

Briefing Paper

Change to Hospital-Based OPO Voting Privileges

OPTN/UNOS Membership and Professional Standards Committee

*Prepared by: Sally Aungier
UNOS Member Quality Department*

Contents

Executive Summary	1
What problem will this proposal address?	2
Why should you support this proposal?	2
How was this proposal developed?	2
How well does this proposal address the problem statement?	4
Was this proposal changed in response to public comment?	5
Which populations are impacted by this proposal?	7
How does this proposal impact the OPTN Strategic Plan?	7
How will the OPTN implement this proposal?	8
How will members implement this proposal?	8
Hospital and Histocompatibility Laboratories	8
OPOs	8
Will this proposal require members to submit additional data?	8
How will members be evaluated for compliance with this proposal?	8
How will the sponsoring Committee evaluate whether this proposal was successful post implementation?	9
Policy or Bylaws Language	10

Change to Hospital-Based OPO Voting Privileges

Affected Policies: OPTN Bylaws, Article I: Membership; Appendix B, Membership Requirements for Organ Procurement Organizations (OPOs); and Appendix M: Definitions

Sponsoring Committee: Membership and Professional Standards Committee

Public Comment Period: August 3, 2018 – October 3, 2018

Board of Director's Date: December 3-4, 2018

Executive Summary

There exist multiple types of OPOs: independent OPOs and hospital-based OPOs (HOPOs). Under the current OPTN Bylaws, only independent OPOs are permitted to vote in OPTN matters; HOPOs do not have any voting privileges in OPTN elections except as a part of their supporting hospital. Recognizing that some HOPOs serve multiple transplant hospital members within their DSA and their interests may not always align with the single hospital with which they are affiliated, this proposal would grant HOPOs a vote in OPTN regional and national matters if the HOPO is able to demonstrate functional separation between the OPO and transplant programs of the transplant hospital member.

Allowing HOPOs to have a separate vote would allow a DSA's organ procurement interests to be represented in OPTN voting matters and primarily supports the OPTN strategic goal of promoting efficiency in the management of the OPTN.

What problem will this proposal address?

Appendix B of the Bylaws state, "A hospital-based OPO is not independent from the transplant hospital it serves." Furthermore, the Bylaws only provide a single vote to a hospital-based OPO (HOPO) and its corresponding transplant hospital. A HOPO is accountable to all the transplant programs in its service area, and based on the Bylaws current voting provisions, the representation of organ procurement interests in a hospital-based OPO's DSA is limited.

This is important because a HOPO may have different perspectives than the transplant hospital with which it shares a vote. Further, these Bylaws support a perception that the HOPO is under the control of the affiliated transplant hospital, potentially generating mistrust between the hospital-based OPO and other transplant hospitals within its DSA.

Why should you support this proposal?

This solution gives the HOPOs the opportunity to submit a request to be considered for voting status if it meets the qualifications. The HOPO must provide documentation of a level of separation from its supporting hospital to avoid the concern that giving the HOPO voting status would result in multiple votes for one member. Granting HOPOs voting privileges will improve the efficiency of the OPTN ensuring that the perspectives of these members are better represented in OPTN voting matters.

How was this proposal developed?

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

This letter from the administrative directors raises the following points:

- "Unlike at the time the OPTN Bylaws were first drafted, several hospital-based OPOs now serve more than one transplant hospital and therefore are not "under the control" of the affiliated transplant hospital for actions taken for the purpose of donor evaluation, donor management, organ allocation and other functions provided in service to all transplant programs within the DSA. The OPO is an independent actor and incorporates recommendations from, and is accountable to, all transplant programs it serves in policy and protocol implementation, regardless of hospital affiliation."
- "By not allowing the hospital-based OPO to vote on OPTN-related matters, the OPO is unable to participate in developing policies that are in the best interest of organ donation within the DSA."
- "...we believe not granting voting rights to hospital-based OPOs could generate mistrust and suspicion between the OPO and all other transplant hospitals within the service area by enabling the perception that the OPO is "under the control" of the affiliated hospital's transplant program."
- "Most hospital-based OPOs operate in chains of accountability to hospital administration that are separate and distinct from transplant programs. Consequently, it is possible, and often likely, that the interest of OPOs will diverge from those of the transplant program. By not allowing hospital-based OPO voting rights, the best interests of organ procurement in the affected DSA are not represented in the OPTN. The interests of the transplant center will prevail. This could present barriers to increasing organ donation."

