

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

CHARTER

This Charter governs the structure and operation of the Organ Procurement and Transplantation Network (OPTN). By accepting membership in the OPTN, each Member agrees to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; OPTN Final Rule, 42 CFR Part 121; this Charter; the OPTN Bylaws; and OPTN policies as in effect from time to time. The OPTN will conduct ongoing and periodic reviews and evaluations of each Member OPO and Transplant Hospital for compliance with the OPTN Final Rule and OPTN policies. All OPTN Members are subject to review and evaluation for compliance with OPTN policies. All such compliance monitoring is performed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), to operate the OPTN (OPTN Contract).

ARTICLE I. Organization

The OPTN is a private, not-for-profit entity with an expertise in organ procurement and transplantation. The OPTN is a part of the OPTN Contractor's organization and operations. The OPTN Contractor is United Network for Organ Sharing (UNOS), a Virginia non-stock, not-for-profit corporation which is qualified as a tax-exempt public charity under Section 501(c)(3) of the Internal Revenue Code. The OPTN Contract has a current term of October 1 through September 30, 2003, with two possible extensions of one year each.

ARTICLE II. Purpose

The primary purposes of the OPTN are to operate and monitor an equitable system for allocating organs donated for transplantation; maintain a waiting list of potential recipients; match potential recipients with organ donors according to established medical criteria for allocation of organs and, to the extent feasible, for listing and de-listing transplant patients; facilitate the efficient, effective placement of organs for transplantation; and increase organ donation. To accomplish these purposes, the OPTN:

- (a) Establishes, maintains, and monitors compliance with voluntary and mandatory membership criteria/policies and procedures for institutions and interested parties and training and experience criteria as consistent with Federal regulations for primary personnel at transplant programs. Policies may become mandatory through a process involving consideration and recommendation as a mandatory policy by the OPTN and official adoption by the Secretary of the Department of Health and Human Services (HHS) of the policy as mandatory.
- (b) Establishes, maintains, and monitors compliance with voluntary and mandatory criteria/policies and procedures for the safe and efficient acquisition and transportation of donor organs and for the allocation and distribution of these organs equitably among transplant patients, consistent with Federal law and regulations. Policies may become mandatory through a process involving consideration and recommendation as a mandatory policy by the OPTN and official adoption by the Secretary of HHS of the policy as mandatory.
- (c) Collects, analyzes, and publishes data on pre-transplant and post-transplant events to advance the fields of organ transplantation, organ procurement, organ preservation, and immunogenetics.

ARTICLE III. Board of Directors

The OPTN shall be governed by a Board of Directors composed of not less than 34 nor more than 44 members. The Board of Directors shall include:

- (a) Approximately 50% transplant surgeons and physicians;

- (b) At least 25% transplant candidates, transplant recipients, organ donors, and family members representing the diversity of the population of transplant candidates, transplant recipients, organ donors, and family members served by the OPTN, including, to the extent practicable, the minority and gender diversity of this population. These members shall be required to certify that they are not employees of, and do not have a similar relationship with Organ Procurement Organizations (OPOs) (defined below), Transplant Hospitals (defined below), voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant professionals. The Board of Directors may, however, waive this requirement for not more than 50% of this category of members;
- (c) Representatives of OPOs, Transplant Hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public, as well as at least one member representing pediatric-specific interests; and
- (d) The Project Officer for the OPTN Contract and the Director of the Division of Transplantation, within the Health Resources and Services Administration, HHS, or their designees, as *ex-officio*, non-voting members.

The Board of Directors shall elect an Executive Committee from the membership of the Board and establish such other committees as are necessary to perform the duties of the OPTN.

The OPTN Board of Directors shall be elected in parallel with and using the same processes as the OPTN Contractor's Board of Directors, resulting in identical memberships, if the OPTN Contract provides for such an arrangement. This will enable the OPTN Contractor to perform tasks required by the OPTN Contract under the governance of the OPTN Board of Directors. Activities of the Board of Directors, while constituted as the OPTN Board, shall be limited to activities of the OPTN (*i.e.*, those activities for which costs are reimbursed under the OPTN Contract). To accomplish this, separate agendas or sections within combined agendas shall identify OPTN versus OPTN Contractor business. The Board of Directors shall convene as the OPTN Board for purposes of conducting OPTN affairs and the OPTN Contractor Board for purposes of conducting OPTN Contractor affairs. Consistent with this framework, OPTN Committees are appointed in parallel with OPTN Contractor Committees and operate under these same procedures.

