Public Comment Proposal

Proposal to Revise the OPTN Charter

OPTN Executive Committee

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Proposal to Revise the OPTN Charter

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Executive Summary

The OPTN Charter governs the structure and operations of the OPTN. The OPTN contract requires the OPTN Contractor to work with the OPTN Board of Directors to review the Charter and “ensure that the OPTN Charter is specific to the OPTN and...that the OPTN Charter encompasses all aspects of OPTN operations.”¹ After an extensive review of the Charter, the OPTN Executive Committee proposes revisions to eliminate redundancy or inconsistency with the National Organ Transplant Act (NOTA) and the OPTN Final Rule; and is specific to the work of the OPTN.

¹ Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HHSH250201900001C, November 1, 2018.
Purpose

The OPTN Charter governs the structure and operations of the OPTN.² An organization’s charter typically outlines the purpose of the organization, explains the identity of the organization (i.e. membership, non-profit, etc.), and outlines the governing and membership structure of an organization. The current OPTN Contract requires the OPTN Contractor to work with the OPTN Board of Directors to review the Charter to ensure that the OPTN Charter is specific to the OPTN and...that the OPTN Charter encompasses all aspects of OPTN operations.”³

Background

The OPTN Charter outlines the purpose of the OPTN, its Board and governance structure, and its membership. As the OPTN is authorized by the National Organ Transplant Act (NOTA), the Charter must be consistent with the requirements in NOTA.⁴ Likewise, the Charter must be consistent with the OPTN Final Rule, which provides more detailed requirements regarding the OPTN Board of Directors’ composition and the OPTN’s membership.⁵

The OPTN Executive Committee reviewed the OPTN Charter and determined that, while it was largely consistent with both NOTA and the Final Rule, there were some provisions that required revision.

Overview of Proposal

After the introduction, the OPTN Charter is divided into four articles: 1) Organization; 2) Purpose; 3) Board of Directors; and 4) Membership. The OPTN Executive Committee reviewed each section and proposes the following changes.

Introduction

The Executive Committee determined that the existing introduction section is too compliance focused, and it repeats operational details that are better left to the OPTN Bylaws. The Executive Committee proposes cutting out a substantial portion of the introduction to simply focus on the purpose of the Charter.

Organization

The Organization section is designed to describe the type of legal entity that the OPTN is. To that end, the Executive Committee proposes explicitly referencing NOTA and the fact that NOTA authorizes the existence of the OPTN to be operated by contract with the U.S. Department of Health and Human Services. To eliminate any risk of inconsistency, the Executive Committee proposes minor changes to the way the OPTN’s non-profit status is described to ensure that the language mirrors the statutory language.⁶

³ Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HHS0250201900001C, November 1, 2018.
⁴ 42 U.S.C. §274
⁵ 42 C.F.R. §121
⁶ 42 U.S.C. §274(a)
Per the specific requirement of the current OPTN Contract, the OPTN Executive Committee also proposes removing the reference to UNOS as the OPTN Contractor, though it proposes retaining an explanation of the OPTN Contractor’s relationship to the OPTN.

Purpose

The Purpose section should outline all the functions of the OPTN. However, the Executive Committee determined that the current Purpose section only focuses on a subset of the work that the OPTN performs. The OPTN’s purposes are already detailed in NOTA. Rather than re-writing all of the OPTN’s functions in the Charter, the Executive Committee instead proposes cross-referencing the list of OPTN functions in NOTA.7

Board of Directors

NOTA requires the OPTN to have a Board of Directors that is comprised of organ procurement organizations, transplant hospitals, voluntary health associations, and the general public.8 The OPTN Final Rule provides more granular detail about the composition of the OPTN Board.9 While the current OPTN Charter substantially mirrors the requirements of NOTA and the Final Rule, there are a couple of minor wording differences. The Executive Committee proposes mirroring the exact language of the Final Rule with regard to Board composition, with two additions.

First, the current charter requires the OPTN Board to include at least one director that represents “pediatric-specific interests.” Neither NOTA nor the Final Rule include this requirement, but the Executive Committee determined that requiring the Board to include a representative specifically focused on the pediatric population is incredibly important. Therefore, the Executive Committee proposes retaining this requirement in the Charter.

