

## **ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)**

### **BYLAWS**

These Bylaws govern 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; these 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

### MEMBERS

- 1.1 Membership Categories.** 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. References in these Bylaws to “Members” shall include Institutional Members, Public Organization Members, Medical/Scientific Members, Business Members, and Individual Members, except as otherwise noted. By amendment to the Bylaws, the Board of Directors may establish additional categories of Members so long as they conform to requirements of law and regulations applicable to the OPTN.
- 1.2 Institutional Members.** An Institutional Member shall be one of the following:
- a.** 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).
  - b.** A hospital (i) 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 (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital).
  - c.** 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.
- 1.3 Medical/Scientific Members.** A Medical/Scientific Member shall meet the following criteria:
- a.** 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:
    - (1) 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
    - (2) 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 1.2 above, Medical/Scientific Membership listed in Article 1.3(a)(1) above, or Public Organization Membership listed in Articles 1.4(a)(1) or 1.4(b) below.
- 1.4 Public Organization Members.** A Public Organization Member shall meet the following criteria:
- a.** 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:

- (1) 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
  - (2) 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 1.2 above, Medical/Scientific Membership listed in Article 1.3(a)(1) above, or Public Organization Membership listed in Article 1.4(a)(1) above or Article 1.4(b) below, or
- b. 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 these Bylaws, Appendix B, additional membership requirements for Institutional Members, Public Organization Members, and Medical/Scientific Members. Failure to conform with such requirements shall be cause for any corrective action described in Appendix A of these Bylaws.

- 1.5 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.

The Board of Directors shall from time to time review these criteria and establish as part of these Bylaws additional membership requirements for Business Members. Failure to conform with such requirements shall be cause for any corrective action described in Appendix A of these Bylaws.

- 1.6 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:

- a. Individuals who have served or are presently serving on the OPTN Board of Directors, or an OPTN Committee.
- b. Individuals who are themselves or are family members of: a transplant candidate, transplant recipient, or organ or tissue donor.
- c. Individuals who are presently employed by or are independent contractors with OPOs, Transplant Hospitals, or Histocompatibility Laboratories.
- d. 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.
- e. 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 1.6 (a, b, c, or d) above.

- 1.7 Application Process and Requirements/Appeal Protocol.** The process and requirements for applying to be an OPTN Member are set forth in Appendix A of these Bylaws. The protocol for appealing decisions of the OPTN with respect to membership also are set forth in Appendix A. Members shall be elected by majority vote of the Directors present at any meeting at which a quorum is present.

- 1.8 Terms.** The term of an Institutional Member shall be indefinite. The term of Public Organization Members, Medical/Scientific Members, Business Members, and Individual Members shall be two years;

any of these Members may serve for successive terms upon application and approval for such term. Public Organization Members, Medical/Scientific Members, Business Members, and Individual Members may resign at any time by written notice to the Executive Director.

**1.9 Voting Privileges and Responsibilities.** There shall be six classes of voting Members: (i) Transplant Hospital Members, (ii) OPO Members, (iii) Histocompatibility Laboratory Members, (iv) Medical/Scientific Members, (v) Public Organization Members, and (vi) Individual Members. OPTN Members designated “OPTN Members Not in Good Standing” shall not have voting or other OPTN Member privileges until such designation has been removed; provided, however, that all OPTN Members, including Members designated “OPTN Members Not in Good Standing” shall be obligated to comply with OPTN Member responsibilities. Business Members shall not be entitled to voting privileges in OPTN affairs.

**a. Transplant Hospital Members.** Each Transplant Hospital Member shall be entitled to one vote on OPTN affairs requiring a vote of the Membership; provided, however, that a Transplant Hospital must have received approval as a designated transplant program for at least one organ before it is entitled to vote on affairs of the OPTN.

**b. OPO Members.** Each OPO Member shall be entitled to one vote on OPTN affairs requiring a vote of the Membership; provided, however, that an OPO must be independent of the Transplant Hospital(s) it serves, which may include a single Transplant Hospital, before it is entitled to vote on affairs of the OPTN. 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 OPO that is separate and not under the direct or indirect control of the governing body of any of the OPO’s Transplant Hospitals or of the governing body of a commonly controlled group of the OPO’s Transplant Hospitals.