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

The Association of Organ Procurement Organizations (AOPO) also supported the request made by the seven OPOs.

The MPSC discussed this letter on March 1, 2018, at its in-person meeting. The Committee indicated general support for these changes, but suggested that any changes would need language that assured separation within the hospital organization between the OPO and transplant programs at the hospital.

The chair tasked a work group of the committee to develop the HOPO proposal for further consideration. The work group met monthly from March through June 2018.

The work group agreed that it should focus on developing appropriate standards to provide HOPOs a separate vote. These standards would reflect critical considerations that demonstrate some level of independence between the OPO and transplant hospital for the sake of providing the HOPOs a separate vote. HOPOs that do not meet these standards would continue to have a single, shared vote between the transplant hospital and the OPO, or it could make the necessary organizational changes to apply for a separate vote. The work group participated in a brainstorming session on the characteristics that would demonstrate sufficient separation between the OPO and the transplant programs at the transplant hospital.

Ultimately, the work group recommended and 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 Committee was concerned that if this distinction was not made that a member institution could effectively hold two votes strongly influenced by the singular perspectives of the hospital where the HOPO is located.

The Committee decided that OPOs requesting a separate vote must demonstrate the following:

1. The OPO administrative director² does not serve in a leadership role in the transplant hospital
2. The OPO administrative director² does not report to leadership at the transplant hospital

The committee considered but ultimately did not include the following requirements:

1. The OPO is CMS certified
2. The OPO has a separate governing board from the supporting transplant hospital

Regarding CMS certification, the Committee recognized that all OPOs, independent and hospital-based, are required to be CMS certified as stated in Article 1.3 of the Bylaws; this requirement did not need to be restated. Regarding the separation of the HOPO and supporting hospital's governing board, the MPSC discussed this concept with members of the Transplant Administrators Committee (TAC) who noted that none of the HOPOs would have a separate governing board since the hospital governing board would also serve as the HOPOs governing board. Additionally, all HOPOs would have a medical advisory board that would include members from all hospitals served by the OPO. As a result of this feedback, the MPSC removed the separate governing board requirement from the proposal.

The MPSC also solicited feedback from the OPO Committee prior to asking the MPSC to consider the final language distributed for public comment. The OPO Committee leadership was generally supportive of the proposal and its concepts and did not have any significant feedback or suggestions.

The proposal also contains some revisions that make the language more consistent with the styles used for OPTN policies and bylaws. Language regarding voting privileges contained in the introduction to the

² *The administrative director refers to positions including but not limited to the Executive Director, Chief Executive Officer or President of the OPO. The MPSC acknowledges that many OPO Medical Directors appropriately serve in a leadership role in a transplant hospital.

OPTN Bylaws, Appendix B is being deleted since the status of an OPO as independent or hospital based is not relevant to OPO membership requirements.

The Committee approved the language for public comment on a conference call held on June 26, 2018. The proposed 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 proceeding 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.
- Article 1.3: Members
 - 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.³
 - 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.

How well does this proposal address the problem statement?

The proposed language is crafted to provide voting privileges to those HOPOs that can demonstrate that their position and vote would be based on concerns distinct from the supporting transplant hospital. The Committee included requirements that the OPOs demonstrate that each OPO has a certain level of separation from the transplant programs at the hospital. Of the 58 OPTN OPO members, seven are currently considered HOPOs and could apply for separate voting privileges in OPTN matters. The MPSC would evaluate each request independently and would only grant voting privileges to OPOs that can satisfactorily demonstrate independence from the transplant hospital with which they are affiliated. The MPSC does not anticipate that this change would impact the 51 currently independent OPOs or any of the other transplant hospital members those OPOs serve.

