

National Indian Health Board



Regulation Review and Impact Analysis Report (RRIAR) v. 7.01

July 31, 2017

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-

- Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products; Extension of Comment Period - Comments due 7/10/2017 (Ref. #7).
- Agency Information Collection; CMS-10418 Medical Loss ratio Annual Reports, MLR Notices, and Recordkeeping Requirements - Comments due 7/3/2017 (Ref. #33).
- Medicare Program; CY 2018 Updates to the Quality Payment Program - Comments due 8/21/2017 (Ref. #36).
- Agency Information Collection: Virtual Groups for MIPS (CMS-10652) - Comments due 8/14/2017 (Ref. #37).
- Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients - Comments due 7/12/2017 (Ref. #38).
- Data Collection Materials for the Evaluation of the Administration for Community Livings American Indian, Alaska Natives, and Native Hawaiian Programs (OAA Title VI) – Comments due 7/20/2017 (Ref. #39).
- Agency Information Collection: (1)Extension of State Medicaid HIT Plan, Planning Advance Planning Document, and Implementation Advance Planning Document for Section 4201 of the Recovery Act; (2) Extension of Disclosure Requirement for the In-Office Ancillary Services Exception; (3) Conditions of Participation for Critical Access Hospitals (CAHs) and Supporting Regulations – Comments due 8/25/2017 (Ref. #40).
- Agency Information Collection: The Veterans' Outcome Assessment (VOA) (Veteran Survey Interview) – Comments due 8/25/2017 (Ref. #41).

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

- NIHB/NCAI Joint Comment to FCC: Actions to Accelerate Adoption and Accessibility of Broadband-Enabled Health Care Solutions and Advanced Technologies (GN Docket No.17-26) – Submitted 5/24/2017.
- Medicare Program: Hospital Inpatient Prospective Payment System; Provider-Based Status of IHS and Tribal Facilities Proposed Rule (CMS-1677-P) – Submitted 6/13/2017.

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

- FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) Proposed Rule (CMS-1679-P) – Received at OMB 3/14/2017, pending review (Ref. #31).
- CY 2018 Updates to the Quality Payment Program Proposed Rule (CMS-5522-P) – Received at OMB 3/22/2017, pending review (Ref. #36).
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements Proposed Rule (CMS-1675-P) – Received at OMB 3/23/2017, pending review.

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- CY 2018 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Proposed Rule (CMS-1674-P) – Received at OMB 4/5/2017, pending review.
- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements (CMS-1672-P) Proposed Rule – Received at OMB 4/9/2017, pending review.
- CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates Proposed Rule (CMS-1678-P) – Received at OMB 4/17/2017, pending review (Ref #14).
- Patient Protection and Affordable Care Act; Market Stabilization (CMS-9929-F) – Received at OMB 3/31/2017 and concluded- consistent with change at OMB on 4/12/2017 (Ref. #22).
- CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B Proposed Rule (CMS-1676-P) – Received at OMB 4/17/2017, pending review.
- Expedited Coverage of Innovative technology (ExCITe) Proposed Rule (CMS-3344-P) – Received at OMB 4/26/2017, pending review.
- Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements Proposed Rule (CSM-3342-P) – Received at OMB 4/26/2017, pending review.
- Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to Comprehensive Care for Joint Replacement Model Proposed Rule (CMS-5519-F3) – Received at OMB 4/26/2017, pending review (Ref. #13).
- Coverage of Certain Preventative Services Under the Affordable Care Act Interim Final Rule – Received at OMB 5/23/2017, pending review.
- Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions Proposed Rule (CMS-2294-P) – Received at OMB 6/14/2017, pending review (Ref. #1).
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System – Rate Update Notice (CMS-1673-N) – Received at OMB 6/20/2017, pending review.

IV. Recent final rules issued-

- Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements; Corrections – Effective 3/21/2017 (Ref. #2).
- Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; EHR Incentive Payment Programs; Payment to Non-excepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing Program; Establishment of Payment Rates Under the Medicare PFS for Non-excepted Items and Services Furnished by an Off-Campus Provider-Based Hospital; Correcting Amendment – Effective 4/6/2017 (Ref. #14)
- Possession, Use, and Transfer of Select Agents and Toxins – Addition of *Bacillus cereus* Biovar anthracis to HHS List of Select Agents and Toxins – Effective 4/12/2017 (Ref. #15).
- Release of VA Records relating to HIV – Effective 4/24/2017 (Ref. #6).
- Medicare Program; Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR); Delay of Effective Date – Effective 5/20/2017 (Ref. #13).
- 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date – Effective 5/22/2017 (Ref. #3).
- Medicaid Program; Disproportionate Share Hospital (DSH) Payments – Treatment of Third Party Payers in Calculating Uncompensated Care Costs – Effective 6/2/2017 (Ref. #1).
- Patient Protection and Affordable Care Act (ACA); Market Stabilization – Effective 6/19/2017 (Ref#11).
- Rural Health Care Support Mechanism – Effective 6/21/2017 (Ref. #42).
- Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies; Delay of Effective Date – Effective 1/13/2018 (Ref. #11).



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| 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 |
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| 1. | <p>Medicaid Program; Disproportionate Share Hospital (DSH) Payments – Treatment of Third Party Payers in Calculating Uncompensated Care Costs</p> <p>ACTION: Final Rule AGENCY: CMS FILE CODE: CMS-2399-F</p> | <p>Published: 4/3/2017</p> <p>Received at OMB: 6/14/2017</p> <p>Effective: 6/2/2017</p> | <ul style="list-style-type: none"> The final rule is effective June 2, 2017 and addresses how third-party payments are treated when calculating the hospital-specific limitation on Medicaid disproportionate share hospital (DSH) payments. According to CMS, the final rule clarifies current policy that uncompensated care costs for Medicaid-eligible individuals include only those that remain after accounting for payments that hospitals receive by or on behalf of Medicaid-eligible individuals. This includes Medicare and other third-party payments that compensate the hospitals for care furnished to Medicaid-eligible individuals. Previously, hospitals were given the difference between the total cost of inpatient and outpatient care for Medicaid patients and the total Medicaid payments received. CMS Response: The rule as proposed would not have a significant impact on Indian Tribes because the language of this rule accurately reflects existing policy that is currently being enforced, applied and implemented uniformly across all states, except in limited instances where we have suspended enforcement of the existing policy in light of court orders. Further, this policy has been previously articulated in the 2008 DSH final rule. During the development of the 2008 DSH final rule, the agency held the required tribal consultation. <ol style="list-style-type: none"> Federal law requires state Medicaid programs to make DSH payments to hospitals that serve large Medicaid and uninsured populations. Under the hospital-specific DSH limit, federal financial participation is limited to a hospital's uncompensated care costs. Under the final rule, uncompensated care costs include only those costs for Medicaid-eligible individuals that remain after accounting for payments made to hospitals by or on behalf of Medicaid-eligible individuals, including Medicare and other third-party payments. "As a result, the hospital-specific limit calculation will reflect only the costs for Medicaid eligible individuals for which the hospital has not received payment from any source," according to the final rule. CMS said the final rule clarifies existing policy regarding how hospital DSH payments are calculated. | <ul style="list-style-type: none"> NIHB provided comments on the proposed rule: CMS-2399-P on the Medicaid Program DSH Payments- Treatment of Third Party Payers in Calculating Uncompensated Care Costs in September 2016. In August of 2015, during the Health Financial Systems (HFS) user group meeting it was stated that CMS was considering using the Worksheet S-10 for the 75% calculation. The problem for Indian Health Care Providers (IHCP) is that when this was reviewed CMS indicated that IHCP had no uncompensated care. Additional consultation with the Indian Health Service and Tribes is necessary for CMS to ensure that IHS and Tribal facilities continue to access third party revenue for Tribal health programs. | <ul style="list-style-type: none"> The proposed rule would make clearer the interpretation that uncompensated care costs include only those costs for Medicaid eligible individuals remaining after accounting for payments received by hospitals by or on behalf of Medicaid eligible individuals, including Medicare and other third party payments that compensate the hospitals for care furnished to such individuals. This policy has been previously articulated in the 2008 DSH final rule. For FY 2018, CMS proposes to begin incorporating uncompensated care cost data from Worksheet S-10 of the Medicare Cost report in the methodology for distributing these funds under Factor 3. The Factor 3 hospital payments represent 75% of the total amount for uncompensated care payments. The 32 IHS and Tribal hospitals (non-critical access hospitals) received \$14.3 million during FY 2015 for what CMS describes as Factor 3 payments for uncompensated care. These payments were based on each hospital's number of low-income days as percentage of the nation's total low-income days. CMS proposes to re-define uncompensated care costs for Factor 3 payments as the costs of charity care and non-Medicare bad debt and to incorporate Worksheet S-10 data over a three-year period, where insured low income day data will be averaged with uncompensated care cost data. For FY 2018, CMS proposes to use Worksheet S-10 data from FY 2014 |