ARTICLE IV. Membership.

There shall be five categories of members of the OPTN. These are: Institutional Members, Medical/Scientific Members, Public Organization Members, Business Members, and Individual Members. By amendment to the Bylaws of the OPTN, the Board of Directors may establish additional categories of Members in order to conform to requirements of law and regulations applicable to the OPTN.

(a) **Institutional Members.** An Institutional Member shall be one of the following:

- (i) An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation, other than OPTN membership (OPO).
- (ii) A hospital (a) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (b) that participates in the Medicare or Medicaid programs (Transplant Hospital).
- (iii) An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility

Laboratory). For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals.

(b) **Medical/Scientific Members.** A Medical/Scientific Member shall meet the following criteria:

- (i) An established, non-profit organization or institution with at least one year of operating history that has an interest in the fields of organ donation or transplantation, defined as:
 - (a) An organization or institution that serves as a medical or scientific membership organization and includes within its membership professional members who are involved in organ transplantation, or
 - (b) An organization or institution that is supported by letters of recommendation for OPTN membership from at least three other organizations or institutions, each of which meets the criteria for Institutional Membership listed in Article IV(a) above, Medical/Scientific Membership listed in Article IV(b)(i)(a) above, or Public Organization Membership listed in Articles IV(c)(i)(a) or IV(c)(ii) below.

(c) **Public Organization Members.** A Public Organization Member shall meet the following criteria:

- (i) An established, non-profit organization or institution with at least one year of operating history that has an interest in the fields of organ donation or transplantation, defined as:
 - (a) An organization or institution that engages in organ donation activities or represents or provides direct support or services to transplant recipients, transplant candidates, or their families, or
 - (b) An organization or institution that is supported by letters of recommendation for OPTN membership from at least three other organizations or institutions, each of which meets the criteria for Institutional Membership listed in Article IV(a) above, Medical/Scientific Membership listed in Article IV(b)(i)(a) above, or Public Organization Membership listed in Article IV(c)(i)(a) above or Article IV(c)(ii) below, or
- (ii) A hospital with at least one year of operating history that participates in the Medicare or Medicaid programs and has an interest in the fields of organ donation or transplantation, defined by the referral of at least one potential organ or tissue donor per year for donation.

The Board of Directors shall from time to time review these criteria and establish as part of the Bylaws of the OPTN, additional membership requirements for Institutional Members, Public Organization Members, and Medical/Scientific Members.

(d) **Business Members.** A Business Member shall be an established organization or institution with at least one year of operating history that has an interest in the fields of organ donation or transplantation, defined as engaging in commercial activities with two or more active Institutional Members.

(e) **Individual Members.** An Individual Member shall be a person with an interest and/or expertise in the fields of organ donation or transplantation, defined to include one or more of the following:

- (i) Individuals who have served or are presently serving on the OPTN Board of Directors, or an OPTN Committee.
- (ii) Individuals who are themselves or are family members of: a transplant candidate, transplant recipient, or organ or tissue donor.
- (iii) Individuals who are presently employed by or are independent contractors with OPOs, Transplant Hospitals, or Histocompatibility Laboratories.
- (iv) Individuals who were formerly employed by or were formerly independent contractors with OPOs, Transplant Hospitals, or Histocompatibility Laboratories and individuals formerly employed by Federal or State government agencies involved in the field of organ donation and transplantation, who demonstrate continued active interest in and involvement with the fields of organ donation or transplantation.
- (v) Individuals who otherwise have an active interest in and involvement with the fields of organ donation or transplantation demonstrated by letters of recommendation for OPTN membership from at least three persons, each of whom meets the criteria for Individual Membership listed in Article IV(e) (i,)-(iv) above.