

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.

Request for Recognition of a Voluntary Consensus Standard

OMB Control Number 0910-NEW

The draft guidance for industry entitled "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality" provides guidance to industry about the procedures the Center for Drug Evaluation and Research follows when a request for recognition of a voluntary consensus standard is received. The guidance outlines justifications for why a standard may be recognized wholly, partly, or not at all. The guidance also provides that any interested party may request recognition of a standard. Specifically, this process will allow CDER to:

- Receive a candidate consensus standard, with relevant information (e.g., the scope of the standard and the

purpose), from internal or external parties for informal recognition.

- Determine whether to informally recognize a standard in whole or in part following an internal scientific evaluation.

- List the informally recognized standards in a publicly searchable database on CDER's website, accompanied by an information sheet describing the scope and the extent of CDER's informal recognition of that standard and any other relevant information about it.

Request for Recognition of a Voluntary Consensus Standard

We estimate that FDA will receive nine requests annually. We estimate that each request will take less than 1 hour to prepare.

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
Request for recognition of a voluntary consensus standard	9	1	9	1	9

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

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: February 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02326 Filed 2-13-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Council on Graduate Medical Education (COGME) has scheduled a public meeting. Information about COGME and the agenda for this meeting can be found on the COGME website at <https://www.hrsa.gov/>

[advisory-committees/graduate-medical-edu/index.html](https://www.hrsa.gov/advisory-committees/graduate-medical-edu/index.html).

DATES: June 5, 2019, 8:30 a.m.–5:00 p.m. and June 6, 2019, 8:30 a.m.–2:00 p.m. ET.

ADDRESSES: This meeting will be held in-person and through teleconference and webinar. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

- Conference call-in number is: 1-888-455-0640.
- Passcode is: HRSA COUNCIL (voice response).

- Webinar link is: <https://hrsa.connectsolutions.com/cogme>.

FOR FURTHER INFORMATION CONTACT: Kennita R. Carter, MD, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 15N-116, Rockville, Maryland 20857; 301-945-3505; or KCarter@hrsa.gov.

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on policy, program development, and other matters of significance as specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include (1) the nature and financing of medical education training; (2) the

development of performance measures and longitudinal evaluation methods of medical education programs; (3) foreign medical school graduates; (4) the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses; (5) deficiencies in databases of the supply and distribution of the physician workforce and postgraduate programs for training physicians; and (6) appropriation levels for certain programs under Title VII of the PHS Act. Additionally, COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the council. COGME submits reports to the Secretary of HHS, the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce.

During the June 2019, meeting, COGME will discuss the topic of rural health in relation to workforce development and graduate medical education financing. Agenda items are subject to change as priorities dictate. Refer to the COGME website for any updated information concerning the meeting. The meeting agenda will be available on the COGME website at least 14 calendar days prior to the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide written statements or make oral comments to COGME should be sent to Kennita R. Carter, DFO, using the contact information above at least three business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Kennita R. Carter, DFO, using the contact information listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-02317 Filed 2-13-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) has scheduled public meetings for the 2019 calendar year (CY). Information about ACTPCMD, agendas, and materials for these meetings can be found on the ACTPCMD website at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html>.

DATES: June 11, 2019, 8:30 a.m. Eastern Time (ET)–5:00 p.m. ET; August 8, 2019, 8:30 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or via Adobe Connect webinar. In-person ACTPCMD meetings will be held at

5600 Fishers Lane, Rockville, Maryland 20857. Instructions for joining the meetings either in person or remotely will be posted on the ACTPCMD website 30 business days before the date of the meeting. For meeting information updates, visit the ACTPCMD website meeting page at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings.html>

FOR FURTHER INFORMATION CONTACT:

Kennita Carter, MD, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, 15N116, Rockville, Maryland 20857; (301) 945-3505 or BHWACTPCMD@hrsa.gov.

SUPPLEMENTARY INFORMATION:

ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the committee, including findings and recommendations made by the committee concerning the activities under Section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary, Chairman, and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. ACTPCMD also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C of the PHS Act, and recommends appropriation levels for programs under this Part.

During ACTPCMD's CY 2019 meetings, the committee will discuss matters concerning policy, program development, and other matters of significance concerning medicine and dentistry activities. Refer to the ACTPCMD website listed above for all current and updated information concerning CY 2019 ACTPCMD meetings, including draft agendas and meeting materials that will be posted at least 10 business days before the start of each meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement

or make oral comments to the ACTPCMD should be sent to Kennita Carter using the contact information above at least five business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Kennita Carter using the contact information listed above at least 10 business days before the meeting(s) they wish to attend. Since all in-person meetings will occur in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-02318 Filed 2-13-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: April 23, 2019, 9:00 a.m. to 5:00 p.m. Eastern Time (ET) and April 24, 2019, from 9:00 a.m. to 3:00 p.m. ET.

ADDRESSES: This meeting will be held in-person and will be webcast. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. The deadline for online registration is 12:00 p.m. ET on April 19, 2019. Instructions on how to access the meeting via