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| | | | <p>However, the American Hospital Association disagrees. After CMS released the proposed rule in September, the AHA sent a letter to CMS arguing the rule is more than a clarification and actually establishes new policy. The AHA urged CMS to withdraw the proposed rule.</p> <p>4. CMS issued its original policy in sub-regulatory guidance in August. The agency released the final rule a few weeks after a federal court barred CMS from using sub-regulatory guidance to calculate Medicaid DSH payments for New Hampshire hospital</p> | | <p>cost reports in combination with insured low income days from the two preceding periods for determining the distribution of uncompensated care payments. Unless changes are approved by CMS on the allocation of Factor 3 funds, IHS Federal and Tribal hospitals could ultimately lose all payments under Factor 3 of the uncompensated care pool of funds.</p> |
| 2. | <p>Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements; Corrections</p> <p>ACTION: Final Rule; Correction AGENCY: CMS FILE CODE: CMS-1654-CN4</p> | <p>Published: 3/22/2017 Effective: 3/21/2017</p> | <ul style="list-style-type: none"> • There was a technical error in an element of the payment calculation for several services that is identified and corrected in this correcting document. These corrections are effective as if they had been included with the document published November 15, 2016. Accordingly, the corrections are applicable beginning January 1, 2017. • Due to a technical error in the allocation of indirect practice expense (PE) for CPT codes 97161 through 97168, the incorrect CY 2017 PE relative value units (RVUs) were included in Addendum B. The corrected CY 2017 PE RVUs for these codes are reflected in the corrected Addendum B available on the CMS Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/index.html. | <p>No recommendations for this correction.</p> | <p>No analysis for this correction.</p> |
| 3. | <p>340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date</p> <p>ACTION: Interim Final Rule/ Delay of Effective Date AGENCY: HRSA FILE CODE: RIN 0906-AA89</p> | <p>Published: 3/6/2017 Effective: 5/22/2017</p> | <p>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).</p> | <p>No recommendations.</p> | <ul style="list-style-type: none"> • Section 602 of Public Law 102–585, the “Veterans Health Care Act of 1992,” enacted section 340B of the PHSA, “Limitation on Prices of Drugs Purchased by Covered Entities,” codified at 42 U.S.C. 256b. The 340B Program permits covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” • The revisions to 42 CFR part 10 of the final rule are described according to the applicable section of the final rule. This final rule replaces § 10.1, § 10.2, § 10.3, and § 10.10, adds a new § 10.11, and eliminates § 10.20 and § 10.21. |
| 4. | <p>Notice to Propose the Re-Designation of the Service Delivery Area for the Tolowa</p> | <p>Published: 5/1/2017</p> | <ul style="list-style-type: none"> • The entire State of California, excluding the counties of Alameda, Contra Costa, Los Angeles, Marin, | | |



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| | <p>Dee-ni' Nation (Smith River Rancheria); Extension of Comment Period</p> <p>ACTION: Notice of Extension of Comment Period AGENCY: IHS</p> | <p>Due Date: 6/30/2017</p> | <p>Orange, Sacramento, San Francisco, San Mateo, Santa Clara, Kern, Merced, Monterey, Napa, San Benito, San Joaquin, San Luis Obispo, Santa Cruz, Solano, Stanislaus, and Ventura, are designated a Purchased/Referred Care (PRC) Service Delivery Area, formerly referred to as a Contract Health Service Delivery Area, by statute.</p> <ul style="list-style-type: none"> • The notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Service Delivery Area for the Tolowa Dee-ni' Nation (Tribe) previously known as the Smith River Rancheria of Smith River, California. • The Tolowa Dee-ni's Tribal Headquarters is located three miles south of the California-Oregon border in Northern California. • The current Service Delivery Area for the Tolowa Dee-ni' Nation Tribal members is the statutorily established California PRC Service Delivery Area. • The expanded PRC Service Delivery Area for the Tolowa Dee-ni' Nation includes the statutorily established California PRC Service Delivery Area and Curry County in the State of Oregon. | | |
| <p>5.</p> | <p>Request for Information for the Development of FY19 Trans-NIH Plan for HIV-Related Research</p> <p>ACTION: Request for Information (RFI) AGENCY: NIH</p> | <p>Published: 3/29/2017</p> <p>Due Date: 5/15/2017</p> | <ul style="list-style-type: none"> • 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. | <p>No recommendations.</p> | |
| <p>6.</p> | <p>Release of VA Records relating to HIV</p> <p>ACTION: Final Rule</p> | <p>Published: 3/23/2017</p> <p>Effective:</p> | <ul style="list-style-type: none"> • The Department of Veterans Affairs (VA) is amending its medical regulations governing the release of VA medical records. Specifically, VA | <p>No recommendation.</p> | |



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| | AGENCY: VA | 4/24/2017 | <p>is eliminating the restriction on sharing a negative test result for the human immunodeficiency virus (HIV) with veterans' outside providers.</p> <ul style="list-style-type: none"> • HIV testing is a common practice today in healthcare and the stigma of testing that may have been seen in the 1980s when HIV was first discovered is no longer prevalent. Continuing to protect negative HIV tests causes delays and an unnecessary burden on veterans when VA tries to share electronic medical information with the veterans' outside providers through electronic health information exchanges. • VA will also eliminate restrictions on negative test results of sickle cell anemia. This final rule eliminates the current barriers to electronic medical information exchange. | | |
| 7. | <p>Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products; Extension of Comment Period</p> <p>ACTION: Proposed Rule; Extension of Comment Period AGENCY: FDA FILE CODE: FDA-2016-N-2527</p> | <p>Published: 3/22/2017 Due Date: 7/10/2017</p> | <ul style="list-style-type: none"> • The Food and Drug Administration (FDA) 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-nitrosornicotine (NNN) in finished smokeless tobacco products. • FDA is taking this action in response to requests for an extension to allow interested persons additional time to submit comments. FDA is also providing notice of a typographical error in a formula in the Laboratory Information Bulletin (LIB) titled, "Determination of N-nitrosornicotine (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", FDA 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. | <p>NIHB has recommended that Tribes concerned with the new N-Nitrosornicotine level in finished smokeless tobacco products comment on this proposed rule. NIHB will not be commenting on this proposed rule.</p> | |



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| 8. | <p>Proposals from the Federal Interagency Working Group for Revision of the Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity</p> <p>ACTION: Notice and Request for Comments AGENCY: OMB</p> | <p>Published: 3/1/2017 Due Date: 4/30/2017</p> | <ul style="list-style-type: none"> • OMB requests comments on the proposals that it has received from the Federal Interagency Working Group for Research on Race and Ethnicity (Working Group) for revisions to OMB's Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. The Working Group's report and proposals, which are presented here in brief and available on https://www.whitehouse.gov/briefing-room/presidential-actions/related-omb-material and on http://www.regulations.gov in their entirety, are the result of a two-year, focused review of the implementation of the current standards. • The Working Group's report reflects an examination of current practice, public comment received in response to the Federal Register Notice posted by OMB on September 30, 2016, and empirical analyses of publicly available data. The report also notes statutory needs and feasibility considerations, including cost and public burden. Initial proposals and specific questions to the public appear under the section Issues for Comment. • None of the proposals have yet been adopted and no interim decisions have been made concerning them. The Working Group's report and its proposals are being published to solicit further input from the public. OMB plans to announce its decision in mid-2017 so that revisions, if any, can be reflected in preparations for the 2020 Census. • OMB can modify or reject any of the proposals, and OMB has the option of making no changes. The report and its proposals are published in this Notice because OMB believes that they are worthy of public discussion, and OMB's decision will benefit from obtaining the public's views on the recommendations. | | |
| 9. | <p>Notice to Propose the Re-Designation of the Service Delivery Area for the Passamaquoddy Tribe at Indian Township</p> <p>ACTION: Notice AGENCY: IHS</p> | <p>Published: 3/8/2017 Due Date: 4/7/2017</p> | <p>This notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Purchased/Referred Care (PRC) Service Delivery Area (SDA) for the Passamaquoddy Tribe's reservation at Indian Township (Passamaquoddy at Indian Township or Tribe) in Maine. This notice does not propose to change or expand the PRC SDA for the Tribe's Pleasant Point reservation. This notice only relates to the expansion of the Tribe's PRC SDA for the Indian Township reservation.</p> | <p>No recommended that the Passamaquoddy Tribe comment.</p> | |
| 10. | <p>Agency Information Collection Activities; Data Collection Materials for the Evaluation of the Administration for Community Living's American</p> | <p>Published: 2/23/2017 Due Date: 4/24/2017</p> | <ul style="list-style-type: none"> • The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of | | |



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| | <p>Indian, Alaska natives, and Native Hawaiian Programs</p> <p>ACTION: Notice AGENCY: Administration for Community Living</p> | | <p>information the agency proposes to collect related to an evaluation of the American Indian, Alaska Natives and Native Hawaiian Programs. The notice solicits comments on the information collection requirements relating to the evaluation of the Title VI of the Older Americans Act.</p> <ul style="list-style-type: none"> • With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility; (2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology. | | |
| <p>11.</p> | <p>Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies; Delay of Effective Date</p> <p>ACTION: Final Rule- Delay of Effective Date AGENCY: CMS FILE CODE: CMS-3819-F</p> | <p>Published: 4/3/2017 Due Date: 6/2/2017 Effective: 1/13/2018</p> | <ul style="list-style-type: none"> • The CMS finalized rules governing home health agencies that will improve the quality of health care services for Medicare and Medicaid patients and strengthen patients’ rights. These Medicare and Medicaid Conditions of Participation are the minimum health and safety standards a home health agency must meet in order to participate in the Medicare and Medicaid programs. • Home health care allows patients to receive needed health care services within the comfort and safety of their own homes. Patients receive coordinated services ranging from skilled nursing to physical therapy to medical social services, all under the direction of their physician. Currently, there are more than 5 million Medicare and Medicaid beneficiaries receiving home health care from nearly 12,600 Medicare and Medicaid-participating home health agencies nationwide. | | <p>The final rule includes:</p> <ul style="list-style-type: none"> • A comprehensive patient rights condition of participation that clearly enumerates the rights of home health agency patients and the steps that must be taken to assure those rights. • An expanded comprehensive patient assessment requirement that focuses on all aspects of patient wellbeing. • A requirement that assures that patients and caregivers have written information about upcoming visits, medication instructions, treatments administered, instructions for care that the patient and caregivers perform, and the name and contact information of a home health agency clinical manager. • A requirement for an integrated communication system that ensures that patient needs are identified and addressed, care is coordinated among all disciplines, and that there is active communication between the home health agency and the patient’s physician(s). |



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| | | | | | <ul style="list-style-type: none"> • A requirement for a data-driven, agency-wide quality assessment and performance improvement (QAPI) program that continually evaluates and improves agency care for all patients at all times. • A new infection prevention and control requirement that focuses on the use of standard infection control practices, and patient/caregiver education and teaching. • A streamlined skilled professional services requirement that focuses on appropriate patient care activities and supervision across all disciplines. • An expanded patient care coordination requirement that makes a licensed clinician responsible for all patient care services, such as coordinating referrals and assuring that plans of care meet each patient's needs at all times. • Revisions to simplify the organizational structure of home health agencies while continuing to allow parent agencies and their branches. • New personnel qualifications for home health agency administrators and clinical managers. |
| 12. | <p>Supplemental Nutrition Assistance Program (SNAP): Eligibility, Certification, and Employment and Training Provisions of the Food, Conservation and Energy Act of 2008; Extension of Effective Dates and Comment Period</p> <p>ACTION: Final Rule and Interim Final Rule AGENCY: Food and Nutrition Services, USDA FILE CODE: FNS 2011-0008</p> | <p>Published: 2/21/2017</p> <p>Due Date: 4/6/2017</p> | <ul style="list-style-type: none"> • Implements provisions of the Food, Conservation and Energy Act of 2008 (FCEA) affecting the eligibility, benefits, certification, and employment and training (E&T) requirements for applicant or participant households in the Supplemental Nutrition Assistance Program (SNAP). • The rule amends the SNAP regulations to: raise the minimum standard deduction and the minimum benefit for small households; eliminate the cap on the deduction for dependent care expenses; index resource limits to inflation; exclude retirement and education accounts from countable resources; clarify reporting requirements under simplified reporting; permit States to provide transitional benefits to households leaving State-funded cash assistance programs; allow States to establish telephonic and gestured signature systems; permit States to use E&T funds to provide job retention services; | | |



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| | | | <p>and update requirements regarding the E&T funding cycle.</p> <ul style="list-style-type: none"> • These provisions are intended to more accurately reflect needs, reduce barriers to participation, and improve efficiency in the administration of the program. • This rule also replaces outdated language in SNAP certification regulations with the new program name and updates procedures for accessing SNAP benefits in drug and alcohol treatment centers and group living arrangements with use of electronic benefit transfer (EBT) cards. • This rule provides States with regulatory options for conducting telephone interviews in lieu of face-to-face interviews and for averaging student work hours. • The Department is issuing an interim final rule (with a request for additional comment) that will require that drug and alcohol treatment and group living arrangements (GLA) centers to: Submit completed change report forms to the State agency when a resident leaves the center; notify the State agency within 5 days when the center is not able to provide the resident with their EBT card at departure; and return EBT cards to residents with prorated benefits based up on the date of their departure. | | |
| 13. | <p>Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR); Delay of Effective Date</p> <p>ACTION: Interim Final Rule with Comment Period; Delay of Effective Date AGENCY: CMS FILE CODE: CMS-5519-F2</p> | <p>Published: 3/21/2017</p> <p>Due Date: 4/19/2017</p> <p>Effective: 5/20/2017</p> | <ul style="list-style-type: none"> • Amends 42 CFR Parts 510 and 512. Implements three new Medicare Parts A and B episode payment models, a Cardiac Rehabilitation (CR) Incentive Payment model and modifications to the existing Comprehensive Care for Joint Replacement model under section 1115A of the Social Security Act. • Acute care hospitals in certain selected geographic areas will participate in retrospective episode payment models targeting care for Medicare fee-for-service beneficiaries receiving services during acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes. All related care within 90 days of hospital discharge will be included in the episode of care. | | |
| 14. | <p>Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; EHR Incentive Payment Programs; Payment to Non-accepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based</p> | <p>Published: 4/6/2017</p> <p>Received at OMB: 4/12/2017</p> <p>Effective: 4/6/2017</p> | <ul style="list-style-type: none"> • In the November 14, 2016 issue of the Federal Register (81 FR 79562), we published a final rule with comment period that made changes to the demonstration of meaningful use criteria under § 495.40. This correcting amendment corrects a technical error in § 495.40 resulting from an error in that final rule with comment period. • On page 79892 of the CY 2017 OPPTS/ASC final rule with comment period, CMS made a technical error in an amendatory instruction. Accordingly, CMS are revising § 495.40(b)(2)(i)(G) | <ul style="list-style-type: none"> • A key element of the proposed regulation has to do with the defining the term “off-campus outpatient department of a provider,” section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider that is not located on the campus of such provider, or within the distance from a remote location of a | <ul style="list-style-type: none"> • CMS proposes a number of changes relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs may be exempt from application of payment changes under this provision. CMS explains the recent trend of hospital acquisition of physician practices, integration of those practices as a department of the hospital, |



