OPTN Policy Notice Change to Hospital-Based OPO Voting Privileges

| Sponsoring Committee: | Membership and Professional Standards Committee |
|-------------------------|--|
| Policy/Bylaws Affected: | OPTN Bylaws, Article I: Membership; Appendix B, Membership Requirements for Organ Procurement Organizations (OPOs); and Appendix M: Definitions |
| Public Comment: | August 3, 2018 – October 3, 2018 |
| Effective Date: | December 4, 2018 |

Problem Statement

The OPTN received a request in February 2018 from the administrative directors of the seven Hospitalbased Organ Procurement Organizations (HOPOs).¹ This request provided reasons for changing the Bylaws to grant HOPOs individual votes on OPTN matters, instead of the single vote that was provided for OPOs and transplant hospitals located within the same hospital.

A HOPO is accountable to all the transplant programs in its service area, and based on the Bylaws voting provisions, the representation of organ procurement interests in a hospital-based OPO's DSA was limited. A HOPO may have different perspectives than the transplant hospital with which it shares a vote.

The Committee agreed that separation between HOPO and the supporting transplant hospital leadership was necessary to demonstrate OPO independence for a separate vote. The Committee further agreed that the OPO administrator should be dedicated to running that OPO and must not report to an individual or body that is heavily influenced by the transplant hospital. The proposal was supported during public comment and approved by the Board of Directors on December 4, 2018.

Summary of Changes

The Board of Directors adopted the recommended changes to the Bylaws that provide the option for HOPO to apply for voting privileges

The newly approved language includes the following changes to OPTN Bylaws:

- Article I: Membership
 - A minor change was made to the table title to make it consistent with other sections of the Bylaws.
 - The header within the table was modified and the word "rights" replaced with "privileges" to make it consistent with the preceding language in that section of the Bylaws.
 - The description of the OPO voting privileges was expanded to include HOPOs that meet the qualifications in Section 1.3.C.
 - The language describing when a member can vote was stricken because it exists elsewhere in the Bylaws and does not need to be repeated here.

¹ Anderson, M, Balbis, D, Kochik, R, McBride, V, Seely, M, Seiler, S, Stocks, L, letter to Brian Shepard, February 12, 2018.

- Article 1.3: Members.
 - o It is not necessary to cite the CMS regulation number.
 - Section 1.3. A: The word "independent" was stricken since this bylaw proposal would now include HOPOs.
 - Section 1.3. C: The first paragraph was amended to address both types of OPOs. Independent OPOs have one vote, as would any HOPO that meets the qualifications delineated in this section.
 - Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)
 - The introductory portion of this section has been removed because it repeats the same language that is found in Appendix M (Definitions). There are no other changes in Appendix B.
- Appendix M: Definitions
 - Hospital-based OPO The definition was amended to be consistent with the CMS definition as found in Part 1, Chapter 31, Organ Acquisition Payment Policy.
 - o Independent OPO (IOPO) The voting language was removed from the definition.
 - Voting Members This section was amended to include hospital-based OPOs that meet the qualifications for voting privileges.

What Members Need to Do

The OPTN will distribute instructions to hospital based OPOs. If the OPO would like to apply for a separate OPTN vote from its supporting transplant hospital, the OPO will need to submit the following documents

- Letter requesting separate vote
- Supporting Documents
 - Organizational charts for the supporting transplant hospital and the OPO
 - Other documentation relevant to the OPO administrative director's role

The request will be reviewed by the MPSC, and it will make a recommendation to the OPTN Board of Directors. The Board will approval or reject the OPO's request for voting privileges. Voting privileges will be active upon Board approval.

If a HOPO, that has been granted separate voting privileges, no longer meets the qualifications it must notify UNOS in writing within 30 days of no longer meeting the qualifications and provide documentation of the reasons the qualifications are no longer met.

No other members will need to take any action to implement this proposal.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (example).

Article I: Membership

1.1 Membership Guidelines

B. Overview of the Voting Process

This section provides an overview of the voting process for OPTN members. Only these six membership categories have voting privileges:

- 1. Transplant hospital members
- 2. OPO members
- 3. Histocompatibility laboratory members
- 4. Medical/scientific members

- 5. Public organization members
- 6. Individual members

Business members do not have voting privileges in the OPTN.

OPTN members designated Members Not in Good Standing do not have voting or other membership privileges. However, members designated Members Not in Good Standing must continue to fulfill their OPTN member responsibilities.

