

individual during an interview. The CMS-43 application follows the questions and requirements used by SSA to determine Title II eligibility. This is done not only for consistency purposes, but because certain Title II and Title XVIII insured status and relationship requirements must be met in order to qualify for Medicare under the end stage renal disease provisions. *Form Number:* CMS-43 (OMB control number: 0938-0800); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 10,400. (For policy questions regarding this collection contact Carla Patterson at 410-786-8911.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Termination of Premium Hospital and Supplementary Medical Insurance; *Use:* The CMS-1763 form provides us and the Social Security Administration (SSA) with the enrollee's request for termination of Part B, Part A or both Part B and A premium coverage. The form is completed by an SSA claims or field representative using information provided by the Medicare enrollee during an interview. The purpose of the form is to provide to the enrollee with a standardized format to request termination of Part B, Part A premium coverage or both, explain why the enrollee wishes to terminate such coverage, and to acknowledge that the ramifications of the decision are understood. *Form Number:* CMS-1763 (OMB control number: 0938-0025); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 101,000; *Total Annual Responses:* 101,000; *Total Annual Hours:* 16,867. (For policy questions regarding this collection contact Carla Patterson at 410-786-8911.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment; *Use:* The collected information is used primarily for payment, but is also used for claim validation as well as for other legislated functions such as quality monitoring, program integrity, and oversight. *Form Number:* CMS-10174 (OMB control number: 0938-0982); *Frequency:* Monthly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 779; *Total Annual Responses:* 1,409,828,464; *Total Annual Hours:*

2,820. (For policy questions regarding this collection contact Ivan Iveljic at 410-786-3312.)

5. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicaid Payment for Prescription Drugs—Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs; *Use:* States are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive federal financial participation for these drugs. Physicians, serving as respondents to states, submit National Drug Code numbers and utilization information for “J” code physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars. *Form Number:* CMS-10215 (OMB control number: 0938-1026); *Frequency:* Weekly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 20,000; *Total Annual Responses:* 3,910,000; *Total Annual Hours:* 16,227. (For policy questions regarding this collection contact Lisa Ferrandi at 410-786-5445.)

6. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Retirement Benefit Information; *Use:* Section 1818(d)(5) of the Social Security Act provides that former state and local government employees (who are age 65 or older, have been entitled to Premium Part A for at least 7 years, and did not have the premium paid for by a state, a political subdivision of a state, or an agency or instrumentality of one or more states or political subdivisions) may have the Part A premium reduced to zero. These individuals must also have 10 years of employment with the state or local government employer or a combination of 10 years of employment with a state or local government employer and a non-government employer. The CMS-R-285 form is an essential part of the process of determining whether an individual qualifies for the premium reduction. The Social Security Administration will use this information to help determine whether a beneficiary meets the requirements for reduction of the Part A premium. *Form Number:* CMS-R-285 (OMB control number: 0938-0769); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 125. (For policy questions regarding this

collection contact Carla Patterson at 410-786-8911.)

Dated: March 16, 2017.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2017-05535 Filed 3-20-17; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-1066]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting for Custom Device Exemption

**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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the annual reporting for custom devices.

**DATES:** Submit either electronic or written comments on the collection of information by May 22, 2017.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-1066 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting for Custom Device Exemption.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any

information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

**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.

#### Annual Reporting for Custom Device Exemption

OMB Control Number 0910-0767—Extension

The custom device exemption is set forth at section 520(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient’s medical condition or physician’s special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- Devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (limited to no more than five units per year) qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, “devices” that qualify for the custom device exemption contained in section 520(b) of the FD&C Act were clarified to include no more than “five units per year of a particular device type” that otherwise meet all the requirements necessary to qualify for the custom device exemption.

In the **Federal Register** of September 24, 2014 (79 FR 57112), FDA announced the availability of the guidance entitled “Custom Device Exemption.” FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the Food, Drug, and Cosmetic Act (the FD&C Act). The intent of the guidance is to define terms used in the custom device exemption, explain how to interpret the “five units per year of a particular device type” language contained in the FD&C Act, describe information that FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to

submit an annual report for devices distributed under the custom device exemption.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reporting for custom devices .....	33	1	33	40	1,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 13, 2017.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2017-05349 Filed 3-20-17; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Mental Health; Notice of Closed Meeting**

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 meeting.

The meeting 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 Mental Health Special Emphasis Panel, Mental Health Services Research Conflicts.

*Date:* April 7, 2017.

*Time:* 12:00 p.m. to 1:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301-451-2356, [gavinevanskm@mail.nih.gov](mailto:gavinevanskm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: March 15, 2017.  
**Melanie J. Pantoja,**  
*Program Analyst, Office of Federal Advisory Committee Policy.*  
 [FR Doc. 2017-05487 Filed 3-20-17; 8:45 am]  
**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Eunice Kennedy Shrive National Institute of Child Health and Human Development; Notice of Committee Establishment**

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. App.), the Director, National Institutes of Health (NIH), announces the establishment of the Task Force on Research Specific to Pregnant Women and Lactating Women (Task Force) as required by section 2041 of the 21st Century Cures Act, Public Law 114-255.

The Task Force will provide advice and guidance to the Secretary, Department of Health and Human Services (Secretary), regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities. The Task Force will, not later than 18 months after the establishment, prepare and submit a report to the Secretary, the Committee on Health, Education, Labor and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

It is determined that the Task Force is in the public interest in connection with the performance of duties imposed on the NIH by statute, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of

Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496-2123, or [spaethj@od.nih.gov](mailto:spaethj@od.nih.gov).

Dated: March 15, 2017.

**Jennifer S. Spaeth,**  
*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2017-05486 Filed 3-20-17; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Notice of Diabetes Mellitus Interagency Coordinating Committee Meeting**

**SUMMARY:** The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on April 26-27, 2017. The topic for this meeting will be “Opportunities for Research Supported by the Special Statutory Funding Program for Type 1 Diabetes Research.” The meeting is open to the public. Non-federal individuals planning to attend the workshop should register by email to Charlemae Clarke, The Scientific Consulting Group, Inc. ([cclarke@scgcorp.com](mailto:cclarke@scgcorp.com); please put “Registration DMICC T1D Meeting” in the subject line) at least 7 days prior to the workshop.

**DATES:** The meeting will be held on April 26, 2017 from 8:00 a.m. to 5:45 p.m. and on April 27, 2017 from 8:00 a.m. to 3:00 p.m.

**ADDRESSES:** The meeting will be held in the Conference Room (terrace level) at 5635 Fishers Ln., Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** An agenda for the DMICC meeting will be available by contacting Charlemae Clarke, The Scientific Consulting Group, Inc. ([cclarke@scgcorp.com](mailto:cclarke@scgcorp.com); please put “Agenda Request for DMICC T1D Meeting” in the subject line). For further information concerning this meeting, contact Dr. B. Tibor Roberts, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and