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| <p>Purchasing Program; Establishment of Payment Rates Under the Medicare PFS for Non-excepted Items and Services Furnished by an Off-Campus Provider-Based Hospital; Correcting Amendment</p> <p>ACTION: Correcting Amendment AGENCY: CMS FILE CODE: CMS-1656-F2</p> | | | <p>to accurately reflect the language we previously included in the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79892), but which was not codified in the Code of Federal Regulations. Specifically, paragraph (b)(2)(i)(G) specifies that for CY 2018, an eligible hospital or critical access hospital (CAH) must satisfy certain required objectives and associated measures if an eligible hospital or CAH attests to CMS or to a State for the Medicaid Electronic Health Record (EHR) Incentive Program.</p> | <p>hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of “off-campus outpatient department of a provider,” for purposes of paragraphs (1)(B)(v) and (21)(B), an off-campus PBD that was billing under subsection (t) with respect to covered OPD services furnished prior to the date of enactment of paragraph (t)(21), that is, November 2, 2015. CMS refers to this exception as providing “excepted” status to certain off-campus PBDs and certain items and services furnished by such excepted off-campus PBDs, which would continue to be paid under the OPPTS.</p> <ul style="list-style-type: none"> • It is our understanding that CMS is taking a very narrow interpretation of 42 CFR 413.65(m) and its interpretation of this proposed rule where off campus outpatient facilities may apply to the Indian health system. Therefore we recommend that CMS ensure that grandfathered status remains intact and is clearly referenced for Tribes as well as IHS in the final rule. • We fail to understand the benefit of applying this policy to a federally-funded health system that the United States has a federal trust responsibility to provide health care services to Alaska Native and American Indians. This federal trust responsibility alone is justification for exempting the Indian health care system from the provider based rule. | <p>and the resultant increase in the delivery of physician’s services in a hospital setting results in higher Medicare payments than the total payment amount made by Medicare when the beneficiary receives those same services in a physician’s office.</p> <ul style="list-style-type: none"> • CMS explains that Medicare pays a higher amount because it generally pays two separate claims for these services—one under the OPPTS for the institutional services and one under the MPFS for the professional services furnished by a physician or other practitioner. Medicare beneficiaries are responsible for the cost-sharing liability, if any, for both of these claims, often resulting in significantly higher total beneficiary cost-sharing than if the service had been furnished in a physician’s office. • The proposed rule describes changes to the amounts and factors used to determine the payment rates for Medicare services paid under OPPTS and those paid under the ASC payment system. This provision requires that, beginning January 1, 2017, payment for certain items and services furnished in certain off-campus provider-based departments (PBDs) (collectively referenced as non-excepted items and services) shall occur “under the applicable payment system.” This proposed rule includes several policies relating to which off-campus PBDs and which items and services furnished by such off-campus PBDs application of payment changes under this provision might not apply. In addition, under this proposed rule the Medicare Physician Fee Schedule (MPFS) would serve as the “applicable payment system” for the majority of the items and services furnished by non-excepted off-campus PBDs. |
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| 15. | <p>Possession, Use, and Transfer of Select Agents and Toxins – Addition of Bacillus cereus Biovar anthracis to HHS List of Select Agents and Toxins</p> <p>ACTION: Interim Rule; adopted as final rule with public comments AGENCY: CDC FILE CODE: CDC–2016–0045</p> | <p>Published: 4/12/2017</p> <p>Effective: 4/12/2017</p> | <ul style="list-style-type: none"> • On September 14, 2016, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) published in the Federal Register (81 FR 63138) an interim final rule and request for comments which added Bacillus cereus Biovar anthracis to the list of HHS select agents and toxins as a Tier 1 select agent. CDC received two comments, both of which supported the rule change. • CDC received two comments, both of which supported adding B. cereus Biovar anthracis to the list of HHS select agents and toxins. While both commenters supported the addition, one commented that the regulation of B. cereus Biovar anthracis will “restrict the ability of future laboratories and organizations to test for and analyze possible pBXO1 and pBXO2 isolates.” The commenter further argued that “new laboratories seeking the ability to analyze this select agent will incur substantial costs and urged HHS/CDC reassess the impacts that a \$37,000 buyin for new laboratories might have on the ability to understand this deadly microbe.” HHS/CDC made no changes based on this comment. HHS/CDC is not proposing to regulate other strains of B. cereus that have B. anthracis toxin genes as the data available do not suggest those strains pose a severe threat to public health. | • | • |
| 16. | <p>Submission to OMB for Review and Approval; Agency Information Collection: NURSE Corps Loan Repayment Program OMB No.0915-0140-Revision</p> <p>ACTION: Notice AGENCY: HRSA</p> | <p>Published: 4/11/2017</p> <p>Due Date: 5/11/2017</p> | <ul style="list-style-type: none"> • The NURSE Corps Loan Repayment Program (NURSE Corps LRP) assists in the recruitment and retention of professional Registered Nurses (RNs), including advanced practice RNs (e.g., nurse practitioners, certified registered nurse anesthetists, certified nurse-midwives, clinical nurse specialists), dedicated to working at eligible health care facilities with a critical shortage of nurses (e.g., a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing, by decreasing the financial barriers associated with pursuing a nursing profession. The NURSE Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private nonprofit Critical Shortage Facility or in an eligible, accredited school of nursing. • The information is used to consider an applicant for a NURSE Corps LRP contract award and to monitor a participant’s compliance with the service requirements. • Individuals must submit an application to participate in the program. The | | |



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| | | | <p>application asks for personal, professional, educational, and financial information required to determine the applicant's eligibility to participate in the NURSE Corps LRP.</p> <ul style="list-style-type: none"> • The semi-annual employment verification form asks for personal and employment information to determine if a participant is in compliance with the service requirements. The Authorization to Release Employment Information form has been revised as a self-certification within the NURSE Corps LRP application process, with applicants clicking a box. This contributes to a decrease in the overall burden by 550 hours. | | |
| 17. | <p>Agency Information Collection; Rural Health Network Development Planning Performance Improvement and Measurement System Database, OMB No.0915-0384-Extension</p> <p>ACTION: Notice AGENCY: HRSA</p> | <p>Published: 4/11/2017</p> <p>Due Date: 6/12/2017</p> | <ul style="list-style-type: none"> • 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. | | |
| 18. | <p>Agency Information Collection; Comment Request – Medicare Prescription Drug Coverage; Medicare Health Outcomes Survey; Withholding Medicare Payments to Recover Medicaid Overpayments</p> <p>ACTION: Notice AGENCY: CMS</p> | <p>Published: 4/6/2017</p> <p>Due Date: 6/5/2017</p> | <ul style="list-style-type: none"> • 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 | | |