Table 1-1 below summarizes the voting privileges for each OPTN membership type:

| Table 1-1: Membership Voting Privileges | | | |
|---|---|---|--|
| Membership Type | Number of Votes | Additional Requirements to Qualify for Voting Rights <u>Privileges</u> | |
| Transplant hospital | One per transplant hospital | The transplant hospital must have current approval as a designated transplant program for at least one organ. | |
| OPO | One per OPO | The OPO must be independent, <u>or a</u> <u>hospital-based OPO that is able to</u> <u>demonstrate all of the qualifications as</u> defined in <u>according to</u> <u>Section 1.3.C.</u> | |
| Histocompatibility laboratory | One per histocompatibility laboratory | The histocompatibility laboratory must be independent, as defined in <u>according</u> <u>to</u> <i>Section 1.4</i> . | |
| Medical/scientific | One per Medical/scientific member | None | |
| Public organization | No more than 12, cast by public organization member electors | Public organization members must provide services or be involved in national or regional activities. | |
| Individual | No more than 12, cast by individual member electors | None | |

Table 1-1: Membership Voting Privileges

A majority of all members eligible to vote, either in person or by proxy, constitutes a quorum for transacting business at any meeting of members. When a quorum is achieved, majority vote of members may transact any business at the meeting, except when different voting requirements are defined in these Bylaws. A member or member elector can may only vote once on each resolution.

OPTN business that requires a vote of the membership may include election of the Board of Directors (see Article II: Board of Directors), election of the officers (see Article VI: Officers), and amendment of these Bylaws (see Article X: Amendment of Charter and Bylaws).

1.3 OPO Members

An OPO member is any organ procurement organization (OPO), as designated by the Secretary of the HHS under *Section 1138(b)* of the Social Security Act or any organization that meets all

requirements under *Section 1138(b)* except for OPTN membership. <u>certified by the Center for</u> <u>Medicare/Medicaid Services (CMS), and designated as a qualified OPO by the Secretary of HHS.</u>

A. OPO Member Representatives

Independent Voting OPO members have the following responsibilities:

- 1. Appoint a representative to vote and act for the member in all affairs of the OPTN.
- 2. Appoint an alternate representative who will have authority if the representative is unable to vote or act.
- 3. Submit in writing to the Executive Director the name and address of its representative and alternative representative to receive all meeting notices.

C. OPO Membership Voting Privileges

Each OPO member has one vote, provided that the OPO is independent. <u>Each independent OPO</u> <u>member has one vote</u>. An independent OPO (IOPO) is defined for this purpose as one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves.

Hospital-based OPOs may request and will receive separate voting privileges from the supporting transplant hospital only if they can demonstrate *both* of the following:

- 1. <u>The hospital-based OPO administrative director is not in a leadership role within the</u> <u>transplant programs at the supporting transplant hospital. A leadership role is defined as a</u> <u>role that involves any administrative or organizational decision making responsibilities in any</u> <u>of the transplant programs at the transplant hospital.</u>
- 2. <u>The hospital-based OPO administrative director is not subordinate to the leadership in any</u> <u>transplant programs at the supporting transplant hospital.</u>

<u>A hospital-based OPO must submit a written request to the OPTN Contractor and provide</u> documentation demonstrating that it meets these qualifications to receive voting privileges.

If a hospital-based OPO that has been granted separate voting privileges no longer meets the qualifications above, then it must notify the OPTN Contractor in writing within 30 days of no longer meeting the qualifications and provide documentation of the reasons the qualifications are no longer met and the OPO will no longer have voting privileges. The OPO may reapply for voting privileges at any time that it meets the qualifications.

Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)

An OPO member is any OPO that has been designated by the Secretary of the U.S. Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or any organization that meets all requirements under Section 1138(b), except for OPTN membership.

Only independent OPOs (IOPO) have voting privileges in the OPTN. An IOPO is defined as one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves.

A hospital-based OPO is not independent from the transplant hospital it serves. Hospital-based OPOs are held to the same standards and requirements as OPO members, but do not have a vote on OPTN business separate from the vote granted the transplant hospital member that controls it.

For more information on membership types, terms, voting privileges, and responsibilities, see Article I: Membership of these Bylaws.

Definitions

Hospital-based OPO

Appendix M:

An organ procurement organization that is not independent from the transplant hospital it serves. <u>A hospital-based OPO receives financial support from the transplant hospital where it resides, or</u> the transplant hospital provides supervision over the operations to the extent that it represents <u>control over the hospital-based OPO's operations</u>. All OPOs must be designated by the Centers for Medicare and Medicaid Services (CMS) and are responsible for the procurement of organs for transplantation and the promotion of organ donation. Hospital-based OPOs are held to the same standards and requirements as OPO members. but do not have a vote on OPTN business separate from the vote granted the transplant hospital member with whom it is associated.

See also independent OPO and OPO member.

Independent OPO (IOPO)

An OPO that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves. An OPO member must be an IOPO to have a vote on OPTN business. See also *Hospital-based OPO* and *OPO member*.

Voting Members

References in these Bylaws to *voting members* include those members who have a vote on OPTN business. Voting members are transplant hospital members, independent OPO members (IOPOs), <u>hospital-based OPOs that qualify for voting privileges according to Section 1.3.C.</u>, independent histocompatibility laboratory members, medical/scientific members, public organization member electors, and individual member electors.

#