Nevertheless, the MPSC recognizes that this proposal may generate discussion regarding the rights of hospital-based histocompatibility laboratories.

This proposal is focused solely on hospital-based OPOs and does not solicit feedback about the voting qualifications for any other member type. A separate project would need to be reviewed and approved by the Policy Oversight Committee and Executive Committee if changes were considered for other member types.

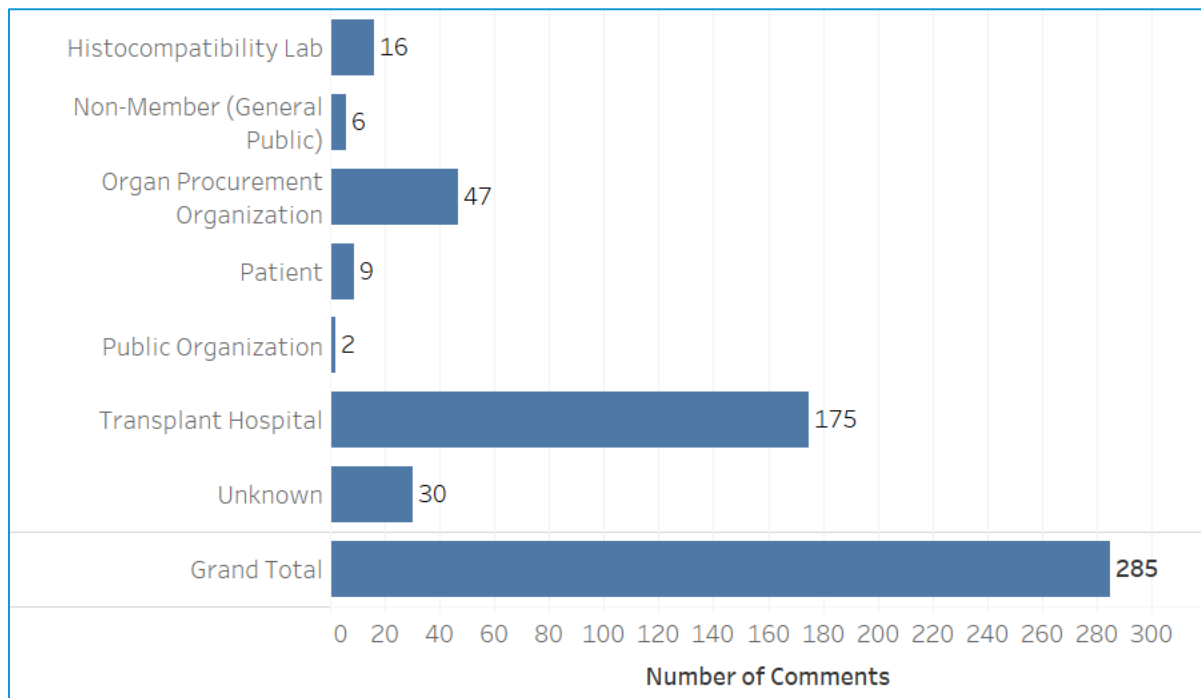
³ CMS definition as found in Part 1, Chapter 31, Organ Acquisition Payment Policy, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R471pr1.pdf>

The Bylaws currently do not grant hospital-based histocompatibility laboratories a vote in OPTN matters. The MPSC acknowledged that the rationale for granting some HOPO members a vote may also apply to some histocompatibility members. However, the MPSC believes it is important to evaluate each membership category’s privileges independently and therefore decided to limit the focus of this project to HOPOs.

Was this proposal changed in response to public comment?

