TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

<table>
<thead>
<tr>
<th>Section of guidance/recordkeeping activity</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1. and 6.4 SOPs for DMCs</td>
<td>37</td>
<td>1</td>
<td>37</td>
<td>8</td>
<td>296</td>
</tr>
<tr>
<td>4.4.3.2. DMC meeting records</td>
<td>370</td>
<td>1</td>
<td>370</td>
<td>2</td>
<td>740</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>1,036</strong></td>
</tr>
</tbody>
</table>

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

<table>
<thead>
<tr>
<th>Section of guidance/disclosure activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4.1.2. Sponsor notification to the DMC regarding waivers.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0.25 (15 minutes) ..</td>
<td>0.25</td>
</tr>
<tr>
<td>4.4.3.2. DMC reports of meeting minutes to the sponsor.</td>
<td>370</td>
<td>2</td>
<td>740</td>
<td>1</td>
<td>740</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>740.25</strong></td>
</tr>
</tbody>
</table>

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


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2015–22680 Filed 9–8–15; 8:45 am]

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.


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 designees, 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 the membership of the Council.

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 tests that could be developed in an appropriate time frame to be of significant clinical and public health utility to combat the development and spread of antibiotic resistant bacteria.