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| | | | Hospitals; Medicaid and Supporting Regulations. | | |
| 19. | <p>Agency Information Collection; Comment Request (CMS-10501 and CMS 10635)</p> <p>ACTION: Notice AGENCY: CMS</p> | <p>Published: 4/6/2017</p> <p>Due Date: 5/8/2017</p> | <ul style="list-style-type: none"> Collection Request: Revision of a currently approved information collection; Title of Information Collection: Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange; Use: Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a–7c(a)(2)) authorizes the Secretary and the Attorney General to consult, and arrange for the sharing of data with, representatives of health plans for purposes of establishing a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. The result of this authority has been the establishment of the HFPP. Montana Health and Economic Livelihood Partnership (HELP) Federal Evaluation; Use: CMS approved the Montana Health and Economic Livelihood Partnership (HELP) demonstration in November 2015. The demonstration provides flexibility for the expanded Medicaid population under the Affordable Care Act for individuals in the state of Montana. Montana expects to achieve the following: (1) Premiums and copayment liability that will encourage HELP Program enrollees to be discerning health care purchasers, take personal responsibility for their health care decisions and develop health-conscious behaviors as consumers of health care services; and (2) 12 month continuous eligibility to improve continuity of care. The State also seeks to demonstrate the following over the life of the demonstration: (1) Premiums will not pose a barrier to accessing care for HELP Program beneficiaries; (2) HELP Program enrollees will exhibit health conscious health care behaviors without harming beneficiary health; and (3) 12 month continuous eligibility will promote continuity of coverage and reduce churning rates. | | |
| 20. | <p>Proposed Collection; Comment Request for Health Plan Administrator (HPA) Return of Funds</p> <p>ACTION: Notice and Request for Comments AGENCY: IRS</p> | <p>Published: 3/31/2017</p> <p>Due Date: 5/30/2017</p> | <ul style="list-style-type: none"> The IRS solicited 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. | | |



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| <p>21.</p> | <p>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 State of IHS and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices</p> <p>ACTION: Proposed Rule AGENCY: CMS File Code: CMS-1677-P</p> | <p>Issued: 4/14/2017</p> <p>Published: 4/28/2017</p> <p>Due Date: 6/13/2017</p> | <ul style="list-style-type: none"> 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. CMS also made 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). CMS is also 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 | <ul style="list-style-type: none"> NIHB appreciates the efforts of CMS to clarify the provider based status of Indian Health Service and Tribal facilities under 42 CFR § 413.65(m). NIHB recommends specific additional language to further clarify § 413.65(m). In order to qualify to be grandfathered from application of the provider-based rules, an IHS or Tribal facility must meet one of the conditions in § 413.65(m)(1) through (3). NIHB recommends that the conditions listed in 42 § 413.65(m)(1) through (3) be revised to add an additional condition to include facilities owned and operated by a Tribe or Tribal Organization pursuant to a contract or compact under the Indian Self-Determination Act. NIHB believes that the 3-year time period is too long. Hospitals need to use the Hospital Readmission Reduction Rates as data to improve readmissions for their hospitals. A 3-year period makes it difficult to work on performance improvement if the data is not reflective of a current period. TTAG supports the removal of the PSI-90 measure. PSI-90 measure is a claims-based calculation. We also encourage the review of the PSI-90 measure as a whole. The data does not provide Tribal hospitals usable data to improve performance. Currently, there is no Extraordinary Circumstances Exception (ECE) policy for IHS or Tribally-operated programs, although tribal programs have requested an exception from CMS in previous fiscal years. NIHB would like to request an ECE specifically for IHS and tribal healthcare programs. | <ul style="list-style-type: none"> NIHB and TTAG submitted comments. The proposed rule makes two specific revisions to 42 CFR § 413.65(m). The first is to remove the date limitation in § 413.65(m) that restricted the grandfathering provision to IHS or Tribal facilities and organizations furnishing services on or before April 7, 2000. NIHB agrees with removal of the date limitation. Under the program, payments for discharges from an “applicable hospital” under Section 1886(d) of the Social Security Act are reduced to account for excess levels of hospital readmissions based on a hospital’s risk adjusted readmission rate during a 3-year period for certain medical conditions. The proposed period for calculating the FY 2018 readmissions rate is the 3-year period of July 1, 2013 through June 30, 2016. CMS has proposed removing the Patient Safety for Selected Indicators measures 90 (PSI 90) beginning in FY 2016 Value-Based Purchasing PSI-90 measures for the FY 2019 period due to the difficulty of calculating performance scores with ICD-10 upgrades. Subsection (d) hospitals under the Social Security Act are required to report data on certain measures in a given fiscal year to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that period. CMS is proposing to refine two previously adopted measures regarding the assessment of ischemic stroke severity and patient communications on pain levels during a hospital stay. The proposed rule would update the Extraordinary Circumstances Exception (ECE) policy to streamline the processing of ECE |
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| | | | | <ul style="list-style-type: none"> • NIHB appreciates and is support of the CMS proposed support for increased flexibility with regards to the low-volume hospital payment adjustment for IHS and Tribal hospitals. • TTAG appreciates the attempt to align programs and reduce reporting burdens. However, we feel that it also introduces an additional layer of complexity to have different reporting policies based on the method of reporting. One way to avoid this would be to make the same modifications to all CQM reporting (attestation or electronic). • Overall, for the Medicare and Medicaid EHR Incentive Programs, we also suggest aligning the CQM reporting period with the EHR Performance Measures reporting period to decrease complexity and confusion. • NIHB is in support of the proposal that an EHR certified for CQMs under the 2015 Edition certification criteria would not need to be recertified each time it is updated to a more recent version of the CQMs. In addition, NIHB would like to request flexibility in the hardship exemption if unable to meet that timeframe in addition to/besides if a certified EHR technology (CEHRT) was decertified. • TTAG is in support of the proposal to modify the EHR reporting period in 2018 for new and returning participations to a 90 day period. • TTAG requests that CMS consult with IHS, Tribes, and Tribal organizations to create an exemption or modifications for IHS or Tribally-operated facility accreditation reporting standards. • NIHB requests that CMS recognize that the I/T grandfather clause | <p>requests under the hospital-acquired condition (HAC) Reduction Program, Hospital inpatient quality reporting (IQR) Program, Hospital Readmissions Reduction Program, as well as other quality reporting and value-based purchasing programs. ECE requests allow a program to be exempted from program reporting requirements due to an extraordinary circumstance not within a provider's control.</p> <ul style="list-style-type: none"> • The proposed rule includes changes to the low-volume hospital payment adjustment for IHS and Tribal hospitals in regards to the calculation of the mileage criterion, which requires that a qualifying low-volume hospital be located at least 25 miles from the nearest subsection (d) hospital. For hospitals to qualify, they must be more than 25 road miles away from another hospital and have less than 200 discharges. Conversely, CMS is proposing additional flexibility to IHS and Tribal hospitals and the populations they serve due to their unique nature. • CMS is proposing two changes related to electronic clinical quality measure (eCQM) certification requirements: (1) to require reporting from all eCQMs with EHR technology certification; and (2) to note that certified EHR technology does not need to be recertified each time it is updated to a more recent version of the eCQM specifications. • CMS is proposing to modify the CY 2017 electronic CQM reporting policies, but not for eligible hospitals (EHs) and Critical Access Hospitals (CAHs) reporting via attestation • The proposed rule would require private AOs to post all final accreditation survey reports and acceptable CoPs for the most recent three years on their company website. According to CMS, the |
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| | | | | <p>exempts qualifying facilities from compliance with the management integration requirements of both: (1) the provider-based rules; and, (2) Part 482.</p> <ul style="list-style-type: none"> NIHB recommends that Tribal Grandfathered FQHCs be excluded from the annual requirement for a separate facility cost report given that the cost report is not necessary to set the reimbursement rate. NIHB requests that CMS eliminate the date restriction to qualify for Tribal grandfathered FQHC status for the same reasons CMS proposes to eliminate the date restriction for the Tribal provider-based status. | <p>proposal is intended to address concerns regarding disparities in accreditation reports, promote informed patient decision-making processes, and align the public disclosure requirements with those already in place for nursing homes, critical access hospitals (CAHs), and short-term acute care hospitals.</p> |
| <p>22.</p> | <p>Patient Protection and Affordable Care Act (ACA); Market Stabilization</p> <p>ACTION: Final Rule AGENCY: CMS FILE CODE: CMS-9929-F</p> | <p>Published: 4/18/2017</p> <p>Received at OMB: 3/31/2017</p> <p>Concluded-Consistent with Change: 4/12/2017</p> <p>Effective: 6/19/2017</p> | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> NIHB, TTAG, and TSGAC submitted comments on the proposed rule on March 7, 2017. Section 1311(c)(6) of the Affordable Care Act (ACA) establishes enrollment periods, including special enrollment periods (SEP) for qualified individuals, for enrollment in the Qualified Health Plans (QHPs) through an Exchange. Special enrollment periods exist to ensure that individuals who lose health coverage during the year or who experience other qualifying life events such marriage or the birth or adoption of a child) can enroll in a QHP outside of the open enrollment period for 60 days (30 days for employment-based health plans). Special enrollment periods are an important consumer protection to ensure access to health insurance. NIHB supports the exclusion of Marketplace enrollees who qualify for and SEP, including AI/ANs and their dependents from the proposed restrictions. | <ul style="list-style-type: none"> CMS highlights concerns about some individuals using the special enrollment periods (SEPs) to change plan metal levels based on ongoing health needs during the coverage year, which could cause a negative impact on the risk pool. CMS proposes to establish restrictions in § 155.420 on the ability of existing Marketplace enrollees to change plan metal levels during the coverage year. However, the Proposed Rule would exclude Marketplace enrollees who qualify for an SEP, such as AI/ANs and their dependents. In the Proposed Rule, CMS states a need for further flexibility in the <i>de minimis</i> variation range for all metal levels of coverage to help issuers design new plans for future years and to allow more plans to keep their cost-sharing the same from year to year. CMS proposes to allow most Marketplace plans to have an allowable variance in AV of -4 percentage points and +2 percentage points; bronze plans affected by previous change in the 2018 Notice could have an allowable variance in AV of -4 |



