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.

[FR Doc. 2016–03908 Filed 2–23–16; 8:45 am]

BILLING CODE 4120–01–P

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

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Outcomes Evaluation Survey for Graduates of the FDA Commissioner's Fellowship Program (OMB Control Number 0910–NEW)

Collecting outcomes information from the CFP graduates will allow FDA's Office of the Commissioner to easily and efficiently elicit and review information from the CFP graduates needed to collect program feedback. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of surveys being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their experience with the FDA while a Commissioner's Fellow.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Fellowship Program Survey	10	1	10	0.50 (30 minutes)	5

[1] The capital costs or operating and maintenance costs associated with this collection of information is $300 annually.

FDA based these estimates on the number of fellows who that have graduated and left the Agency over the past 5 years.

Dated: February 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03791 Filed 2–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Request for Expressions of Interest From Coverage Organizations; Coverage Organizations Interested in Providing Input Regarding Private Payer Coverage to Medical Device Sponsors Who Request Their Participation in a Pre-Submission Meeting With the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for expressions of interest.

SUMMARY: The Food and Drug Administration (FDA) is requesting expressions of interest from organizations that evaluate clinical evidence used to support private payer coverage decisions for medical devices (coverage organizations) that wish to provide input to medical device developers (sponsors) on clinical trial design or other plans for gathering clinical evidence needed to support positive coverage decisions. These coverage organizations include third-party commercial health insurance organizations, payer/provider organizations, health technology assessment groups and various organizations that evaluate clinical evidence and make coverage recommendations to and decisions for private payers and health plans. The Center for Devices and Radiological Health (CDRH) is taking this step to assist sponsors in identifying such organizations and soliciting clinical trial design or other evidence-gathering input from them.

If coverage organizations express interest, FDA intends to provide a mechanism for such organizations to identify themselves so that medical device sponsors who would like to obtain coverage input can voluntarily contact them to participate in a FDA Pre-Submission meeting. Early input from payers regarding their evidentiary needs can streamline the process from FDA approval or clearance to payer coverage and improve public health by facilitating earlier access to innovative, safe, and effective medical devices.

DATES: This notice will be effective February 24, 2016.

ADDRESSES: Expressions of interest should be emailed to *CDRH-Innovation@fda.hhs.gov* and contain the subject line ''Expression of Interest in Providing Input Regarding Private Payer Coverage to Medical Device Sponsors.'' The body of the email should contain your organization's name, email, and mailing address.

FOR FURTHER INFORMATION CONTACT: CDRH Innovation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5410, Silver Spring, MD 20993–0002, *CDRH-Innovation@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The mission of CDRH is to protect and promote public health. This is accomplished in part by fulfilling its vision that patients in the U.S. have access to safe and effective high quality medical devices of public health importance first in the world.

In the September 17, 2010, **Federal Register** notice (75 FR 57045), the Centers for Medicare and Medicaid Services (CMS) and FDA introduced Parallel Review, which is intended to reduce the time between FDA marketing approval or clearance and CMS's National Coverage Determinations (NCDs). As part of that program, sponsors met with FDA and CMS at various times, to discuss the type of clinical evidence that would support positive decisions by each agency. The Parallel Review process improves the public health and quality of patient care by facilitating earlier access to innovative medical devices for Medicare beneficiaries. Based in part on the lessons learned from the Parallel Review program and from Pre-Submission meetings involving CMS, FDA found that early input from payers regarding their evidentiary needs can streamline the process from FDA approval or clearance to payer coverage.

CDRH wishes to facilitate the voluntary inclusion, by sponsors in their Pre-Submission meetings, of those organizations that evaluate clinical evidence used to support private payer coverage determinations for medical devices (coverage organizations), so that sponsors can obtain early input from both FDA and private payers, and plan accordingly. The communications within the scope of this notice consist of input from coverage organizations to sponsors on clinical trial design or other