

MD 20993-0002, 301-796-1500; or Stephen Ripley, Center for Biologics Evaluation and Research, 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FDA is announcing the availability of a draft guidance for industry entitled "Pediatric HIV Infection: Drug Development for Treatment." This draft guidance provides general recommendations on the development of products for the treatment of human immunodeficiency virus (HIV) infection in pediatric patients (birth to younger than 17 years of age), including recommendations on when sponsors should initiate pediatric formulation development and begin pediatric studies to evaluate antiretroviral drug products for the treatment of HIV infection.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on drug development for treatment of pediatric HIV infection. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either 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

Dated: May 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership To Serve on the Council on Graduate Medical Education

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Council on Graduate Medical Education (COGME). COGME provides advice and recommendations to the Secretary of HHS; the Senate Committee on Health, Education, Labor and Pensions; and the U.S. House of Representatives Committee on Energy and Commerce on matters concerning the supply and distribution of physicians in the United States, physician workforce trends, training issues, financing policies, and other matters of significance related to physician workforce and graduate medical education.

DATES: The agency will accept nominations on a continuous basis.

ADDRESSES: Nomination packages may be mailed to Advisory Council Operations, Bureau of Health Workforce, HRSA, Room 11W45C, 5600 Fishers Lane, Rockville, Maryland 20857 or submitted electronically by email to: BHWAdvisoryCouncilFRN@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Kennita R. Carter, MD, Designated Federal Official, COGME at 301-945-3505 or email at kcarter@hrsa.gov. A copy of the current COGME charter, membership, and reports can be obtained by accessing the COGME website <https://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/>.

SUPPLEMENTARY INFORMATION: COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of COGME; develops, publishes, and implements performance measures and longitudinal evaluations; and recommends appropriation levels for certain Public Health Service Act (PHSA) Title VII programs. Meetings take place twice a year.

Nominations: HRSA is requesting nominations for voting members of COGME to include representatives of practicing primary care physicians, national and specialty physician organizations, foreign medical graduates, medical student and house staff associations, schools of allopathic and osteopathic medicine, public and private teaching hospitals, and representatives of health insurers, business, and labor. Additionally, HRSA encourages nominations of medical students, residents, and/or fellows. Members receive appointments based on their competence, interest, and knowledge of the mission of the profession involved.

The Secretary of HHS will consider nominations of all qualified individuals within the areas of subject matter expertise noted above. In making such appointments, the Secretary shall ensure a broad geographic representation of members and a balance between urban and rural educational settings.

Professional organizations, employers, or colleagues may nominate one or more qualified persons for membership. Individuals selected for appointment to COGME will be invited to serve for 4 years. COGME members are appointed as special government employees and receive a stipend and reimbursement for per diem and travel expenses incurred for attending meetings and/or conducting other business on behalf of COGME, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service.

To evaluate possible conflicts of interest, individuals selected for consideration for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. The selected candidates must fill out the U.S. Office of Government Ethics (OGE) Confidential Financial Disclosure Report, OGE Form 450. Disclosure of this information is necessary to determine if the selected candidate is involved in any activity that may pose a potential conflict with their official duties as a member of the Committee.

A nomination package should include the following information for each nominee: (1) A letter of nomination from an employer, a colleague, or a professional organization stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of COGME), and the nominee's field(s) of expertise; (2) a letter of interest from the nominee stating the reasons they would like to serve on COGME; (3) a biographical sketch of the nominee, including a copy of his/her curriculum vitae and his/her contact information (address, daytime telephone number, and email address); and (4) the name, address, daytime telephone number, and email address where the person nominating the individual can be contacted.

HRSA will collect and retain nomination packages to create a pool of possible future COGME voting members. When a vacancy occurs, HRSA may review nomination packages from the appropriate category and may contact nominees at that time.

Nominations should be updated and resubmitted every 4 years to continue to be considered for committee vacancies.

HHS strives to ensure a balance of the membership of COGME in terms of points of view presented and the committee's function and makes every effort to ensure the representation of views of women, all ethnic and racial groups, and people with disabilities on HHS Federal Advisory Committees. Therefore, we encourage nominations of qualified candidates from these groups and endeavor to make appointments to COGME without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Authority: Section 762 of the PHSA (42 U.S.C. 294o), as amended. COGME is governed by provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees and applies to the extent that the provisions of FACA do not conflict with the requirements of PHSA Section 762.

Amy P. McNulty,

Acting 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 Information
Collection Request Title: Health Center Patient Survey, Reinstatement With Change

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 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 should be received no later than July 13, 2018.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Lisa Wright-Solomon, Room 14N39, 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 Lisa Wright-Solomon, 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: Health Center Patient Survey, OMB No. 0915-0368—Reinstatement with Change.

Abstract: HRSA supported health centers (those entities funded under section 330 of the Public Health Service Act) deliver comprehensive, affordable, quality primary health care to nearly 26 million patients nationwide, regardless of their ability to pay. Nearly 1,400 health centers operate more than 11,000 service delivery sites in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. In the past, HRSA has conducted the Health Center Patient Survey (HCPS), which surveys patients of HRSA funded health centers. The HCPS collects information about sociodemographic characteristics, health conditions, health behaviors, access to and use of health care services, and satisfaction with health care received at HRSA funded health centers. HRSA will use the same overarching modules from the 2014 HCPS but will

employ changes designed to streamline the questionnaire to minimize burden and to standardize questions with other national surveys enabling comparative analyses with particular focus on HHS and HRSA priority areas (e.g., mental health and substance use). Survey results come from in-person, one-on-one interviews with patients who are selected as nationally representative of the Health Center Program patient population.

Need and Proposed Use of the Information: The HCPS uniquely focuses on comprehensive, nationally representative, individual level data from the perspective of health center patients. By investigating how well HRSA funded health centers meet the health care needs of the medically underserved and how patients perceive their quality of care, the HCPS serves as an empirically based resource to inform HRSA policy, funding, and planning decisions.

Likely Respondents: Patients at HRSA supported 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. Compared to previous HCPS, the estimated burden hours for an individual respondent remains the same in the reinstatement. However, the total annual burden hours and number of survey respondents is anticipated to increase in order reflect the growing number of patients served by the Health Center Program. 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
Grantee Recruitment	220	1	220	2.00	440
Site Recruitment and Training	700	1	700	3.15	2,205
Patient Screening	13,120	1	13,120	0.17	2,230
Patient Survey	9,058	1	9,058	1.25	11,323