National Indian Health Board

Regulation Review and Impact Analysis Report v. 10.01

PURPOSE:

The purpose of the Regulation Review and Impact Analysis Report (RRIAR) is to identify and summarize key regulations issued by the Centers for Medicare and Medicaid Services (CMS) pertaining to Medicare, Medicaid, CHIP, and health reform that affect (a) American Indians and Alaska Natives and/or (b) Indian Health Service, Indian Tribe and tribal organization, and urban Indian organization providers. 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.

STRUCTURE:

- **Section I** lists key regulations issued by CMS on which Tribal organizations filed comments, providing a synopsis of the CMS action, identifying the recommendations made by Tribal organizations, and evaluating the extent to which the recommendations made by Tribal organizations were incorporated into subsequent CMS actions.
- **Section II** lists additional key regulations issued by CMS, providing due dates for comments, a synopsis of the CMS action, and additional analysis, if any, prepared by the NIHB. This section includes final regulations recently released as well as regulations under Office of Management and Budget (OMB) review.

I. Regulations with comments submitted by NIHB, TTAG, and/or other Tribal organizations—

- Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, CMS-9926-P—Submitted 2/19/2019 (Ref. #2019-001)
- Re-Review of Indian-Specific Summary of Benefits and Coverage Documents and Recommendation for Additional, Targeted Action—Submitted 4/11/2019 (Ref. #2019-002)
- Basic Health Program; Federal Funding Methodology for Program Years 2019 and 2020, CMS-2407-PN—Submitted 5/2/2019 (Ref. #2019-003)
- Request for Information Regarding State Relief and Empowerment Waivers, CMS-9936-NC2—Submitted 7/2/2019 (Ref. #2019-004)
- Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission, CMS-2406-P2—Submitted 9/13/2019 (Ref. #2019-005)
- TTAG Letter re: Medicaid Fiscal Accountability Regulation, CMS-2393-N—Submitted 02/01/2020 (Ref. #2020-001)

II. Additional Regulations

A. Regulations with pending due dates for public comments —

- Transparency in Coverage, CMS-9915-P—Due 01/29/2020 (Ref. #2020-002)
- Medicaid Fiscal Accountability Regulation (MFAR), CMS-2393-N—Due 02/01/2020 (Ref. #2020-001)
- Request for Information on Coordinating Care From Out-of-State Providers for Medicaid-Eligible Children With Medically Complex Conditions, CMS-2324-NC—Due 03/23/2020 (Ref. #2020-013)
- Information Collection on Medicare Current Beneficiary Survey, CMS-P-0015A—Due 03/16/2020 (Ref. #2020-011)
- Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, CMS-3380-

P—Due 02/21/2020 (Ref. #2020-004)

- Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies (Part II) —Due 03/06/2020 (Ref. #2020-009)
- HHS Notice of Benefit and Payment Parameters for 2021, CMS-9916-P—Due 03/02/2020 (Ref. #2020-015)

B. Recent final rules issued—

- Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, CMS-3317-F & CMS-3295-F—Effective 11/29/2019 (Ref. #2019-034)
- Medicare and Medicaid Programs; Adjustment of Civil Monetary Penalties for Inflation; Continuation of Effectiveness and Extension of Timeline for Publication of the Final Rule, CMS-6076-RCN—Effective 09/06/2020 (Ref. #2020-008)
- CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B, CMS-1715-F and IFC—Effective 01/01/2020, correction published on 01/01/2020 (Ref. #2019-068)
- Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, CMS-1717-FC—Effective 01/01/2020, correction published on 01/03/2020 (Ref. #2019-061)
- Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, CMS-1713-F—Effective 01/01/2020 (Ref. #2019-059)
- Basic Health Program; Federal Funding Methodology for Program Years 2019 and 2020, CMS-2407-FN—Effective 01/06/2020 (Ref. #2019-003)
- CMS, HHS: Patient Protection and Affordable Care Act; Exchange Program Integrity, CMS-9922-F—Effective 02/25/2020 (Ref. #2020-007)
- CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates; Price Transparency Requirements for Hospitals to Make Standard Charges Public, CMS-1717-F2—Effective 01/01/2021 (Ref. #2019-069)
- Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2020 Rates, CMS-1716-F—Effective 10/01/2019 (Ref. #2019-072)
- CY 2020 Home Health Prospective Payment System Rate Update and Quality Reporting Requirements (CMS-1711-F) —Effective 01/01/2020 (Ref. #2019-071)

C. Regulations under Office of Management and Budget (OMB) review (listed below only; not shown in table)—

- Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payments, CMS-3337-P—Received 6/6/2019
- International Pricing Index Model For Medicare Part B Drugs, CMS-5528-P—Received 6/20/2019
- Medicare Coverage of Innovative Technologies, CMS-3372-P—Received 7/30/2019
- Comprehensive Care for Joint Replacement Model Three Year Extension and Modifications to Episode Definition and Pricing, CMS-5529-P—Received 8/22/2019
- Preadmission Screening and Resident Review—Update, CMS-2418-P—Received 10/31/2019

- Strengthening the Program Integrity of the Medicaid Eligibility Determination Process (CMS-2421-P)—Received 12/20/2019 (NPRM scheduled for 04/2020)
- Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value Based Payments (VBP) for Drugs Covered in Medicaid, CMS-2482-P—Received 12/27/2019
- Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2021 Rates, CMS-1735—Received 01/30/2020

D. Regulations in Prerule Stage

- Assurance of Medicaid Transportation Request for Information, CMS-2481-NC

E. Regulations in Final Rule Stage

- Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid, and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP, CMS-2334-F3
- Covered Outpatient Drug; Further Delay of Inclusion of Territories In Definitions of State and United States, CMS-2345-IFC3
- Medicaid and CHIP Managed Care, CMS-2408-F
- Interoperability and Patient Access, CMS-9115-F
- Methods for Assuring Access to Covered Medicaid Services—Rescission, CMS-2406-F
- Administrative Simplification: Update of Retail Pharmacy Standards, CMS-0055-F
- Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2020; Risk Adjustment Data Validation, CMS-4185-F2

I. REGULATIONS WITH COMMENTS RECENTLY SUBMITTED BY NIHB, TTAG, AND/OR OTHER TRIBAL ORGANIZATIONS

Ref. #	Short Title/Current Status/Agency/File Code	Dates (Issued/ Due/ Action)	Brief Summary of Proposed Agency Action	Summary of NIHB/TTAG/TSGAC Recommendations	NIHB Analysis
2019-001	**Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020** ACTION: Final Rule AGENCY: CMS, HHS FILE CODE: CMS-9926-~~P~~F RIN: 0938-AT37	Published: 1/24/2019 Due Date: 2/19/2019 NIHB File Date: 2/19/2019 Subsequent Action: Final Rule issued 4/25/2019 Effective Date: 6/24/2019	This final rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters; and user fees for Federally-Facilitated Exchanges (FFEs) and State-Based Exchanges on the Federal Platform (SBE-FPs). It finalizes changes that will allow greater flexibility related to the duties and training requirements for the Navigator program and changes that will provide greater flexibility for direct enrollment entities, while strengthening program integrity oversight over those entities. It finalizes a change intended to reduce the costs of prescription drugs. This final rule also includes changes to Exchange standards related to eligibility	NIHB recommendations— 1. **Regulatory Action to Address "Silver Loading"**: Silver loading—the practice of increasing of silver plan premiums to compensate for the termination of CSR payments to issuers by the Trump administration in late 2017—has helped stabilize the Marketplace and make Marketplace coverage more affordable for AI/ANs and others; CMS should continue to allow silver loading until Congress passes legislation that would appropriate funding for CSR payments and end silver loading. 2. **Allowance of Mid-Year Formulary Changes**: The proposed rule would allow individual, small group, and large group	In the 4/25/2019 Final Rule— 1. **Regulatory Action to Address "Silver Loading"**: Accepted in part. CMS indicated that the agency will take into consideration all comments regarding potential regulation action to address silver loading. 2. **Allowance of Mid-Year Formulary Changes**: Accepted. CMS stated, "Given the complexity of this issue, and the

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			and enrollment; exemptions; and other related topics.	market issuers, if providing enrollees with 120 days' notice, to adopt mid-year formulary changes to incentivize greater enrollee use of lower-cost generic drugs—a provision that might disrupt access to certain drugs for enrollees or make enrollees responsible for new or unexpected costs; in the final rule, CMS should, at minimum, retain the requirement that issuers provide enrollees with 120 days' notice prior to any mid-year formulary changes but also should consider eliminating this provision.	challenges of balancing the interests of consumers with the importance of mitigating the effects of rising prescription drug costs, we are not finalizing the proposal at this time. Rather, we will continue to examine the issue of mid-year formulary changes and may provide guidance on this issue in the future. In the meantime, to the extent issuers make mid-year formulary changes consistent with applicable state law, our expectation is that all issuers (in the individual, small group, and large group markets) will continue to provide certain consumer protections that ... are generally consistent with current industry practice."
2019-002	**Re-Review of Indian-Specific Summary of Benefits and Coverage Documents and Recommendation for Additional, Targeted Action** ACTION: Letter to CCIIO AGENCY: TTAG FILE CODE: NA RIN: NA	Published: 4/11/2019 Due Date: None	This letter highlights findings from a re-review of Summary of Benefits and Coverage (SBC) documents issued by qualified health plan (QHP) issuers operating through Health Insurance Marketplaces. The TSGAC re-reviewed a sample of SBC documents for 2019 to assess their accuracy in describing the cost-sharing protections provided to eligible AI/ANs under the ACA. The re-review was conducted following 1) a prior finding of significant deficiencies in the SBCs and 2) a subsequent effort by CCIIO to educate health plan issuers and state regulators on the proper application of the Indian-specific cost-sharing protections.	TTAG/TSGAC recommendations— 1. **Response to TSGAC Re-Review of SBCs**: In response to the TSGAC re-review, 1) contact individual health plan issuers identified in the report, inform them of the deficiencies in their SBCs, and educate them on the need to act rapidly to correct these deficiencies; and 2) given the amount of time that certain health plan issuers have posted inaccurate descriptions of the Indian-specific cost-sharing protections in their SBCs, conduct a review of the operations of these issuers to determine if they have applied the L-CSVs correctly and completely, and, if they have not, require them to make whole individual AI/AN enrollees for any erroneous cost-sharing expenditures made. 2. **Authority for SBC Reviews**: In sub-regulatory guidance, clarify which governmental agency has lead responsibility for reviewing the SBCs, depending on the type of Marketplace, and indicate that	

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				CCIIO will enforce requirements in the absence of adequate lead-party oversight. 3. **Scope of SBC Reviews**: Indicate that reviews of SBCs are not performed merely to determine if SBC documents are posted at a live Web link but that a thorough evaluation of their content is required. 4. **Recommendation of Specific Corrections to SBC**: Although the Z-CSV and L-CSV SBC templates are offered as a guide to issuers and the specific language contained in the templates are not mandated for use, in reviewing issuer SBCs, recommend specific language to correct inaccuracies or confusing descriptions. 5. **Descriptors for Z-CSV and L-CSV Plan SBCs**: Establish consistent descriptors to place in the header on the front page of each Indian-specific SBC—such as (1) "AI/AN 02 CSV" and "AI/AN 03 CSV," (2) "AI/AN Z-CSV" and "AI/AN L-CSV," or (3) "AI/AN Zero" and "AI/AN Limited"—and through a link to the "Glossary of Health Coverage and Medical Terms," define the descriptors. 6. **Indication of Limited AI/AN Eligibility for Z-CSV and L-CSV Plans**: Through a link to the "Glossary of Health Coverage and Medical Terms," indicate that "AI/AN" eligibility for the Z-CSV and L-CSV plans, in part, is limited to "an enrolled Tribal member in a federally-recognized Tribe or a shareholder in an Alaska Native regional or village corporation." 7. **Application of Indian-Specific Protections in Coverage Examples**: Require issuers to present the net out-of-	

