DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, Maryland 20857

CHARTER

ADVISORY COMMITTEE ON ORGAN TRANSPLANTATION (ACOT)

Authority

42 U.S.C. 217a; Section 222 of the Public Health Service Act, as amended; 42 CFR 121.12. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Objectives and Scope of Activities

The ACOT shall provide advice to the Secretary on proposed Organ Procurement and Transplantation Network (OPTN) policies and such other matters as the Secretary determines.

Description of Duties

The Committee shall 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. One of its principal functions shall be to 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.

The Committee shall, 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. It shall 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.

Agency or Official to Whom the Committee Reports

The Committee provides advice to the Secretary of Health and Human Services, acting through the Administrator, Health Resources and Services Administration (HRSA).

Support

Management and support services shall be provided the Healthcare Systems Bureau, Health Resources and Services Administration (HRSA).

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 $120,200. Estimated annual person-years of staff support required is .82, at an estimated annual cost of $147,583.

Designated Federal Officer (DFO)
A full-time employee, appointed in accordance with Agency procedures, will serve as the DFO (or designee). In the event that the DFO cannot fulfill the assigned responsibilities for the Committee, then the HRSA Administrator (or her designee) will temporarily appoint one or more permanent full-time or part-time employees to carry out the assigned duties. The DFO will approve or call all of the 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.

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 and the Federal Advisory Committee Act. 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.

Duration
Continuing.

Termination
Unless renewed by appropriate action prior to its charter expiration, this Committee will terminate two years from the date the charter is filed.

Membership and Designation
The Committee shall consist of up to 25 members, who are Special Government Employees, and 6 ex-officio, non-voting members. Members and Chair 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. Members shall not serve while they are also serving on the OPTN Board of Directors. To the extent practicable, Committee members should represent the minority, gender and geographic diversity of 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 and Prevention, and the Agency for Healthcare Research and Quality; the Administrator of the Centers for Medicare and Medicaid Services; the Commissioner of the Food and Drug Administration; and the Chair of the Advisory Committee on Blood Safety and Availability – 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.

Members shall be invited to serve for 4-year terms.

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 back 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.

Recordkeeping

Records of the 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, subjects to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date

September 1, 2016.

APPROVED:

AUG 30 2016
Date

Jason E. Bennett
Director, Division of the Executive Secretariat