



CHARTER

ADVISORY COMMITTEE ON ORGAN TRANSPLANTATION

1. Committee's Official Designation: The Committee shall be known as the Advisory Committee on Organ Transplantation (ACOT or "the Committee").
2. Authority: Authorized by 42 U.S.C. 217a; Section 222 of the Public Health Service Act, as amended. The Committee is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463 (5 U.S.C. App. 2), which sets forth standards for the formation of advisory committees.
3. Objectives and Scope of Activities: ACOT shall provide advice to the Secretary on proposed Organ Procurement and Transplantation Network (OPTN) policies and such other matters as the Secretary determines.
4. Description of Duties: The Committee shall: (1) advise the Secretary, acting through the Administrator, Health Resources and Services Administration (HRSA) on all aspects of organ donation, procurement, allocation and transplantation, and on such other matters that the Secretary determines; (2) advise the Secretary on Federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation; (3) at the request of the Secretary, review significant proposed OPTN policies submitted for the Secretary's approval to recommend whether they should be made enforceable; and (4) provide expert input to the Secretary on the latest advances in the science of transplantation, the OPTN's system of collecting, disseminating and ensuring the validity, accuracy, timeliness and usefulness of data, and additional medical, public health, patient safety, ethical, legal, financial coverage, social science, and socioeconomic issues that are relevant to transplantation.
5. Agency or Official to Whom the Committee Reports: The Committee provides advice to the Secretary of Health and Human Services, acting through HRSA's Administrator.
6. Support: Management and support services shall be provided by the Healthcare Systems Bureau, HRSA.
7. Estimated Annual Operating Costs and Staff Years: Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support is \$113,100. The estimate of annual person-years of staff support required is .62, at an estimated annual cost of \$104,020.

8. Designated Federal Officer (DFO): A full-time employee, appointed in accordance with Agency procedure. The DFO will approve or call all ACOT and subcommittees meetings, prepare and approve all meetings agendas, attend all ACOT and subcommittee meetings, adjourn any meetings when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Advisory Committee reports. The DFO or his/her designee shall be present at all meetings of the full Committee and subcommittees. In the event that the DFO cannot fulfill the assigned responsibilities for the Committee, then the HRSA Administrator (or designee) will temporarily appoint one or more permanent full-time or part-time employees to serve as DFO.
9. Estimated Number and Frequency of Meetings: Meetings may be held up to three (3) times during the fiscal year. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act, 5 U.S.C. 552b(c), and FACA. Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.
10. Duration: Continuing.
11. Termination: Unless renewed by appropriate action prior to its expiration, this charter will expire 2 years from the date the charter is filed.
12. Membership and Designation: The Committee shall consist of up to 25 members, who are Special Government Employees (SGEs), and 6 ex-officio, non-voting members. SGEs and the Chair (who is also an SGE) shall be selected by the Secretary from individuals knowledgeable in such fields as deceased and living organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, living organ donors, and family members of deceased and living organ donors. Concurrent service on ACOT and the OPTN Board of Directors is not permitted. To the extent practicable, committee SGEs should represent the minority, gender, and geographic diversity of the transplant candidates, transplant recipients, organ donors, and family members served by the OPTN.

The ex-officio, non-voting members shall include Directors of the National Institutes of Health, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality; the Administrator of the Centers for Medicare and Medicaid Services; and the Commissioner of the Food and Drug Administration – or their designees. The Secretary also may appoint other non-voting ex-officio members, or designees of such officials, as the Secretary deems necessary for the Committee to effectively carry out its function.

SGEs shall be invited to serve for a term of up-to 4 years.

13. Subcommittees: Standing and ad hoc subcommittees, composed of members of the parent committee, and others, with approval and/or recommendation of the DFO, may be established to perform specific functions within the Committee's jurisdiction. Subcommittees must report to the parent committee, and do not provide advice or work products directly to the Department or agency. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.
14. Recordkeeping: Records of ACOT, formally and informally established subcommittees, or other subgroups of ACOT, shall be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved Agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

15. Filing Date: August 31, 2020

Approved: August 31, 2020

August 31, 2020
Date



Thomas J. Engels
Administrator, Health Resources and Services
Administration