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				pocket costs in the Coverage Examples to reflect application of the Indian-specific cost-sharing protections (i.e., assuming enrollees receive services from an IHCP or from a non-IHCP through a referral from an IHCP) and insert a note indicating that cost-sharing might be greater if seen at a non-IHCP without referral from an IHCP. 8. **Revised SBC Templates for Z-CSV and L-CSV Plans**: Revise the CCIIO Z-CSV and L-CSV SBC templates, as appropriate, based on the review of existing SBCs.	
2019-003	**Basic Health Program; Federal Funding Methodology for Program Years 2019 and 2020** ACTION: Proposed Methodology AGENCY: CMS, HHS FILE CODE: CMS-2407-PN RIN: 0938-ZB42	Published: 4/2/2019 Due Date: 5/2/2019 TTAG File Date: 5/2/2019	This document proposes the methodology and data sources necessary to determine federal payment amounts in program years 2019 and 2020 to states that elect to establish a Basic Health Program (BHP) under the ACA to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges. Prior to the publication of the final notice, the federal government will make BHP payments using the methodology described in the Final Administrative Order published on 8/24/2018. The federal government will conform payments for 2019 to the finalized 2019 payment methodology through reconciliation.	TTAG recommendations— 1. **Reference Premium for CSR Calculation**: In the final methodology, CMS should modify the assumption used with regard to the selection of QHPs by AI/ANs and assume that AI/ANs who enroll in QHPs will enroll in the second lowest-cost bronze plan, rather than the lowest-cost bronze plan, to reflect more accurately actual plan selections by AI/ANs. 2. **Premium Tax Credit (PTC) Adjustment**: In the final methodology, CMS should maintain the assumption that AI/ANs who enroll in a QHP will expend the full value of PTCs available to them.	In the 11/05/19 Final Rule— **1. Reference Premium for CSR Calculation**: CMS noted that Section 1331(a)(2)(A)(i) of the Affordable Care Act requires that states operating BHPs must ensure that individuals do not pay a higher monthly premium than they would have if they had been enrolled in the second lowest cost silver-level QHP in an Exchange, factoring in any PTC individuals would have received. 2. **PTC Adjustment**: CMS noted that the only portion of the rate affected by the use of the lowest-cost bronze-level QHP is the CSR portion of the BHP payment; due to the discontinuance of CSR payments and the accompanying modification to the BHP payment methodology, the CSR portion of the payment is assigned a value of 0, and any change to the assumption about which bronze-level QHP is used would therefore have no effect on the BHP payments.
2019-004 (See also	**Request for Information Regarding State Relief and Empowerment Waivers**	Published: 5/3/2019 Due Date: 7/2/2019	This request for information (RFI) solicits public comment on ideas for innovative programs and waiver concepts that states could consider in developing a 1332 waiver plan. Treasury and CMS (collectively, the	TTAG recommendations— 1. **Indian-Specific Protections Under the ACA**: The ACA contains a number of Indian-specific protections, and a section	

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pre-2017 RRIAR #14.c.)	ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-9936-NC2	TTAG File Date: 7/2/2019	Departments) seek feedback and ideas on how states might take advantage of new flexibilities provided in recently published October 2018 guidance.	1332 waiver could have a direct negative impact on AI/ANs because of changes in Indian-specific and non-Indian specific provisions of the law; to ensure that a section 1332 waiver does not adversely affect AI/ANs, CMS should clarify that representations made by a state pertaining to the state satisfying the requirements for granting such a waiver must consider the specific impact on each individual AI/AN and not remain limited to the overall, or average, impact on the population as a whole. 2. **Other Indian-Specific Protections**: The Balanced Budget Act of 1997 (BBA) established Social Security Act section 1932(a)(2)(C)—which provides that no state can require AI/ANs to enroll in a Medicaid managed care system, except in cases in which an I/T/U operates the system—and American Recovery and Reinvestment Act of 2009 (ARRA) section 5006 provides a number of protections for AI/ANs who elect to enroll in Medicaid managed care; to ensure that a section 1332 waiver does not adversely affect AI/ANs, CMS should emphasize the importance of maintaining the Indian-specific protections contained in section 1932(a)(2)(C) and section 5006 under such a waiver. 3. **Tribal Consultation**: Final CMS/Treasury guidance on section 1332 waivers issued on 10/24/2018 does not discuss the health care and health insurance concerns unique to AI/ANs or the status of Tribes as sovereign nations with a government-to-government relationship with the United States; CMS should ensure that states engage in meaningful consultation with Tribes as they explore and pursue creative ways to design section 1332 waivers.	

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2019-005	**Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: CMS-2406-P2 RIN: 0938-AT41	Published: 7/15/2019 Due Date: 9/13/2019 TTAG File Date: 9/13/2019	This proposed rule would remove the regulatory text that sets forth the current required process for states to document whether Medicaid payments in fee-for-service systems are sufficient to enlist enough providers to assure beneficiary access to covered care and services consistent with the Medicaid statute.	TTAG recommendations— 1. **Withdrawal of Rule**: CMS should withdraw the proposed rule, which would significantly weaken the ability of agency to monitor and enforce access to covered services in Medicaid programs and would repeal essentially all requirements state Medicaid programs must follow to ensure and demonstrate that their rates satisfy Medicaid access requirements. 2. **Alternative Changes**: CMS should consider more modest changes to reduce the administrative burden for states; these changes could include, for example, adopting a standard reporting template and metrics for Access Monitoring Review Plans (AMRPs) and offering states more technical and financial assistance. 3. **Tribal Consultation**: Along with states, CMS should involve Tribes in efforts to develop a comprehensive strategy for monitoring access to covered care and services in Medicaid.	
2020-001	**Medicaid Program; Medicaid Fiscal Accountability Regulation** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: CMS-2393-P OCN: 0938-AT50	Published: 11/18/2019 Due Date: 02/1/2020 TTAG File Date: 02/1/2020	This proposed rule would promote transparency by establishing new reporting requirements for states to provide CMS with certain information on supplemental payments to Medicaid providers, including supplemental payments approved under either Medicaid state plan or demonstration authority, and applicable upper payment limits. Additionally, the proposed rule would establish requirements to ensure that state plan amendments proposing new supplemental payments are consistent with the proper and efficient operation of the state plan and with efficiency, economy, and quality of care. This proposed rule addresses the financing of supplemental and base	TTAG recommendations— 1. **Tribal Consultation re: State Share of Financial Participation.** Both IGTs and CPEs are important to Tribal governments and Tribal organizations to assist in financing the Medicaid administrative activities in several states. CMS has issued sub-regulatory guidance affirming that Tribal governments and Tribal organizations can certify expenditures such as the non-Federal share of Medicaid expenditures for administrative services provided by such entities.3 In accordance with this policy, we are pleased to see that Tribal governments are included as a unit of government, yet we	

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			Medicaid payments through the non-federal share, including states' uses of health care-related taxes and bona fide provider-related donations, as well as the requirements on the non-federal share of any Medicaid payment.	are concerned that the proposed rule does not address situations in which a Tribal government does not or is unable to exercise its taxing authority for the purposes of intergovernmental transfers. Limiting the contribution from IGTs to only Tribes with taxing authority is too restrictive in this context, and could prevent Tribes from providing a non-federal match. The TTAG therefore requests that CMS conduct Tribal consultation on the proposed rule changes as to IGTs and the impact on Tribes. 2. **Tribal Consultation re State Plan Requirements.** As drafted, the proposed regulatory provision could be understood to prohibit states from making payments to Indian Health Service (IHS) and Tribally owned or operated facilities at the all-inclusive rates for inpatient and outpatient services, if other facilities are paid on a different basis. That differentiation in payments is common among states, and it has been the long-standing position of the Department of Health & Human Services (HHS) that payment to those facilities at the published all-inclusive rate is appropriate for both the Medicare and Medicaid programs. This could have significant financial impacts in states with many IHS and Tribally owned or operated facilities paid at the all-inclusive rates for inpatient and outpatient services. Furthermore, the proposed revision gives too much discretion to CMS. Under these proposed changes, CMS essentially has to approve, or, on a state-by-state basis, determine whether states are seeking to reimburse services at a justifiable rate. Additionally, states would have to submit a	

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				plan every three years to CMS, which would be administratively burdensome. The TTAG requests that CMS conduct Tribal consultation in order to clarify this provision's impact on Tribes. 3. **Tribal Consultation re: Payments Funded by Certified Public Expenditures to Unit of Government Providers.** TTAG is concerned that the proposed definition for "non-state governmental provider" could be used to preclude certain local government structures from qualifying as permissible CPE entities, contrary to historical practice. Specifically, the requirement that a provider must have access to and exercise administrative control over directly appropriated state funds and/or local tax revenue may exclude Indian Tribes, Tribal organizations, or certain local hospital authorities that have been created as unique and express units of government. The TTAG requests that CMS conduct Tribal consultation on the impact of the proposed definition change.	

II. ADDITIONAL REGULATIONS				
Ref. #	**Short Title/Current Status/Agency/File Code**	**Dates (Issued/ Due/ Action)**	**Brief Summary of Proposed Agency Action**	**NIHB Analysis**
2019-007	**Health Reimbursement Arrangements and Other Account-Based Group Health Plans** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10704 OCN: 0938-1361	Published: 9/6/2019 Due Date: 11/5/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Health Reimbursement Arrangements and Other Account-Based Group Health Plans; *Use*: On 6/20/2019, Treasury, DoL, and HHS (collectively, the Departments) issued final regulations titled "Health Reimbursement Arrangements and Other Account-Based Group Health Plans" under section 2711 of the PHS Act and the health nondiscrimination provisions of HIPAA. The regulations expand the use of health reimbursement arrangements and other account-based group health plans (collectively referred to as HRAs). In general, the regulations expand the use of HRAs by eliminating the current prohibition on integrating HRAs with individual health insurance coverage, thereby permitting employers to offer individual coverage HRAs to employees that they can integrate with individual health insurance coverage or Medicare. The regulations allow employees to use amounts in an individual coverage HRA to pay expenses for medical care (including premiums for individual health insurance coverage and Medicare), subject to certain requirements.	
2019-008	**Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process** ACTION: Final Rule AGENCY: CMS, HHS FILE CODE: CMS-6058-FC RIN: 0938-AS84	Published: 9/10/2019 Due Date: 11/4/2019 Effective Date: 11/4/2019	This final rule with comment period implements statutory provisions that require Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers. In addition, this final rule provides the agency with additional authority to deny or revoke Medicare enrollment for providers and suppliers in certain specified circumstances.	The rule's affiliation disclosure requirement implements an Affordable Care Act provision that is intended to identify individuals and entities that pose a risk to the programs based on their relationships with previously sanctioned entities. The newly added definition of "affiliation" is broad and includes not only ownership interests but even reassignment relationships. An affiliation must be disclosed when it is with a provider or supplier that has one of the following "disclosable events" (also a newly defined term): • Currently has uncollected debt to Medicare, Medicaid or CHIP; • Has been or is subject to a payment suspension under a federal health care program; • Has been or is excluded from Medicare, Medicaid or CHIP; or • Has had its Medicare, Medicaid or CHIP billing privileges denied, revoked or terminated.

				For now, providers and suppliers will not be required to disclose affiliations unless CMS determines that the provider or supplier has at least one affiliation that includes any of the four disclosable events and specifically requests it to do so.
2019-009 (See also pre-2017 RRIAR #121.j.)	**Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-R-263 OCN: 0938-0749	Published: 9/10/2019 Due Date: 10/10/2019	*Type of Information Collection Request*: Reinstatement without change of a previously approved collection; *Title*: Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); *Use*: The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services. This site investigation form also aides the Medicare contractor (the National Supplier Clearinghouse Medicare Administrative Contractor (NSC MAC)) in verifying compliance with the required supplier standards found in 42 CFR 424.57(c).	
2019-010 (See also pre-2017 RRIAR #11.g.)	**Part C Medicare Advantage Reporting Requirements** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10261 OCN: 0938-1054	Published: 9/11/2019 Due Date: 10/11/2019	*Type of Information Collection Request*: Revision with change of a previously approved collection; *Title*: Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); *Use*: Section 1852(m) of the Social Security Act (Act) and CMS regulations at 42 CFR 422.135 allow Medicare Advantage (MA) plans the ability to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat them as basic benefits. MA additional telehealth benefits are limited to services for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act. In addition, MA additional telehealth benefits are services identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (or "electronic exchange") when the physician (as defined in section 1861(r) of the Act) or practitioner (as defined in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. Per § 422.135(d), MA plans can furnish MA additional telehealth benefits only using contracted providers. The changes for the 2020 Reporting Requirements will require plans to report telehealth benefits. The data collected in this measure will provide CMS with a better understanding of the number of organizations utilizing telehealth per contract and also will capture those specialties used for both in-person and telehealth. These data will allow CMS to improve its policy and process surrounding telehealth. In addition, the specialist and facility data aligns with some of the provider and facility specialty types that organizations are required to include in their networks and to submit on their HSD tables in the Network Management Module in Health Plan Management System.	
2019-011	**Medical Necessity and Contract Amendments Under Mental Health Parity**	Published: 9/11/2019 Due Date: 10/11/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Medical Necessity and Contract Amendments Under Mental Health Parity; *Use*: Upon request, regulated entities must provide a medical necessity disclosure. Receiving this information will enable potential and current enrollees to make more educated decisions	

	ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10556 OCN: 0938-1280		given the choices available to them through their plans and may result in better treatment of their mental health or substance use disorder (MH/SUD) conditions. States use the information collected and reported as part of their contracting process with managed care entities, as well as their compliance oversight role. In states where a Medicaid managed care organization (MCO) is responsible for providing the full scope of medical/surgical and MH/SUD services to beneficiaries, the state will review the parity analysis provided by the MCO to confirm that the MCO benefits are in compliance. CMS uses the information collected and reported in an oversight role of State Medicaid managed care programs.	
2019-012 (See also pre-2017 RRIAR #62.)	**External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs)** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-R-305 OCN: 0938-0786	Published: 9/11/2019 Due Date: 10/11/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs) and Supporting Regulations; *Use*: State agencies must provide to the external quality review organization (EQRO) information obtained through methods consistent with the protocols specified by CMS. This information is used by the EQRO to determine the quality of care furnished by an MCO. Since the EQR results are made available to the general public, this allows Medicaid/CHIP enrollees and potential enrollees to make informed choices regarding the selection of their providers. It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid/CHIP MCOs. States use the information during their oversight of these organizations.	
2019-013 (See also pre-2017 RRIAR #110.i.)	**Medicare Self-Referral Disclosure Protocol** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10328 OCN: 0938-1106	Published: 9/11/2019 Due Date: 10/11/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Medicare Self-Referral Disclosure Protocol; *Use*: Section 6409 of the ACA requires the HHS secretary to establish a voluntary self-disclosure process that allows providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Social Security Act. In addition, section 6409(b) of the ACA gives the HHS secretary authority to reduce the amounts due and owing for the violations. To determine the nature and extent of the noncompliance and the appropriate amount by which an overpayment may be reduced, the HHS secretary must collect relevant information regarding the arrangements and financial relationships at issue from disclosing parties. The HHS secretary also can collect supporting documentation, such as contracts, leases, communications, invoices, or other documents bearing on the actual or potential violation(s). Most of the information and documentation required for submission to CMS in accordance with the SRDP is information that health care providers of services and suppliers keep as part of customary and usual business practices.	
2019-014 (See also pre-2017 RRIAR #118.)	**Hospital Wage Index Occupational Mix Survey** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10079 OCN: 0938-0907	Published: 9/11/2019 Due Date: 10/11/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Hospital Wage Index Occupational Mix Survey; *Use*: Section 304(c) of Public Law 106-554 mandates an occupational mix adjustment to the wage index, requiring the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. The proposed data collection that is included in this submission complies with this statutory requirement. The purpose of the occupational mix adjustment is to control for the effect of hospital employment choices on the wage index. For example, hospitals may choose to employ	

			different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.	
2019-015	**Frequently Asked Questions (FAQs) Regarding Enhanced Direct Enrollment (EDE) Participation Requirements for Non-Issuer Users of Primary EDE Entity Environments Serving Consumers in States with Federally-Facilitated Exchanges (FFEs) and State-Based Exchanges on the Federal Platform (SBE-FPs)** ACTION: Guidance AGENCY: CCIIO/CMS, HHS FILE CODE: NA RIN: NA	Published: 9/11/2019 Due Date: None	This guidance answers FAQs to clarify the requirements for prospective upstream non-issuer users of an enhanced direct enrollment (EDE) environment discussed in the document titled "Third-party Auditor Operational Readiness Reviews for the Enhanced Direct Enrollment Pathway and Related Oversight Requirements" (EDE Guidelines). Any prospective hybrid, non-issuer upstream EDE Entity, as clarified in this guidance, planning to participate in EDE for PYs 2019 and 2020 must notify CMS as soon as possible of its intent to submit an audit consistent with the processes detailed in this document.	
2019-016 (See also pre-2017 RRIAR #60.c. and #60.n.)	**Health Insurance Common Claims Form** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-1500/1490S OCN: 0938-1197	Published: 9/12/2019 Due Date: 11/12/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR part 424, subpart C (CMS-1500 and CMS-1490S); *Use*: The CMS-1500 and the CMS-1490S forms are used to deliver information to CMS in order for CMS to reimburse for provided services. Medicare Administrative Contractors use the data collected on the CMS-1500 and the CMS-1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to beneficiaries. The CMS-1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, other third-party payers (commercial and nonprofit health insurers) and other Federal programs (e.g., TRICARE, RRB, and Medicaid) can use the CMS-1500. The CMS-1490S (Patient's Request for Medical Payment) was explicitly developed for easy use by beneficiaries who file their own claims.	
2019-017 (See also pre-2017 RRIAR #121.i.)	**Independent Diagnostic Testing Facilities (IDTFs) Site Investigation Form** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10221 OCN: 0938-1029	Published: 9/12/2019 Due Date: 11/12/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Independent Diagnostic Testing Facilities (IDTFs) Site Investigation Form Revisions; *Use*: The data collection is used by Medicare contractors and/or their subcontractors on site visits to verify compliance with required IDTF performance standards. If a subcontractor is used, the subcontractor collects the information from the IDTF through an interview and forwards it to the Medicare contractor for evaluation. The collection and verification of this information defends and protects Medicare beneficiaries from illegitimate IDTFs. These procedures also protect the Medicare Trust	

			Fund against fraud. The data collected also ensure that applicants have the necessary credentials to provide the health care services for which they intend to bill Medicare.	
2019-018 (See also pre-2017 RRIAR #2.e.)	**Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10237 OCN: 0938-0935	Published: 9/12/2019 Due Date: 11/12/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits; *Use*: This information collection includes the process for organizations wishing to provide health care services under MA plans. These organizations must complete an application annually (if required), file a bid, and receive final approval from CMS. The MA application process has two options for applicants that include (1) request for new MA product or (2) request for expanding the service area of an existing product. CMS utilizes the application process as the means to review, assess, and determine if applicants are compliant with the current requirements for participation in the MA program and to make a decision related to contract award. This collection process is the only mechanism for organizations to complete the required MA application process. The application process is open to all health plans that want to participate in the MA program. The application is distinct and separate from the bid process, and CMS issues a determination on the application prior to bid submissions, or before the first Monday in June.	
2019-019 (See also pre-2017 RRIAR #72.c.)	**Physician Certifications/ Recertifications in Skilled Nursing Facilities Manual Instructions** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-R-5 OCN: 0938-0454	Published: 9/12/2019 Due Date: 11/12/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Physician Certifications/Recertifications in Skilled Nursing Facilities Manual Instructions; *Use*: Section 1814(a) of the Social Security Act (the Act) requires specific certifications to receive Medicare payments for certain services. Before the enactment of the Omnibus Budget Reconciliation Act of 1989, section 1814(a)(2) of the Social Security Act required that, in the case of post-hospital extended care services, a physician certify that the services are or were required because the individual needs or needed, on a daily basis, skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, an SNF can provide only on an inpatient basis. The physician certification requirements were included in the law to ensure that patients require a level of care covered by the Medicare program and because the physician serves a key figure in determining the utilization of health services. In addition, it set forth qualification requirements that a nurse practitioner or clinical nurse specialist must meet in order to sign certification or recertification statements (these requirements later were revised in the Balanced Budget Act of 1997). Effective with items and services furnished on or after January 1, 2011, section 3108 of the Affordable Care Act added physician assistants to the existing authority for nurse practitioners and clinical nurse specialists.	
2019-020 (See also pre-2017	**Healthcare Common Procedure Coding System (HCPCS)** ACTION: Request for Comment AGENCY: CMS, HHS	Published: 9/12/2019 Due Date: 11/12/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Healthcare Common Procedure Coding System (HCPCS)—Level II Code Modification Request Process; *Use*: In October 2003, the HHS secretary delegated authority under the Health Insurance Portability and Accountability Act (HIPAA) to CMS to maintain and distribute HCPCS Level II Codes. As stated in 42 CFR 414.40(a), CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes. CMS has maintained and distributed the HCPCS code set via modifications of codes,	

RRIAR #191.a.)	FILE CODE: CMS-10224 OCN: 0938-1042		modifiers, and descriptions as a direct result of data received from applicants. Thus, information collected in the application is significant to codeset maintenance.	
2019-021 (See also pre-2017 RRIAR #134.h.)	**Home Office Cost Statement** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-287-19 OCN: 0938-0202	Published: 9/12/2019 Due Date: 11/12/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Home Office Cost Statement; *Use*: Home offices of chain organizations vary greatly in size, number of locations, staff, mode of operations, and services furnished to the facilities in the chain. The home office of a chain is not in itself certified by Medicare. The relationship of the home office is that of a related organization to participating providers (See 42 CFR 413.17). When a provider claims costs on its cost report allocated from a home office, the Home Office Cost Statement constitutes the documentary support required of the provider to receive payment for home office costs in the cost report. Each contractor servicing a provider in a chain must receive a detailed Home Office Cost Statement as a basis for reimbursing the provider for cost allocations from a home office or chain organization. Form CMS-287-19 is needed to determine the reasonable cost incurred by a provider in furnishing medical services to Medicare beneficiaries and reimbursement due to or from the provider.	
2019-022 (See also pre-2017 RRIAR #175.b.)	**Medicaid Drug Use Review (DUR) Program** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-R-153 OCN: 0938-0659	Published: 9/16/2019 Due Date: 10/16/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Medicaid Drug Use Review (DUR) Program; *Use*: States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient name, address, telephone number, date of birth/age, gender, history, e.g., allergies, drug reactions, list of medications, and pharmacist comments relevant to the drug therapy of the individual. States must conduct RetroDUR, which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, or inappropriate or medically unnecessary care. Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of state DUR programs. The information submitted by states is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to state experiences with DUR. States benefit from the information and can enhance their programs each year based on state-reported innovative practices compiled by CMS from the DUR annual reports.	
2019-023 (See also pre-2017 RRIAR #121.d.)	**Notification of FLS and CMS of Co-Located Medicare Providers** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10088 OCN: 0938-0897	Published: 9/17/2019 Due Date: 11/18/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Notification of FLS and CMS of Co-Located Medicare Providers; *Use*: Many long-term care hospitals (LTCHs) are co-located with other Medicare providers (acute care hospitals, inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), or inpatient psychiatric facilities (IPFs)), which could lead to potential gaming of the Medicare system based on inappropriate patient shifting. In regulations at 42 CFR 412.22(e)(3) and (h)(6) CMS requires LTCHs to notify Medicare administrative contractors (MACs) and CMS of co-located providers. Under §§ 412.22(e)(3) and (h)(6), an LTCH or a satellite of an LTCH that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital, must notify its MAC and CMS in writing of its co-location within 60 days of its first cost reporting period that began on or after October 1, 2002.	

2019-024 (See also pre-2017 RRIAR #121.c.)	**Medicare Participation Agreement for Physicians and Suppliers** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-460 OCN: 0938-0373	Published: 9/17/2019 Due Date: 10/17/2019	*Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title*: Medicare Participation Agreement for Physicians and Suppliers; *Use*: Section 1842(h) of the Social Security Act permits physicians and suppliers to voluntarily participate in Medicare Part B by agreeing to take assignment on all claims for services to beneficiaries. The law also requires that the HHS secretary provide specific benefits to the physicians, suppliers and other individuals who choose to participate. Form CMS-460 is the agreement by which the physician or supplier elects to participate in Medicare. By signing the agreement to participate in Medicare, the physician or supplier agrees to accept the Medicare-determined payment for Medicare-covered services as payment in full and to charge the Part B beneficiary no more than the applicable deductible or coinsurance for the covered services.	
2019-025	**Medicaid Program Face-to-Face Requirements for Home Health Services and Supporting Regulations** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10609 OCN: 0938-1319	Published: 9/23/2019 Due Date: 11/22/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use*: 42 CFR 440.70(f) and (g) require that physicians (or for medical equipment, authorized non-physician practitioners (NPPs), including nurse practitioners, clinical nurse specialists and physician assistants) document that a face-to-face encounter occurred with the Medicaid beneficiary prior to the physician making a certification that home health services are required. The burden associated with this requirement is the time and effort to complete this documentation. The burden also includes writing, typing, or dictating the face-to-face documentation and signing/dating the documentation.	
2019-026 (See also pre-2017 RRIAR #11.d.)	**Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10142 OCN: 0938-0944	Published: 9/23/2019 Due Date: 11/22/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use*: Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations, Medicare Advantage organizations (MAO) and prescription drug plans (PDP) are required to submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by CMS. The MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid.	
2019-027	**Medicaid Program; State Disproportionate Share Hospital Allotment Reductions** ACTION: Final Rule AGENCY: CMS, HHS FILE CODE: CMS-2394-F RIN: 0938-AS84	Published: 9/25/2019 Effective Date: 11/25/2019	The ACA requires aggregate reductions to state Medicaid disproportionate share hospital (DSH) allotments annually beginning with fiscal year (FY) 2020. This final rule delineates the methodology to implement the annual allotment reductions.	
2019-028	**QHP Issuers Data Collection for Notices for Plan or Display Errors**	Published: 9/25/2019 Due Date: 10/25/2019	*Type of Information Collection Request*: Extension without change of a currently approved collection; *Title*: QHP Issuers Data Collection for Notices for Plan or Display Errors Special Enrollment Periods; *Use*: In the HHS Notice of Benefit and Payment Parameters for 2017 (CMS-9937-F), CMS finalized 45 CFR 156.1256, which requires qualified health plan	

