an annual basis.  This research has the following goals: (1) Provide data for Federal policymakers evaluating the effects of National and State health care reforms. (2) Provide descriptive data on the current employer-sponsored health insurance system and data for modeling the differential impacts of proposed health policy initiatives. (3) Supply critical State and National estimates of health insurance spending for the National Health Accounts and Gross Domestic Product. The MEPS–IC is conducted pursuant to AHRQ’s statutory authority to conduct surveys to collect data on the cost, use and quality of health care, including types and costs of private insurance, 42 U.S.C. 299b–2(a), and to conduct research on health care, 42 U.S.C. 299a. |  |
| **Agency Information Collection; Proposed Project- Access to Recovery Program (OMB No. 0930- 0266) Reinstatement**  **AGENCY: SAMHSA**  **Notice** | Published:  4/26/2017  **Due Date:**  **6/26/2017** | | The Substance Abuse and Mental Health Services Administration’s (SAMHSA), Center for Substance Abuse Treatment (CSAT) is charged with the Access to Recovery (ATR) program which will allow grantees (States, Territories, the District of Columbia and Tribal Organizations) a means to implement voucher programs for substance abuse clinical treatment and recovery support services. The ATR data collection (OMB No. 0930–0266) will be a reinstatement from the previous approval that expires on May 31, 2017. There will be no changes to the two client-level tools. | Send comments to Summer King, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–B, Rockville, Maryland 20857, OR email a copy to summer.king@samhsa.hhs.gov. |
| **Agency Information Collection; Delta States Rural Development Network Grant Program**  **AGENCY: HRSA**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-24/pdf/2017-08187.pdf> | Published:  4/24/2017 | | The Delta Program supports projects that demonstrate evidence-based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke, or obesity to improve health status in rural communities throughout the Delta Region. Key features of projects are adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability.  Need and Proposed Use of the Information: For this program, performance measures include: (a) Access to care, (b) population demographics, (c) staffing, (d) sustainability, (e) project specific domains, and (f) health related clinical measures. | Likely Respondents: The respondents are the recipients of the Delta States Rural Development Network Program. |
| **Agency Information Collection; National Council for Behavioral Health’s IT Survey**  **AGENCY: HHS**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-24/pdf/2017-08188.pdf> | Published:  4/24/2017 | | The Office of the National Coordinator for Health IT (ONC) in coordination with Substance Abuse and Mental Health Services Administration (SAMHSA) seeks to conduct a survey in 2017 of SAMSHA to examine the adoption and use of health IT as well as interoperability across community behavioral health care settings. Data from the survey will help ONC and SAMSHA monitor progress and enhance programs and policy to improve the use of health IT and expand interoperability across these settings. HHS Secretary may include behavioral health providers to participate in MACRA value-based payment initiatives such as MIPS in the future. | Likely Respondents: The respondents will include mid-level and executive level staff (IT Directors, CIO, and CEOs) of behavioral healthcare organizations that are involved in the management and maintenance of their organization’s health IT infrastructure. |
| **Delegation of Authority to the Assistant Secretary for Mental Health and Substance Use**  **AGENCY: HHS**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-21/pdf/2017-08050.pdf> | Published:  4/21/2017 | | HHS Secretary Price has delegated authority to the Assistant Secretary for Mental Health and Substance Use, or his or her successor, through Sec. 1003(a), (c), and (d) of the 21st Century Cures Act to support the Opioid Grant Program. |  |
| **Opioid State Targeted Response Grants**  **AGENCY: HHS**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-21/pdf/2017-08046.pdf> | Published:  4/21/2017 | | Last month President Trump announced the President’s Commission on Combating Drug Addiction and the Opioid Crisis. This Commission is tasked with studying the scope and effectiveness of the federal response to this crisis and providing recommendations to the President for improving it. As the Administration develops a comprehensive strategy to improve the federal response to combat opioids, the U.S. Department of Health and Human Services (HHS) must ensure the Opioid State Targeted Response grants are aligned accordingly and put to the best use possible.  HHS is seeking input from |  |
| **Agency Information Collection; Summary of the use and burden associated with Health Insurance Benefit Agreement; ASC Forms for Medicare Program Certification; Consumer Experience Survey Data Collection; and Beneficiary and Family Centered Data Collection**  **AGENCY: CMS**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-14/pdf/2017-07568.pdf> | Published:  4/14/2017  **Due Date:**  **6/13/2017** | | **CMS–1561/1561A Health Insurance Benefit Agreement**  CMS–370 and CMS–377 ASC Forms for Medicare Program Certification  CMS–10488 Consumer Experience Survey Data Collection  CMS–10393 Beneficiary and Family Centered Data Collection |  |
| **Agency Information Collection; Data System for Organ Procurement and Transplantation Network**  **AGENCY: HRSA**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-14/pdf/2017-07526.pdf> | Published: 4/14/2017  **Due Date:**  **5/15/2017** | | Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). This is a request for revisions to a subset of the current OPTN data collection forms associated with donor organ procurement and an individual’s clinical characteristics at the time of registration, transplant, and follow-up after transplant. In 2015, the OPTN Board of Directors approved policies that necessitate the addition of new data elements to registration forms for heart, lung, heart/ lung, liver, intestine, kidney, pancreas, and kidney/pancreas recipients. The OPTN also approved policies that impact the data collection for deceased donor registration, pancreas candidate registration, kidney/pancreas candidate registration, pancreas follow-up, and kidney/pancreas follow-up forms. The policy modifications necessitate changes to 17 of the 52 forms contained in this data collection. | Paperwork Reduction Act of 1995  Likely Respondents: Transplant programs, organ procurement organizations, histocompatibility laboratories, medical and scientific organizations, and public organizations. |
