



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10185, CMS-10336, CMS-10341, CMS-10417, CMS-10538, and CMS-10544]

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 THE 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

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

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

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

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office 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: Medicare Part D Reporting Requirements and Supporting Regulations; Use: Data collected via Medicare Part D Reporting Requirements is an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Each section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP level, e.g. Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution.

For CY2019 Reporting Requirements, the following 6 reporting sections will be reported and collected at the Contract-level or Plan-level: (1) Enrollment and Disenrollment – to evaluate sponsors’ processing of enrollment, disenrollment, and reinstatement requests in accordance with CMS requirements. (2) Medication Therapy Management (MTM) Programs – to evaluate Part D MTM programs, and sponsors’ adherence to CMS requirements. (3) Grievances – to assess sponsors’ compliance with timely and appropriate resolution of grievances filed by their enrollees. (4) Improving Drug Utilization Review Controls – to determine the impact of formulary-level edits at point of sale in sponsors’ processing of opioid prescriptions. (5) Coverage Determinations and Redeterminations - to assess sponsors’ compliance with appropriate resolution of coverage determinations and redeterminations requested by their enrollees. (6) Employer/Union Sponsored Sponsors - to ensure PDPs and the employer groups that contract with the PDPs properly utilize appropriate waivers and modifications. Form Number: CMS-10185 (OMB control number: 0938-0992); Frequency: Annually and semi-annually; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 627; Total Annual Responses: 13,603; Total Annual Hours: 14,748. (For policy questions regarding this collection contact Chanelle Jones at 410-786-8008.)

2. Type of Information Collection Request: Extension of a currently approved information collection; Title of Information Collection: Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Use: The American Recovery and Reinvestment Act of 2009 (Recovery Act) (P. L. 111-5) was enacted on February 17, 2009. The Recovery Act includes many measures to modernize our nation's infrastructure, and improve affordable health care.

Expanded use of health information technology (HIT) and certified electronic health record (EHR) technology will improve the quality and value of America's health care. Title IV of Division B of the Recovery Act amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified EHR technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the "Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act."

The HITECH Act creates incentive programs for EPs and eligible hospitals, including CAHs, in the Medicare Fee-for-Service (FFS), MA, and Medicaid programs that successfully demonstrate meaningful use of certified EHR technology. In their first payment year, Medicaid EPs and eligible hospitals may adopt, implement or upgrade to certified EHR technology. It also, provides for payment adjustments in the Medicare FFS and MA programs starting in FY 2015 for EPs and eligible hospitals participating in Medicare that are not meaningful users of certified EHR technology. These payment adjustments do not pertain to Medicaid providers.

The first final rule for the Medicare and Medicaid EHR Incentive Program, which was published in the **Federal Register** on July 28, 2010 (CMS-0033-F), specified the initial criteria EPs, eligible hospitals and CAHs, and MA organizations must meet in order to qualify for incentive payments; calculation of incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs,

eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology beginning in 2015; and other program participation requirements. On the same date, the Office of the National Coordinator of Health Information Technology (ONC) issued a closely related final rule (45 CFR Part 170, RIN 0991-AB58) that specified the initial set of standards, implementation specifications, and certification criteria for certified EHR technology. ONC has also issued a separate final rule on the establishment of certification programs for health information technology (HIT) (45 CFR Part 170, RIN 0991-AB59). The functionality of certified EHR technology should facilitate the implementation of meaningful use. Subsequently, final rules have been issued by CMS (77 FR 53968) and ONC (77 FR 72985) to create a Stage 2 of meaningful use criteria and other changes to the CMS EHR Incentive Programs and the 2014 Edition Certification Criteria for EHR technology.

The information collection requirements contained in this information collection request are needed to implement the HITECH Act. In order to avoid duplicate payments, all EPs are enumerated through their National Provider Identifier (NPI), while all eligible hospitals and CAHs are enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider's tax identification number and NPI or CCN combination in order to make payment, validate payment eligibility and detect and prevent duplicate payments for EPs, eligible hospitals and CAHs. Form Number: CMS-10336 (OMB Control Number: 0938-1158); Frequency: Occasionally; Affected Public: Private sector; Number of Respondents: 201,694; Total Annual Responses: 201,694; Total Annual Hours: 2,131,142. (For policy questions regarding this collection contact Elizabeth Holland at (410) 786-1309).

3. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428; Use: This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. Form Number: CMS-10341 (OMB control number: 0938-1162); Frequency: Yearly and quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 37; Total Annual Responses: 300; Total Annual Hours: 24,092. (For policy questions regarding this collection contact Tonya Moore at 410-786-0019.)

4. Type of Information Collection Request: Extension without change of a currently approved collection; Title of Information Collection: Medicare Fee-for-Service Early Review of Medical Records; Use: The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, MACs are encouraged to automate this process; however it may require the evaluation of medical records and related documents to determine whether Medicare claims were billed in compliance with coverage, coding, payment, and billing policies.

The information required under this collection is requested by Medicare contractors to determine proper payment, or if there is a suspicion of fraud. Medicare contractors request the information from providers/suppliers submitting claims for payment when data analysis indicates

aberrant billing patterns or other information which may present a vulnerability to the Medicare program. Extensive instructions to CMS contractors on medical review processes and procedures are contained in CMS' Program Integrity Manual, 100-08 which can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html>. Form Number: CMS-10417 (OMB control number: 0938-0969); Frequency: Occasionally; Affected Public: Private Sector (Business or other for-profits; Not-for-profit institutions; Number of Respondents: 2,410,278; Total Annual Responses: 2,410,278; Total Annual Hours: 1,197,189. (For policy questions regarding this collection contact Daniel Schwartz at 410-786-4197.)

5. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Hospice Information for Medicare Part D Plans; Use: The form would be completed by the prescriber or the beneficiary's hospice, or if the prescriber or hospice provides the information verbally to the Part D sponsor, the form would be completed by the sponsor. Information provided on the form would be used by the Part D sponsor to establish coverage of the drug under Medicare Part D. Per statute, drugs that are necessary for the palliation and management of the terminal illness and related conditions are not eligible for payment under Part D. The standard form provides a vehicle for the hospice provider, prescriber or sponsor to document that the drug prescribed is "unrelated" to the terminal illness and related conditions. It also gives a hospice organization the option to communicate a beneficiary's change in hospice status and care plan to Part D sponsors. Form Number: CMS-10538 (OMB control number: 0938-1269); Frequency: Occasionally; Affected

Public: Private sector (business or other for-profits); Number of Respondents: 424; Total Annual Responses: 376,487; Total Annual Hours: 31,374. (For policy questions regarding this collection contact Shelly Winston at 410-786-3694.)

6. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Good Cause Processes; Use: Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D-1(b)(1)(B)(v) of the Act generally directs us to establish rules related to enrollment, dis-enrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, subpart B in each of the Parts C and D regulations sets forth requirements with respect to involuntary dis-enrollment procedures at 42 C.F.R. §§ 422.74 and 423.44, respectively. In addition, section 1876(c)(3)(B) establishes that individuals may be dis-enrolled from coverage as specified in regulations. Thus, current regulations at 42 C.F.R. 417.460 specify that a cost plan, specifically a Health Maintenance Organization (HMO) or competitive medical plan (CMP), may dis-enroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. Within these regulatory provisions, individuals dis-enrolled for nonpayment of premiums are afforded a grace period in which to request reinstatement. As part of the reinstatement request process, they must demonstrate good cause for failure to pay within the initial grace period that led to their involuntary dis-enrollment and pay all overdue premiums within three calendar months after the dis-enrollment date. Form

Number: CMS-10544 (OMB control number: 0938-1271); Frequency: Reporting – Monthly;
Affected Public: Private Sector (Business or other for-profit institutions); Number of
Respondents: 10,008; Total Annual Responses: 10,008; Total Annual Hours: 6,665. (For policy
questions regarding this collection contact Carla Patterson at 410-786-1000.)

Dated: June 5, 2018.

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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