No, this proposal was not changed in response to public comment. During the public comment period (August 3, 2018 – October 3, 2018), this proposal received 285 comments. Most (n = 175) comments were from transplant hospitals. Comments included input and feedback from the OPTN/UNOS Organ Procurement Organization (OPO) Committee, professional societies, individuals, and attendees at regional meetings. The proposal was also presented during a national webinar open to the public on August 6, 2018.

Figure 1: Public Comment Participation



There was a high degree of support for the proposals with less than 2% of all respondents indicating opposition. Of note, the following professional societies provided support for this proposal moving forward to the OPTN/UNOS Board of Directors: the American Society for Histocompatibility and Immunogenetics (ASHI), Association of Organ Procurement Organizations (AOPO), American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), and the American Nephrology Nurses Association (ANNA). All eleven regions considered the proposal on their non-discussion agenda and voted in favor of supporting it.

Table 1: Regional Feedback*

Region	Vote	Support/Oppose
1	4-8-1-0-0	Support
2	8-24-2-0-0	Support
3	12-12-8-1-0	Support
4	19-9-2-0-0	Support
5	11-18-4-0-1	Support
6	26-17-1-1-0	Support
7	11-11-5-0-0	Support
8	11-0-3-0-0	Support
9	8-10-2-1-0	Support
10	10-12-2-1-2	Support
11	8-14-1-0-0	Support

**From left to right the votes were tallied accordingly: Strongly support – support – abstain/neutral – oppose – strongly oppose*

Across member types and geographic area, support was also consistent. Figures 2 and 3 show sentiment by member type and state. Prior to public comment, there was some concern that hospital based histocompatibility laboratories (who, as mentioned above are similar to hospital based OPOs and do not currently receiving OPTN voting privileges) might oppose this proposal. That concern was not reflected during public comment.

Figure 2: Sentiment by Member Type

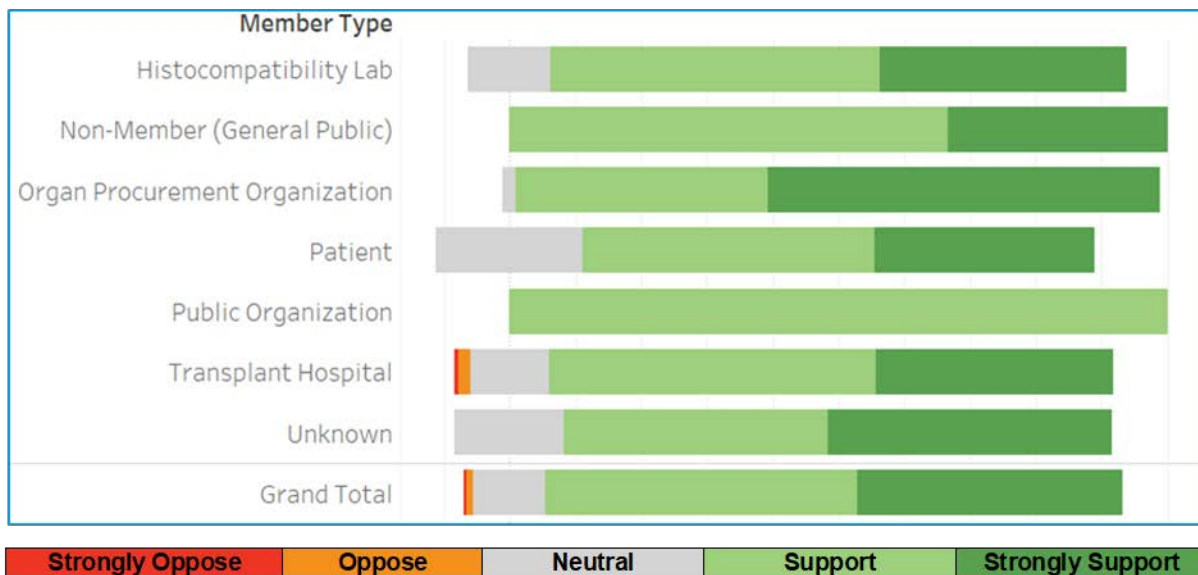
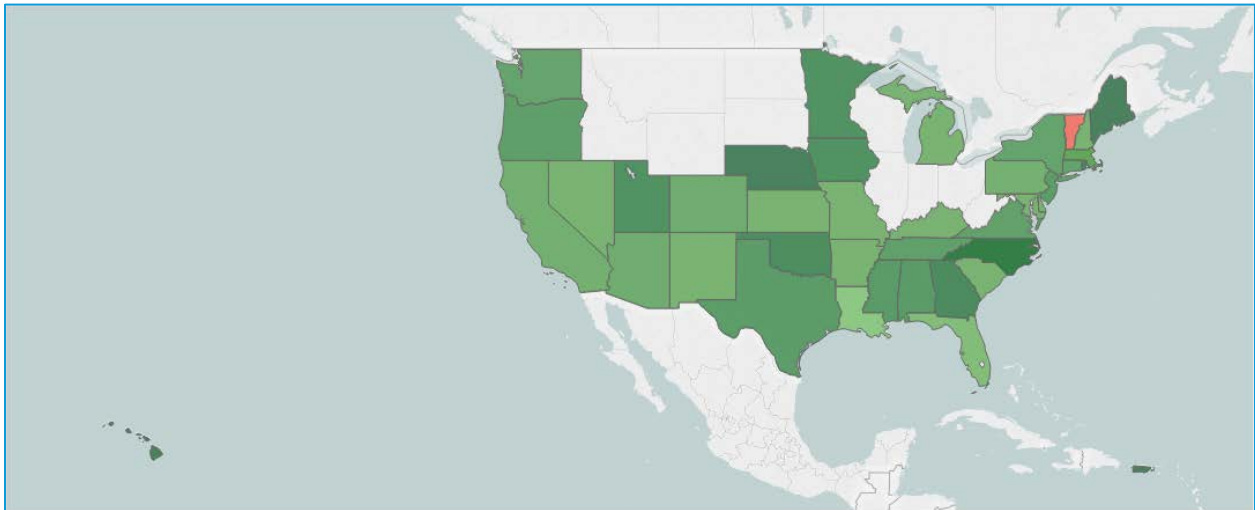