| **Agency Information Collection; Rural Health Network Development Planning Performance Improvement and Measurement System Database, OMB No.0915-0384-Extension**  **AGENCY: HRSA**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-11/pdf/2017-07220.pdf> | Published:  4/11/2017  **Due Date:**  **6/12/2017** | | Rural Health Network Development Planning Performance Improvement and Measurement System Database. The purpose of the Rural Health Network Development Planning Program (Network Planning) is to assist in the development of an integrated health care network, specifically for entities that do not have a history of formal collaborative efforts. Health care networks can be an effective strategy to help smaller rural health care providers and health care service organizations align resources, achieve economies of scale and efficiency, and address challenges more effectively as a group than as single providers. This program promotes the planning and development of healthcare networks in order to: (1) achieve efficiencies; (2) expand access to, coordinate, and improve the quality of essential health care services; and (3) strengthen the rural health care system as a whole.  Need and Proposed Use of the Information: Performance measures for the Network Planning program serve the purpose of quantifying awardee-level data that conveys the successes and challenges associated with the grant award. The approved measures encompass the following principal topic areas: network infrastructure, network collaboration, sustainability, and network assessment. | Paperwork Reduction Act of 1995  Likely Respondents: The respondents for these measures are Network Planning program award recipients. |
| **Agency Information Collection; Comment Request – Medicare Prescription Drug Coverage; Medicare Health Outcomes Survey; Withholding Medicare Payments to Recover Medicaid Overpayments**  **AGENCY: CMS**  **Notice**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-06/pdf/2017-06830.pdf> | Published:  4/6/2017  **Due Date:**  **6/5/2017** | | Revision of CMS–10147 Medicare Prescription Drug Coverage and Your Rights  Revision of CMS–10203 Medicare Health Outcomes Survey (HOS)  Extension CMS–R–21 Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31  Extension of CMS–R–148 Limitations on Provider Related Donations and Health Care Related Taxes; Limitation on Payment to Disproportionate Share Hospitals; Medicaid and Supporting Regulations. | Paperwork Reduction Act of 1995 |
| **Executive Order 13784 Establishing the President’s Commission on Combating Drug Addiction and the Opioid Crisis**  <https://www.gpo.gov/fdsys/pkg/FR-2017-04-03/pdf/2017-06716.pdf> | Published:  4/3/2017 | | Sec. 2. Establishment of Commission. There is established the President’s Commission on Combating Drug Addiction and the Opioid Crisis (Commission).  Sec. 3. Membership of Commission. (a) The Commission shall be composed of members designated or appointed by the President. (b) The members of the Commission shall be selected so that membership is fairly balanced in terms of the points of view represented and the functions to be performed by the Commission.  Sec. 4. Mission of Commission. The mission of the Commission shall be to study the scope and effectiveness of the Federal response to drug addiction and the opioid crisis described in section 1 of this order and to make recommendations to the President for improving that response. The Commission shall: (a) identify and describe existing Federal funding used to combat drug addiction and the opioid crisis; (b) assess the availability and accessibility of drug addiction treatment services and overdose reversal throughout the country and identify areas that are underserved; (c) identify and report on best practices for addiction prevention, including healthcare provider education and evaluation of prescription practices, and the use and effectiveness of State prescription drug monitoring programs; (d) review the literature evaluating the effectiveness of educational messages for youth and adults with respect to prescription and illicit opioids; (e) identify and evaluate existing Federal programs to prevent and treat drug addiction for their scope and effectiveness, and make recommendations for improving these programs; and (f) make recommendations to the President for improving the Federal response to drug addiction and the opioid crisis. |  |
| **Proposed Collection; Comment Request for Health Plan Administrator (HPA) Return of Funds**  **AGENCY: IRS**  **Notice and Request for Comments**  <https://www.gpo.gov/fdsys/pkg/FR-2017-03-31/pdf/2017-06392.pdf> | Published: 3/31/2017  **Due Date:**  **5/30/2017** | | Currently, the IRS is soliciting comments concerning Form 13560, Health Plan Administrator (HPA) Return of Funds. Title: Form 13560, Health Plan Administrator (HPA) Return of Funds. OMB Number: 1545–1891. Form Number: Form 13560. Abstract: Form 13560 is completed by Health Plan Administrators (HPAs) and accompanies a return of funds in order to ensure proper handling. This form serves as supporting documentation for any funds returned by an HPA and clarifies where the payment should be applied and why it is being sent. | Paperwork Reduction Act of 1995 |
| **Request for Information for the Development of FY19 Trans-NIH Plan for HIV-Related Research**  **AGENCY: NIH**  **Request for Information (RFI)**  <https://www.gpo.gov/fdsys/pkg/FR-2017-03-29/pdf/2017-06183.pdf> | Published:  3/29/2017  **Due Date:**  **5/15/2017** | | Through this Request for Information (RFI), the Office of AIDS Research (OAR) in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), National Institutes of Health (NIH), invites feedback from investigators in academia, industry, health care professionals, patient advocates and health advocacy organizations, scientific or professional organizations, federal agencies, community, and other interested constituents on the development of the fiscal year (FY) 2019 Trans-NIH Plan for HIV-Related Research (FY 2019 AIDS Research Plan). This plan is designed to identify and articulate future directions to maximize the NIH’s investments in HIV/AIDS research.  High Priority topics of research for support include: (1) Reducing the incidence of HIV/ AIDS; (2) Developing the next generation of HIV therapies; (3) Identifying strategies towards a cure; (4) Improving the prevention and treatment of HIV-associated comorbidities, coinfections, and complications; and (5) Cross-cutting basic research, behavioral and social science research, health disparities, and training. |  |
| **Tobacco Product Standard for NNitrosonornicotine Level in Finished Smokeless Tobacco Products; Extension of Comment Period**  **AGENCY: FDA**  **Proposed Rule; Extension of Comment Period**  <https://www.gpo.gov/fdsys/pkg/FR-2017-03-22/pdf/2017-05490.pdf> | Published:  3/22/2017  **Due Date:**  **7/10/2017** | | The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule that appeared in the Federal Register of January 23, 2017. In the proposed rule, FDA requested comments on its proposal to establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments. The Agency is also providing notice of a typographical error in a formula in the Laboratory Information Bulletin (LIB) titled, ‘‘Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC–MS/MS’’ (LIB No. 4620, January 2017). In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled ‘‘Regulatory Freeze Pending Review’’, the Agency is also taking this opportunity to provide notice that, as with all regulatory actions subject to such memorandum, this proposed rule is being reviewed consistent with the memorandum. |  |
