

THE SECRETARY OF HEALTH AND HUMAN SERVICES WASHINGTON, D.C. 20201

CHARTER

PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-ESISTANT BACTERIA

Authority

Executive Order 13676, dated September 18, 2014, requires establishment of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Objectives and Scope of Activities

Executive Order 13676 directs the Secretary of Health and Human Services (Secretary) to establish the Advisory Council in consultation with the Secretaries of Defense and Agriculture. The Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy) and the National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan). The Advisory Council shall function solely for advisory purposes.

Description of Duties

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to:

- 1. Preserve the effectiveness of antibiotics by optimizing their use;
- 2. Advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship;
- 3. Strengthen surveillance of antibiotic-resistant bacterial infections;
- 4. Prevent the transmission of antibiotic-resistant bacterial infections;
- 5. Advance the development of rapid point-of-care and agricultural diagnostics;

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- 6. Further research on new treatments for bacterial infections;
- 7. Develop alternatives to antibiotics for agricultural purposes;
- 8. Maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and
- 9. Improve international coordination of efforts to combat antibiotic resistance.

Agency or Official to Whom the Committee Reports

As stipulated in Executive Order 13676, the Advisory Council provides advice, information, and recommendations to the Secretary. The Secretary will provide the President with all written reports created by the Advisory Council.

Support

To the extent permitted by law and subject to the availability of appropriations, the Department of Health and Human Services (HHS) shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions. Management and support services provided to the Advisory Council will be the responsibility of the Office of the Assistant Secretary for Health (OASH), which is a coordinating and program office within the Office of the Secretary.

To the extent permitted by law, the agencies that comprise the Task Force for Combating Antibiotic-Resistant Bacteria shall provide the Advisory Council with such information as it may require for purposes of carrying out its functions.

Estimated Annual Operating Costs and Staff Years

The estimated annual cost for operating the Advisory Council, including compensation and travel expenses for members, but excluding staff support is \$472,000. The estimate for annual person years of staff support required is 5.0, at an estimated annual cost of \$654,017.

Designated Federal Officer

The Assistant Secretary for Health (ASH), in consultation with the Secretary, will select the Designated Federal Officer (DFO) from among full-time or permanent part-time staff within OASH or another organizational component within the HHS, who have knowledge of the subject matter and skills and experience necessary to manage the Advisory Council. The ASH may appoint an Alternate DFO, who will carry out the assigned duties in the event that the DFO cannot fulfill the assigned responsibilities for the Advisory Council. In the absence of a DFO

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or Alternate DFO, the ASH will temporarily appoint one or more permanent full-time or part time program staff to carry out the assigned duties.

The DFO will schedule and approve all meetings of the Advisory Council and of its respective subcommittees. The DFO will prepare and approve all meeting agendas. The DFO may collaborate with the Advisory Council Chair in this activity, and when deemed appropriate, with chairs of any existing subcommittees that have been established by the Advisory Council. The DFO, Alternate DFO, or designee will attend all meetings of the Advisory Council and all meetings of any subcommittees/working groups that have been assembled to assist the Advisory Council. The DFO has authority to adjourn meetings, when it is determined to be in the public interest, and the DFO can be directed by the Secretary or designee to chair meetings of the Advisory Council.

Estimated Number and Frequency of Meetings

The Advisory Council will meet, at a minimum, two times per fiscal year depending on the availability of funds. Meetings will be open to the public, except as determined otherwise by the Secretary, or other official to whom authority has been delegated, in accordance with guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). Notice of all meetings will be provided to the public in accordance with the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.). Meetings will be conducted and records of the proceedings will be kept, as required by applicable laws and Departmental policies. A quorum is required for the Advisory Council to meet to conduct business. A quorum will consist of a majority of the Advisory Council's voting members.

When the Secretary or designee determines that a meeting will be closed or partially closed to the public, in accordance with stipulations of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report will be prepared by the DFO that includes, at a minimum, a list of the members and their business addresses, the Advisory Council's functions, date and place of the meeting, and a summary of the Advisory Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

Duration

Continuing. The Advisory Council was established by an Executive Order; no specific end date was established for the Advisory Council to operate.

Termination

Unless renewed by appropriate action prior to its expiration, the charter for the Advisory Council will expire two years from the date it is filed.

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Membership and Designation

The Advisory Council will consist of not more than 30 members, including the voting and nonvoting members and the Chair and Vice Chair. The Secretary will designate the Chair and Vice Chair from among the voting public members of the Advisory Council who have demonstrated ability both to lead the work of similar bodies and to work effectively in partnership with federal agencies and partner organizations.