**c. Histocompatibility Laboratory Members.** Histocompatibility Laboratories, as a class, shall be represented by 33 separate Histocompatibility Laboratory Member Electors. Each Histocompatibility Laboratory Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Histocompatibility Laboratory Member Electors shall be elected by and from among the Histocompatibility Laboratory Members as follows:

(i) Histocompatibility Laboratory Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect two Histocompatibility Laboratory Member Electors from their respective region. If there are no Histocompatibility Laboratory Members residing within a Region, then the number of national Histocompatibility Laboratory Member Electors described in (ii) below shall be increased by two for every such Region without Histocompatibility Laboratory Members.

(ii) All Histocompatibility Laboratory Members, collectively, shall elect eleven national Histocompatibility Laboratory Member Electors or, if there are no Histocompatibility Laboratory Members residing in one or more regions, as many national Histocompatibility Laboratory Member Electors as necessary so that there are no more than and no fewer than 33 Histocompatibility Laboratory Member Electors.

(iii) Any person serving as or designated by the named OPTN Representative for a Histocompatibility Laboratory Member may serve as a Histocompatibility Laboratory Member Elector upon nomination for and election to this office. OPTN Representatives for Histocompatibility Laboratory Members may submit their own names as candidates for Histocompatibility Laboratory Member Elector, representing Histocompatibility Laboratory Members at the regional or national level. For the number of Histocompatibility Laboratory Member Electors to be elected regionally or nationally, those receiving the highest number of votes among eligible candidates shall be elected.

(iv) The term of a Histocompatibility Laboratory Member Elector shall be two years. Histocompatibility Laboratory Member Electors may serve successive terms.

(v) Nominations and elections for Histocompatibility Laboratory Member Elector shall be conducted through the Internet using the OPTN web site, [www.optn.org](http://www.optn.org), and/or the United States mail.

The number of Histocompatibility Laboratory Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 9% and 11% of the then current total number of Institutional Members.

Notwithstanding the foregoing, in the event the total number of Histocompatibility Laboratory Members at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Histocompatibility Laboratory Member Electors, the process for voting through Member Electors described above shall be suspended and each such Histocompatibility Laboratory Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.

**d. Medical/Scientific Members.** Medical/Scientific Members that provide services and/or are involved in activities on an interregional or national basis, as a class, shall be represented by 24 separate national Medical/Scientific Member Electors. Each Medical/Scientific Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Medical/Scientific Member Electors shall be elected by and from among the Medical/Scientific Members as follows:

- (i) All Medical/Scientific Members, collectively, shall elect the 24 national Medical/Scientific Member Electors.
- (ii) Any person serving as or designated by the named OPTN Representative for a Medical/Scientific Member may serve as a Medical/Scientific Member Elector upon nomination for and election to this office. OPTN Representatives for Medical/Scientific Members may submit their own names as candidates for Medical/Scientific Member Elector, representing Medical/Scientific Members at the national level. For the number of Medical/Scientific Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.
- (iii) The term of a Medical/Scientific member Elector shall be two years or the remaining OPTN Membership term of the Medical/Scientific member with whom the Medical/Scientific Member Elector is affiliated, whichever is shorter. Medical/Scientific Member Electors may serve successive terms.
- (iv) Nominations and elections for Medical/Scientific Member Elector shall be conducted through the Internet using the OPTN web site, [www.optn.org](http://www.optn.org), and/or the United States mail.

The number of Medical/Scientific Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 6% and 8% of the then current total number of Institutional members.

Medical/Scientific Members must provide services and/or be involved in activities on an interregional or national basis to participate in the election of Medical/Scientific Member Electors.

Notwithstanding the foregoing, in the event the total number of Medical/Scientific Members in good standing at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Medical/Scientific Member Electors, the process for voting through Member Electors described above shall be suspended and each such Medical/Scientific Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.

