Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for sponsors, clinical investigators, industry, institutional review boards, and FDA staff, entitled ''FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions.'' When finalized, this draft guidance would modify FDA's current policy on categorization of IDE devices. In September 1995, the Health Care Financing Administration (now known as CMS) published a final rule and entered into an Interagency Agreement (IA) with FDA regarding reimbursement categorization of investigational devices. (60 FR 48417, September 19, 1995.) The rule at 42 CFR part 405, subpart B established that certain devices with an IDE approved by FDA (and certain services related to those devices) may be covered under Medicare, and set forth the process by which FDA would assist CMS in identifying such devices. FDA would assign a device with an FDA approved IDE to one of two categories: Experimental/Investigational (Category A) devices or Non-experimental/Investigational (Category B) devices based on the level of risk the device presented to patients. The IA set forth criteria, agreed upon by CMS and FDA, which FDA would use to categorize devices. The categorization would then be used by CMS as part of its determination of whether or not devices met the requirements for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act (42 U.S.C. 1385y). CMS and FDA both recognized that experience in categorizing devices might require changes to the Interagency Agreement.

In the more than 20 years since the IA was signed, FDA has received a number of IDEs which do not easily fit into any of the eight subcategories identified in the IA. There have been several developments, such as: The publication of the guidance document entitled ''Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies;'' (Ref. 1) and a subsequent increase in submission of early feasibility studies to FDA, as well as modifications to CMS's regulation regarding IDEs (42 CFR part 405, subpart B), which have prompted FDA and CMS to revise their shared understanding regarding the categorization of IDE devices.

On December 2, 2015, FDA's CDRH and CMS's CAG executed an MOU to streamline and facilitate the efficient categorization of investigational medical devices. The MOU will become effective June 2, 2016. This guidance document is intended to implement the MOU and describes the criteria that FDA intends to use to help determine the appropriate category for a device to be studied. This guidance document also describes a pathway for changing the device category from Category A to Category B.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16001 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA and CMS regulations. These collections of information are 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. The collections of information in 42 CFR part 405, subpart B have been approved under OMB control number 0938–1250.

V. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies, available at *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm279103.pdf.*

Dated: May 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12828 Filed 5–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than July 1, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for

HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Opioid Overdose Reversal Grant Program OMB No. 0906–xxxx—New.

Abstract: This program is authorized by Section 711(b) of the Social Security Act (U.S.C. 912(b), as amended and the Consolidated and Further Continuing Appropriations Act (P.L. 113–235). The purpose of this grant program is to reduce the incidences of morbidity and mortality related to opioid overdoses in rural communities through the purchase and placement of emergency devices used to rapidly reverse the effects of opioid overdose and training of licensed healthcare professionals and emergency responders on their use.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Public Law 103–62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy, including: (a) The number of counties served by the program; (b) the number and type of devices purchased and distributed and the location of the distribution; (c) the number of training sessions and the number of individuals trained; and (d) the number of individuals who were administered Narcan and the outcome. These measures will speak to the Office's progress toward meeting the set goals.

Likely Respondents: Rural Opioid Overdose Reversal Grant Program award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Opioid Overdose Reversal Grant Program Performance Measures	18	1	18	4	72
Total	18	.....	18	.....	72

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–12745 Filed 5–31–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; Clinical Trials Review Committee.

Date: June 23–24, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892–7924, 301–435–2222, *copeka@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 25, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12756 Filed 5–31–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Clinical and Basic Science Review Committee.

Date: June 23–24, 2016.

Time: 10:30 a.m. to 11:00 a.m.