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| **Dear Tribal Leader Letter (Contract Support Costs Policy) Training Videos**  **IHS (no reference number)**  **AGENCY: IHS**  Dear Tribal Leader Letter  <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2017_Letters/CSC-Training-Modules-DTLL.pdf>  <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/DTLL-CSCpolicy10272016.pdf> | **Released:** 4/26/2017  **Due date:** None | | This Dear Tribal Leader Letter announces that IHS has launched a series of 5 video training modules for CSC to complement the updated IHS CSC policy (October 2016).  Training Videos: <https://www.ihs.gov/ODSCT/contract-support-costs/>.  As part of this revised policy, IHS will apply the medical inflation rate to calculate estimated annual increases to ongoing direct CSC, a change that will provide Tribes with additional access to resources. This revised policy also makes available to Tribes an option to reconcile and determine the full, final CSC expenditures within 90 days of the end of the annual performance period. In addition, this revised policy includes new tools, such as the CSC Negotiation Template, which provides a way to calculate CSC consistently and in a transparent manner. This revised policy, which IHS has published in the Indian Health Manual at Part 6, Chapter 3, is available at <https://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p6c3>.  Analysis  On June 10, 2016, NIHB made a number of recommendations on the proposed version of this revised policy. These recommendations, as well as the responses from IHS, appear below.   1. **Duplication Issue**: Much of the new content in the Contract Support Costs (CSC) policy concerns the controversial “duplication” issue--i.e., how to account for costs requested as CSC that might duplicate amounts already transferred by IHS--with footnote 1 on page 9 and footnote 10 on page 41 summarizing the competing agency and tribal views on this issue; the final CSC policy should either adopt the tribal position on this issue (i.e., nothing in the ISDEAA disqualifies any category of costs for consideration as CSC, as long as a given type of cost meets the definitional provisions set forth in 25 U.S.C. § 450j-1(a)(3), where the duplication provision appears) or retain these footnotes unchanged.   **Response: Accepted**. IHS retained these footnotes.   1. **Duplication in Recurring Service Unit Tribal Shares**: The CSC policy provides an optional (and prospective) provision under which 3% of Recurring Service Unit Tribal Shares would constitute a duplication of CSC amounts otherwise due (page 18); IHS should adopt this provision, with the following caveats:  * a. **Grandfathering in Existing Agreements**: This provision should grandfather in existing and longstanding agreements over contracted amounts (including existing agreements about duplicated amounts or the lack thereof) and apply only (1) to new or expanded programs; (2) where new costs are placed into the indirect cost pool of a Tribe, causing the pool to grow by more than 2% for that reason; or (3) to past ongoing contracted operations where the Tribe chooses to negotiate a new amount with IHS.   **Response: Not accepted**. IHS did not address this issue.   * b. **Clarification of “2% in the Value of the IDC pool”**: IHS should explain the term “2% in the value of the IDC pool” at the top of page 18, since this provision as written could indicate a change in the pool leading to an increase in an indirect cost rate exceeding 2 percentage points (i.e., from a 30% rate to a rate in excess of 32%), rather than an increase in the size of the pool exceeding 2% of the value of the pool.   **Response: Not accepted**. IHS did not provide a definition for this term.   * c. **Interpretation of “New Type” of Cost**: In deciding whether a cost constitutes a “new type” so as to trigger a detailed duplication analysis (or the 3% offset), IHS should interpret this phrase liberally in favor of the awardee, in accordance with the letter and spirit of ISDEAA.   **Response: Accepted in part**. IHS specified that, in such cases, the “review will be conducted under Alternative A and will be limited to those new types of costs” and that the costs would have to result “in a change of more than 5% in the value of the IDC pool,” rather than 2% as previously proposed.   * d. **Avoiding Disproportionate Impact on Tribes with Low Rates**: Tribes with low indirect cost rates necessarily have few costs in their pools and therefore less duplication, but this provision makes no accommodation to such Tribes.   **Response: Not accepted**. IHS did not address this issue.   1. **Startup and Pre-Award Costs (page 12)**: If IHS retains compromise provisions calling for a post year-end tribal self-certification that Tribes have spent startup costs on negotiated startup activities and provisions stating that Tribes can either repay excess startup costs or apply them to the CSC requirement for the subsequent year, the agency should revise these provisions to allow Tribes to apply any excess funds to health care.   **Response: Not accepted**. IHS finalized this provision with no changes.   1. **Direct Contract Support Costs (DCSC) (pages 12-14; and pages 58 and 59)**:  * a. **Renegotiation of DCSC**: IHS should retain provisions retaining DCSC costs as recurring costs, subject to an inflationary adjustment, and calling for renegotiation only in limited circumstances.   **Response: Accepted**. IHS retained this provision.   * b. **Inflation adjustment**: IHS should switch the inflationary adjustment to a medical inflation rate (as discussed in footnote 2, page 13) and make this change in 2016.   **Response: Accepted**. IHS adopted this change.   * c. **Identification of Additional Permissible DCSC Item**: Examples of DCSCs appear in the standards for the review and approval of CSC in Manual Exhibit 6-3-G, and in the tables on pages 58 and 59, items permissible for inclusion in the DCSC calculations as fringe costs are shown; IHS should add payments made to satisfy federal employer shared responsibility requirements under section 4980H of the Internal Revenue Code (Code) for applicable employees (added to the Code by ACA) as an example of allowable fringe costs under DCSCs.   **Response: Not accepted**. IHS did not adopt this change.   1. **Indirect Costs (pages 14-17)**:  * a. **Negotiating Estimated Indirect CSC Requirement at Front End**: Given IHS insistence upon an “incurred cost” approach to estimating and paying CSC requirements, the agency assumption of the calculation of CSC based on the entire contracted amount if at least that much in total tribal health care funding (from whatever source) was spent in the preceding year would limit the adverse impact on Tribes; IHS should retain this assumption if it does not return to its past practice of simply calculating CSC on the contracted amount for the current year.   **Response: Accepted**. IHS retained this provision.   * b. **Negotiating Final Indirect CSC Requirement After Year End**: Because IHS has seized upon the “incurred cost” approach, the agency has discussed in recent years waiting as long as 5 years to reconcile final CSC requirements against not only full audits, but subsequent indirect cost rate carryover schedules issued two and even four years out; IHS should return to a policy of negotiating final amounts for each year within 90 days of the end of that contract year based on the best available data at the time.   **Response: Not accepted**. IHS did not adopt this change.   * c. **Aged IDC Rates**: The compromise approach that IHS developed to permit close-out of the CSC negotiation process within a few months after the close of the contract year poses some concerns; IHS should carefully monitor the impact of this policy.   **Response: Not accepted**. IHS did not address this issue within the scope of the revised policy.   * d. **Bilateral amendments**: The new practice of doing post-year bilateral amendments to reflect finally-negotiated CSC amounts (pages 16-17) would impose a substantial additional burden upon IHS, as well as tribal, personnel; IHS should take this increased burden into account.   **Response: Not accepted**. IHS did not address this issue within the scope of the revised policy.   * e. **Overpayments**: When the parties agree that the awardee has received an overpayment, the policy provides that the awardee must either pay back IHS or IHS will apply the overpayment to the CSC need of the awardee in the subsequent year; IHS should recognize the right of the Tribe to apply the “overpayment” to direct services, such as health care, and failing that, to ensure right of the Tribe to decide on the handling of the overpayment, should revise the last sentence of section 6-3.2E.1.b.6 (page 17) to read as follows (new language underlined; removed language in strikethrough): “If the awardee was overpaid, the awardee will have the option to either (a) ~~it will~~ reimburse IHS for the overpayment; or, (b) agree that IHS will apply the overpayment to the awardee’s CSC need in the subsequent year.”   **Response: Accepted**. IHS adopted this change.   1. **Negotiating Indirect-like Costs (pages 17, 57)**: IHS should retain language on page 17 and in Exhibit H (page 57 and footnote 14) recognizing the right of a Tribe to negotiate indirect-like costs even if the Tribe also receives indirect CSC amounts as a result of having an indirect cost rate.   **Response: Accepted**. IHS retained this provision.   1. **Annual Funding Report to Tribes (pages 23-24)**: IHS should retain its clarification that it will produce a funding report independent of any reports due to Congress and that it will provide its funding report to Tribes annually regardless of any delays associated with issuance of any congressional report.   **Response: Accepted**. IHS retained this provision.   1. **CSC on Federal Programs, Services, Functions or Activities Supported with Third- Party Revenues**:The CSC policy remains neutral on the disputed issue of whether IHS by law must add CSC funding to support the delivery of federal programs, services, functions, or activities financed with third-party revenues (page 55, note 12), as well as on MSPI/SASP, DVPI, and CHEF funds; IHS should retain this position.   **Response: Accepted**. IHS retained this footnote.   1. **Impact on Ratemaking Process**: The CSC policy affects not only awardee relationships with IHS, but also with the cognizant agencies charged with negotiating indirect cost rates, in turn affecting relationships with every other federal agency with which awardees interact; IHS should consider how these agencies would deal with the CSC policy treatment of overpayments during the year-end reconciliation process.   **Response: Accepted**. IHS did not address this issue within the scope of the revised policy.   1. **Training**: The CSC policy is so long, complex, and daunting that non-expert tribal leaders and staff—not to mention IHS negotiators—likely would have difficulty understanding and applying it; IHS should develop a thorough and thoughtful training curriculum for both tribal and IHS personnel, with input from the CSC Workgroup on the best ways to make the necessary training available.   **Response: Not accepted**. IHS did not address this issue within the scope of the revised policy.   1. **Calculation Template**: IHS and tribal representatives have reached agreement on a summary worksheet showing the basic math behind the CSC calculation process (Exhibit F, page 37), but the various tabs that feed into the summary sheet (part of an Excel workbook) are not included because of a lack of agreement of them; IHS should make the negotiation of these tabs its highest priority.   **Response: Not accepted**. IHS did not address this issue within the scope of the revised policy. | 11/1/2016: Final policy issued. See analysis to the left. |
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| **FAQs on Medicaid and CHIP Managed Care Final Rule**  **CMS (no reference number)**  **AGENCY: CMS**  Medicaid and CHIP Managed Care Final Rule (CMS-2390-F) Frequently Asked Questions (FAQs)  [https://www.medicaid.gov/federal-policy-guidance/downloads/faq-11-10-2016.pdf](https://www.medicaid.gov/federal-policy-guidance/downloads/faq-11-10-2016.pdf%20) | **Released:** 11/10/2016  **Due date:** None | | This document addresses frequently asked questions (FAQs) related to the Medicaid and CHIP Managed Care Final Rule (CMS-2390-F) (“Final Rule”). CMS encourages states, managed care plans, and other stakeholders to submit questions to [ManagedCareRule@cms.hhs.gov](mailto:ManagedCareRule@cms.hhs.gov) to inform future guidance and FAQs. In addition, presentations from past Webinars and additional guidance documents are available at <https://www.medicaid.gov/medicaid/managed-care/guidance/final-rule/index.html>. | 11/16/2016: Final rule. No comments requested. |
| **Health-related Agency Actions Pending at OMB** | | | | |
| Revision of Requirements for Long-Term Care Facilitations: Arbitration Agreements (CSM-3342-P)  AGENCY: HHS/CMS | Received at OMB:  4/26/2017 | Proposed Rule | |  |
| Expedited Coverage of Innovative technology (ExCITe) (CMS-3344-P)  AGENCY: HHS/CMS | Received at OMB:  4/26/2017 | Proposed Rule | |  |
| Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to Comprehensive Care for Joint Replacement Model (CMS-5519-F3)  AGENCY: HHS/CMS | Received at OMB:  4/26/2017 | Proposed Rule  Economically Significant | |  |
| CY 2018 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1676-P)  AGENCY: HHS/CMS | Received at OMB:  4/17/2017 | Proposed Rule  Economically Significant | |  |
| CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1678-P)  AGENCY: HHS/CMS | Received at OMB:  4/12/2017 | Proposed Rule  Economically Significant | |  |
| CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements (CMS-1672-P)  AGENCY: HHS/CMS | Received at OMB:  4/9/2017  **Pending Review** | Proposed Rule  Economically Significant | |  |
| CY 2018 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS-1674-P)  AGENCY: HHS/CMS | Received at OMB:  4/5/2017  **Pending Review** | Proposed Rule  Economically Significant | |  |
| CY 2018 Updates to the Quality Payment Program (CMS-5522-P)  AGENCY: HHS/CMS | Received at OMB:  3/22/2017  **Pending Review** | Proposed Rule  Economically Significant  Affordable Care Act [PPACA, P.L. 111-148 & 111-152] | |  |
| **DoL and IRS/Treasury** |  |  | |  |
