

previous year to determine whether the results consistent. In addition to comparing the unweighted and weighted frequencies, the input and output specifications are reviewed, and the flowcharts are compared to the skip instructions and universes for each question. If a difference is found, steps are taken to determine whether the change is legitimate or whether there is a factor other than the programming of the questionnaire such as the location or context of the question in the questionnaire. If a difference persists, the paradata are reviewed to determine whether there are changes in the mean or median time spent on that question, whether interviewers had a high rate of backing up to return to that question, and whether other questions in that

battery were similarly affected. Persistent differences will be examined to determine whether there is any other interviewer effect such as results comparing newly hired and experienced interviewers and newly added primary sampling units compared to continuing primary sampling units. In addition, national estimates on the key set of indicators that are released in a quarterly report as part of the Early Release program will be monitored by NHIS analysts.

In accordance with the 1995 initiative to increase the integration of surveys within the DHHS, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The NHIS has

long been used by government, academic, and private researchers to evaluate both general health and specific issues, such as smoking, diabetes, health care coverage, and access to health care. It is a leading source of data for the Congressionally-mandated "Health US" and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, "Healthy People 2020."

Burden hours have seen a net increase of 1,367 hours compared to 2015 due to the removal of the screener questionnaire and the addition of the questionnaire redesign activities. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Family Member	Family Questionnaire	45,000	1	23/60
Sample Adult	Sample Adult Questionnaire	36,000	1	15/60
Adult Family Member	Sample Child Questionnaire	14,000	1	10/60
Adult Family Member	Supplements	45,000	1	20/60
Adult Family Member	Special Projects	15,000	1	20/60
Adult Family Member	Reinterview Questions	5,000	1	5/60
Total				49,000

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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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 *January 7, 2016*:

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, Email: 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. Email 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-193 and CMS-R-244]

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 *February 8, 2016*.

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. Email 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-R-193 Important Message from Medicare (IM)

CMS-R-244 Programs for All-inclusive Care of the Elderly (PACE) 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