marketing decision. These challenges may include differences between the OUS and U.S. clinical conditions, regulatory requirements (including human subject protections), and/or study populations that may be sufficient to affect the adequacy of the data for use in establishing the safety and/or effectiveness of the studied device. This guidance focuses on considerations sponsors of device submissions should take into account when initiating, or relying on previously collected data from, an OUS clinical study to support an Investigational Device Exemption, Premarket Notification (510(k)), De Novo Petition, Humanitarian Device Exemption, or Premarket Approval Application. This guidance also notes other important considerations to take into account when initiating or relying on OUS data. FDA believes that promoting greater clarity concerning FDA's use of foreign study data will minimize the possibility for additional or duplicative U.S. studies, further efforts to harmonize global clinical trial standards, and promote public health and innovation.

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on acceptance of clinical data from foreign studies conducted OUS. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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 Centers 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.regulations.gov*. Persons unable to download an electronic copy of ''Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1741 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations.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 parts 50 and 56 have been approved under OMB control number 0910–0755; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 has been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09176 Filed 4–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of May 2015.

The National Advisory Committee on Rural Health and Human Services will convene its seventy seventh meeting in the time and place specified below:

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Time: May 27, 2015, 8:45 a.m.—5:00 p.m.; May 28, 2015, 8:30 a.m.—5:15 p.m.; May 29, 2015, 8:30 a.m.—11:00 a.m.

Place: Natural Bridge State Park, 2135 Natural Bridge Rd, Slade, KY 40376, (606) 663–2214.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Wednesday morning, at 8:45 a.m., the meeting will be called to order by the Chairperson of the Committee: The Honorable Ronnie Musgrove. The Committee will examine the issue of an increasing difference between life expectancy among the urban and rural populations of the United States. The day will conclude with a period of public comment at approximately 4:45 p.m.

Thursday morning at approximately 8:30 a.m., the Committee will break into Subcommittees and depart for site visits. Subcommittees will visit the Center of Excellence in Rural Health in Hazard, Kentucky, and the Marcum & Wallace Memorial Hospital in Irvine, Kentucky. The day will conclude at the Natural Bridge State Park with a period of public comment at approximately 5:00 p.m.

Friday morning at 8:30 a.m., the Committee will meet to summarize key findings and develop a work plan for the next quarter and the following meeting.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, MSLS, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, 17W29–C, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Catherine Fontenot at the Federal Office of Rural Health Policy (FORHP) via telephone at (301) 945–0897 or by email at *cfontenot@hrsa.gov*. The Committee

meeting agenda will be posted on the Committee's Web site at *http://www.hrsa.gov/advisorycommittees/rural/*.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–09080 Filed 4–20–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps (NAC).

Date and Time: May 6, 2015 from 2:00 p.m.–3:30 p.m. (EST).

Place: Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The NAC provides advice to the Secretary of the Department of Health and Human Services and the Administrator of the Health Resources and Services Administration (HRSA), with respect to their responsibilities for designating areas of the United States with critical health professional shortages (*i.e.,* Health Professional Shortage Area) and assigning health care personnel to improve the delivery of health services in these areas.

Agenda: The members of the NAC will discuss: (a) The activities and goals for fiscal year 2016 for the National Health Service Corps; (b) their vision and approaches for future NAC meetings; and (c) planning for an in-person meeting. The official agenda will be available 2 days prior to the meeting on the HRSA Web site at: *http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/.* Agenda items are subject to change as priorities dictate.

Public Comment: Requests to make oral comments or provide written comments to the NAC should be sent to CAPT Shari Campbell, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call should notify CAPT Campbell at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments. Interested parties should refer to the meeting, in the subject line, as the HRSA National Advisory Council on the National Health Service Corps. The conference call-in number is: 888–566–5974. The passcode is: 4439136.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the NAC should contact CAPT Shari Campbell, Designated Federal Official, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: CAPT Shari Campbell, Designated Federal Official, Bureau of Health Workforce, HRSA, Parklawn Building, Room 8C–26, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 594–4251; or (3) send an email to *scampbell@hrsa.gov.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–09078 Filed 4–20–15; 8:45 am]

BILLING CODE 4165–15–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 May 21, 2015.

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: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations.

OMB No. 0915–0327—Revision

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act; ''Limitation on Prices of Drugs Purchased by Covered Entities''), provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula (''ceiling price'').

A manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed in the 340B Program database. Manufacturers rely on the information in the 340B database to determine if a covered entity is participating in the 340B Program or for any notifications of changes to eligibility that may occur within a quarter. By signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements, including any changes that occur after execution of the PPA.

Covered entities which choose to participate in the 340B Program must comply with the requirements of Section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, Section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

Need and Proposed Use of the Information: Section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with