DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10519 and CMS-10583]

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 any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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 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: Reports Clearance Office at (410) 786-1326.

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-10519 Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support

CMS-10583 Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease

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: Revision of a currently approved collection; Title of Information Collection: Physician Quality Reporting System (PQRS) and the Electronic Prescribing Incentive (eRx) Program Data Assessment, Accuracy and Improper Payments Identification Support; Use: The incentive and reporting programs have data integrity issues, such as rejected and improper payments. This four year project will evaluate incentive payment information

for accuracy and identify improper payments, with the goal of recovering these payments. Additionally, based on the project's results, recommendations will be made so that we can avoid future data integrity issues.

Data submission, processing, and reporting will be analyzed for potential errors, inconsistencies, and gaps that are related to data handling, program requirements, and clinical quality measure specifications of PQRS and eRx program. Surveys of Group Practices, Registries, and Data Submission Vendors (DSVs) will be conducted in order to evaluate the PQRS and eRx Incentive Program. Follow-up interviews will occur with a small number of respondents. Form Number: CMS-10519 (OMB control number: 0938-1255); Frequency: Annually; Affected Public: Business or other for-profits; Number of Respondents: 115; Total Annual Responses: 115 Total Annual Hours: 201. (For policy questions regarding this collection contact Timothy Jackson at 410-786-4006.)

2. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Data Collection for Medicare Beneficiaries Receiving Beta Amyloid Positron Emission Tomography (PET) for Dementia and Neurodegenerative Disease Use: In the Decision Memorandum #CAG-00431N issued on September 27, 2013, CMS determined there is sufficient evidence that the use of beta amyloid PET is promising in 2 scenarios: (1) to exclude Alzheimer's Disease (AD) in narrowly defined and clinically difficult differential diagnoses; and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD. CMS will cover one beta amyloid PET scan per patient through Coverage with Evidence Development under section 1862(a)(1)(E) of the Social Security Act, in clinical studies that meet specific criteria established by CMS. Clinical studies must be approved by CMS, involve subjects from appropriate populations, and be comparative and longitudinal. Radiopharmaceuticals used in

the scan must be FDA approved. Approved studies must address defined research questions established by CMS. Clinical studies in this National Coverage Determination (NCD) must adhere to the designated timeframe and meet standards establish by CMS in the NCD. Consistent with section 1142 of the Social Security Act, the Agency for Healthcare and Quality (AHRQ) supports clinical research studies that CMS determines meet specifically identified requirements and research questions.

To qualify for payment, providers must prescribe beta amyloid PET for beneficiaries with a set of clinical criteria specific to each cancer. Data elements will be transmitted to CMS for evaluation of the short and long-term benefits of beta amyloid PET to beneficiaries and for use in future clinical decision making. Form Number: CMS–10583 (OMB control number: 0938–NEW); Frequency: Annually; Affected Public: Private sector (Business or other for-profit); Number of Respondents: 300; Total Annual Responses: 3,700; Total Annual Hours: 6,475. (For policy questions regarding this collection contact Stuart Caplan at 410-786-8564).

Dated: September 22, 2015.

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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