Figure 3 shows support and opposition stratified by geography.⁴ Of the states with a response, all but one state reflected support or strong support for the proposal.

Figure 3: Sentiment by State



The Membership and Professional Standards Committee considered this supportive feedback when it met in person on October 16-17, 2018, in Chicago. They voted 35 For, 0 Against, 1 Abstention to send the bylaw proposal to the OPTN/UNOS Board of Directors for consideration during their December 3-4, 2018 meeting.

Which populations are impacted by this proposal?

This proposal has no known impact on specific candidate or recipient populations. Instead, the proposal has the potential to impact the OPTN's seven hospital-based OPOs, who may apply for separate OPTN voting privileges, and the 18 transplant hospitals these OPOs serve.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* No expected impact on this goal.
2. *Improve equity in access to transplants:* No expected impact on this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* No expected impact on this goal.
4. *Promote living donor and transplant recipient safety:* No expected impact on this goal.
5. *Promote the efficient management of the OPTN:* Allowing HOPOs to have an independent vote would allow those DSAs' organ procurement interests to be represented in OPTN voting matters. Additionally, these changes are intended to build trust among all the transplant hospitals within the DSA served by a hospital-based OPO by helping to eliminate perceptions that hospital-based OPOs are controlled by their affiliated transplant hospitals.

⁴ Some commenters did not identify their state. Therefore, they are not included in Figure 3. Notably, the state was not collected for participants at the region 10 meeting.

How will the OPTN implement this proposal?

A HOPO must submit a written request to the OPTN staff and provide documentation demonstrating that it meets these qualifications to receive voting privileges. This documentation should include organizational charts for the supporting transplant hospital and the OPO as well as any other documentation relevant to the OPO administrative director's role. The OPTN will provide explanatory information providing examples of acceptable and unacceptable reporting structures.