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| | | | <ul style="list-style-type: none"> • Change the CMS 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. | <ul style="list-style-type: none"> • Health Care Improvement Act (HCIA) can enroll in a qualified health plan (QHP) or change from one QHP to another once per month. This provision was provided to assist AI/ANs who relocate from an area with IHS and Tribal health programs to one in which the Indian health system is unavailable, creating a greater need for these individuals to secure health insurance coverage. In addition, the provision facilitates the transition of a Tribe to use comprehensive health insurance coverage as a vehicle for ensuring the available funding to support access to the full range of medically necessary health care services. • NIHB recommends that if CMS moves forward with the proposal to promote continuous coverage, American Indians and Alaska Natives (AI/ANs) should be exempt and CMS should not impose a new requirement that would disrupt the purpose and function of the monthly special enrollment periods (SEPs). • NIHB opposes the significant proposed expansion of the <i>de minimis</i> AV variations. Congress established firm actuarial valuations for each plan metal level and only permitted <i>de minimis</i> variation “to account for differences in actuarial estimates” in the ACA.5 The proposal could reduce the value of health care for middle-income and low-income consumers. • NIHB recommends that CMS (a) retain its current policy of restricting silver level Marketplace plans to an allowable variance in actuarial value (AV) of -2 percentage points and +2 percentage points; (b) impose a similar requirement on all bronze level plans, if the agency | <p>percentage points and +5 percentage points.</p> <ul style="list-style-type: none"> • The Proposed Rule would impose detrimental effects on AI/AN enrollees if the allowable <i>de minimis</i> variation for Marketplace plans is further expanded. The AV for the “reference plan” (second-lowest-cost silver plan) could fall by as much as 4 percentage points from the 70percent standard under the ACA, while the AV for the lowest-cost bronze plan could increase by as much as 5 percentage points from the 60percent standard. This would result in a 9 percentage point net increase in the effective cost of bronze-level coverage for an AI/AN enrollee, amounting to a 15percent increase in net costs to a bronze plan enrollee. In fact, depending on the household income of the AI/AN enrollee and the resulting net premium costs after consideration of the value of the available premium tax credits, the increase in the net premium costs to the AI/AN enrollee could be substantially greater than 15percent when purchasing a bronze plan. • Under the Proposed Rule, CMS will defer to state network adequacy reviews in all states “with the authority at least equal to the ‘reasonable access standard’ defined in § 156.230 and means to assess issuer network adequacy,” regardless whether the state has an FFM or State-Based Marketplace (SBM). In states that lack the authority and means to conduct sufficient reviews, CMS would rely on issuer accreditation (commercial or Medicaid) from an accrediting entity recognized by HHS for ensuring network adequacy, rather than having federal officials perform a time and distance evaluation. |
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| | | | | <p>intends to move forward with the proposed changes; and (c) ensure that for the purposes of calculating premium tax credits, the reference plan premium is adjusted to reflect no less than a 70percent actuarial value (AV).</p> <ul style="list-style-type: none"> • NIHB opposes any proposal that would jeopardize access to providers with the appropriate experience and expertise to treat individuals living with chronic illnesses and disabilities in Indian Country. NIHB recommends that CMS retain its current policy of conducting reviews using the time and distance evaluation to determine the network adequacy of qualified health plans (QHPs) offered through Federally-facilitated Marketplaces (FFMs); alternatively, if the agency intends to move forward with the proposal to rely on state reviews and issuer accreditation, at minimum steps must be taken toward ensuring that states (and accrediting entities) use the time and distance evaluation in their reviews. • NIHB strongly opposes the CMS indication that the relaxed standard would preserve adequate access to care because issuers will not be obliged to continue to offer contracts in the service areas of their plans, therefore impacting critical health care services. NIHB recommends that CMS not diminish the current ECP standard requiring issuers to contract with 30percent of available ECPs in the service area of each of their plans. NIHB recommends that CMS retain the proposal to allow insurers to continue to use the “write-in” process to identify ECPs in 2018. | <ul style="list-style-type: none"> • In the Proposed Rule, CMS proposes to allow issuers to contract with only 20percent, rather than 30 percent, of available ECPs in the services area of each of their plans to meet the general enforcement standard. The current standard of 30percent falls short of requiring issuers to contract with all ECPs in the service area of their plans, and eroding this standard will lead to limiting access to care for Marketplace enrollees, including AI/ANs living in medically underserved areas. • In the Proposed Rule, CMS states that not all qualified ECPs have submitted a petition for inclusion of the HHS ECP list. The Proposed Rule would allow issuers to continue to use the write-in process to identify ECPs in 2018, provided that issuers arrange for these provider to submit an ECP petition by no later than the deadline for issuer submission of changes to the qualified health plan application. |
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| 23. | <p>Agency Information Collection; Data System for Organ Procurement and Transplantation Network</p> <p>ACTION: Notice AGENCY: HRSA</p> | <p>Published: 4/14/2017</p> <p>Due Date: 5/15/2017</p> | <ul style="list-style-type: none"> 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. | | |
| 24. | <p>Agency Information Collection; Delta States Rural Development Network Grant Program</p> <p>ACTION: Notice AGENCY: HRSA</p> | <p>Published: 4/24/2017</p> | <ul style="list-style-type: none"> 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. | | |
| 25. | <p>Agency Information Collection; National Council for Behavioral Health's IT Survey</p> <p>ACTION: Notice AGENCY: HHS</p> | <p>Published: 4/24/2017</p> | <ul style="list-style-type: none"> 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. | | |



