

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Section of guidance/recordkeeping activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
4.1. and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total					1,036

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹

Section of guidance/disclosure activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.4.1.2. Sponsor notification to the DMC regarding waivers.	1	1	1	0.25 (15 minutes) ..	0.25
4.4.3.2. DMC reports of meeting minutes to the sponsor.	370	2	740	1	740
Total					740.25

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

Dated: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nominations to the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Health (OASH) is seeking nominations of qualified individuals to be considered for appointment as members of the Presidential Advisory Council on HIV/AIDS (PACHA). The PACHA is a federal advisory committee within the Department of Health and Human Services (HHS). Management support for the activities of this Council is the responsibility of the OASH. The qualified individuals will be nominated to the Secretary of Health and Human Services for consideration for appointment as members of the PACHA. Members of the Council, including the Chair, are appointed by the Secretary. Members are invited to serve on the Council for up to four-year terms. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective

prevention and care of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

DATES: All nominations must be received no later than 5:00 p.m. (ET) on October 9, 2015 at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Ms. B. Kaye Hayes, Executive Director, PACHA, Department of Health and Human Services, Office of HIV/AIDS and Infectious Disease Policy, 200 Independence Avenue SW., Room 443-H, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, 200 Independence Avenue SW., Room 443-H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 205-1178. More detailed information about PACHA can be obtained by accessing the Council's page at the AIDS.gov Web site at www.aids.gov/pacha.

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are

selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. Pursuant to advance written agreement, Council members shall receive no stipend for the advisory service they render as members of PACHA. However, as authorized by law and in accordance with federal travel regulations, PACHA members may receive per diem and reimbursement for travel expenses incurred in relation to performing duties for the Council.

This announcement is to solicit nominations of qualified candidates to fill current vacancies on the PACHA.

Nominations: In accordance with the PACHA charter, persons nominated for appointment as members of the PACHA should be among prominent community leaders and authorities with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. The following information should be included in the package of material submitted for each individual being nominated for consideration of appointment:

- Name, return address, daytime telephone number, and affiliation(s) of

the individual being nominated, the basis for the individual's nomination, and a statement bearing an original signature of the nominated individual that, if appointed, he or she is willing to serve as a member of the Council;

- Name, return address, and daytime telephone number at which the nominator may be contacted. Nominations from organizations must identify a principal contact person; and a

- Copy of a current resume or curriculum vitae for the nominated individual.

Individuals can nominate themselves for consideration of appointment to the Council. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable.

The Department is legally required to ensure that the membership of HHS federal advisory committees is fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Council. Appointment to the Council shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as members of the Council. Individuals being considered for appointment as public voting members will be required to complete and submit a report of their financial holdings. An ethics review must be conducted to ensure that individuals appointed as members of PACHA are not involved in any activity that may pose a potential conflict of interest for the official duties that are to be performed.

Dated: August 24, 2015.

B. Kaye Hayes,

Executive Director, Presidential Advisory Council on HIV/AIDS.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Public Consultation on Antimicrobial Resistance Rapid, Point-of-Care Diagnostic Test Challenge

Authority: 15 U.S.C. 3719.

SUMMARY: The U.S. Department of Health and Human Services (HHS) intends to hold a prize competition in which up to \$20 million will be made available, subject to the availability of funds, for the delivery of one or more successful rapid point-of-care diagnostics that may be used by health care providers to identify bacterial infections. The National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) are sponsoring the prize competition and will convene a public consultation to seek comments regarding the technical criteria and performance characteristics of the diagnostic(s) for which the prize(s) will be offered.

DATES: The public consultation will be held on October 7, 2015, 8:30 a.m. to 3:30 p.m. PDT. Written comments can be submitted to the <https://www.challenges.gov> Web site for this competition beginning on October 1 at 8:30 a.m. EDT to October 6, 2015 at 5:00 p.m. EDT.

ADDRESSES: The public consultation will be held at the Marriott Marquis San Diego Marina, 333 West Harbor Drive, San Diego, California, 92101.

FOR FURTHER INFORMATION CONTACT: Robert W. Eisinger, Ph.D., National Institutes of Health, Division of Program Coordination, Planning, and Strategic Initiatives, Telephone: 301-496-2229, Email: Robert.eisinger@nih.gov.

SUPPLEMENTARY INFORMATION: On September 18, 2014, the President issued Executive Order 13676 on Combating Antibiotic-Resistant Bacteria (<https://www.whitehouse.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria>) and the Antimicrobial Resistance Challenge was called for in the accompanying White House Fact Sheet <https://www.whitehouse.gov/the-press-office/2014/09/18/fact-sheet-obama-administration-takes-actions-combat-antibiotic-resistance>). The development and use of rapid, point-of-care, and innovative diagnostic tests for identification and characterization of resistant bacteria was a goal identified in the National Strategy for Combating Antibiotic-Resistant Bacteria released in

September 2014 (https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf) and addressed in the National Action Plan for Combating Antibiotic-Resistant Bacteria released in March 2015 (https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf).

In conformance to the above documents, the NIH and BARDA are sponsoring a prize competition, and the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are contributing technical and regulatory expertise to develop the award evaluation process.

The aim of the prize competition is to incentivize the development of one or more *in vitro* diagnostic tests that would be of significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria. For example, such a diagnostic test could be used by health care providers to identify bacterial infections in patients to help guide their decisions about the necessity of prescribing antibiotics, and if so, which antibiotics may be effective—thus promoting antibiotic stewardship. Another important diagnostic use could be to facilitate clinical trials for new antibacterial products by allowing for the enrichment of patient populations with specific infections, thus advancing the development of new antibacterial agents. The prize-winning diagnostic(s) must exhibit a set of predefined technical criteria and performance characteristics based on the intended use(s).

When exercising prize authority under the America COMPETES Act (<http://www.gpo.gov/fdsys/pkg/PLAW-111publ358/html/PLAW-111publ358.htm>), agencies are to “consult widely both within and outside the federal Government” when developing prize competitions. As such, HHS is seeking input from the medical, public health, and scientific communities; the pharmaceutical and medical diagnostic sectors; patients and other advocacy groups; and the public at-large in order to receive broad input on the type(s) of diagnostic(s) that may be developed in an appropriate time frame to be of significant utility in combating the development and spread of antibiotic resistant bacteria.

HHS has previously issued a Request for Information (RFI) to obtain comments on several topics as they pertain to a rapid, point-of-care diagnostic test(s) that could be developed in an appropriate time frame to be of significant clinical and public