| **OPM** |  |  | |  |
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| **Recently Submitted Comments** | | | | |
| **Catastrophic Health Emergency Fund**  **IHS (RIN 0905-AC97)**  **AGENCY: IHS**  Catastrophic Health Emergency Fund  <https://www.gpo.gov/fdsys/pkg/FR-2016-01-26/pdf/2016-01138.pdf>  <https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05555.pdf> | **Released:** 6/6/2016  **Due date: Open for Tribal consultation through October 31, 2016** | | IHS administers the Catastrophic Health Emergency Fund (CHEF), which serves to meet the extraordinary medical costs associated with the treatment of victims of disasters or catastrophic illnesses within the responsibility of the agency. This proposed rule would establish: definitions governing CHEF; a requirement that a Service Unit shall not qualify for reimbursement for the cost of treatment until the cost of the episode of care has reached a certain threshold; a procedure for reimbursement for certain services exceeding a threshold cost; a procedure for payment for certain cases; and a procedure to ensure payment will occur from CHEF if other sources of payment (federal, state, local, or private) are available.  An IHS press release on this proposed rule is available at <https://www.ihs.gov/newsroom/index.cfm/pressreleases/2016pressreleases/ihs-seeks-comment-on-new-regulation-for-catastrophic-health-emergency-fund/>.  Due date extension (2/25/2016): IHS issued a document that extends the comment period for this proposed rule from March 11, 2016, to April 11, 2016.  Due date extension (3/11/2016): IHS issued a document that extends the comment period (a second time) for this proposed rule by 60 days, from March 11, 2016, to May 10, 2016.  Dear Tribal Leader Letter  **IHS on June 1, 2016,** issued a Dear Tribal Leader Letter announcing tribal consultation on this proposed rule. IHS will not move forward with this proposed rule until tribal consultation has occurred, including an in-person consultation session at NIHB Annual Consumer Conference on September 19 and at NCAI on October 9-14, in Phoenix, AZ. This letter comes in response to numerous requests from Tribes and tribal organizations to conduct tribal consultation before finalizing the rule. This letter is available at <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/55756-1-DTLL-CHEF.pdf>.  Tribal Consultation  On July 29, HHS issued a Dear Tribal Leader Letter announcing that IHS will hold telephone and in-person tribal consultation sessions on the proposed rule. Information on the sessions appears below.  **Telephone Sessions**  **Date**: Tuesday, August 16, 2016  **Time**: 3 p.m. to 4 p.m. ET  **Call-in number**: 1-888-790-3108  **Passcode**: 4110567  **Date**: Monday, October 24, 2016  **Time**: 1 p.m. to 2 p.m. ET  **Call-in number**: 1-888-790-3108  **Passcode**: 4110567  **In-Person Sessions**   * NIHB Annual Consumer Conference in Scottsdale, Arizona, on September 19, 2016, from 9 a.m. to 9:50 a.m. * National Congress of American Indians 73rd Annual Convention and Marketplace in Phoenix, Arizona, on October 9, 2016, from 1 p.m. to 2 p.m.   A copy of this letter is available at <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/55914-1_CHEF_DTLL_07292016.pdf>. | 1/26/2016: See summary of proposed regulations below:    **4/27/2016:** Three issues in particular of concern are (1) use of term “referral” in relation to an authorization for payment, (2) inclusion of Tribal self-insured plans in the definition of “alternative resources”, and (3) lack of Tribal consultation.  5/9/2016: Comments filed by TSGAC and other Tribal organizations.      6/2/2016: IHS on 6/1 issued a DTLL announcing tribal consultation on this proposed rule. See the column to the left for more information.  7/6/2016: IHS and CMS are preparing a document on Payer-of-last resort scenarios.  7/21/2016: TSGAC requested that IHS set a termination date for the reconsideration period, to follow the September 19 consultation at the NIHB Consumer Conference.  8/2/2016: HHS issued a letter announcing telephone and in-person consultation sessions.  10/5/2016: Tribal reps recommending that Tribes submit a red-lined draft of the proposed rule.  11/1/2016: Final TSGAC comments are embedded below. |
| **Dear Tribal Leader Letter (Contract Support Costs Policy)**  **IHS (no reference number)**  **AGENCY: IHS**  Dear Tribal Leader Letter  <http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/54891-1_DTLL_CSC_Consultation_to_OD_1-7-16.pdf>  <http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/DTLLCSCConsultationPolicy041116.pdf> | **Released:** 1/7/2016  **Due date: Open**  **Released subsequent letter:** 4/11/2016  **Due date: ~~60 days (approx. 6/10/2016)~~**  **Final policy issued (see above entry)** | | This letter seeks to initiate a consultation on the IHS Contract Support Costs (CSC) policy. IHS plans to update and implement a new policy in 2016. The policy, developed in 1992 and revised several times since then through coordination and consultation with AI/AN Tribes and tribal organizations, aims to provide uniform and equitable guidance on the preparation and negotiation of requests for CSC funds for new and existing awards authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA). The new policy comes in response to a June 2012 Supreme Court decision on CSC claims against the Department of the Interior in the case *Salazar v. Ramah Navajo Chapter* (Ramah). The impact of this decision generated additional review for IHS, although not a party to the Ramah case, and its CSC policy.  The current CSC policy appears in the Indian Health Manual at Part 6, Chapter 3 (2007), available online at <https://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p6c3>. IHS last initiated consultation on this policy in October 2011. **As IHS updates this policy, please send written input or feedback to Robert G. McSwain by mail at the address below or by e-mail at** [**consultation@ihs.gov**](mailto:consultation@ihs.gov).  Subsequent letter (4/11/2016): This Dear Tribal Leader Letter opens a tribal consultation for a 60-day period to consult with AI/AN Tribes and tribal organizations on the revised IHS Contract Support Costs (CSC) policy. IHS seeks to goal is to finalize and implement the revised CSC policy this year. The revised CSC policy is available at <http://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/2016IHSCSCPolicy04122016.pdf>. | 6/10/2016: TSGAC proposed comments: |