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| 26. | <p>Delegation of Authority to the Assistant Secretary for Mental Health and Substance Use</p> <p>ACTION: Notice AGENCY: HHS</p> | <p>Published: 4/21/2017</p> | <ul style="list-style-type: none"> • 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. | | |
| 27. | <p>Opioid State Targeted Response Grants</p> <p>ACTION: Notice AGENCY: HHS</p> | <p>Published: 4/21/2017</p> | <ul style="list-style-type: none"> • 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. | | |
| 28. | <p>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</p> <p>ACTION: Notice AGENCY: CMS</p> | <p>Published: 4/14/2017</p> <p>Due Date: 6/13/2017</p> | <ul style="list-style-type: none"> • 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 | | |
| 29. | <p>Seeks Comment and Data on Actions to Accelerate Adoption and Accessibility of Broadband-Enabled Health Care Solutions and Advanced Technologies</p> <p>ACTION: Notice and Request for Comment AGENCY: FCC</p> | <p>Issued: 4/24/2017</p> <p>Due Date: 6/24/2017</p> | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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. • 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. | |



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| | | | <p>and care ecosystem. Commenters should address the agency’s authority on all issues raised in this Notice.</p> <ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> • 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. | | |
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| | | | <ul style="list-style-type: none"> • 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. | | |
| 30. | <p>Agency Information Collection; Proposed Project- Re-Engineered Visit for Primary Care</p> <p>ACTION: Notice AGENCY: AHRQ</p> | <p>Published: 5/5/2017</p> <p>Due Date: 6/5/2017</p> | <ul style="list-style-type: none"> • 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. | | |



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| 31. | <p>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</p> <p>ACTION: Proposed Rule AGENCY: CMS FILE CODE: CMS-1679-P</p> | <p>Published: 5/4/2017</p> <p>Received at OMB 3/14/2017, pending review.</p> <p>Due Date: 6/26/2017</p> | <ul style="list-style-type: none"> • 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). | | |
| 32. | <p>Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities: Revisions to Case-Mix Methodology</p> <p>ACTION: Advanced Notice of Proposed Rulemaking AGENCY: CMS</p> | <p>Published: 5/4/2017</p> <p>Due Date: 6/26/2017</p> | <ul style="list-style-type: none"> • Solicits 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 case mix 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. | | |
| 33. | <p>Agency Information Collection; CMS-10418 Medical Loss ratio Annual Reports, MLR Notices, and Recordkeeping Requirements</p> | <p>Published: 5/2/2017</p> <p>Due Date: 7/3/2017</p> | <ul style="list-style-type: none"> • 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 | | |



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| | <p>ACTION: Notice AGENCY: CMS</p> | | <p>implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, 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.</p> <ul style="list-style-type: none"> • 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. | | |
| <p>34.</p> | <p>Agency Information Collection; Proposed Project- Medical Expenditure Panel Survey- Insurance Component</p> <p>ACTION: Notice AGENCY: AHRQ</p> | <p>Published: 4/28/2017</p> <p>Due Date: 6/27/2017</p> | <ul style="list-style-type: none"> • 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: <ol style="list-style-type: none"> (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 | | |



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| | | | 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. | | |
| 35. | <p>Agency Information Collection; Proposed Project- Access to Recovery Program (OMB No. 0930- 0266) Reinstatement</p> <p>ACTION: Notice AGENCY: SAMHSA</p> | <p>Published: 4/26/2017</p> <p>Due Date: 6/26/2017</p> | <ul style="list-style-type: none"> 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. | | |
| 36. | <p>Medicare Program; CY 2018 Updates to the Quality Payment Program</p> <p>ACTION: Proposed Rule AGENCY: CMS FILE CODE: CMS-5522-P</p> | <p>Issued: 6/20/2017</p> <p>Due Date: 8/21/2017</p> | <ul style="list-style-type: none"> CMS issued the proposed rule that would make changes in the second year of the Quality Payment Program as required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The goal is to simplify the program, especially for small, independent, and rural practices, while ensuring fiscal sustainability and high-quality care within Medicare. The proposal allows for the exemption of small providers participating in the program by increasing the low-volume threshold to \$90,000 or less in Medicare Part B charges or 200 or less Medicare patients annually. The original threshold was \$30,000 in Medicare Part B charges or 100 Medicare patients. The agency believes the move will exclude about 134,000 clinicians from MIPS. CMS also outlined some proposals on how to participate in MIPS through virtual groups. The proposed rule defines a virtual group as a combination of two or more taxpayer identification numbers (TINs) composed of a solo practitioner or a group with 10 or fewer eligible clinicians under the TIN that elects to form a virtual group with at least one other solo practitioner or group for a performance period of a year. A representative for the group must submit written notice by December 1 of the calendar year prior to the start of the applicable performance period to submit an agreement amongst virtual group participants. The low-volume threshold will not be granted at the virtual group level. "[S]olo practitioners (individual MIPS eligible clinicians) or groups with 10 or fewer eligible clinicians that are determined not to exceed the low-volume threshold at the individual or group | <ul style="list-style-type: none"> The proposal allows for the exemption of small providers participating in the program by increasing the low-volume threshold to \$90,000 or less in Medicare Part B charges or 200 or less Medicare patients annually. This will benefit Tribal providers from rural and small practices from being required to participate, thus limiting the possibility for a negative payment adjustment. | |



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| | | | <p>level would not be eligible to participate in MIPS as an individual, group or virtual group," the rule stated.</p> <ul style="list-style-type: none"> • CMS has awarded about \$20 million this year to 11 organizations to help small practices prepare for MACRA. An additional \$80 million is slated for 2018 through 2021. | | |
| 37. | <p>Agency Information Collection: Virtual Groups for MIPS (CMS-10652)</p> <p>ACTION: Notice AGENCY: CMS FILE CODE: CMS-10652</p> | <p>Published: 6/14/2017</p> <p>Due Date: 8/14/2017</p> | <ul style="list-style-type: none"> • CMS acknowledges the unique challenges that small practices and practices in rural areas may face with the implementation of the Quality Payment Program. To help support these practices and provide them with additional flexibility, CMS has created a virtual group reporting option starting with the 2018 MIPS performance period. CMS held webinars and small, interactive feedback sessions to gain insight from clinicians as we developed our policies on virtual groups. During these sessions, participants expressed a strong interest in virtual groups, and indicated that the right policies could minimize clinician burden and bolster clinician success. • This information collection request is related to the statutorily required virtual group election process proposed in the CY 2018 Quality Payment Program proposed rule. A virtual group is a combination of Tax Identification Numbers (TINs), which would include at least two separate TINs associated with a solo practitioner TIN and National Provider Identifier (TIN/NPI) or group with 10 or fewer MIPS eligible clinicians and another solo practitioner (TIN/NPI) or group with 10 or fewer MIPS eligible clinicians. | <p>No recommendations. The majority of Tribal health care providers will probably not utilize the virtual groups reporting option. NIHB will comment on the virtual groups in the CY 2018 Updates to the Quality Payment Program Proposed Rule.</p> | |
| 38. | <p>Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients</p> <p>ACTION: Request for Information AGENCY: CMS FILE CODE: CMS-9928-NC</p> | <p>Published: 6/12/2017</p> <p>Due Date: 7/12/2017</p> | <ul style="list-style-type: none"> • CMS is seeking recommendations on how to create a more flexible, streamlined approach to the regulatory structure of the individual and small group markets. The goal is to identify and eliminate or change regulations that are outdated, unnecessary, or ineffective; impose costs that exceed benefits; or create inconsistencies that otherwise interfere with regulatory reform initiatives and policies. • CMS is looking for valuable feedback on how to change existing regulations in ways that put patients first, promote greater consumer choice, enhance affordability and return more control over healthcare to the States," said CMS Administrator Seema Verma. • HHS is interested in soliciting public comments about changes to existing regulations or guidance, or other actions within HHS's authority, that could further the following goals with respect to the individual and small group health insurance markets: | | |



