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 September 15, 2014.

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:* Reinstatement of a previously approved collection; *Title of Information Collection:* Hospital Conditions of Participation and Supporting Regulations; *Use:* The information collection requirements described in this information collection request are needed to implement the Medicare and Medicaid conditions of participation (CoP) for 4,890 accredited and non-accredited hospitals and an additional 101 critical access hospitals (CAHs) that have distinct part psychiatric or rehabilitation units (DPUs). CAHs that have DPUs must comply with all of the hospital CoPs on these units. This package reflects the paperwork burden for a total of 4,991 (that is, 4,890 hospitals and 101 CAHs which include 81 CAHs that have psychiatric DPUs and 20 CAHs that have rehabilitation DPUs). The information collection requirements for the remaining 1,183 CAHs have been reported in a separate package under CMS–10239.

The CoPs and accompanying requirements specified in the supporting regulations are used by our surveyors as a basis for determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid. CMS and the health care industry believe that the availability to the facility of the type of records and general content of records, which the supporting regulations specify, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. Subsequent to publication of the 60-day **Federal Register** notice (January 31, 2014; 79 FR 5417), the burden has been recalculated. *Form Number:* CMS–R–48 (OMB control number: 0938–0328); *Frequency:* Yearly; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 4,991; *Total Annual Responses:* 17,279,717; Total Annual Hours: 14,424,655. (For policy questions regarding this collection contact Scott Cooper at 410–786–9465.)

Dated: August 11, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–19260 Filed 8–14–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1279]

Pilot Program for Qualification of Medical Device Development Tools

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is soliciting proposals to participate in a pilot program for Medical Device Development Tools (MDDT) qualification (MDDT Pilot Program). Under the MDDT Pilot Program, FDA intends to work together with developers of tools that meet the criteria for the proposed program, to determine whether certain tools may be developed and qualified in order to facilitate more predictable, efficient, and transparent regulatory evaluation when MDDTs are used to generate valid scientific evidence for medical device premarket applications.

DATES: FDA will begin accepting nominations for participation in the voluntary MDDT Pilot Program *September 15, 2014.*

FOR FURTHER INFORMATION CONTACT: Joan Adams-White, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3650, Silver Spring, MD 20993–0002, 301–796–5421, *Joannie.Adams-White@fda.hhs.gov;* or Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3614, Silver Spring, MD 20993–0002, 301–796–6349, *Kathryn.ocallaghan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 14, 2013 (78 FR 68459), the Food and Drug Administration (FDA) announced the availability of the draft guidance entitled ''Medical Device Development Tools'' (*http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm374427.htm*) (MDDT draft guidance). When finalized, the draft guidance will represent FDA's current thinking on qualification of MDDTs for use in device development and evaluation. The proposed MDDT qualification process is intended to support the development of MDDTs—tools that manufacturers and FDA use to assess and measure the performance,

safety, and effectiveness of medical devices. MDDT tools qualified by FDA can then be relied upon by the medical device industry in support of their device submissions to the Agency, potentially reducing time and other resources needed to develop new products. This proposed voluntary qualification process is intended to enable submitters of MDDT proposals chosen for this pilot program to work closely with FDA to determine the amount and type of evidence and other information needed to support qualification for a specific tool and context of use.

The anticipated benefits of the proposed MDDT qualification process include facilitating timely development of tools that manufacturers and FDA use to assess and measure the performance, safety, and effectiveness of medical devices. FDA expects that manufacturers can better rely on MDDTs that have been FDA reviewed and accepted (qualified), and made available through this voluntary program, which supports innovative medical device development and promotes regulatory science. The proposed MDDT qualification process supports the FDA's plan to advance regulatory science—the science of developing new tools, methods and approaches to assess the safety, effectiveness, performance, and quality of medical devices. Advancements in regulatory science help to bridge the gap between research and discovery of medical devices and the actual delivery of the device to patients. The proposed qualification process also supports FDA's strategic priority of strengthening the clinical trial enterprise by potentially increasing the efficiency of the clinical studies. Finally, this proposed qualification process supports FDA's strategic priority actions to strike the right balance between premarket and postmarket data collection, leading to earlier access to beneficial innovative technologies for patients in the United States. For example, an MDDT qualified for use as an intermediate or surrogate endpoint could facilitate more efficient development and evaluation of devices, especially for those intended to address unmet medical needs.