	Special Enrollment Periods ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10595 OCN: 0938-1301		(QHP) issuers, in the case of a material plan or benefit display error included in 45 CFR 155.420(d)(12), to notify their enrollees of the error and the eligibility of their enrollees for a special enrollment period (SEP) within 30 calendar days after the issuer is informed by an Federally-Facilitated Exchange (FFE) that the error is corrected, if directed to do so by the FFE. This requirement provides notification to QHP enrollees of errors that might have impacted their QHP selection and enrollment and any associated monthly or annual costs, as well as the availability of an SEP under § 155.420(d)(12) for the enrollee to select a different QHP, if desired. CMS is renewing this information collection request (ICR) in connection with standards regarding Plan or Display Errors SEPs. CMS has changed the title of the package to reflect its subject matter better. The burden estimate for the ICR included in this package reflects the time and effort for QHP issuers to provide notifications to enrollees on the ICRs regarding Plan or Display Errors SEPs.	
2019-029 (See also pre-2017 RRIAR #11.m.)	**Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10062 OCN: 0938-0878	Published: 9/25/2019 Due Date: 11/25/2019	*Type of Information Collection Request*: Extension without change of a currently approved collection; *Title*: Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments; *Use*: The 1997 Balanced Budget Act (BBA) and later legislation required CMS to adjust per-beneficiary payments with a risk adjustment methodology using diagnoses to measure relative risk due to health status instead of only demographic characteristics such as age, sex, and Medicaid eligibility. The purpose of risk adjustment is to pay plan sponsors accurately based on the health status and diagnoses of their Medicare enrollees. Section 1853 (a)(3) of the Social Security Act as enacted by Section 4001 of Subtitle A of the BBA required the HHS secretary to implement a risk adjustment methodology that accounted for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice (now Medicare Advantage) organizations by January 1, 2000. The BBA also required that Medicare+Choice organizations submit data for use in developing risk adjusted payments.	
2019-030 (See also pre-2017 RRIAR #16.d.)	**Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10344 OCN: 0938-1127	Published: 9/25/2019 Due Date: 11/25/2019	*Type of Information Collection Request*: Extension without change of a currently approved collection; *Title*: Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services; *Use*: Each month, CMS deems individuals automatically eligible for the full Medicare Part D Low-Income Subsidy (LIS), based on data from state Medicaid agencies and the Social Security Administration (SSA). The SSA sends a monthly file of Supplementary Security Income-eligible beneficiaries to CMS. Similarly, the state Medicaid agencies submit Medicare Modernization Act files to CMS that identify full subsidy beneficiaries. CMS deems the beneficiaries as having full subsidy and auto-assigns these beneficiaries to benchmark Part D plans. Part D plans receive premium amounts based on the monthly assessments.	
2019-031 (See also pre-2017	**Electronic Funds Transfer Authorization Agreement** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-588	Published: 9/25/2019 Due Date: 11/25/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Electronic Funds Transfer Authorization Agreement; *Use*: Section 1815(a) of the Social Security Act provides the authority for the HHS secretary to pay providers/suppliers of Medicare services at such time or times as the secretary determines appropriate (but no less frequently than monthly). Under Medicare, CMS, acting for the Secretary, contracts with fiscal intermediaries and carriers to pay claims submitted by providers/suppliers that furnish services to Medicare beneficiaries. Under CMS payment policy, Medicare providers/suppliers have the option of receiving payments electronically.	

RRIAR #63.b.)	OCN: 0938-0626			
2019-032 (See also pre-2017 RRIAR #121.a.)	**Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-855B OCN: 0938-XXXX	Published: 9/25/2019 Due Date: 11/25/2019	*Type of Information Collection Request*: New collection; *Title*: Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers; *Use*: Form CMS-855B, the Medicare enrollment application for suppliers serves to gather information from the supplier that tells CMS the name of the supplier, whether the supplier meets certain qualifications needed to become a Medicare health care provider or supplier, where the supplier practices or renders services, and other information necessary to establish correct claims payments. Form CMS-855B includes an attachment for opioid treatment programs (OTPs). This attachment is used only to capture the OTP personnel and consists of limited data fields (name, Social Security number, national provider identifier, and license number) in response to the "SUPPORT for Patients and Communities Act" signed into law on October 24, 2018.	
2019-033	**Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care** ACTION: Final Rule AGENCY: CMS, HHS FILE CODE: CMS-3346-F, CMS-3334-F, & CMS-3295-F RIN: 0938-AT23	Published: 9/30/2019 Effective Date: 11/29/2019	This final rule reforms Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. This final rule also eliminates or reduces requirements that impede quality patient care or that divert resources away from furnishing high quality patient care. Additionally, this final rule updates fire safety standards for Medicare and Medicaid participating end-stage renal disease (ESRD) facilities by adopting the 2012 edition of the Life Safety Code and the 2012 edition of the Health Care Facilities Code. Finally, this final rule updates the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs.	
2019-034	**Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care**	Published: 9/30/2019 Effective Date: 11/29/2019	This final rule revises the discharge planning requirements that hospitals (including short-term acute-care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. This final rule also implements discharge planning requirements that will give patients and their family access to information to help them to make informed decisions about their post-acute care, while addressing their goals of care and treatment preferences. It also updates one provision regarding patient rights in hospitals.	

	ACTION: Final Rule AGENCY: CMS, HHS FILE CODE: CMS-3317-F & CMS-3295-F RIN: 0938-AS59			
2019-035	**Hospital Survey for Specified Covered Outpatient Drugs (SCODs)** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10709 OCN: 0938-XXXX	Published: 9/30/2019 Due Date: 11/29/2019	*Type of Information Collection Request*: New collection; *Title*: Hospital Survey for Specified Covered Outpatient Drugs (SCODs); *Use*: In the CY 2018 OPPS/ASC payment system final rule, CMS finalized a policy to adjust payment for separately payable outpatient drugs acquired by eligible hospitals at discounted rates under the HRSA 340B program from average sales price (ASP) plus 6% to ASP minus 22.5%. According to 42 U.S.C. 256b, eligible hospitals include Medicare disproportionate share hospital (DSH) adjustment of greater than 11.75%, children's hospitals, critical access hospitals, cancer hospitals, rural referral centers and sole community hospitals. On December 27, 2018, the U.S. District Court for the District of Columbia ruled that the HHS secretary exceeded his statutory authority to adjust payment rates under the hospital outpatient prospective payment system (OPPS) for separately payable, 340B-acquired drugs. CMS believes that it is important to begin obtaining acquisition costs for specified covered outpatient drugs to set payment rates based on cost for 340B-acquired drugs when they are furnished by certain covered entity hospitals. CMS will use the acquisition cost data hospitals submit in response to this survey will to help determine payment amounts for drugs acquired under the 340B program.	
2019-036	**Opportunity for States to Participate in a Wellness Program Demonstration Project to Implement Health-Contingent Wellness Programs in the Individual Market** ACTION: Guidance AGENCY: CCIIO/CMS, HHS FILE CODE: NA RIN: NA	Published: 9/30/2019 Due Date: None	This bulletin announces an opportunity for states to apply to participate in a wellness program demonstration project. Participating States can implement nondiscriminatory health-contingent wellness programs in the individual market, as described in section 2705(l) of the Public Health Service Act (PHS Act). This bulletin outlines the participation requirements; the criteria HHS, in consultation with DoL and Treasury, will use to evaluate applications; instructions on application submissions and appeals; and potential future opportunities for additional states to apply.	
2019-037	**Executive Order on Protecting and Improving Medicare for Our Nation's Seniors** ACTION: Executive Order AGENCY: White House FILE CODE: NA RIN: NA	Published: 10/3/2019 Due Date: None	This executive order seeks to "protect and improve Medicare by building on those aspects of the program that work well, including the market-based approaches in the current system." Under this executive order: • Within 1 year, the HHS secretary shall propose regulations and implement other administrative actions to promote Medicare Advantage (MA) plans; • Within 1 year, the HHS secretary shall propose regulations to provide beneficiaries with improved access to providers and plans by adjusting network adequacy requirements for MA plans;	

			• Within 1 year, the HHS secretary shall propose reforms to the Medicare program to enable providers to spend more time with patients, in part by proposing regulations that would (1) eliminate billing requirements, conditions of participation, supervision requirements, benefit definitions, and other licensure requirements and (2) ensure appropriate reimbursement for time spent with patients; • Within 1 year, the HHS secretary shall propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients by (1) streamlining the approval, coverage, and coding process for new drugs and medical devices and (2) modifying the Value-Based Insurance Design payment model to remove any disincentives for MA plans to cover items and services not covered by fee-for-service (FFS) Medicare if those items and service can reduce costs and improve the quality of care; • The HHS secretary shall ensure that Medicare payments and policies encourage competition and a diversity of sites for patients to access care; • Within 1 year, the HHS secretary shall propose regulations that would provide Medicare beneficiaries with improved quality care and cost data, as well as use Medicare claims data to give health care providers additional information regarding practice patterns for services that might pose undue risks to patients or that are outside recommended standards of care; • The HHS secretary shall propose regulatory or sub-regulatory changes to the Medicare program, to take effect by January 1, 2021, and shall propose such changes annually thereafter, to combat fraud, waste, and abuse in the Medicare program; • Within 180 days, the HHS secretary shall recommend approaches to transition toward market-based pricing in FFS Medicare; • Within 1 year, the HHS secretary shall propose regulatory changes to the Medicare program to reduce the burden on providers and eliminate regulations that create inefficiencies or otherwise undermine patient outcomes; and • Within 180 days, the HHS secretary, in coordination with the Social Security commissioner, shall revise current rules or policies to preserve the Social Security retirement insurance benefits of beneficiaries who choose not to receive benefits under Medicare Part A, and propose other administrative improvements to Medicare enrollment processes; and • Within 1 year, the HHS secretary shall identify and remove unnecessary barriers to private contracts that allow Medicare beneficiaries to obtain the care of their choice and facilitate the development of market-driven prices.	
2019-038 (See also pre-2017 RRIAR #11.f.)	**Contract Year 2021 Plan Benefit Package (PBP) Software and Formulary Submission** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-R-262	Published: 10/4/2019 Due Date: 12/3/2019	*Type of Information Collection Request*: Revision with change of a currently approved collection; *Title*: Contract Year 2021 Plan Benefit Package (PBP) Software and Formulary Submission; *Use*: Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and prescription drug plan (PDP) organizations must submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their plan benefit packages, including information on premiums, cost-sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe	

	OCN: 0938-0763		their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. CMS uses these data to review and approve the benefit packages that the plans will offer to Medicare beneficiaries. CMS also uses these data to populate data on Medicare Plan Finder, which allows beneficiaries to access and compare MA plans and PDPs.	
2019-039	**Administrative Simplification HIPAA Compliance Review** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10662 OCN: 0938-xxxx	Published: 10/4/2019 Due Date: 12/3/2019	*Type of Information Collection Request*: New collection; *Title*: Administrative Simplification HIPAA Compliance Review; *Use*: CMS has authority for administering and enforcing compliance with the Administrative Simplification non-privacy HIPAA rules. Federal regulations at 45 CFR 160.310 require that a covered entity provide records and compliance reports to the HHS secretary in cooperation with a compliance review. These regulations provide that a covered entity must permit HHS, or its delegated entity, access during normal business hours to its facilities, books, records, and other information necessary to determine compliance, as well as provide that if the HHS secretary determines that "exigent circumstances exist, such as when documents may be hidden or destroyed," the covered entity must permit access at any time without notice. CMS requires this information collection to retrieve information necessary to conduct a compliance review as described in CMS-0014-N (68 FR 60694). Covered entities will submit these forms to the CMS Program Management National Standards Group.	
2019-040	**Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: CMS-1720-P RIN: 0938-AT64	Published: 10/17/2019 Due Date: 12/31/2019	This proposed rule would address any undue regulatory impact and burden of the physician self-referral law. This proposed rule would implement exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It also would create a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; create a new exception for donations of cybersecurity technology and related services; and amend the existing exception for EHR items and services. In addition, this proposed rule provides guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.	This proposed rule would address any undue regulatory impact and burden of the physician self-referral law—or "Stark Law." This rulemaking follows a history of rulemakings related to the physician self-referral law. The proposed rule would create new, permanent exceptions to the Stark Law for value-based arrangements. CMS is soliciting comments about the role of price transparency in the context of the Stark Law and whether to require cost-of-care information at the point of a referral for an item or service.
2019-041 (See also pre-2017	**PACE State Plan Amendment Preprint** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10227	Published: 10/18/2019 Due Date: 12/17/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: PACE State Plan Amendment Preprint; *Use*: If a state elects to offer PACE as an optional Medicaid benefit, it must complete a State Plan Amendment (SPA) preprint packet described as "Enclosures 3, 4, 5, 6, and 7." CMS will review the information provided to determine if the state has properly elected to cover PACE services as a State Plan option.	

