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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10583]

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

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 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 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 <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: 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 established 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: December 3, 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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