| **Dear Tribal Leader Letter (Core Provider Network)**  **VA (no reference number)**  **AGENCY: VA**  Dear Tribal Leader Letter  <https://www.gpo.gov/fdsys/pkg/FR-2016-09-29/pdf/2016-23483.pdf> (FR notice) | **Released:**  9/12/2016  **Due date: 11/5/2016** | | This Dear Tribal Leader Letter announces that VA seeks tribal consultation to assist in developing the core provider network in a manner that would build on existing department relationships with tribal health programs and facilitate future collaboration to improve health care services provided to all eligible, VA-enrolled veterans, regardless of whether they are IHS-eligible. Specifically, VA seeks input from tribal leaders regarding tribal health program participation in the core provider network and a potential transition from the current reimbursement agreement structure to a model under which tribal health programs deliver care to all eligible, VA-enrolled veterans using a standard reimbursement rate. To gather this input, **VA plans to hold an in-person tribal consultation session on Wednesday, September 28, 2016, from 9 a.m. to 11 a.m., in the Smithsonian National Museum of the American Indian (NMAI) in Washington, D.C.** Interested parties should RSVP to [tribalgovernmentconsultation@va.gov](mailto:tribalgovernmentconsultation@va.gov). VA also invites written comments at [tribalgovernmentconsultation@va.gov](mailto:tribalgovernmentconsultation@va.gov). For more information, please contact Majed Ibrahim at [majed.ibrahim@va.gov](mailto:majed.ibrahim@va.gov).  A copy of the letter is embedded below.    Federal Register Notice  In the September 29, 2016, Federal Register, VA issued a notice on this tribal consultation. The due date for submitting comments remains unchanged. | 9/14/2016: See notice on date of in-person tribal consultation.  10/5/2016: Key points to be submitted in comments:   * Extend existing Master MOU and individual agreements 5 years * Approve pending contract proposals from Tribes / THOs * Create VA-Tribal work group   A key reason for the request to extend contracts – and not fold Tribal contracts into the CHOICE program – is the Tribal –VA MOUs have payment protections as well as important options for implementing innovative delivery options, such as sharing resources between VA and Tribal facilities and sharing staff.  11/8/2016: Final NIHB comment is embedded below.    11/18/2016: Final TSGAC comment is available at <http://www.tribalselfgov.org/wp-content/uploads/2016/11/VA-Consultation-comments-11-2-2016-final.pdf>. |
| **Dear Tribal Leader Letter (Realignment of IHS Headquarters)**  **IHS (no reference number)**  **AGENCY: VA**  Dear Tribal Leader Letter  <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/DTLL_HeadquartersRealignment_10052016.pdf> | **Released:**  10/5/2016  **~~Due date: 11/5/2016~~**  **Extended date: 1/13/2017** | | This Dear Tribal Leader Letter announces that IHS seeks tribal consultation on a proposed realignment of IHS Headquarters offices. This realignment seeks to impact how IHS Headquarters operates and accomplishes its oversight responsibilities, with clearer and more transparent lines of accountability. To improve efficiency and effectiveness of program operations, this realignment also moves some IHS Division-level components under different senior staff leadership. In addition to these organizational changes, this realignment makes management process changes, as well improves procurement planning and budget monitoring. **IHS will accept comments on this realignment through November 5, 2016**. Once IHS finalizes the realignment chart and functional statements, they will appear as a notice in the Federal Register with an effective date 30 days after the publication date.  Request for Due Date Extension  NIHB on October 17 sent a letter to IHS requesting a due date extension. A copy of the letter appears below.    IHS posting of Tribal comments received to date:  <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/Enclosure_SummaryofHQProposedRealignment.pdf> | 11/8/2016: Final TSGAC comment is embedded below. |
| **Indian Addendum for Contracting with Medicaid/CHIP Managed Care Entities**  **CMS (no reference number)**  **AGENCY: CMS**  All Tribes Call: Indian Health Care Addendum for Contracting with Medicaid and CHIP Managed Care Entities  <https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/All-Tribes-Calls.html> | **Released:** 10/26/2016  **Call date: 11/9/2016**  **Due date:**  **11/16/2016** | | On April 25, 2016, CMS released a final rule on managed care in Medicaid and CHIP. The final rule incorporated the Indian protections in Section 5006 of the American Recovery and Reinvestment Act. The Indian-specific provisions in the final rule appear in the section titled “Standards for Contracts Involving Indians, Indian Health Care Providers, and Indian Managed Care Entities.”    In the final rule, CMS committed to developing sub-regulatory guidance through consultation on the use of Medicaid and CHIP Indian Managed Care (I/T/U Addendum). The I/T/U Addendum seeks to help facilitate contracts between Indian health care providers (IHCPs) and managed care plans by identifying several specific provisions established in federal law that apply when contracting with IHCPs.  Through an October 5, 2016, All Tribes Call, CMS obtained tribal input and advice on an Informational Bulletin in development by the Center for Medicaid & CHIP Services (CMCS) that highlights the Indian-specific provisions of the final rule. CMS indicated on that call that it would hold a separate call on the I/T/U Addendum. CMCS will then release the Informational Bulletin and I/T/U Addendum as a single guidance.  All Tribes Call on the I/T/U Addendum will provide an overview of the I/T/U Addendum and address any questions. Details on the All Tribes Call appear below.  Date: Wednesday, November 9, 2016  Time: 2:30-4:00 p.m. ET  Conference number: 1-844-224-0415  Pin: 3744369  The I/T/U Addendum is available at <http://files.kauffmaninc.com/projects/cms/all-tribes-calls/Indian_addendum_CIB_10172016.pdf>.  Interested parties can submit written comments on the I/T/U Addendum to [tribalaffairs@cms.hhs.gov](mailto:tribalaffairs@cms.hhs.gov) by close of business on November 16, 2016.  A recording of the October 5, 2016, All Tribes Call is available at <http://cms.us9.list-manage.com/track/click?u=c0033d065eadb44cbd20725a3&id=0c552b4c6a&e=e7f2317dff>. | 10/27/2016: See notes to the left.  All Tribes Call 11/9/2016 at 2:30 pm Eastern.  11/2/2016: A tribal redline version of this addendum is embedded below. |
| **Dear Tribal Leader Letter (Realignment of IHS Headquarters)**  **IHS (no reference number)**  **AGENCY: VA**  Dear Tribal Leader Letter  <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/DTLL_HeadquartersRealignment_10052016.pdf> | **Released:**  10/5/2016  **~~Due date: 11/5/2016~~**  **Extended date: 1/13/2017** | | This Dear Tribal Leader Letter announces that IHS seeks tribal consultation on a proposed realignment of IHS Headquarters offices. This realignment seeks to impact how IHS Headquarters operates and accomplishes its oversight responsibilities, with clearer and more transparent lines of accountability. To improve efficiency and effectiveness of program operations, this realignment also moves some IHS Division-level components under different senior staff leadership. In addition to these organizational changes, this realignment makes management process changes, as well improves procurement planning and budget monitoring. **IHS will accept comments on this realignment through November 5, 2016**. Once IHS finalizes the realignment chart and functional statements, they will appear as a notice in the Federal Register with an effective date 30 days after the publication date.  Request for Due Date Extension  NIHB on October 17 sent a letter to IHS requesting a due date extension. A copy of the letter appears below.    IHS posting of Tribal comments received to date:  <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/Enclosure_SummaryofHQProposedRealignment.pdf>  Due Date Extension and Teleconferences  On November 15, 2016, IHS issued a Dear Tribal Leader Letter announcing an extension of the due date for comments on this tribal consultation until January 13, 2017. The letter also announced that IHS will hold three national teleconferences to collect input from Tribes (see below for details). A copy of the letter is available at <https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/2016_Letters/DTLLSigned111516.pdf>. | 11/8/2016: Final TSGAC comment is embedded below.    11/18/2016: IHS has announced a due date extension and three national teleconferences regarding this tribal consultation. See the column to the left. |
