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.

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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

plans for gathering clinical evidence needed to support positive coverage decisions. It is not intended to include sponsors' communications of clinical evidence to coverage organizations. These coverage organizations include third-party commercial health insurance organizations, payer/provider organizations, health technology assessment groups and various other organizations that evaluate clinical evidence and make coverage recommendations to and decisions for private payers and health plans.

Timely access to innovative medical devices has been a significant issue in the delivery of high quality health care. Generally, access to medical devices first requires FDA approval or clearance for marketing, and, for broad patient access to innovative devices, coverage by payers. In this context, a ''payer'' refers to those organizations that may provide both coverage and reimbursement for the use of a medical device within a variety of clinical settings. They are generally third-party commercial health insurance companies, health plans, payer-provider organizations, and others.

Without proper planning, medical device sponsors developing innovating devices might encounter delays or barriers to payer coverage. Development of medical devices often occurs in a sequential manner, whereby the sponsor initially interacts with FDA to determine whether or not clinical evidence would be required in a subsequent marketing application for FDA approval or clearance. If clinical data are required, the sponsor may further interact with FDA to develop the study protocol for the pivotal clinical trial. Next, the sponsor initiates and conducts the clinical trial and then submits that clinical evidence to FDA in a premarket submission. Lastly, the FDA reviews the submission and issues a regulatory decision. It is after these steps have been completed that the sponsor may begin marketing the device; however, the clinical evidence sufficient for marketing the device is not always the same as that needed to support payer coverage decisions.

Payer evidentiary requirements for coverage depend on the payer. In some cases, payers may make their own independent coverage decisions. In other cases, payers may rely on Health Technology Assessments (HTAs) conducted by others, including CMS.

While some clinical evidence developed in a pivotal clinical trial undertaken to support FDA approval or clearance could support payer coverage decisions, outcome endpoints needed by payers, such as comparison to other therapies and the associated costs of those therapies, are often not fully collected. If the sponsor subsequently learns that these data are needed for coverage determinations, even if the data exist, it may be difficult to collect and analyze retrospectively, years after the pivotal clinical study was initiated. It is similarly challenging to conduct an additional clinical trial after FDA approval or clearance designed only to meet a payer's needs. Either situation can result in delays to coverage and broad patient access, with negative implications for the public health.

Further, it may be difficult for sponsors to identify and engage with coverage organizations, and as a result, sponsors may not consider the evidentiary needs of coverage organizations when planning their pivotal clinical study.

If coverage organizations express interest, CDRH intends to create a mechanism for such organizations to identify themselves so medical device sponsors who would like to obtain coverage input can voluntarily contact them to participate in an FDA Pre-Submission meeting. CDRH intends to list interested coverage organizations on its Web site. Sponsors who voluntarily meet with coverage organizations early in the device development process may obtain the information to initially design a clinical trial that can capture both the data necessary for FDA marketing clearance or approval and that necessary to support a positive payer coverage decision, to modify their pivotal study to satisfy both sets of requirements, or to develop other plans to collect the necessary data. This may help avoid delays to patient access that may result if clinical trials are conducted, or data are collected, sequentially when it could have been done concurrently.

Sponsors are not required to include a coverage organization in any Pre-Submission meeting. Coverage organizations are not required to submit expressions of interest in order to be included in a Pre-Submission meeting. The regulatory and evidentiary standards FDA uses for decisionmaking would not change; under any review scenario, FDA would continue to make its decisions under its authority and with its own standards, independent of the coverage organization's input.

II. Expression of Interest by Coverage Organizations

CDRH's Pre-Submission program, by providing a forum to support communication with sponsors prior to the finalization of their clinical trial design, serves as a potential tool to facilitate sponsor communication with coverage organizations that make private coverage determinations in a manner that would promote the public health (Ref. 1). FDA is requesting that organizations that evaluate clinical evidence used to support private payer decisions for medical devices, and that may be interested in communicating to device sponsors about the evidence needed to support positive coverage determinations, send an email to *CDRH-Innovation@fda.hhs.gov* to express interest. The subject line of the email should state: ''Expression of Interest in Providing Input Regarding Private Payer Coverage to Medical Device Sponsors.'' The body of the email should contain the organization's name, email, and mailing address. If necessary, we may follow up with organizations that respond solely to clarify their identifying information.

Additional information may also be posted on the CDRH Payer Communication Task Force Web site. For general questions or concerns, contact CDRH Innovation at the email listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site address after this document publishes in the **Federal Register**.)

1. FDA Guidance, ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff.'' Available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.*

Dated: February 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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