FDA is proposing a new voluntary MDDT Pilot Program. Information learned and experiences gained from the MDDT Pilot Program will help inform the final guidance document and processes. FDA plans to prioritize proposals based on public health need or potential to impact multiple device development programs. Additionally, for the purposes of the pilot, proposals are expected to be prioritized based on feasibility, timeline, and FDA resources. See section II.B. Appropriate Candidates, for details.

II. MDDT Pilot Program

FDA has developed a pilot program for interested tool developers. This document outlines: (1) The guiding principles underlying the MDDT Pilot Program, (2) appropriate candidates for the MDDT Pilot Program, and (3) the procedures FDA intends to follow in the MDDT Pilot Program.

A. Guiding Principles

The following basic principles underlie the MDDT Pilot Program described in this document. FDA intends that these principles create a common understanding between the submitter and FDA about the goals and parameters of the MDDT Pilot Program:

1. For qualified MDDTs, FDA intends to make public the context of use, summary of evidence, and basis of the qualification determination (analogous to summaries of approved devices). FDA will keep proprietary information confidential. Submitters must consent to make MDDTs accessible to the public for use (e.g. through sales, open source, etc.), and not restrict to certain private entities, such as a single manufacturer.

2. FDA and the MDDT Pilot Program places no requirements on licensing/cost/degree of access to intellectual property associated with a tool, nor does it consider restrictions related to patent claims. An MDDT submitter may include and protect proprietary methods as long as access to the tool is not restricted to certain private entities.

3. Participating in this MDDT Pilot Program does not guarantee qualification of an MDDT, nor is a submitter precluded from withdrawing from the MDDT Pilot Program.

4. Due to FDA resource constraints, FDA intends to limit the MDDT Pilot Program to no more than 15 candidates.

B. Appropriate Candidates

The process for MDDT qualification can be initiated in one of three ways: (1) A tool developer chooses to pursue qualification for his or her tool to allow for use across multiple device development programs; (2) need and interest in an area is determined by individual or consortia of stakeholders (may include academia, industry, medical societies); or (3) FDA identifies an area of need and calls for development of tools in a specific area.

Appropriate candidates for the MDDT Pilot Program are:

1. Tools which fit into one of the following categories:

- Clinical Outcome Assessments such as patient-reported outcomes or clinical outcomes based on clearly defined subjective clinical decision making as a measure of treatment benefit;
- Biomarker Tests such as in vitro laboratory tests or medical imaging methods, or other objective measurement methods used to detect or measure a biomarker; or
- Nonclinical Assessment Models such as in vitro (''bench'') models, animal models, or computer models to measure a parameter of interest or to substitute for another generally accepted test or instrument.

2. Tools which address the following factors:

- Public health need met by one or more of the following:
  - Context of use includes life-threatening or serious chronic diseases/conditions, or both;
  - No/poor alternatives or unmet scientific need;
  - Innovative technology with no established paradigm for regulatory assessment; or
  - Gain major efficiencies in device development and evaluation time.
- Scope of impact:
  - Potential to impact multiple device development programs; or
  - Potential to impact multiple device sponsors.

3. FDA intends to prioritize candidates for the pilot program based on the following factors:

- Tool readiness: Does the tool exist in prototype or final form?
- Acceptance of proposed context of use: Does available information support acceptance of the tool principle/method of measurement for the proposed context of use, or for any use?
- Timeline: What is the expected timeline to submission of a qualification package?
- Potential for public health impact: Does the tool address an unmet public health need or significantly reduce product development timelines, or both?

