

Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Antimicrobial Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Antimicrobial Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/ucm094132.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: October 7, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, codified at 5 U.S.C. App.), notice is hereby given that a meeting is scheduled for the Advisory Committee on Heritable Disorders in Newborns and Children. This meeting will be open to the public but advance registration is required to ensure sufficient webinar capacity. The registration link is <https://www.blsmeetings.net/achdncnovember2016/>. The registration deadline is Wednesday, November 2, 2016, 11:59 p.m. Eastern Time.

DATES AND TIMES: November 3, 2016, 9:00 a.m. to 5:00 p.m. (Meeting time is tentative.)

November 4, 2016, 9:00 a.m. to 1:00 p.m. (Meeting time is tentative.)

ADDRESSES: This meeting will be held by webinar only.

FOR FURTHER INFORMATION CONTACT:

Anyone interested in obtaining other relevant information should contact Alaina Harris, Maternal and Child Health Bureau, HRSA, Room 18W66, 5600 Fishers Lane, Rockville, Maryland 20857; email: aharris@hrsa.gov.

SUPPLEMENTARY INFORMATION: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by the Public Health Service Act, Title XI, § 1111 (42 U.S.C. 300b-10), was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/ inherited disorders for screening that

have been adopted by the Secretary are included in the Recommended Uniform Screening Panel and constitute part of the comprehensive guidelines supported by HRSA. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.*, policy years) beginning on or after the date that is 1-year from the Secretary's adoption of the condition for screening.

The Committee will hear presentations and discussions on topics related to newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The Committee will also hear updates from the Laboratory Standards and Procedures workgroup, Follow-up and Treatment workgroup, and Education and Training workgroup. Agenda items are subject to changes as priorities indicate. Tentatively, the Committee is expected to review and/or vote on the following: Approving newborn screening surveillance case definitions and whether or not the nominated condition Guanidinoacetate Methyltransferase deficiency should be referred for a full evidence-based review. The Committee will not be voting on a proposed addition of a condition to the Recommended Uniform Screening Panel. The meeting agenda will be available 2 days prior to the meeting on the Committee's Web site: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Members of the public may submit written and/or present oral comments at the meeting. All comments are part of the official Committee record. Advance registration is required to submit written comments and/or present oral comments. Written comments must be submitted by October 19, 2016, 11:59 p.m. Eastern Time in order to be included in the November meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.*, parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments.

Individuals who wish to provide oral comments must register by October 30, 2016, 11:59 p.m. Eastern Time. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may

be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted.

More information on the Advisory Committee is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request; Evaluation and Initial Assessment of HRSA Teaching Health Centers

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than December 13, 2016.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N-39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Evaluation and Initial Assessment of HRSA Teaching Health Centers.

OMB No.: 0915-0376—Extension.

Abstract: Section 5508 of the Affordable Care Act of 2010 amended section 340H of the Public Health Service Act to establish the Teaching Health Center Graduate Medical Education (THCGME) program to support new and the expansion of existing primary care residency training programs in community-based settings. The primary goals of this program are to increase the production of primary care providers who are well prepared to practice in community settings, particularly with underserved populations, and to improve the overall number and geographic distribution of primary care providers.

Need and Proposed Use of the Information: To ensure these goals are achieved, the George Washington University (GW) is conducting an evaluation of the training, administrative and organizational structures, clinical service, challenges, innovations, costs associated with training, and outcomes of Teaching Health Centers (THCs). GW has developed questionnaires for implementation with all THC matriculating residents, graduating residents, and graduated residents at 1 year post-graduation. The matriculation questionnaire aims to collect background information on THC residents to better understand the characteristics of individuals who apply and are accepted to THC programs. The graduation questionnaire collects

information on career plans. The alumni questionnaire collects information on career outcomes (including practice in primary care and in underserved settings) following graduation as well as feedback on the quality of training.

Statute requires that THCGME program award recipients report annually on the types of primary care resident approved training programs that the THCs provided for residents, the number of approved training positions for residents, the number of residents who completed their residency training at the end of the academic year and care for vulnerable populations, and any other information as deemed appropriate by the Secretary. The described data collection activities have served to meet this statutory requirement for the THCGME program award recipients in a uniform and consistent manner and have allowed comparisons of this group to other trainees in non-THC programs. GW seeks renewal of these measures with no changes.

Likely Respondents: Respondents are medical and dental residents as well as graduates of Teaching Health Centers.

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 Information Collection Request 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
THC Graduate Survey	300	1	300	0.33	99
THC Matriculant Survey	300	1	300	0.25	75
THC Graduation Survey	300	1	300	0.25	75
Total	900		900		249