Voting Members. There will public voting members selected from individuals who are engaged in research on, or implementation of, interventions regarding efforts to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The public voting members will represent balanced points of view from human biomedical, public health, and agricultural fields to include surveillance of antibiotic-resistant infections, prevention and/or interruption of the spread of antibiotic-resistant threats, or development of rapid diagnostics and novel treatments. The public voting members may be physicians, veterinarians, epidemiologists, microbiologists, or other health care professionals (e.g., nurses, pharmacists, others); individuals who have expertise and experience as consumer or patient advocates concerned with antibiotic resistance, or in the fields of agriculture and pharmaceuticals; and they also may be from State or local health agencies or public health organizations. The voting public members will be appointed by the Secretary, in consultation with the Secretaries of Defense and Agriculture. All public voting members will be classified as special Government employees (SGEs).

Ex-officio Members (non-voting). The Advisory Council will include members selected to represent various federal agencies, including HHS, DoD, and USDA, that are involved in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. The federal *ex- officio* members shall possess the knowledge, skills, experience, and expertise necessary to generate informed and intelligent recommendations with respect to the issues mandated by Executive Order 13676. Federal agencies will be invited to participate as non-voting *ex-officio* members of the Advisory Council, as it is deemed necessary by the Secretary, in consultation with the Secretaries of Defense and Agriculture, to accomplish the mission the Advisory Council.

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Liaison Representatives (non-voting). The Advisory Council structure also may include non-voting liaison representatives from organizations and/or interest groups that have involvement in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. Individuals from among the following sectors may be invited to serve as non-voting liaison representatives:

- Professional organizations representing: infectious disease; epidemiology; infection control; physicians; nurses; pharmacists; microbiologists; veterinarians
- Public health organizations representing laboratories, health officials, or epidemiologists (state/territorial, county, or local)
- Organizations advocating for patients and consumers
- Organizations representing state departments of agriculture
- Hospitals
- Foundations with an interest in antibiotic resistance and promoting antibiotic stewardship
- National Preparedness and Response Science Board
- Pharmaceutical industry-human health
- Pharmaceutical industry-animal health
- Vaccines
- Food producer (livestock)
- Food producer (poultry)
- Food producer (seafood)
- In vitro diagnostics
- Food retailer
- Food processor
- Animal feed producers
- Farm bio-security

Invitations may be extended to other organizations and/or interest groups to participate as non-voting liaison representatives, as it is deemed necessary by the Secretary or designee to accomplish the established mission of the Advisory Council.

Terms and Compensation. The public voting and non-voting liaison representative members will be appointed to serve for overlapping terms of up to four years. Any member who is appointed to fill the vacancy of an unexpired term will be appointed to serve for the remainder of that term. The Chair and Vice Chair will be appointed to serve for three years, unless otherwise specified. Terms of more than two years are contingent upon renewal of the Advisory Council charter by appropriate action prior to its expiration. A member may serve after the expiration of their term until their successor has taken office, but no longer than 180 days.

Pursuant to an advance written agreement, the public voting members shall receive no stipend from the federal government for the services they perform during their tenure on the Advisory

Council. However, the public voting members are entitled to receive per diem and reimbursement for travel expenses incurred for attending meetings of the Advisory Council, as authorized by 5 U.S.C. Sec. 5703, as amended, for persons who are employed intermittently in the Government service. The non-voting liaison representatives may be allowed to receive per diem and any applicable expenses for travel that is performed to attend meetings of the Advisory Council in accordance with federal travel regulations.

Subcommittees/Working Groups

With approval or recommendation of the Secretary or designee, the Advisory Council may establish standing and *ad hoc* subcommittees and/or working groups to provide assistance for carrying out its function. These subgroups may consist of members of the Advisory Council, as well as other individuals (federal and non-federal) who are concerned and knowledgeable about antibiotic-resistant bacteria and other topics pertaining to the Advisory Council mission.

The Department Committee Management Officer will be notified upon establishment of each subcommittee or working group, and will be provided information on its name, membership, function, and estimated frequency of meetings. All reports and recommendations of a subcommittee or workgroup must be reported back to the full Advisory Council for action. No activity of a subcommittee or working group can be given directly to the Secretary without being provided for discussion by the full Advisory Council.

Recordkeeping

Records of the Advisory Council and the respective subcommittees or working groups will be handled in accordance with General Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of information Act, 5 U.S.C. 552.

Filing Date: MAR 24 2015

Approved:

Jira M. Burwell

MAR 24 2015

Date: