

delay or disorder comparison group (DD), and a second comparison group of children randomly drawn from the entire study cohort population (POP). It is expected that the 5 SEED 3 study sites will have a total of 1,875 children enroll and complete the study protocol. The data collection process will take approximately 9 hours 10 minutes (ASD

group); 5 hours 30 minutes (POP group); 2 hours 45 minutes (DD group) to complete, which includes (1) maternal telephone interview with questions about maternal reproductive history and pregnancy with the index child, (2) parent-completed questionnaires about parental and child health and child development, (3) in-person child

developmental evaluation, (4) maternal and child anthropometry measurements, (5) biosampling from biological parents and child, and (6) abstraction of maternal prenatal and labor and delivery medical records. The estimated total burden hours are 18,431. There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number responses per respondent | Average burden per response (in hours) | Total burden hours |
|---------------------|---|-----------------------|---------------------------------|--|--------------------|
| Parent | SCQ | 1,875 | 1 | 30/60 | 938 |
| Parent | Pregnancy Reference form | 1,875 | 1 | 15/60 | 469 |
| Parent | Maternal Interview | 1,875 | 1 | 60/60 | 1,875 |
| Parent | Self-Administered Forms | 1,875 | 1 | 88/60 | 2,750 |
| Parent | HIPAA Medical Records Release | 1,500 | 1 | 20/60 | 500 |
| Parent/Child | Clinic/Home Visit—Developmental Assessment. | 3,000 | 1 | 238/60 | 11,900 |
| Total | | 12,000 | | | 18,431 |

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 Identifier: CMS-P-0015A]

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 April 25, 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 the 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-P-0015A Medicare Current Beneficiary Survey

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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey; *Use:* CMS is the largest single payer of health care in the United States. With full implementation of the Affordable Care Act of 2010 (ACA), the agency will play a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. One of our critical aims is to be an effective steward, major force, and trustworthy partner in leading the transformation of the health care system. We also aim to provide Americans with high quality care and better health at lower costs through improvement. At the forefront of these initiatives is the newly formed Center for Medicare and Medicaid Innovation (CMMI).

CMMI is authorized by Section 1115A of the Social Security Act, as established by section 3021 of the ACA and was established to “test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished” to Medicare, Medicaid and CHIP beneficiaries. Implicit across all of CMMI activities is an emphasis on diffusion—finding and validating innovative models that have the potential to scale, facilitating rapid adoption, and letting them take root in organizations, health systems, and communities across America.

The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is an in-person, nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Enterprise Data and Analytics (OEDA) in partnership with the CMMI. The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (e.g. fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 20 years (encompassing over 1 million interviews), and consists of three annual interviews per survey participant.

The MCBS continues to provide unique insight into the Medicare program and helps CMS and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. The revision will streamline some questionnaire sections, add a few new measures, and update the wording of questions and response categories. Most of the revised questions reflect an effort to bring the MCBS questionnaire in line with other national surveys that have more current wording of questions and response categories with well-established measures. As a whole, these revisions do not change the respondent burden; there is a small increase in overall burden reflecting a program change to oversample small population groups. *Form Number:* CMS-P-0015A (OMB control number: 0938-0568); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 16,071; *Total Annual Responses:* 43,199; *Total Annual Hours:* 60,103. (For policy questions regarding this collection contact William Long at 410-786-7927.)

Dated: February 19, 2016.

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

Food and Drug Administration

[Docket No. FDA-2016-N-0566]

Agency Information Collection Activities; Proposed Collection; Comment Request; Outcomes Evaluation Survey for Graduates of the Food and Drug Administration Commissioner's Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the

proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on Outcomes Evaluation Survey for Graduates of the FDA Commissioner's Fellowship Program.

DATES: Submit either electronic or written comments on the collection of information by April 25, 2016.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: 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. “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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and