RRIAR #5.b.)	OCN: 0938-1027			
2019-042 (See also pre-2017 RRIAR #210.)	**Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10243 OCN: 0938-1037	Published: 10/18/2019 Due Date: 12/17/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use*: In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. This project will include two collections of individual-level data using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations: elderly adults; younger adults with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury. States will conduct functional assessments in client homes using the TEFT FASI Item Set. States will conduct the second data collection to demonstrate their use of the FASI data elements.	
2019-043 (See also pre-2017 RRIAR #11.k.)	**Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10316 OCN: 0938-1113	Published: 10/18/2019 Due Date: 12/17/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use*: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides a requirement to collect and report performance data for Part D prescription drug plans (PDPs). Specifically, the MMA requires CMS to conduct consumer satisfaction surveys regarding the Medicaid Advantage (MA) and PDP contracts. CMS developed the Disenrollment Survey to capture the reasons for disenrollment at a time as close as possible to the actual date of disenrollment. Through this survey, CMS seeks to: (1) obtain information about beneficiary expectations relative to provided benefits and services (for both MA plans and PDPs) and (2) determine the reasons that prompt beneficiaries to disenroll voluntarily.	
2019-044	**Applicable Integrated Plan Coverage Decision Letter** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10716 OCN: 0938-xxxx	Published: 10/18/2019 Due Date: 12/17/2019	*Type of Information Collection Request*: New collection; *Title*: Applicable Integrated Plan Coverage Decision Letter; *Use*: The Bipartisan Budget Act (BBA) of 2018 directed the establishment of procedures to unify Medicare and Medicaid grievance and appeals procedures to the extent feasible for dual-eligible special needs plans (D-SNPs), beginning in 2021. Under implementing regulations, applicable integrated plans as defined at 42 CFR 422.561 must issue form CMS-10716 when a declining a request for either a medical service or payment covered under the Medicare or Medicaid benefit. The notice explains why the plan denied the service or payment and informs the plan enrollees of their appeal rights.	
2019-045 (See also pre-2017 RRIAR #138.a.)	**Organ Procurement Organization's (OPOs) Health Insurance Benefits Agreement and Supporting Regulations** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-576A OCN: 0938-0512	Published: 10/18/2019 Due Date: 11/18/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Organ Procurement Organization's (OPOs) Health Insurance Benefits Agreement and Supporting Regulations; *Use*: The Medicare and Medicaid final conditions for coverage for organ procurement organizations (OPOs) require OPOs to sign agreements with CMS to receive reimbursement and perform their services. The information provided on this form serves as a basis for continuing the agreements with CMS and the OPOs for participation in the Medicare and Medicaid.	

2019-046 (See also pre-2017 RRIAR #7.q.)	**Cooperative Agreement to Support Navigators in Federally-Facilitated Exchanges** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10463 OCN: 0938-1215	Published: 10/23/2019 Due Date: 12/23/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Cooperative Agreement to Support Navigators in Federally-Facilitated Exchanges; *Use*: Section 1311(i) of the ACA requires Exchanges to establish a Navigator grant program. Navigators assist consumers by providing education about, and facilitating selection of, qualified health plans (QHPs) within the Exchanges, as well as perform other required duties. As a condition of award, Navigator grant awardees must agree to cooperate with any federal evaluation of the program and provide required weekly, monthly, quarterly, annual, and final (at the end of the cooperative agreement period) reports in a form prescribed by CMS, as well as any additional reports as required.	
2019-047 (See also pre-2017 RRIAR #92.hh.)	**Annual Eligibility Redetermination, Product Discontinuation and Renewal Notices** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10527 OCN: 0938-1254	Published: 10/24/2019 Due Date: 11/25/2019	*Type of Information Collection Request*: Extension of a currently approved collection; *Title*: Annual Eligibility Redetermination, Product Discontinuation and Renewal Notices; *Use*: Section 1411(f)(1)(B) of the ACA directs the HHS secretary to establish procedures to redetermine the eligibility of individuals on a periodic basis in appropriate circumstances. Section 1321(a) of the ACA provides authority for the HHS secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, qualified health plans (QHPs), and other components of title I of the ACA. Under section 2703 of the Public Health Service Act (PHS Act), as added by the ACA, and sections 2712 and 2741 of the PHS Act, enacted by the HIPAA, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies. The final rule titled "Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges" (79 FR 52994) provides that an Exchange can choose to conduct the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the coverage year; or (3) using an alternative proposed by the Exchange and approved by the HHS secretary. The final rule also amends the requirements for product renewal and re-enrollment (or non-renewal) notices sent by QHP issuers in the Exchanges and specifies content for these notices.	
2019-048 (See also pre-2017 RRIAR #71.o.)	**End Stage Renal Disease Application and Survey and Certification Report** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-3427 OCN: 0938-0360	Published: 10/28/2019 Due Date: 12/27/2019	*Type of Information Collection Request*: Reinstatement with change of a previously approved collection; *Title*: End Stage Renal Disease Application and Survey and Certification Report; *Use*: Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. Part II is completed by the Medicare/Medicaid state survey agency to determine facility compliance with ESRD conditions for coverage.	
2019-049 (See also pre-2017	**Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting**	Published: 10/28/2019 Due Date: 12/27/2019	*Type of Information Collection Request*: Extension without change of a currently approved collection; *Title*: Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; *Use*: The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where a vulnerability to the Medicare program might exist. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers complete the administrative information (e.g., patient	

RRIAR #3.c. and #3.d.)	**Documentation Requirements** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-484, 846, 847, 848, 849, 10125, and 10126 OCN: 0938-0679		name and address, items ordered, etc.) on each CMN. Suppliers also must provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). Suppliers then send each CMN to the treating physician or other clinicians (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the medical condition of the beneficiary and signs the CMN. The physician or other clinician returns the CMN to the supplier, which submits the CMN electronically to CMS, along with a claim for reimbursement.	
2019-050 (See also pre-2017 RRIAR #7.jjj.)	**Establishment of Exchanges and Qualified Health Plans** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10400 OCN: 0938-1156	Published: 10/28/2019 Due Date: 11/27/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Establishment of Exchanges and Qualified Health Plans; *Use*: As directed by the final rule titled Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange assumed responsibilities related to the certification and offering of qualified health plans (QHPs). Under 45 CFR 156.280(e)(5)(ii), each QHP issuer that offers non-excepted abortion services must submit to the state insurance commissioner a segregation plan describing how the QHP issuer establishes and maintains separate payment accounts for any QHP covering non-excepted abortion services, and pursuant to § 156.280(e)(5)(iii), each QHP issuer must annually attest to compliance with ACA section 1303 and applicable regulations. This segregation plan is used to verify that the financial and other systems of the QHP issuer fully conform to the segregation requirements required by the ACA.	
2019-051 (See also pre-2017 RRIAR #5.e.)	**The PACE Organization Application Process** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10631 OCN: 0938-1326	Published: 10/29/2019 Due Date: 12/30/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: The PACE Organization Application Process in 42 CFR part 460; *Use*: The Programs of All-Inclusive Care for the Elderly (PACE) consist of pre-paid, capitated plans that provide comprehensive health services to frail, older adults in the community who are eligible for nursing home care according to state standards. This information collection is mandated under sections 1894(f) and 1934(f) of the Social Security Act and at 42 CFR part 460, subpart B, which addresses the PACE organization (PO) application and waiver process. An entity wishing to become a PO must submit an application to CMS describing how the entity meets all the requirements in the PACE program. The application must include an assurance from the State Administering Agency (SAA) of the state in which the PO is located. CMS recently issued a final PACE rule (CMS-4168-F), effective August 2, 2019, to update and modernize the PACE program. In addition to codifying the current automated processes for the submission and review of both initial and service area expansion PO applications, this rule modifies existing regulatory provisions and requirements. As a result, certain attestations associated with the application are no longer applicable, and others need require updates to reflect updated regulatory requirements. CMS also has made minor changes to certain document upload requirements for clarification purposes based on experience reviewing applications.	
2019-052	**Proposed Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization Process**	Published: 10/29/2019 Due Date: 12/30/2019	*Type of Information Collection Request*: New collection; *Title*: Proposed Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization Process and Requirements for a Potential National Model; *Use*: CMS seeks approval to potentially expand the RSNAT Prior Authorization Model nationally if the HHS secretary determines that the expansion criteria are met. If such a national model moves forward, CMS would	

	and Requirements for a Potential National Model ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-10708 OCN: 0938-xxxx		use this information collection to determine proper payment for repetitive, scheduled non-emergent ambulance transports. The information required would include all medical documents and information to show that the number and level of transports requested are reasonable and necessary for the beneficiary and meet other Medicare requirements.	
2019-053 (See also pre-2017 RRIAR #176.)	**Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: CMS-416 OCN: 0938-0354	Published: 10/31/2019 Due Date: 12/30/2019	*Type of Information Collection Request*: Revision of a currently approved collection; *Title*: Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report; *Use*: The collected baseline data is used to assess the effectiveness of state early and periodic screening, diagnostic, and treatment (EPSDT) programs in reaching eligible children (by age group and basis of Medicaid eligibility). This assessment is coupled with state results in attaining the participation goals set for the state. The information gathered from this report permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program.	
2019-054	**Centers for Medicare & Medicaid Services Serious Mental Illness (SMI) and Serious Emotional Disturbance (SED) Demonstration Opportunity Technical Assistance Questions and Answers** ACTION: Q &A AGENCY: CMS, HHS	Published: 11/04/2019	The Centers for Medicare & Medicaid Services (CMS) is committed to supporting states in improving access and quality of care for beneficiaries with serious mental illness (SMI) or serious emotional disturbance (SED). On November 13, 2018, CMS announced a new SMI/SED demonstration opportunity in a State Medicaid Director Letter (SMDL). These technical assistance questions and answers are related to that SMI/SED demonstration opportunity, specifically clarifying the state's ability to claim federal financial participation (FFP) for services delivered to individuals during short term stays for acute care in psychiatric hospitals or residential treatment settings that qualify as Institutions for Mental Diseases (IMD).	Source: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/faq110419.pdf
2019-055	**Updated Medicaid and CHIP Scorecard**	Published: 11/04/2019	The Scorecard increases transparency into the administration and outcomes of Medicaid and the Children's Health Insurance Program (CHIP). The data in this section help explain the Medicaid and CHIP programs by highlighting: • Who enrolls in Medicaid and CHIP • How states deliver care in Medicaid • State efforts to collect and report data that support ongoing program improvement • Medicaid and CHIP expenditures States establish and administer their own Medicaid and CHIP programs. As a result, the populations and benefits covered by Medicaid and CHIP vary across states. For example, in all states Medicaid provides health care coverage for some low-income people, families and children, pregnant women, the elderly, and people with disabilities. In some states Medicaid also covers all low-income adults below a certain income level. This group is sometimes called "expansion adults." In CHIP, states can choose to set income levels higher than the	Source: https://www.medicaid.gov/state-overviews/scorecard/index.html

			federal minimum threshold, and to cover pregnant women. Federal law also requires states to provide certain "mandatory" benefits and allows states to cover other "optional" benefits in Medicaid and CHIP. States deliver Medicaid and CHIP benefits by directly paying providers – called "fee-for-service" payments – or through contracted arrangements with managed care organizations that oversee benefit delivery.	
2019-056	**Implementation of Section 5052 of the SUPPORT for Patients and Communities Act – State Plan Option under Section 1915(l) of the Social Security Act** ACTION: State Medicaid Director Letter FILE CODE: SMDL 19-0003	Published: 11/06/2019	This letter provides guidance on the implementation of section 5052 of the "Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act," also known as the SUPPORT for Patients and Communities Act (Pub. L.115-271). Section 5052 of the SUPPORT for Patients and Communities Act amended the institution for mental diseases (IMD) exclusion and established a new section 1915(l) of the Social Security Act (Act) to include a state plan option to provide services to Medicaid Beneficiaries age 21 through 64 who have at least one substance use disorder (SUD) diagnosis and reside in an eligible IMD from October 1, 2019 through September 30, 2023. The Centers for Medicare & Medicaid Services (CMS) is committed to supporting states that are interested in adding this option to their Medicaid state plan.	Source: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd19003.pdf
2019-057	**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances-July Through September 2019** ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-9119-N DOCUMENT NUMBER: 2019-24235	Published: 11/06/2019	This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other Federal Register notices that were published from July through September 2019, relating to the Medicare and Medicaid programs and other programs administered by CMS.	
2019-058	**Managed Care Contract Review Redesign Project**	Published: 11/08/2019	The Centers for Medicare & Medicaid Services (CMS) is collaborating with the National Association of Medicaid Directors (NAMD), an organization whose members are state Medicaid directors from all states, the District of Columbia, and U.S territories, to improve CMS' managed care plan contract review process by increasing efficiencies and transparency, and decreasing administrative burden. Both CMS and states have identified the contract review process as an area in need of significant improvement. The volume of state managed care contract submissions has risen steadily over the past several years without significant process improvements to offset the increased workload. Under the current process, contract reviews are taking an average of 254 days to approve, and are consuming a growing proportion of CMS resources. The redesign project will address these issues by expediting the review process so that states and CMS can rebalance their resources, and focus on assuring accessible, high quality health care, and improving health outcomes for Medicaid beneficiaries.	Source: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib110819.pdf
2019-059	**End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals**	Published: 11/08/2019 Effective Date: 01/01/2020	This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2020. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). This rule also updates requirements for the ESRD Quality Incentive Program (QIP). In addition, this rule establishes a methodology for calculating fee	

	With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements ACTION: Final Rule AGENCY: CMS, HHS FILE CODE: CMS-1713-F OCN: 0938-AT70		schedule payment amounts for new Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items and services, and a methodology for making adjustments to the fee schedule amounts established using supplier or commercial prices if such prices decrease within 5 years of establishing the initial fee schedule amounts. This rule also revises existing regulations related to the DMEPOS competitive bidding program. This rule also streamlines the requirements for ordering DMEPOS items, and develops a new list of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements. Finally, this rule summarizes responses to requests for information on data collection resulting from the ESRD PPS technical expert panel, changing the basis for the ESRD PPS wage index, and new requirements for the competitive bidding of diabetic testing strips.	
2019-060	**CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements** ACTION: Final Rule with Comment Period AGENCY: CMS, HHS FILE CODE: CMS-1711-FC OCN: 0938-AT68	Published: 11/08/2019 Due Date: 12/30/2019 Effective Date: 01/01/2020	This final rule with comment period updates the home health prospective payment system (HH PPS) payment rates and wage index for CY 2020; implements the Patient-Driven Groupings Model (PDGM), a revised case-mix adjustment methodology, for home health services beginning on or after January 1, 2020. This final rule with comment period also implements a change in the unit of payment from 60-day episodes of care to 30-day periods of care, as required by section 51001 of the Bipartisan Budget Act of 2018, hereinafter referred to the "BBA of 2018", and finalizes a 30-day payment amount for CY 2020. Additionally, this final rule with comment period: Modifies the payment regulations pertaining to the content of the home health plan of care; allows therapist assistants to furnish maintenance therapy; and changes the split percentage payment approach under the HH PPS. For the Home Health Value-Based Purchasing (HHVBP) model, we are finalizing provisions requiring the public reporting of the Total Performance Score (TPS) and the TPS Percentile Ranking from the Performance Year 5 (CY 2020) Annual TPS and Payment Adjustment Report for each home health agency in the nine Model states that qualified for a payment adjustment for CY 2020. This final rule with comment period also finalizes the following updates to the Home Health Quality Reporting Program (HH QRP): Removal of a measure; adoption of two new measures; modification of an existing measure; and a requirement for HHA's to report standardized patient assessment data beginning with the CY 2022 HH QRP. Additionally, we are finalizing our proposal to re-designate our current HH QRP regulations in a different section of our regulations and to codify other current policies in that new regulatory section with one substantive change as well as a few	

			technical edits. We are not finalizing our proposal to remove question 10 from all of the HH Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. Lastly, it sets forth routine updates to the home infusion therapy payment rates for CY 2020, payment provisions for home infusion therapy services for CY 2021 and subsequent years, and solicits comments on options to enhance future efforts to improve policies related to coverage of eligible drugs for home infusion therapy.	
2019-061	**Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage** ACTION: Final Rule and Comment Period AGENCY: CMS, HHS FILE CODE: CMS-1717-FC OCN: 0938-AT74	Published: 11/12/2019 Due Date: 12/31/2019 Effective Date: 01/01/2020	This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year 2020 based on our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, this final rule with comment period establishes a process and requirements for prior authorization for certain covered outpatient department services; revise the conditions for coverage of organ procurement organizations; and revise the regulations to allow grandfathered children's hospitals-within-hospitals to increase the number of beds without resulting in the loss of grandfathered status; and provides notice of the closure of two teaching hospitals and the opportunity to apply for available slots for purposes of indirect medical education (IME) and direct graduate medical education (DGME) payments.	
2019-062	**Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2020** ACTION: Final Rule and Comment Period AGENCY: CMS, HHS FILE CODE:CMS- 6089-N and IFC DOCUMENT NUMBER: 2019-24443	Published: 11/12/2019 Effective Date: 01/01/2020	This notice announces a $595.00 calendar year (CY) 2020 application fee for institutional providers that are initially enrolling in the Medicare or Medicaid program or the Children's Health Insurance Program (CHIP); revalidating their Medicare, Medicaid, or CHIP enrollment; or adding a new Medicare practice location. This fee is required with any enrollment application submitted on or after January 1, 2020 and on or before December 31, 2020	
2019-063	**Medicare Program; CY 2020 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts** ACTION: Notice AGENCY: CMS, HHS	Published: 11/13/2019 Effective Date: 01/01/2020	This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2020 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2020, the inpatient hospital deductible will be $1,408. The daily coinsurance amounts for CY 2020 will be: $352 for the 61st through 90th day of hospitalization in a benefit period; $704 for lifetime reserve days; and $176 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.	

	FILE CODE: CMS-8071-N OCN: 0938-AT76			
2019-064	**CY 2020 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement** ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-8072-N OCN: 0938-AT77	Published: 11/13/2019 Effective Date: 01/01/2020	This annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year (CY) 2020. This premium is paid by enrollees age 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the "uninsured aged") and by certain disabled individuals who have exhausted other entitlement. The monthly Part A premium for the 12 months beginning January 1, 2020 for these individuals will be $458. The premium for certain other individuals as described in this notice will be $252.	
2019-065	**Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2020** ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-8073-N OCN: 0938-AT78	Published: 11/13/2019 Effective Date: 01/01/2020	This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2020. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2020, and the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. The monthly actuarial rates for 2020 are $283.20 for aged enrollees and $343.60 for disabled enrollees. The standard monthly Part B premium rate for all enrollees for 2020 is $144.60, which is equal to 50 percent of the monthly actuarial rate for aged enrollees (or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees) plus $3.00 repayment amount required under current law. (The 2019 standard premium rate was $135.50, which included the $3.00 repayment amount.) The Part B deductible for 2020 is $198.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment, he or she will have to pay a total monthly premium of about 35, 50, 65, 80 or 85 percent of the total cost of Part B coverage plus a repayment amount of $4.20, $6.00, $7.80, $9.60 or $10.20 respectively.	
2019-066	**Further Guidance to Medicaid Bipartisan Budget Act (BBA) of 2018 and changes to Medicaid Provisions Passed in April 2019 – Third Party Liability in Medicaid and CHIP** ACTION: Informational Bulletin AGENCY: CMS, HHS	Published: 11/14/2019	On February 9, 2018, President Trump signed the Bipartisan Budget Act of 2018 (Pub. L. 115- 123) into law. This new law includes several provisions which modify third party liability (TPL) rules related to special treatment of certain types of care and payment. The intent of this Informational Bulletin is to further clarify CMS guidance issued in our June 2018 Bulletin on key provisions related to third party liability in Medicaid and CHIP. This guidance also addresses the April 2019 changes to the Bipartisan Budget Act of 2013, which allows for payment up to 100 days instead of 90 days after a claim is submitted for claims related to medical support	Source: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib111419.pdf
2019-067	**Medicare-Medicaid Integration and Unified**	Published: 11/14/2019	Dual Eligible Special Needs Plans (D-SNPs) are Medicare Advantage (MA) plans that are specifically designed to integrate and coordinate care for dually eligible individuals by focusing on enrollment and care management for this population. As of September 2019,	Source:

	Appeals and Grievance Requirements for State Medicaid Agency Contracts with Medicare Advantage Dual Eligible Special Needs Plans (D-SNPs) for Contract Year 2021 ACTION: Informational Bulletin AGENCY: CMS, HHS		approximately 2.7 million dually eligible individuals (one out of every five dually eligible individuals) were enrolled in one of the 480 D-SNPs. The Bipartisan Budget Act (BBA) of 2018 strengthened D-SNP Medicare-Medicaid integration requirements and unified Medicare and Medicaid grievance and appeals procedures for some DSNPs beginning in 2021. On April 16, 2019, CMS finalized rules (hereafter referred to as the April 2019 final rule) implementing these new statutory provisions. States play an important role in D-SNP implementation of these requirements. This bulletin contains information for states to consider when updating their Contract Year (CY) 2021 contracts with D-SNPs (submitted to CMS in July 2020). This bulletin also highlights important information that states need to ensure that D-SNPs in their markets meet the new requirements beginning in CY 2021. We strongly recommend states use the information in this bulletin to engage with D-SNPs on these new requirements as soon as possible.	https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib111419-2.pdf
2019-068	**CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements** ACTION: Final Rule and Interim Final Rule AGENCY: CMS, HHS FILE CODE: CMS-1715-F and IFC OCN: 0938-AT72	Published: 11/15/2019 Due Date: 12/31/2019 Effective Date: 01/01/2020	This major final rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program quality reporting requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; the establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations. In addition, we are issuing an interim final rule with comment period (IFC) to establish coding and payment for evaluation and management, observation and the provision of self-administered Esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible.	Fact Sheet: https://www.cchpca.org/sites/default/files/2019-11/FINALIZED%20PFS%20CY%202020%20FINAL.pdf
2019-069	**CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public** ACTION: Final Rule AGENCY: CMS, HHS FILE CODE:CMS-1717-F2 OCN: 0938-AU22	Published: 11/15/2019 Effective Date: 01/01/2021	This final rule establishes requirements for hospitals operating in the United States to establish, update, and make public a list of their standard charges for the items and services that they provide. These actions are necessary to promote price transparency in health care and public access to hospital standard charges. By disclosing hospital standard charges, we believe the public (including patients, employers, clinicians, and other third parties) will have the information necessary to make more informed decisions about their care. We believe the impact of these final policies will help to increase market competition, and ultimately drive down the cost of health care services, making them more affordable for all patients.	**News update:** Hospitals groups sued the Trump administration today over the sweeping new transparency rules forcing them to disclose what health insurers pay for their services. The lawsuit, filed in the U.S. District Court for the District of Columbia, claims HHS doesn't have the authority to force hospitals to publish secret rates they've negotiated with insurers. It also argues the rules, slated to take effect in 2021, violate the First Amendment. "Had Congress wanted to give CMS the authority to order disclosure of these payer-specific negotiated charges in addition, it would have said so expressly," major lobby groups said in the lawsuit.

				With respect to Tribal facilities, the news is good. The rule says: In the CY 2020 OPPS/ASC proposed rule (84 FR 39575 through 39576), we proposed that hospital standard charge disclosure requirements would not apply to federally-owned or operated hospitals, including Indian Health Service (IHS) facilities (including Tribally-owned and operated facilities), Veterans Affairs (VA) facilities, and Department of Defense (DOD) Military Treatment Facilities (MTFs), because, with the exception of some emergency services, these facilities do not provide services to the general public and the established payment rates for services are not subject to negotiation. Instead, each of these facility types is authorized to provide services only to patients who meet specific eligibility criteria. For example, individuals must meet the requirements enumerated at 42 CFR 136.22 through 136.23 to be eligible to receive services from IHS and Tribal facilities. Similarly, under 38 CFR 17.43 through 17.46, VA hospitals provide hospital, domiciliary, and nursing home services…."
2019-070	**Agency Information Collection Activities: Submission for OMB Review; Comment Request: Medicare Outpatient Observation Notice (MOON)** ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-10611, CMS-R-282 and CMS-R-235 DOCUMENT NUMBER: 2019-24929	Published: 11/18/2019 Due Date: 12/18/2019	*Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Outpatient Observation Notice (MOON); *Use:* On August 6, 2015, Congress enacted the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) Public Law 114-42, amending Section 1866(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395cc(a)(1)), by adding a new subparagraph (Y). The NOTICE Act requires hospitals and CAHs to provide written notification and oral explanation to individuals who receive observation services as outpatients for more than 24 hours. The MOON is a standardized notice delivered to persons entitled to Medicare benefits under Title XVIII of the Act who receive more than 24 hours of observation services, informing them that their hospital stay is outpatient and not inpatient, and the implications of being an outpatient. This information collection applies to beneficiaries in Original Medicare and enrollees in Medicare health plans. The Medicare Outpatient Observation Notice (MOON), serves as the written notice component of this mandatory notification process. The standardized content of the MOON includes all informational elements required by statute, in language understandable to beneficiaries, and fulfils the regulatory requirements at 42 CFR part 489.20(y).	The MOON is provided in advance when it is known that patients are receiving outpatient observation services. There were questions regarding Tribal facilities that see a mixture of non-AIAN (non-beneficiaries) and AI/AN patients. Right now IHS facilities do not participate in handing out the MOON because IHS does not charge out-of-pockets costs. AI/ANs should not receive this form. Individual facilities can choose to amend the form by adding pages at the end to notify AI/ANs of this policy. Tribal facilities should reach out directly to the CMS contact person listed in this Notice, if they have any questions.

			The MOON is not given every time items and services are furnished in a hospital or CAH. Rather, hospitals are only required to deliver the MOON to individuals receiving observation services as outpatients for more than 24 hours. (For policy questions regarding this collection contact Janet Miller at Janet.Miller@cms.hhs.gov.)	
2019-071	**Agency Information Collection Activities: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3);** ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-10260, CMS-R-297/CMS-L564, CMS-4040, CMS-10718 and CMS-10146 DOCUMENT NUMBER: 2019-249230	Published 11/18/2019 Due Date: 01/17/2020	*Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3); *Use:* Pursuant to disclosure requirements set out in sections 1851(d)(2)(A) and 1860D-1(c) of the Social Security Act (the Act), and cited in §§ 422.111(a)(3) and 423.128(a)(3), Medicare Advantage (MA) organizations and Part D sponsors must provide notice to plan members of impending changes to plan benefits, premiums and cost sharing in the coming year. To this effect, members will be in the best position to make an informed choice on continued enrollment or disenrollment from that plan at least 15 days before the Annual Election Period (AEP) using the Annual Notice of Change (ANOC) and before the first day of the AEP for the Evidence of Coverage (EOC). MA organizations and Part D sponsors must notify plan members of the coming year changes using the standardized ANOC. Plans must disseminate the EOC at the time of enrollment and at least annually thereafter. CMS requires MA organizations and Part D sponsors to use the standardized documents being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851(d)(3)(A) of the Act and § 422.111 for MA organizations and section 1860D-1(c) of the Act and § 423.128(a)(3) for Part D sponsors. Sections 1851(h)(1) and (2) of the Act require MA organizations and Part D sponsors to obtain CMS approval of marketing materials to ensure that MA organizations and Part D sponsors disclose correct information to current and potential enrollees. CMS collects and retains the MA organization and Part D plan marketing materials via the Health Plan Management System Start Printed Page 63656(HPMS). MA organizations and Part D plans submit marketing materials to the CMS marketing material review process using HPMS. Both current and potential enrollees can review other marketing materials to find plan benefits, premiums, and cost sharing for the coming year (after October 1) and the current year to be in a better position to make. MA organizations and Part D sponsors use the information discussed in the Medicare Communication and Marketing Guidelines (MCMG) to comply with the requirements to seek CMS approval on marketing materials under MA and Part D law and regulations, as described above. CMS requires MA organizations and Part D sponsors to obtain CMS approval of marketing materials to ensure that MA organizations and Part D sponsors disclose correct information to current and potential enrollees. Both current and potential enrollees can review other marketing materials to find plan benefits, premiums, and cost sharing for the coming year (after October 1) and the current year to be in a better position to make informed and educated plan selections. (For policy questions regarding this collection contact Timothy Roe at (410) 786-2006.) 2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Employment Information;	

			Use: The form CMS-L564, also referred to as CMS-R-297, is used, in conjunction with form CMS-40-B, Application for Supplementary Medical Insurance, during an individual's special enrollment period (SEP). Completed by an employer, the CMS-L564 provides proof of an applicant's employer group health coverage. The Social Security Administration (SSA) uses it to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment status. This form is available in both English and Spanish. Section 1837(i) of the Social Security Act (the Act) provides a SEP for individuals who delay enrolling in Medicare Part B because they are covered by a group health plan based on their own or a spouse's current employment status. Disabled individuals with Medicare may also delay enrollment because they have large group health plan coverage based on their own or a family member's current employment status. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. Form CMS L564 provides this proof so that SSA can determine eligibility for the SEP. Individuals eligible for the SEP can enroll in Part B without incurring a late enrollment penalty. Individuals may also use this form to prove that their group health plan coverage is based on current employment status and to have the assessed Medicare late enrollment penalty reduced. The form is available online via Medicare.gov and CMS.gov for individuals who are requesting the SEP to obtain and submit to their employer for completion. The employer must complete and sign the form, and submit it to the individual to accompany their enrollment or late enrollment penalty reduction request. The information on the completed form is reviewed manually by SSA. Thus, the collection of this information does not involve the use of information technology. (For policy questions regarding this collection contact Carla D. Patterson, at (410) 786-1000.) 3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Enrollment in Supplementary Medical Insurance (SMI) and Supporting Regulations in 42 CFR 407.10, 407.11 and 408.40(a)(2); *Use:* Section 1836 of the Social Security Act, and CMS regulations at 42 CFR 407.10, provide the eligibility requirements for enrollment in Part B for individuals age 65 and older who are not entitled to premium-free Part A. The individual must be a resident of the United States, and either a U.S. Citizen or an alien lawfully admitted for permanent residence that has lived in the US continually for 5 years. CMS regulations 42 CFR 407.11 lists the CMS-4040 as the application to be used by individuals who are not eligible for monthly Social Security/Railroad Retirement Board benefits or free Part A. The CMS-4040 solicits the information that is used to determine entitlement for individuals who meet the requirements in section 1836 as well as the entitlement of the applicant or their spouses to an annuity paid by OPM for premium deduction purposes. The application follows the application questions and requirements used by SSA. This is done not only for consistency purposes but to comply with other Title II and Title XVIII requirements because eligibility to Title II benefits and free Part A under Title XVIII must be ruled out in order to	

			qualify for enrollment in Part B only. (For policy questions regarding this collection contact Carla D. Patterson, at (410) 786-1000.) 4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form; *Use:* This information collection is necessary for the Medicare beneficiary (or their legal representative), to enroll in an MA or PDP plan, even if switching plans within the same MA or PDP organization. To consider an election complete, the individual must: Complete an enrollment request; Provide required information to the MA or PDP organization within the required time frames; Submit the completed request to the MA or PDP organization during a valid enrollment period. MA and PDP organizations, applicants to MA and PDP organizations, and the CMS will use the information collected to comply with the eligibility and enrollment requirements for Medicare Part C and Part D plans. Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) enacted August 5, 1997, established Part C of the Medicare program, known as the Medicare + Choice program, (now referred to as Medicare Advantage (MA)). As required by 42 CFR 422.50(a)(5), an MA-eligible individual who meets the eligibility requirements for enrollment into an MA or MAPD plan may enroll during the enrollment periods specified in § 422.62, by completing an enrollment form with the MA organization or enrolling through other mechanisms that the Centers for Medicare & Medicaid Services (CMS) determines are appropriate. Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) enacted December 8, 2003, established Part D of the Medicare Start Printed Page 63657program, known as the Voluntary Prescription Drug Benefit Program. As required by 42 CFR 423.32(a) and (b), a Part D-eligible individual who wishes to enroll in a Medicare prescription drug plan (PDP) may enroll during the enrollment periods specified in § 423.38, by completing an enrollment form with the PDP, or enrolling through other mechanisms CMS determines are appropriate. (For policy questions regarding this collection contact Deme Umo at (410) 786-8854.) 5. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process.	

			CMS requests approval of changes to a currently approved collection under section 1860D-4(g)(1) of the Social Security Act which requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process. Medicare beneficiaries who are enrolled in a Part D plan will be informed of adverse decisions related to their prescription drug coverage and their right to appeal these decisions. The notice provides all ways that the beneficiary can file an appeal under one section. The Part D instructions have also been revised to include a paragraph informing providers that in the case that a request for a coverage determination is denied under Part B due to step therapy requirements, a different notice should be given. This denial notice is primarily issued to Part D plan enrollees (Medicare beneficiaries) and is most commonly sent to enrollees by mail. Relying on electronic transmission of this notice to beneficiaries is impractical. Plans are required by regulation to maintain a website by which beneficiaries can request an appeal. In this version of the notice, website information is more prominently displayed.	
2019-072	**Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals** ACTION: Final Rule and Correction Notice AGENCY: CMS-1716-F and CMS-1716-CN2 OCN: 0938-AT73	Published: 08/02/2019; Correction Notice Published 10/07/2019	We are revising 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 2020 and to implement certain recent legislation. We also are making changes relating to Medicare graduate medical education (GME) for teaching hospitals and payments to critical access hospital (CAHs). In addition, we are providing the market basket update that will 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 2020. We are updating 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 2020. In this FY 2020 IPPS/LTCH PPS final rule, we are addressing wage index disparities impacting low wage index hospitals; providing for an alternative IPPS new technology add-on payment pathway for certain transformative new devices and qualified infectious disease products; and revising the calculation of the IPPS new technology add-on payment. In addition, we are revising and clarifying our policies related to the substantial clinical improvement criterion used for evaluating applications for the new technology add-on payment under the IPPS. We are establishing new requirements or revising existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS exempt cancer hospitals, and LTCHs). We also are establishing new requirements and revising existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare and Medicaid Promoting Interoperability Programs. We are updating policies for the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.	
2020-002	**Transparency in Coverage** ACTION: Proposed Rule	Published: 11/27/2019 Due Date: 01/29/2020	These proposed rules set forth proposed requirements for group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request, to a participant, beneficiary, or enrollee (or his or her authorized representative), including an estimate of such individual's cost-sharing liability for covered	

	AGENCY: CMS, HHS, Treas., DOL FILE CODE: CMS-9915-P OCN: 0938-AU04		items or services furnished by a particular provider. Under these proposed rules, plans and issuers would be required to make such information available on an internet website and, if requested, through non-internet means, thereby allowing a participant, beneficiary, or enrollee (or his or her authorized representative) to obtain an estimate and understanding of the individual's out-of-pocket expenses and effectively shop for items and services. These proposed rules also include proposals to require plans and issuers to disclose in-network provider negotiated rates, and historical out-of-network allowed amounts through two machine-readable files posted on an internet website, thereby allowing the public to have access to health insurance coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending. The Department of Health and Human Services (HHS) also proposes amendments to its medical loss ratio program rules to allow issuers offering group or individual health insurance coverage to receive credit in their medical loss ratio calculations for savings they share with enrollees that result from the enrollee's shopping for, and receiving care from, lower-cost, higher-value providers.	
2020-003	**Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2020 Through September 30, 2021** ACTION: Notice AGENCY: CMS, HHS DOCUMENT NUMBER: 2019-26207	Published: 12/03/2019 Effective Date: 10/01/2020 to 09/30/2021	This notice announces the calculated Federal Medical Assistance Percentages (FMAP) rates, in accordance with sections 1101(a)(8) and 1905(b) of the Social Security Act (the Act), that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of Federal matching for state medical assistance (Medicaid), Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Title IV-E Foster Care Maintenance payments, Adoption Assistance payments and Kinship Guardianship Assistance payments, and the Enhanced Federal Medical Assistance Percentages (eFMAP) rates for the Children's Health Insurance Program (CHIP) expenditures.	
2020-004	**Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: CMS-3380-P OCN: 0938-AU02	Published: 12/23/2020 Due Date: 02/01/2020	This proposed rule would revise the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current measures with new transparent, reliable, and objective measures.	
2020-005	**Medicare and Medicaid Programs: Application From Accreditation Association of**	Published: 12/26/2019 Effective Date:	This final notice announces CMS' decision to approve an application from Accreditation Association of Hospitals/Health Systems—Healthcare Facilities Accreditation Program for continued recognition as a national accrediting organization for critical access hospitals that wish to participate in the Medicare or Medicaid programs.	

	Hospitals/Health Systems-Healthcare Facilities Accreditation Program (AAHHS-HFAP) for Continued CMS-Approval of Its Critical Access Hospital (CAH) Accreditation Program ACTION: Final Notice AGENCY: CMS, HHS FILE CODE: CMS-3377-FN DOCUMENT NUMBER: 2019-27836	12/27/2020 to 12/27/2025	Background: Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH) provided certain requirements are met by the CAH. Section 1861(mm) of the Social Security Act (the Act), sets out definitions for "critical access hospital" and for inpatient and outpatient CAH services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 485, subpart F specify the conditions that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs.	
2020-006	**Information Collection Request: The Commissioned Corps of the U.S. Public Health Service application.** ACTION: Request for Comment AGENCY: CMS, HHS FILE CODE: OS-0937-0025 DOCUMENT NUMBER: 2019-27752	Published: 12/26/2019 Due Date: 01/27/2020	*Information Collection Request Title:* The Commissioned Corps of the U.S. Public Health Service application. *Abstract:* The principal purpose for collecting the information is to permit HHS to determine eligibility for appointment of applicants into the Commissioned Corps of the U.S. Public Health Service (Corps). The Corps is one of the seven Uniformed Services of the United State (37 U.S.C. 101(3)), and appointments in the Corps are made pursuant to 42 U.S.C. 204 et seq. and 42 CFR 21.58. The application consists of forms PHS-50, PHS-1813, and the Commissioned Corps Personal Statement.	
2020-007	**Patient Protection and Affordable Care Act; Exchange Program Integrity** ACTION: Final Rule AGENCY: CMS, HHS FILE CODE: CMS-9922-F DOCUMENT NUMBER: 2019-27713	Published: 12/27/2019 Effective Date: 02/25/2020	This final rule revises standards relating to oversight of Exchanges established by states and periodic data matching frequency. This final rule also includes new requirements for certain issuers related to the collection of a separate payment for the portion of a plan's premium attributable to coverage for certain abortion services.	
2020-008	**Adjustment of Civil Monetary Penalties for Inflation; Continuation of Effectiveness and Extension of Timeline for Publication of the Final Rule**	Published: 01/02/2020 Effective Date: 12/31/2019	This document announces the continuation of, effectiveness of, and the extension of the timeline for publication of a final rule. We are issuing this document in accordance with the Social Security Act (the Act), which allows an interim final rule to remain in effect after the expiration of the timeline specified in the Act if the Secretary publishes a notice of continuation explaining why the regular timeline was not complied with. Effective December 31, 2019, the Medicare provisions adopted in the interim final rule published on September 6, 2016 (81 FR 61538) continue in effect and the regular timeline for publication of the final rule is extended for an additional year, until September 6, 2020.	

	ACTION: Continuation of effectiveness and extension of timeline for publication of the final rule. AGENCY: CMS, HHS, Treas., DOL FILE CODE: CMS-6076-RCN OCN: 0991-AC07			
2020-009	**Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part I, CMS-HCC Risk Adjustment Model**	Published: 01/06/2020 Effective Date: 03/06/2020	As amended by the 21st Century Cures Act, section 1853(a)(1)(I)(iii) of the Social Security Act (the Act) requires that CMS provide at least 60 days for public review and comment of proposed changes under section 1853(a)(1)(I) to the Part C risk adjustment model. Therefore, we are notifying you of the proposed changes in the Medicare Advantage risk adjustment methodology applied under Part C for CY 2021 in accordance with sections 1853(a)(1)(I)(iii) and 1853(b)(2) of the Act, as amended by section 17006 of the 21st Century Cures Act. For CY 2021, we are proposing to continue the transition of the risk adjustment model adopted in the CY 2020 Rate Announcement that incorporated important changes to the Part C risk adjustment model based on section 1853(a)(1)(I) of the Act. This proposal reflects the requirement in the 21st Century Cures Act (Pub. L. 114-255) to phase in changes to the risk adjustment model under section 1853(a)(1)(I) over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years. The proposed changes include continued phasing in of the model that includes changes adopted under subsections (a)(1)(C) and (a)(1)(I) of section 1853. Pursuant to section 1853(b)(2) of the Act, we will provide notification of planned changes in the Medicare Advantage capitation rate methodology and other risk adjustment methodologies applied under the Act for CY 2021, along with annual adjustments to the Medicare Part D benefit parameters for the defined standard benefit, in the Advance Notice of Methodological Changes for CY 2021 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies to be released on or before February 6, 2020. The statute requires CMS to publish the Advance Notice of Methodological Changes no fewer than 60 days before the publication of the Rate Announcement and establishes a minimum 30-day period for the public to comment on the proposals in the Advance Notice.	Source: https://www.cms.gov/files/document/2021-advance-notice-part-i.pdf
2020-010	**CMS: Agency Information Collection Activities: Submission for OMB Review; Comment Request** ACTION: Continuation of effectiveness and extension of timeline for publication of the final rule. AGENCY: CMS, HHS	Published: 01/14/2020 Effective Date: 02/13/2020	*1. Type of Information Collection Request:* Extension of a currently Start Printed approved collection*; Title of Information Collection: Electronic Funds Transfer Authorization Agreement; Use:* Section 1815(a) of the Social Security Act provides the authority for the Secretary of Health and Human Services to pay providers/suppliers of Medicare services at such time or times as the Secretary determines appropriate (but no less frequently than monthly). Under Medicare, CMS, acting for the Secretary, contracts with Fiscal Intermediaries and Carriers to pay claims submitted by providers/suppliers who furnish services to Medicare beneficiaries. Under CMS' payment policy, Medicare providers/suppliers have the option of receiving payments electronically.	

	FILE CODE: CMS-588, CMS-855B and CMS-R-262 DOCUMENT NUMBER: 2020-00426		*2. Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers Revision; *Use:* The primary function of the CMS-855B Medicare enrollment application for suppliers, also known as Health Diagnosing and Treating Practitioners, is to gather information from the supplier that tells CMS who the supplier is, whether the supplier meets certain qualifications to be a Medicare health care provider or supplier, where the supplier practices or renders services, and other information necessary to establish correct claims payments. The CMS-855B form includes an attachment for Opioid Treatment Programs (OTPs). This attachment is only used to capture the OTP personnel and consists of limited data fields (name, Social Security Number, National Provider Identifier, and license number) in response to the "SUPPORT for Patients and Communities Act" that was signed into law on October 24, 2018. This legislation was designed to alleviate the nationwide opioid crisis by: (1) Reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions to the crisis. Section 2005 of the SUPPORT Act establishes a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020. *3. Type of Information Collection Request:* Revision with change of a currently approved collection*; Title of Information Collection:* Contract Year 2021 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. CMS uses this data to review and approve the benefit packages that the plans will offer to Medicare beneficiaries. This allows CMS to review the benefit packages in a consistent way across all submitted bids during with incredibly tight timeframes. This data is also used to populate data on Medicare Plan Finder, which allows beneficiaries to access and compare Medicare Advantage and Prescription Drug plans.	
2020-011	**Information Collection Request: Medicare Current Beneficiary Survey** ACTION: Comment Request	Due Date: 03/16/2020	*Type of Information Collection Request*: Revision with change of a currently approved collection; *Title*: Medicare Current Beneficiary Survey; *Use:* CMS is the largest single payer of health care in the United States. The agency plays a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. A critical aim for CMS is to be an effective steward, major force, and trustworthy partner in supporting innovative approaches to improving quality, accessibility, and affordability in healthcare.	

	AGENCY: CMS, HHS FILE CODE: CMS-P-0015A DOCUMENT NUMBER: 2020-00424		CMS also aims to put patients first in the delivery of their health care needs.	
2020-012	**Request for Information: Scope of Practice Feedback in Response to President Trump's Medicare Executive Order#13890, Protecting and Improving Medicare for Our Nation's Seniors** ACTION: Comment Request AGENCY: CMS, HHS	Due Date: 01/17/2020	The Centers for Medicare & Medicaid Services (CMS) is seeking additional input and recommendations regarding elimination of specific Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. We are seeking feedback in response to part of the President's Executive Order (EO) #13890 on Protecting and Improving Medicare for Our Nation's Seniors. The EO specifically directs HHS to propose a number of reforms to the Medicare program, including ones that eliminate supervision and licensure requirements of the Medicare program that are more stringent than other applicable federal or state laws. These burdensome requirements ultimately limit healthcare professionals, including Physician Assistants (PAs) and Advanced Practice Registered Nurses (APRNs), from practicing at the top of their professional license.	Source: https://www.cms.gov/files/document/feedback-scope-practice.pdf Link to Executive Order: https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/
2020-013	**Request for Information regarding Coordinating Care From Out-of-State Providers for Medicaid-Eligible Children With Medically Complex Conditions** ACTION: Notice AGENCY: CMS, HHS, Treas., DOL FILE CODE: CMS-2324-NC OCN: 0938-ZB57	Published: 01/21/2020 Due Date: 03/23/2020	This document is a request for information (RFI) to seek public comments regarding the coordination of care from out-of-state providers for Medicaid-eligible children with medically complex conditions. We wish to identify best practices for using out-of-state providers to provide care to children with medically complex conditions; determine how care is coordinated for such children when that care is provided by out-of-state providers, including when care is provided in emergency and non-emergency situations; reduce barriers that prevent such children from receiving care from out-of-state providers in a timely fashion; and identify processes for screening and enrolling out-of-state providers in Medicaid, including efforts to streamline such processes for out-of-state providers or to reduce the burden of such processes on them. We intend to use the information received in response to this RFI to issue guidance to state Medicaid directors on the coordination of care from out-of-state providers for children with medically complex conditions.	CMS is soliciting feedback on a number of questions, including: - Barriers to receiving care. Administrative, fiscal, and regulatory barriers that states, providers, beneficiaries, and their families experience that prevent children with medically complex conditions from timely receiving care (such as community and social support services), from out-of-state providers. - Screening and enrolling out of state Medicaid providers. What processes states could use to streamlines or reduce the administrative and fiscal burden on out-of-state providers and states (emergency and non-emergency situations). - Access to quality care. Challenges with referrals to out-of-state providers for specialty services, including community and social supports, for children with medically complex conditions and the impact of these challenges on access to qualified providers. - Payment rates for out of state providers. Best practices for developing

				appropriate and reasonable terms of contracts and payment rates for out-of-state providers, for both Medicaid fee-for-service and Medicaid managed care. As of 2015, care coordination is the most frequently provided health home service, but not all enrollees automatically receive it. Potential Tribal Impact: AI/ANs tend to live in child health care "deserts" and so there is a deep need for high quality child care in these regions. The reality is that Tribes have to cross borders to receive care, so this is an especially important rule for Tribes who straddle two or more state borders, such as those in California, and the Navajo Nation (Gallup Medical Center).
2020-014	**Information Collection Request: Pharmacy Benefit Manager Transparency** ACTION: Notice AGENCY: CMS, HHS FILE CODE: CMS-10725 DOCUMENT NUMBER: 2020-01463	Published: 01/28/2020 Effective Date: 03/30/2020	*Type of Information Collection Request*: New Information Collection; *Title*: Pharmacy Benefit Manager Transparency; Use: The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)—private health and dental insurance plans that are certified as meeting certain standards. The PPACA added section 1150A of the Social Security Act, which requires pharmacy benefit managers (PBMs) to report prescription benefit information to the Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. The Centers for Medicare and Medicaid Services (CMS) files this information collection request (ICR) in connection with the prescription benefit information that PBMs must provide to HHS under section 1150A. The burden estimate for this ICR reflects the time and effort for PBMs to submit the information regarding PBMs and prescription drugs.	
2020-015	**HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans** ACTION: Proposed Rule AGENCY: CMS, HHS FILE CODE: CMS-9916-P DOCUMENT NUMBER: 2020-02021	Published: 02/06/2020 Effective Date: 03/02/2020	This proposed rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters and cost-sharing reductions; and user fees for federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It also proposes changes related to essential health benefits and would provide states with additional flexibility in the operation and establishment of Exchanges. It includes proposed changes related to cost-sharing for prescription drugs; excepted benefit health reimbursement arrangements offered by non-Federal governmental plan sponsors; the medical loss ratio program; Exchange eligibility and enrollment; exemptions from the requirement to maintain coverage; quality rating information display standards for Exchanges; and other related topics. It also proposes to repeal regulations relating to the Early Retiree Reinsurance Program.	