FDA encourages any interested developers who believe their tool is an appropriate candidate for the MDDT Pilot Program to contact FDA before initiating the procedures referenced under the following section titled ''Procedures.''

C. Procedures

FDA has developed the following procedures to ensure adequate information to assess a candidate's suitability for the MDDT Pilot Program is provided to FDA without creating a burdensome new application process:

1. *Nomination.* The submitter may nominate his or her tool for

participation in the MDDT Pilot Program by submitting a proposal to *MDDT@fda.hhs.gov.* FDA intends to acknowledge receipt of nominations via email.

A submitter's proposal for the MDDT Pilot Program should include the following information to assist FDA in processing and responding to nominations:

- A cover letter and a brief statement explaining why the tool is an appropriate candidate for the MDDT Pilot Program as described under section II., B. Appropriate Candidates; and
- A description of the tool, the proposed context of use, a synopsis of the available evidence and plans for additional evidence gathering, and an assessment of the advantages or disadvantages related to the capabilities and limitations of the tool for the proposed context of use.

2. *Submitter Notification.* FDA intends to notify the submitter via email whether or not the tool is an appropriate candidate for the MDDT Pilot Program within approximately 30 days of receipt of the complete information.

3. *Pre-qualification Plan.* If the nominee is deemed an appropriate candidate, the submitter will be notified by FDA and invited to submit a pre-qualification plan within approximately 30 days of being notified by the FDA that its nominee was accepted. One way to present the pre-qualification plan is included in Appendix 1 of the MDDT draft guidance. FDA recommends the pre-qualification and qualification plans be submitted in accordance with FDA guidance entitled ''Medical Devices: Pre-Submission Program and Meetings with FDA Staff'' (*www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf*) as the process for the MDDT pilot program is expected to be modeled after the Pre-Submission Program.

4. *Pre-qualification Meeting.* FDA intends to meet with the submitter, either in person or by phone, in accordance with the process outlined in the FDA guidance on ''Medical Devices: Pre-Submission Programs and Meetings With FDA Staff.'' The qualification review team (which may include FDA as well as external expertise, where appropriate) will interact with the submitter to identify the amount and type of data or information needed for qualification of the tool for the proposed context of use.

5. *FDA Review.* Under the MDDT Pilot Program, the Agency intends to work interactively with submitters as follows:

- Where appropriate, FDA may seek input from external individuals or groups for specific expertise, consistent with all applicable statutory and regulatory requirements, including those respecting confidentiality.
- During the process for MDDT qualification, FDA intends to interact with submitters to efficiently determine the amount and type of information needed to support qualification for a specific tool and context of use, and as needed for clarification or to request additional information.
- When the submitter has the data and information necessary for a complete qualification package, they may submit it to justify qualification of the tool for the proposed context of use. FDA intends to hold a qualification meeting or teleconference to facilitate discussion once the package has been reviewed.

D. Duration of the MDDT Pilot Program

FDA intends to accept requests for participation in the MDDT Pilot Program until such time that the MDDT draft guidance is finalized. FDA may decide to terminate the MDDT Pilot Program at any time or extend the MDDT Pilot Program. The decision to terminate or extend the MDDT Pilot Program will be announced in the **Federal Register**. FDA may also decide to modify the MDDT Pilot Program while it is in effect. Any significant modifications will also be announced in the **Federal Register**.

E. Evaluation

FDA intends to use the experience gained from the MDDT Pilot Program to inform the final version of the MDDT guidance and processes.

III. Paperwork Reduction Act of 1995

This notice contains information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078 (Investigative Device Exemption); the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231 (Premarket Approval); the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 (Premarket Notification); and the collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485.

Dated: August 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19360 Filed 8–14–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Small Grants to Promote Diversity.

Date: September 16, 2014.

Time: 9 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 750, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–8886, *sanoviche@mail.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–13–266–NIDDK Program Project (P01)–ANCA Glomerulonephritis.

Date: October 1, 2014.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases