

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-262, CMS-224-14, CMS-R-240, CMS-10164, CMS-2552-10, CMS-R-306, CMS-10684, CMS-10237, CMS-10524 and CMS-10511]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Contract Year 2020 Plan Benefit Package (PBP) Software and Formulary Submission; Use: CMS requires that MA and PDP organizations submit a completed Plan Benefit Package (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. 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. Additionally, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization. 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.

Form Number: CMS–R–262 (OMB control number 0938–0763); Frequency: Yearly; Affected Public: Private Sector, Business or other for-profits and Not-for-profit institution; Number of Respondents: 570; Total Annual Responses: 6,760; Total Annual Hours: 65,354.50 (For policy questions regarding this collection contact Kristy Holtje at 410-786-2209.)

2. Title of Information Collection: Federal Qualified Health Center Cost Report; Type of Information Collection Request: Extension of a currently approved collection; Use: Under the authority of sections 1815(a) and 1833(e) of the Act, CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. Furthermore, these sections of the Act provide that no Medicare payments will be made to a provider unless it furnishes the information. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, CMS defines adequate cost data and requires cost reports from providers on an annual basis. The Form CMS-224-14 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and to calculate the FQHC settlement

amount. These providers, paid under the FQHC prospective payment system (PPS), may receive reimbursement outside of the PPS for Medicare reimbursable bad debts and pneumococcal and influenza vaccines. The FQHC cost report is also used for rate setting and payment refinement activities, including developing a FQHC market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the FQHC Medicare cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the FQHC PPS, and to conduct additional analysis of the FQHC PPS. Form Number: CMS-224-14 (OMB control number: 0938-1298); Frequency: Yearly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 2,240; Number of Responses: 2,240; Total Annual Hours: 129,920. (For questions regarding this collection contact Julie Stankivic at (410) 786-5725.)

3. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Prospective Payments for Hospital Outpatient Services; Use: Section 1833(t) of the Act, as added by section 4523 of the Balanced Budget Act of 1997 (the BBA) requires the Secretary to establish a prospective payment system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the OPPS, the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. Information from the reports required under sections 413.65(b)(3) and (c) is needed to make these determinations. In addition, section 1866(b)(2) of the Act authorizes hospitals and other providers to impose deductible and coinsurance charges for facility services,

but does not allow such charges by facilities or organizations which are not provider-based. Implementation of this provision requires that CMS have information from the required reports, so it can determine which facilities are provider-based. Form Number: CMS-R-240 (OMB control number: 0938-0798); Frequency: Yearly; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 750; Total Annual Responses: 13,649,150; Total Annual Hours: 680,920 (For policy questions regarding this collection contact Emily Lipkin at 410-786-3633.)

4. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Medicare EDI Enrollment Form and EDI Registration; Use: The Congress, recognizing the need to simplify the administration of health care transactions, enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, on August 21, 1996. Title II, Subtitle F of this legislation directs the Secretary of the Department of Health and Human Services to develop unique standards for specified electronic transactions and code sets for those transactions. The purpose of this Subtitle is to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care industry in general through the establishment of standards and requirements to facilitate the electronic transmission of certain health information. This Subtitle also requires that the Secretary adopt standards for financial and administrative transactions, and data elements for those transactions to enable health information to be exchanged electronically. The Standards for Electronic Transactions final rule, 45 CFR Part 162 Subpart K §162.1101 through Subpart R §162.1802, (hereinafter referred to as “Transactions Rule”) published August

17, 2000 adopted standards for health care transactions and code sets. Subsequent to the Transactions Rule, CMS-0003-P and CMS-0005-P proposed modifications to the adopted standards essential to permit initial implementation of the standards throughout the entire healthcare industry.

Currently, Medicare contractors have a process in place to enroll providers for electronic billing and other EDI transactions. In support of the HIPAA Transactions Rule, the purpose of this Paperwork Reduction Act (PRA) request is to establish a common form that is sufficient to address all HIPAA transactions. Form Number: CMS-10164 (OMB control number: 0938-0983); Frequency: Hourly; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 193,268; Number of Responses: 193,268; Total Annual Hours: 64,423. (For policy questions regarding this collection, contact Matt Klischer at 410-786-7488.)

5. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Hospitals and Health Care Complex Cost Report; Use: Under the authority of sections 1815(a) and 1833(e) of the Act, CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, CMS defines adequate cost data and requires cost reports from providers on an annual basis. The Form CMS-2552-10 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare

beneficiaries and calculate the hospital settlement amounts. These providers, paid under the inpatient prospective payment system (IPPS) and the outpatient prospective payment system (OPPS), may receive reimbursement outside of the PPS for hospital-specific adjustments such as Medicare reimbursable bad debts, disproportionate share, uncompensated care, direct and indirect medical education costs, and organ acquisition costs. The Form CMS-2552-10 cost report is also used for rate setting and payment refinement activities, including developing a hospital market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the hospital cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the IPPS and OPPS, and to conduct additional analysis of the IPPS and OPPS. Form Number: CMS-2552-10 (OMB control number: 0938-0050); Frequency: Yearly; Affected Public: Private Sector (Business or other For-profit and Not-for-profit institutions), State, Local and Tribal Governments, Federal Government; Number of Respondents: 6,088; Total Annual Responses: 6,088; Total Annual Hours: 4,097,224. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278.)

6. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities (PRTFs) for Individuals Under Age 21 and Supporting Regulations; Use: Psychiatric residential treatment facilities are required to report deaths, serious injuries and attempted suicides to the State Medicaid Agency and the Protection and Advocacy Organization. They are also required to provide residents the restraint and seclusion policy in writing, and to document in the residents' records all activities involving the use of restraint and

seclusion. Form Number: CMS-R-306 (OMB control number: 0938-0833); Frequency: Occasionally; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 390; Total Annual Responses: 1,466,823; Total Annual Hours: 449,609. (For policy questions regarding this collection contact Kirsten Jensen at 410-786-8146.)

7. Type of Information Collection Request: New collection (request for a new OMB control number); Title of Information Collection: 21st Century Cures Act Section 12002 IMD Study; Use: The Act requires that HHS conduct a study of the effects of the 2016 Medicaid Managed Care final rule's provisions that clarified policy on coverage of IMD services in lieu of other covered services. The survey is needed to help answer the 5 mandated study questions. The collected data will be used by CMS develop a Report to Congress as required by the Act. Form Number: CMS-10684 (OMB Control Number: 0938-TBD); Frequency: Yearly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 43; Number of Responses: 43; Total Annual Hours: 86. (For questions regarding this collection contact Laura Snyder at (410) 786-3198.)

8. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Advantage Application - Part C and 1876 Cost Plan Expansion Application Regulations under 42 CFR 422 (Subpart K) & 417.400; Use: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Pub. L. 108-173 established the Medicare Prescription Drug Benefit Program (Part D) and made revisions to the provisions of Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA directed that important aspects of the new

Medicare Prescription Drug Benefit Program under Part D be similar to and coordinated with regulations for the MA program. The MMA changes made managed care more accessible, efficient, and attractive to beneficiaries seeking options to meet their needs.

This information collection includes the process for organizations wishing to provide healthcare 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. CMS will collect and review information under the solicitation of Part C applications for the various health plan product types described in the Background section above. CMS will use the information to determine whether the applicants meet the requirements to become an MA organization and are qualified to provide a particular type of MA plan. 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. Form Number: CMS-10137 (OMB control number: 0938-0935); Frequency: Annually; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 380; Total Annual Responses: 400; Total Annual Hours: 6,106. (For policy questions regarding this

collection contact Keith Penn-Jones, at 410-786-3104.)

9. Type of Information Collection Request: Revision of a currently approved collection;
Title of Information Collection: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS); Use: The CMS has had longstanding concerns about the improper payments related to DMEPOS items. The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. The fiscal year (FY) 2017 Medicare FFS program improper payment rate for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) was 44.6%, accounting for over \$3.7 billion in projected improper payments. The CMS has implemented several initiatives in recent years to address these issues, such as the DMEPOS Competitive Bidding Program, as well as heightened screening of suppliers, as authorized by the Affordable Care Act. In addition to those actions, CMS is continuing the use of prior authorization in fee for service Medicare. Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before an item is rendered to a Medicare patient and before a claim is submitted for payment. Prior authorization helps make sure that applicable Medicare coverage, payment, and coding rules are met before item(s) are rendered. Prior to furnishing the item to the beneficiary and prior to submitting the claim for processing, a requester must submit a prior authorization request that includes evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Consistent with §

414.234(d), such evidence must include the order, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request. A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the DMEPOS item likely meets Medicare's coverage, coding, and payment requirements. Suppliers who receive a non-affirmative decision have unlimited resubmission opportunities. Form Number: CMS-10524 (OMB control number: 0938-1293); Frequency: Occasionally; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 321,551; Total Annual Responses: 321,551; Total Annual Hours: 160,775.68 (For policy questions regarding this collection contact Yuliya Cook at (410) 786-0157.)

10. Type of Information Collection Request: Reinstatement; Title of Information Collection: Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies--Revision of Medicare Coverage; Use . Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201-405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.

Medicare may cover Category B (Non-experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. Form Number: CMS-10511 (OMB control number: 0938-1250); Frequency: Yearly; Affected Public: Private Sector (Business or other for-profits, Not-for-Profit Institutions); Number of Respondents: 100; Total Annual Responses: 100; Total Annual Hours: 200. (For policy questions regarding this collection contact Cheryl Gilbreath at 410-786-5919.)

Dated: January 28, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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