

CHARTER

PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Committee's Official Designation

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (“the Advisory Council”).

Authority

The Advisory Council was established initially under Executive Order 13676, dated September 18, 2014. Per the delegation of authority dated March 3, 2020, the President of the United States has delegated his authority to the Secretary of the U.S. Department of Health and Human Services under section 9(a)(1) of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. 10), to renew the Advisory Council. Pursuant to this delegation of authority, the Secretary is renewing the Advisory Council. Per the President's delegation of authority, the Secretary may direct the Advisory Council to perform duties consistent with those assigned to the Advisory Council in section 505(b) of Public Law 116-22 (June 24, 2019), the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA), and may, in the Secretary's discretion, specify the membership of the Advisory Council, consistent with the requirements of the FACA.

Objectives and Scope of Activities

The Advisory Council shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The Advisory Council shall function solely for advisory purposes.

Description of Duties

In carrying out its mission, the Advisory Council shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. Such advice, information, and recommendations may be related to improving:

1. The effectiveness of antibiotics;
2. Research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities;
3. Surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics;

4. Education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals;
5. Methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and
6. Coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

Agency or Official to Whom the Committee Reports

As stipulated in PAHPAIA, the Advisory Council provides advice, information, and recommendations to the Secretary.

Support

To the extent permitted by law and subject to the availability of appropriations, the Department of Health and Human Services (HHS or the Department) 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.

Estimated Annual Operating Costs and Staff Years

The estimated annual cost for operating the Advisory Council, including travel expenses for members, but excluding staff support, is \$582,622. The estimate for annual person years of staff support required is 3.0, at an estimated annual cost of \$542,378.

Pursuant to an advance written agreement, the SGE voting members shall receive no stipend from the federal government for the services they perform during their tenure on the Advisory Council. However, the SGE 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 representative members 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, as determined by the DFO.

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.

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, and/or Alternate DFO, 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 shall meet not less than two times per year, and, to the extent practicable, in coordination with meetings of the Antimicrobial Resistance Task Force established in section 319E(a) of the Public Health Service Act (42 U.S.C. 247d-5(a)). 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 FACA. 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.

Termination

Unless renewed by appropriate action, the charter for the Advisory Council will terminate two years from the date it is filed.

Membership and Designation

The Advisory Council will consist of at least 30 members, including the voting and non-voting members and the Chair and Vice Chair. The Secretary will designate the Chair and Vice Chair from among the voting, special government employee (SGE) 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.

Special Government Employees (voting members). All public voting members will be classified as special government employees (SGEs). SGE members will be selected from individuals who are engaged in a range of fields intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance in humans, animals, or its presence in the environment. Examples include 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 SGEs will represent balanced points of view from human biomedical, public health, environmental, 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. These 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 SGEs will be appointed by the Secretary.

Regular Government Employee Members (non-voting). The Advisory Council will include members selected to represent various federal agencies that are involved in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research for human, animal, or environmental health. The federal *regular government employee (RGE)* members shall possess the knowledge, skills, experience, and expertise necessary to inform the Advisory Council in generating intelligent recommendations with respect to the issues mandated by Public Law No. 116-22, PAHPAIA. Federal agencies will be invited to participate as non-voting *RGE* members of the Advisory Council, as it is deemed necessary by the Secretary to accomplish the mission the Advisory Council.

Liaison Representative Members (non-voting). The Advisory Council structure also may include non-voting liaison representative members from organizations and/or interest groups that have involvement in the advocacy, education, development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. Non-voting liaison representative members shall possess the knowledge, skills, experience, and expertise necessary to inform the Advisory Council in generating intelligent recommendations with respect to the issues mandated by Public Law No. 116-22, PAHPAIA. Individuals from among the following sample sectors may be invited to serve as non-voting liaison representative members:

- Professional organizations or associations representing providers or professionals for human and/or animal health involved in infection control and prevention; this can include physicians, nurses, pharmacists, microbiologists, veterinarians.

- Public health, environmental health, and/or animal health organizations or associations (state/territorial, county, or local) representing laboratories, health officials, epidemiologists, agricultural state departments, or environmental associations.
- Other organizations representing patients and consumer advocates, hospitals, pharmaceutical industry, food producers and retailers, or other commodity groups.

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

Terms. The SGE voting members will be appointed to serve for terms of up to four years; newly appointed members will serve up to four years while renewed members may serve up to an additional three years. The non-voting liaison representative members will serve two-year terms. Any member who is appointed to fill the vacancy of an unexpired term will be appointed to serve for the remainder of that term. A member may serve after the expiration of their term until their successor has taken office, but no longer than 180 days.

Subcommittees

With approval or recommendation of the Secretary or designee, the Advisory Council may establish standing and *ad hoc* subcommittees to provide assistance for carrying out its function. The subcommittee shall consist of only members of the Advisory Council. The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be provided information on its name, membership, function, and estimated frequency of meetings. All reports and recommendations of a subcommittee must be reported back to the full Advisory Council for deliberation and action. No advice or work products of a subcommittee can be given directly to the Secretary.

Recordkeeping

Records of the Advisory Council and the respective subcommittees or working groups will be handled in accordance with General Schedule 6.2 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:

Approved:

Date

Xavier Becerra