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

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

This proposal will not require programming UNetSM or the membership database. The fiscal impact on all departments is very small.

How will members implement this proposal?

Hospital and Histocompatibility Laboratories

This proposal will have no fiscal impact on transplant hospitals or histocompatibility laboratories.

OPOs

If a hospital based OPO would like a separate OPTN vote from its supporting transplant hospital, the OPO will need to submit a written request to the OPTN with supporting documentation demonstrating that the OPO meets the qualifications for separate voting privileges. The fiscal impact of this proposal is expected to be very small. Implementation costs may be seen in the way of minimal staff time to show functional separation. This may impact up to seven OPOs in the U.S. There would be no ongoing expense from this proposal

Will this proposal require members to submit additional data?

As described above, hospital-based OPOs wishing to apply for separate voting privileges will be required to produce documentation as a part of the request. Otherwise, this proposal does not require additional data collection from members.

The collection of these data primarily aligns with OPTN data collection principles of determining if institutional members are complying with policies, and fulfilling the requirements of the OPTN Final Rule.

How will members be evaluated for compliance with this proposal?

Hospital-based OPOs with separate voting privileges may be asked to submit information confirming they continue to meet the Bylaw requirements upon request. HOPOs will be required to notify the OPTN within 30 days if they no longer meet the qualifications outlined in the Bylaws.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The MPSC will identify and track any issues with the proposed language each time it evaluates a hospital-based OPO's request for separate voting privileges or is made aware of a change in the structure of a HOPO that would affect its voting privileges. The MPSC will also solicit feedback from each regional meeting where a HOPO has been granted separate voting privileges regarding any unintended impacts to OPTN voting matters.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

RESOLVED, that changes to OPTN Bylaws 1.1.B (Overview of the Voting Process); 1.3 (OPO Members); 1.3.A (OPO Member Requirements); 1.3.C (OPO Member Voting Privileges); Appendix B (Membership Requirements for Organ Procurement Organizations (OPOs)); and Appendix M (Definitions) as set forth below, are hereby approved, effective December 4, 2018.

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 Privileges
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 hospital-based OPO that is able to demonstrate all of the qualifications as defined in according to Section 1.3.C.</u>
Histocompatibility laboratory	One per histocompatibility laboratory	The histocompatibility laboratory must be independent, <u>as defined in according to Section 1.4.</u>

Membership Type	Number of Votes	Additional Requirements to Qualify for Voting Rights <u>Privileges</u>
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

23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57

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.~~ certified by the Center for Medicare/Medicaid Services (CMS), and designated as a qualified OPO by the Secretary of HHS.

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. Each independent OPO member has one vote. 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:

58 1. The hospital-based OPO administrative director is not in a leadership role within the
59 transplant programs at the supporting transplant hospital. A leadership role is defined as a
60 role that involves any administrative or organizational decision making responsibilities in any
61 of the transplant programs at the transplant hospital.

62 2. The hospital-based OPO administrative director is not subordinate to the leadership in any
63 transplant programs at the supporting transplant hospital.

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

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

71

72 **Appendix B:**

73 **Membership Requirements for Organ Procurement** 74 **Organizations (OPOs)**

75 ~~An OPO member is any OPO that has been designated by the Secretary of the U.S. Department of~~
76 ~~Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or any organization~~
77 ~~that meets all requirements under Section 1138(b), except for OPTN membership.~~
78

79 ~~Only independent OPOs (IOPO) have voting privileges in the OPTN. An IOPO is defined as one that has~~
80 ~~a distinct governing body separate from any transplant hospital or commonly controlled group of~~
81 ~~transplant hospitals it serves.~~
82

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

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

88

89 **Appendix M: Definitions**

90 **Hospital-based OPO**

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

99

100 See also *independent OPO* and *OPO member*.

101

102 **Independent OPO (IOPO)**

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

106
107 **Voting Members**

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

#