| **MIPS and Alternative Payment Model Incentive Under the PFS**  **CMS-5517-FC**  **AGENCY: CMS**  Medicare Program; Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models  <https://qpp.cms.gov/docs/CMS-5517-FC.pdf> (pre-public inspection document)  <https://www.gpo.gov/fdsys/pkg/FR-2016-11-04/pdf/2016-25240.pdf> (published rule) | **Released:**  10/14/2016  **Published:**  11/4/2016  **Due date:**  **12/19/2016** | | The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repeals the Medicare sustainable growth rate (SGR) methodology for updates to the physician fee schedule (PFS) and replaces it with a new approach to payment called the Quality Payment Program that rewards the delivery of high-quality patient care through two avenues: Advanced Alternative Payment Models (Advanced APMs) and the Merit-based Incentive Payment System (MIPS) for eligible clinicians or groups under the PFS. This final rule with comment period establishes incentives for participation in certain APMs and includes the criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making comments and recommendations on physician-focused payment models (PFPMs). APMs are payment approaches, developed in partnership with the clinician community, that provide added incentives to deliver high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. This final rule with comment period also establishes MIPS, a new program for certain Medicare-enrolled practitioners. MIPS will consolidate components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals (EPs) and will continue the focus on quality, cost, and use of certified EHR technology (CEHRT) in a cohesive program that avoids redundancies. In this final rule with comment period, CMS has rebranded key terminology based on feedback from stakeholders, with the goal of selecting terms more easily identified and understood by its stakeholders.  A CMS executive summary of this final rule is available at <https://qpp.cms.gov/docs/QPP_Executive_Summary_of_Final_Rule.pdf>.  A new Quality Payment Program Web site accompanying the announcement of this final rule is available at <https://qpp.cms.gov/>. A related HHS press release is available at <http://www.hhs.gov/about/news/2016/10/14/hhs-finalizes-streamlined-medicare-payment-system-rewards-clinicians-quality-patient-care.html>.  A *Healthcare Dive* article on this final rule is available at <http://www.healthcaredive.com/news/here-are-the-macra-final-rule-changes-you-need-to-know/428341/>.  MACRA QPP Workgroup Assignments  Notes of sections due November 30; comment due December 13  Table of Contents  I. Executive Summary **Pg. 8-39 Sarah Freeman**  II. Provisions of the Proposed Regulations and Analysis of and Responses to Comments **Pg. 40 Susy Postal**  A. Establishing MIPS and the Advanced APM Incentive **Pg. 40 Susy Postal**  B. Program Principles and Goals **Pg. 40 Susy Postal**  C. Changes to Existing Programs **Pg. 41-99 Susy Postal**  D. Definitions (list) **Pg. 100-103/Pg. 1,819 Susy Postal**  E. MIPS Program Details **Pg. 104-1380 (see below)**  **Pg. 104-264 Cara Lowder**  **Pg. 265-425 Jim Roberts**  **Pg. 426-586 Verne Boerner**  **Pg. 587-747 Akilah Kinnison**  **Pg. 748-908 Sunny Stevenson**  **Pg. 909-1,069 Susy Postal**  **Pg. 1070-1,230 Brian Wren**  **Pg. 1,231-1,380 Katie Johnson**  F. Overview of Incentives for Participation in Advanced Alternative Payment Models **Pg.1381-1725 (see below)**  **Pg. 1,381-1,496 Dr. Judy Goforth Parker**  **Pg. 1,497-1,612 Cara Lowder**  **Pg. 1,613-1,725 Sarah Freeman**  III. Collection of Information Requirements **Pg. 1,726-1,770 Brian Wren**  IV. Regulatory Impact Analysis **Pg.1,771 Melissa Gower**  A. Statement of Need **Pg. 1,771 Melissa Gower**  B. Overall Impact **Pg. 1,772-1,775 Melissa Gower**  C. Changes in Medicare Payments **Pg. 1,775-1,802 Melissa Gower**  D. Impact on Beneficiaries **Pg. 1,802-1,804 Melissa Gower**  E. Impact on Other Health Care Programs and Providers Pg.1,804- Pg.1,809 Melissa Gower  F. Alternatives Considered **Pg. 1,809-1,811 Melissa Gower**  G. Assumptions and Limitations **Pg. 1,811-1,812 Melissa Gower**  H. Accounting Statement **Pg. 1,812 Melissa Gower**  V. Appendix **Pg. 1902-2171 (TO BE DETERMINED--Please e-mail Sarah Freeman to get added)**  Analysis  On June 27, 2016, tribal organizations made a number of recommendations on the proposed version of this rule. These recommendations, as well as the responses from CMS, appear below.   1. **Cost of Compliance and Need for Federal Support**: The cost of compliance with the reporting, technology, and care coordination requirements in the proposed rule might prove prohibitive for many I/T/Us; either through funding, assistance, and/or exemptions, CMS should address this issue to ensure that I/T/Us do not have to divert funding that would otherwise go toward health care programs and services or the recruitment of additional providers to address existing vacancies.   **Response: Accepted in part**. CMS stated, “In keeping with the objectives of providing education about the program and maximizing participation, and as mandated by the MACRA, $100 million in technical assistance will be available to MIPS eligible clinicians in small practices, rural areas, and practices located in geographic health professional shortage areas (HPSAs), including IHS, tribal, and urban Indian clinics, through contracts with quality improvement organizations, regional health collaboratives, and others to offer guidance and assistance to MIPS eligible clinicians in practices of 15 or fewer MIPS eligible clinicians.” [page 21]   1. **Low-Volume Threshold Exclusion**: The proposed low-volume threshold exclusion raises concerns, as many eligible clinicians (ECs) might bill less than $10,000 in Medicare allowable charges, if the allowable charges are specific to the Part B physician fee schedule (PFS); CMS should  * For providers not participating in an ACO, clarify whether the low-volume threshold includes the rural health clinic (RHC) all-inclusive rates (AIR) or FQHC PPS (preferred) or whether it excludes these other payment methodologies; * For providers that change positions frequently or work as locums tenans, clarify whether the low-volume threshold will be cumulative throughout the year as they bill under different TINs or will be specific to an NPI/TIN combination (preferred).   **Response: Accepted**. CMS noted that “we are modifying our proposed low-volume threshold to be based on a dollar value of $30,000 of billed Medicare Part B allowed charges during a performance period or 100 Part B-enrolled beneficiary count, which would apply to clinicians in RHCs and FQHCs with billed Medicare Part B allowed charges.” [page 243] In addition, CMS stated, “In sections II.E.2.a. and II.E.2.b. of this final rule with comment period, we describe the identifiers for MIPS eligible clinicians participating in MIPS at the individual or group level. For MIPS eligible clinicians reporting as individuals, we use a combination of billing TIN/NPI as the identifier to assess performance. In order to determine the low-volume status of eligible clinicians reporting individually, we will calculate the low-volume threshold for each TIN/NPI combination. For individual MIPS eligible clinicians billing under multiple TINs, the low-volume threshold is calculated for each TIN/NPI combination. In the case of an individual eligible clinician exceeding the low-volume threshold under any TIN/NPI combination, the eligible clinician would be considered a MIPS eligible clinician and required to meet the MIPS requirements for those TIN/NPI combinations.” [page 243-4]   1. **Need for IHS/Tribal-Specific Data**: The regulatory impact analysis of the proposed rule indicates that CMS has estimated the number of physicians and other professionals that will receive a CPS score in MIPS Year 1, and the number that will get excluded as QPs, but whether this estimate included a category for clinicians who serve AI/AN Medicare beneficiaries remains uncertain; if yes, CMS should share this information with the TTAG, IHS, Tribes, and urban Indian programs, and if no, the agency should add this category in future studies (as well as provide a category or function for comparing IHS, tribal, and urban Indian providers only on the Physician Compare Web site).   **Response: Not accepted**. However, CMS indicated that, “if feasible and appropriate under the statute, we may possibly consider these issues in future rulemaking and will conduct tribal consultation with tribes and tribal officials, as feasible and appropriate.” [page 1514]   1. **Scoring and Payment Adjustments**: The scoring formula and payment adjustment process must account for the unique position of tribal and urban Indian health programs; to that end, CMS should address the following concerns:  * a. **Fairness**: Ensure that the scoring system and weighting of performance categories remains fair, particularly in the absence of available data for one or more category; * b. **Special Rules for Indian Health Programs**: Potentially establish special rules for IHS, tribal, and urban Indian health programs to avoid adverse results; * c. **Emergency Preparedness and Response Sub-Category**: Clarify this sub-category, possibly adding language including the Commissioned Corps of the United States Public Health Service (USPHS) officers, who Indian health programs often employ, in the definition of active duty military MIPS eligible clinicians; * d. **Advancing Care Information Category**: With regard to this category, take into consideration how the high level of staff turnover experienced in Indian Country might impact its ability to meet group reporting requirements, as well as how to accommodate frequent changes in the group of MIPS Eligible Clinicians; implement the proposed method of estimating the proportion of physicians as defined in section 1861(r) who are meaningful EHR users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of at least 75 percent under the proposed scoring methodology for a performance period; avoid removing the Broadband Access Exclusion as written in the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017” final rule for the two measures that require providers to have broadband access.   **Response: Not accepted**. CMS stated, “We appreciate the unique challenges that face MIPS eligible clinicians that are part of IHS, Tribal, and Urban Indian health programs. We considered creating different performance criteria for certain types of clinicians; however, we believe that approach would create more confusion and burden than a cohesive set of criteria. Rather, to ease the participation burden, we have reduced the performance threshold to 3 points for the transition year only, which provides a pathway for MIPS eligible clinicians to engage in MIPS. We are also committed to continuing to work with IHS and its partners to streamline and coordinate programs where possible.” [page 1271]   1. **Utilize Existing Reporting Measures/Systems**: The proposed rule provides for the annual selection of quality measures through a call for quality measures process, with the selection of measures based on certain criteria that align with CMS priorities; CMS should accept the Government Performance Results Act (GPRA) measures that Tribes and urban Indian health program already must report to avoid duplication of effort and to lessen the burden on I/T/Us, as well as accept the IHS RPMS as a qualified entity when compiling the list of entities qualified to submit data as a QCDR.   **Response: Accepted in part**. CMS stated, “There are many GPRA measures that are similar to measures that already exist within the program. In addition, some GPRA measures are similar to measures that are part of a CQMC core measure set. We strive to lessen duplication of measures and to align with measures used by private payers to the extent practicable. If there are measures reportable within GPRA that are not duplicative of measures within MIPS, we recommend the commenters work with measure owners to submit these measures during our annual Call for Measures.” [page 544] In regard to accepting the IHS RPMS, CMS stated, “We would like to explain that while we will consider all entities that seek to qualify as a QCDR, we cannot conclude that a particular entity is capable of meeting our criteria in advance of the qualification process. It is important to note that an entity must meet the criteria in §414.1400(c) and be approved by CMS to qualify as a QCDR. We will develop further subregulatory guidance, including through tribal consultation to address issues raised by entities that want to be QCDRs.” [page 1378-9]   1. **IHS/Tribal/Urban Indian Health Programs as Alternative Payment Models**: The proposed rule rewards participation in APMs; CMS should explore population/provider based APMs or consider other options for categorizing I/T/U health programs as APMs.   **Response: Accepted in part**. CMS stated, “We support the pursuit of developing Other Payer Advanced APMs under a variety of health care payment programs. Payment arrangements not included under Medicare Part B could potentially qualify as Other Payer Advanced APMs for QP Performance Periods in 2019 and later.” [page 1753]   1. **Need for Tribal Consultation**: CMS should engage in meaningful face-to-face tribal consultation to provide a better understanding of how the proposed rule will impact I/T/Us and allow the opportunity for meaningful feedback before adopting the final rule.   **Response: Not accepted**. CMS did not specifically address this issue but did indicate the potential for future tribal consultation related to this rule (see #3 and #5 above). | 1 |