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| | | | <ol style="list-style-type: none"> 1. Empowering patients and promoting consumer choice. What activities would best inform consumers and help them choose a plan that best meets their needs? Which regulations currently reduce consumer choices of how to finance their health care and health insurance needs? Choice includes the freedom to choose how to finance one's healthcare, which insurer to use, and which provider to use. 2. Stabilizing the individual, small group, and non-traditional health insurance markets. What changes would bring stability to the risk pool, promote continuous coverage, increase the number of younger and healthier consumers purchasing plans, reduce uncertainty and volatility, and encourage uninsured individuals to buy coverage? 3. Enhancing affordability. What steps can HHS take to enhance the affordability of coverage for individual consumers and small businesses? 4. Affirming the traditional regulatory authority of the States in regulating the business of health insurance. Which HHS regulations or policies have impeded or unnecessarily interfered with States' primary role in regulating the health insurance markets they know best? | | |
| 39. | <p>Data Collection Materials for the Evaluation of the Administration for Community Living's American Indian, Alaska Natives, and Native Hawaiian Programs (OAA Title VI)</p> <p>ACTION: Notice AGENCY: Administration for Community Living</p> | <p>Published: 6/20/2017</p> <p>Due Date: 7/20/2017</p> | <ul style="list-style-type: none"> • The Data Collection Materials for the Evaluation of the Administration for Community Living's American Indian, Alaska Natives and Native Hawaiian Programs (OAA Title VI) is a new data collection (ICR-New) that will include focus groups for elders and caregiver program participants, interviews with Title VI staff, and a survey for caregiver program participants. • The Evaluation of the Administration for Community Living's American Indian, Alaska Natives and Native Hawaiian Programs will allow ACL/AoA to document the value of the Title VI programs for individuals, families, communities and Tribes/Tribal Organizations. ACL estimates the annual burden of this collection of information as follows: The proposed data collection tools may be found on the ACL Web site at: https://www.acl.gov/about-acl/policyand-regulations. | | |



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| <p>40.</p> | <p>Agency Information Collection: (1)Extension of State Medicaid HIT Plan, Planning Advance Planning Document, and Implementation Advance Planning Document for Section 4201 of the Recovery Act; (2) Extension of Disclosure Requirement for the In-Office Ancillary Services Exception; (3) Conditions of Participation for Critical Access Hospitals (CAHs) and Supporting Regulations.</p> <p>ACTION: Notice AGENCY: CMS</p> | <p>Published: 6/26/2017</p> <p>Due Date: 8/25/2017</p> | <ul style="list-style-type: none"> • CMS-10292 Extension of a currently approved collection; Title of Information Collection: State Medicaid HIT Plan, Planning Advance Planning Document, and Implementation Advance Planning Document for Section 4201 of the Recovery Act; Use: To assess the appropriateness of state requests for the administrative Federal financial participation for expenditures under their Medicaid Electronic Health Record Incentive Program related to health information exchange, our staff will review the submitted information and documentation to make an approval determination of the state advance planning document. Form Number: CMS-10292 (OMB control number: 0938-1088); Frequency: Once and occasionally; Affected Public: State, Local, and Tribal Government. • CMS-10332 Extension of a currently approved collection: Disclosure Requirement for the In-Office Ancillary Services Exception. Use: Section 6003 of the ACA established a disclosure requirement for the in-office ancillary services exception to the prohibition of physician self-referral for certain imaging services. This section of the ACA amended section 1877(b)(2) of the Social Security Act by adding a requirement that the referring physician informs the patient, at the time of the referral and in writing, that the patient may receive the imaging service from another supplier. Physicians who provide certain imaging services (MRI, CT, and PET) under the in-office ancillary services exception to the physician self-referral prohibition are required to provide the disclosure notice as well as the list of other imaging suppliers to the patient. The patient will then be able to use the disclosure notice and list of suppliers in making an informed decision about his or her course of care for the imaging service. CMS would use the collected information for enforcement purposes. Specifically, if we were investigating the referrals of a physician providing advanced imaging services under the in-office ancillary services exception, we would review the written disclosure in order to determine if it satisfied the requirement. • CMS-10239 Extension of a currently approved collection: Conditions of Participation for Critical Access Hospitals (CAH) and Supporting Regulations. Use: At the outset of the critical access hospital (CAH) program, the information collection requirements for all CAHs were addressed together under the following | | |
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| | | | <p>information collection request: CMS–R–48 (OCN: 0938–0328). As the CAH program has grown in both scope of services and the number of providers, the burden associated with CAHs with distinct part units (DPUs) was separated from the CAHs without DPUs. Section 1820(c)(2)(E)(i) of the Social Security Act provides that a CAH may establish and operate a psychiatric or rehabilitation DPU. Each DPU may maintain up to 10 beds and must comply with the hospital requirements specified in 42 CFR subparts A, B, C, and D of part 482. Presently, 105 CAHs have rehabilitation or psychiatric DPUs. The burden associated with CAHs that have DPUs continues to be reported under CMS–R–48, along with the burden for all 4,890 accredited and non-accredited hospitals.</p> | | |
| <p>41.</p> | <p>Agency Information Collection: The Veterans’ Outcome Assessment (VOA) (Veteran Survey Interview)</p> <p>ACTION: Notice AGENCY: VA</p> | <p>Published: 6/26/2017</p> <p>Due Date: 8/25/2017</p> | <ul style="list-style-type: none"> • Veterans Health Administration, Department of Veterans Affairs (VA) is seeking comment on a revision of a currently approved collection, the Veterans Outcome Assessment. • The mental health outcomes information obtained through this new collection will be used by VA leadership, including those in the Offices of Mental Health Operations and Mental Health Services, Network offices, and VA Medical Centers. Such information on Veteran mental health outcomes is crucial to guide resource allocation and programmatic decisions for mental health programs and to intervene effectively to prevent individual adverse outcomes such as suicide, overdose deaths, and morbidities associated with mental illness and to support recovery-oriented treatment designed to improve functioning and reduce symptoms. The data will allow VA policy makers to reliably track national performance on a quarterly basis and to track VISN performance on a yearly basis. These data will reveal trends in outcomes over time and will help in pinpointing programs that are doing well in terms of patient outcomes, so that other programs can emulate their practices, as well as identifying those programs that are performing poorly so that steps can be taken to improve them. Results of the survey will be reported to Congress and will influence decisions on funding. The VOA will thus provide Veterans who are experiencing mental health problems with a direct voice in program evaluation and improvement. Summary data on performance also will be available on a public Web site, as mandated by the NDAA, to provide Veterans and their families with additional information | | |



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| | | | for purposes of managing their mental health treatment and U.S. citizens with information regarding VA’s mental health programs and Veterans satisfaction with their care. | | |
| 42. | Rural Health Care Support Mechanism ACTION: Final Rule AGENCY: FCC | Published: 6/21/2017 Effective: 6/21/2017 | <ul style="list-style-type: none"> The final rule amends the Rural Health Care (RHC) Program rule which defines “health care provider” to implement the provision of the Rural Healthcare Connectivity Act of 2016 amending the Communications Act of 1934 (the Act) to include skilled nursing facilities (SNFs) amongst the list of health care providers eligible to receive RHC Program support. | | |