**e. Public Organization Members.** Public Organization Members that provide services and/or are involved in activities on an interregional or national basis, as a class, shall be represented by 12 separate Public Organization Member Electors. Each Public Organization Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Public Organization Member Electors shall be elected by and from among the Public Organization Members as follows:

- (i) Public Organization Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect one Public Organization Member Elector from their respective region. If there are no Public Organization Members residing within a Region, then the number of national

- Public Organization Member Electors described in (ii) below shall be increased by one for every such Region without Public Organization Members.
- (ii) All Public Organization Members, collectively, shall elect a twelfth national Public Organization Member Elector or, if there are no Public Organization Members residing in one or more regions, as many national Public Organization Member Electors as necessary so that there are no more than and no fewer than 12 Public Organization Member Electors.
  - (iii) Any person serving as or designated by the named OPTN Representative for a Public Organization Member may serve as a Public Organization Member Elector upon nomination for and election to this office. OPTN Representatives for Public Organization Members may submit their own names as candidates for Public Organization Member Elector, representing Public Organization Members at the regional or national level. For the number of Public Organization Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.
  - (iv) The term of a Public Organization Member Elector shall be two years or the remaining OPTN Membership term of the Public Organization Member with whom the Public Organization Member Elector is affiliated, whichever is shorter. Public Organization Member Electors may serve successive terms.
  - (v) Nominations and elections for Public Organization Member Elector shall be conducted through the Internet using the OPTN web site, [www.optn.org](http://www.optn.org), and/or the United States mail.

The number of Public Organization Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 3% and 5% of the then current total number of Institutional Members.

Public Organization Members must provide services and/or be involved in activities on an interregional or national basis to participate in the election of Public Organization Member Electors.

Notwithstanding the foregoing, in the event the total number of Public Organization Members at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Public Organization Member Electors, the process for voting through Member Electors described above shall be suspended and each such Public Organization Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.

- f. Individual Members.** Individual Members, as a class, shall be represented by 12 separate Individual Member Electors. Each Individual Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Individual Member Electors shall be elected by and from among the Individual Members as follows:
- (i) Individual Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect one Individual Member Elector from their respective region. If there are no Individual Members residing within a Region, then the number of national Individual Member Electors described in (ii) below shall be increased by one for every such Region without Individual Members.
  - (ii) All Individual Members, collectively, shall elect a twelfth national Individual Member Elector or, if there are no Individual Members residing in one or more regions, as many national Individual Member Electors as necessary so that there are no more than and no fewer than 12 Individual Member Electors.
  - (iii) With the exception of employees currently employed by or independent contractors currently working with OPOs, Transplant Hospitals, or Histocompatibility Laboratories, any Individual Member may serve as an Individual Member Elector upon nomination for and election to this office. Individual Members may submit their own names as candidates for Individual Member Elector, representing Individual Members at the regional or national level. For the number of Individual Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.

- (iv) The term of an Individual Member Elector shall be two years or the remaining OPTN Membership term of the Individual Member elected to the office of Individual Member Elector, whichever is shorter. Individual Member Electors may serve successive terms.
- (v) Nominations and elections for Individual Member Elector shall be conducted through the Internet using the OPTN web site, [www.optn.org](http://www.optn.org), and/or the United States mail.

The number of Individual Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 3% and 5% of the then current total number of Institutional Members.

Notwithstanding the foregoing, in the event the total number of Individual Members at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Individual Member Electors, the process for voting through Member Electors described above shall be suspended and each such Individual Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.

Affairs of the OPTN involving a vote of the Membership include, for example, election of the Board of Directors (see Article II of these Bylaws), election of the Principal Officers (see Article VI of these Bylaws), and amendment of these Bylaws (see Article X of these Bylaws).

Cumulative voting on affairs of the OPTN is not allowed.

Upon being elected to Membership in the OPTN, each Institutional Member, Medical/Scientific Member and Public Organization Member shall indicate its acceptance by appointing a representative with authority to vote and act for the Member in all affairs of the OPTN and an alternate representative who shall have such authority if the representative is unable to vote or act. Additionally, each Institutional Member, Medical/Scientific Member and Public Organization Member shall notify the Executive Director in writing of the name and address of its representative, to whom all notices may be sent, and of its alternate representative. Upon being elected to Membership in the OPTN, each Business Member shall indicate its acceptance by designating in writing the name of a representative and address to which notices may be sent. Upon his or her election, each Individual Member shall notify the Executive Director in writing of his or her name and address to which notices may be sent.

A majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Member Electors, Medical/Scientific Member Electors, Public Organization Member Electors, and Individual Member Electors, eligible to vote represented in person or by proxy, shall constitute a quorum for the transaction of business at any meeting. A vote of a majority of those present and eligible to vote shall be sufficient to transact any business that might come before the meeting, except where a greater or lesser vote is provided for in the Bylaws.

- 1.10 Member Obligations.** 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; these 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 OPTN Contract. The failure of an organ procurement organization Institutional Member, independent histocompatibility laboratory Institutional Member, Medical/Scientific Member, Public Organization Member, Business Member, or Individual Member to qualify as an OPTN Member according to the administrative requirements under Articles 1.2 – 1.6 of these Bylaws (*e.g.*, an organ procurement organization that ceases to be designated under Section 1138(b) of the Social Security Act) shall be dealt with in accordance with Article 1.11 of these Bylaws.

### **1.11 Removal of Non-Qualifying Members.**

- a. Transplant center Institutional Members that fail to qualify as an OPTN Member under Article 1.2(b) shall be treated in accordance with Article II of Appendix B to these Bylaws.
- b. All other OPTN Members who cease to qualify for OPTN membership under Article I of these Bylaws may be removed as OPTN Members in accordance with the following procedures:
  1. The Member may request removal from OPTN membership by forwarding a written request therefor to the OPTN, or
  2. Even if the Member does not request removal, the OPTN may notify the Member in writing that, unless the Member demonstrates that it continues to meet applicable membership criteria within sixty (60) days of notification, the Member's OPTN membership will be terminated.
    - i. If, within sixty (60) days of such notification, the Member demonstrates, to the satisfaction of the OPTN, that the Member continues to meet OPTN membership requirements, the OPTN shall withdraw its notice of termination.
    - ii. If the Member fails to demonstrate that it continues to meet applicable OPTN membership requirements, its membership in the OPTN will terminate on the sixtieth (60th) day after notification of termination by the OPTN. The Member can appeal this decision to the Secretary of HHS. In the event a Member exercises this right of appeal, the Member shall notify the OPTN Contractor of this exercise by registered or certified mail, return receipt requested. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Secretary shall be submitted to the Membership and Professional Standards Committee or Board of Directors as appropriate for action consistent with the Secretary's decision.
- c. Any Member that requests removal from OPTN membership or is otherwise removed from OPTN membership under this Article 1.11 may later re-apply for membership in accordance with Article 1.7 of these Bylaws.

- 1.12 Meetings.** The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Member Electors, Public Organization Member Electors, Medical/Scientific Member Electors, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to the OPTN. Meetings of the OPTN membership typically shall be open to the public; however, discussions involving confidential matters including, OPTN member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract. Representatives from the Federal government serving on the Board of Directors, or their designees, shall not be precluded from attending such closed sessions of OPTN meetings.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be mailed to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

**1.13 Registration Fees.** Institutional Members shall pay an OPTN Patient Registration Fee to be set by the Board of Directors with approval from the Secretary of HHS for each potential organ recipient listed by such member institution on the computer system waiting list maintained by the OPTN Contractor. If a potential recipient is either placed in an inactive status or removed from the waiting list for some reason other than a transplant and is subsequently placed back on the list in an active status within 90 days, no additional fee will be due. However, placing a patient back on the list after the 90 day allowance or maintaining the patient on the list for the purpose of receiving a new transplant generates another registration fee. Furthermore, potential recipients who are transferred to Transplant Hospitals that are outside the original local OPO's waitlist will cause another registration fee to be paid by the receiving center.

Potential recipients who are listed at multiple Transplant Hospitals will cause a registration fee to be paid by each hospital.

Members who list patients needing more than a single organ transplant (*e.g.*, kidney and pancreas) will only be charged one registration fee.

**1.14 Expenses Incurred on Behalf of Members.** In the event the OPTN Contractor incurs expenses on behalf of a Member pursuant to providing assistance to that Member by, for example, transporting an organ, including but not limited to, courier charges, airline, or other transportation charges, such Member shall reimburse the OPTN Contractor for the expenses incurred.

**1.15 Affiliated Organizations.** Nothing in this Article I shall require an OPTN Member to become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN, to comply with bylaws of any such organization, or to assume any corporate duties or obligations of any such organization.

