DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-70, CMS-R-72, CMS-1557, and CMS-10185]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

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: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-R-70 Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations

CMS-R-72 Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals

CMS-1557 Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations

CMS-10185 Medicare Part D Reporting Requirements and Supporting Regulations

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations; Use: The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are

required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment. Form Number: CMS-R-70 (OMB control number: 0938-0426); Frequency: Reporting – On occasion; Affected Public: Business or other for-profits; Number of Respondents: 400; Total Annual Responses: 21,200; Total Annual Hours: 42,400. (For policy questions regarding this collection contact Tennille Coombs at 410-786-3472.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; Use: In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. Form Number: CMS-R-72 (OMB control number: 0938-0443); Frequency: Reporting – On occasion; Affected Public: Individuals or Households and Business or other for-profit institutions; Number of Respondents: 2,590; Total Annual Responses: 5,228; Total Annual Hours: 2,822. (For policy questions regarding this collection contact Tennille Coombs at 410-786-3472).

3. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Survey Report Form for Clinical Laboratory Improvement Amendments

(CLIA) and Supporting Regulations; Use: The form is used to report surveyor findings during a CLIA survey. For each type of survey conducted (i.e., initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. Form Number: CMS-1557 (OMB control number: 0938-0544); Frequency: Biennially; Affected Public: Private sector (Business or other for-profit and Not-for-profit institutions, State, Local or Tribal Governments and Federal Government); Number of Respondents: 19,183; Total Annual Responses: 9,592; Total Annual Hours: 4,796. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385).

4. 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.)

Dated: February 23, 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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