Second, the Executive Committee proposes retaining the current requirement that a representative from HHS and/or the Health Services Resource Administration (HRSA) serves on the Board of Directors in an ex officio capacity. While NOTA and the OPTN Final Rule do not provide this requirement, the role the HRSA contracting officer on the Board of Directors is critical to ensure HRSA can effectively perform its oversight functions, and to provide valuable input for the OPTN Board’s consideration. The only modification the Executive Committee proposes is to update the terminology for referring to HRSA’s role on the Board. The HHS/HRSA representative that serves on the Board is referred to as the Contracting Officer’s Representative.

The Executive Committee also noticed that the functions of the Board are not entirely detailed in the current charter. The current charter discusses the requirement in NOTA and the Final Rule that the Board selects an Executive Committee and other committees as needed.10 However, the Board is also tasked with selecting an Executive Director.11

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7 42 U.S.C. §274(b)(2)(A)-(O)
8 42 U.S.C. §274(b)(1)(B)(i)
9 42 C.F.R. §121.3(a)(1)
10 42 U.S.C. §274(b)(1)(B)(ii); 42 C.F.R. §121.3(a)(2)
11 42 C.F.R. §121.3(a)(3)
Lastly, the Executive Committee proposes striking language regarding the election of the OPTN Board. The details of the election process are operational and better placed in the OPTN Bylaws, where they already exist. Additionally, striking the discussion of the election also ensures that the OPTN Contractor’s processes are not detailed in the same governing documents as the OPTN’s processes.

Membership

The OPTN is a membership organization. The Final Rule specifies that there are three categories of membership in the OPTN: 1) organ procurement organizations; 2) Transplant hospitals participating in the Medicare or Medicaid programs; and 3) Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation. However, the current Charter details five different membership categories that are not inconsistent with the three higher level categories detailed in the Final Rule, but also are not entirely synched.

To avoid confusion or risk of inconsistency, the Executive Committee proposes repeating the three membership categories in the Charter to align with those in the Final Rule. The details for applying to be a member in any of those three categories will continue to be included the OPTN Bylaws.

The OPTN Contract also requires the OPTN Contractor to identify “the potential addition of new categories resulting from scientific advances in organ procurement and transplantation consistent with the OPTN final rule.” The Executive Committee understands that even if they were to identify a new group of members that would be eligible to join the OPTN, the new group would need to fit within one of the three existing membership categories described in the Final Rule. Most likely, a group “resulting from scientific advances in organ procurement and transplantation” would fit into the third category of membership, “Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation.” The requirements for joining that future type of membership group would be best detailed in the OPTN Bylaws, where all requirements for applying to and remaining a member of the OPTN already exist.

NOTA and Final Rule Analysis

The Executive Committee offers the proposed changes to the OPTN Charter public comment under the authority of NOTA, which states that “The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network...” The OPTN Contract requires the OPTN Contractor to review the OPTN Charter with the OPTN Executive Committee to determine. As described throughout the proposal, the proposed changes are consistent with applicable provisions of NOTA and the OPTN Final Rule.

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12 42 C.F.R. §121.3(b)
13 Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HHS/250201900001C, November 1, 2018.
14 42 U.S.C. §274(a)
15 Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HHS/250201900001C, November 1, 2018.
Implementation Considerations

Member and OPTN Operations

If approved by the OPTN Board of Directors, the revisions to the OPTN Charter would be immediately effective. There would be no impact on OPTN Members or the OPTN.

Conclusion

The proposed revisions to the OPTN Charter are intended to assure the OPTN Charter remains consistent with NOTA and the Final Rule, accurately reflects the relationship between the OPTN and the OPTN Contractor, and covers all aspects of OPTN operations.
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 authorized by the National Organ Transplant Act of 1984, as amended, 42 U.S.C. 273 et seq. The OPTN is a private, not-for-profit nonprofit entity with that has an expertise in organ procurement and transplantation. The OPTN Contractor serves as the OPTN by contract with the Department of Health and Human Services (HHS). 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.

ARTICLE II. PURPOSE
The purpose of the OPTN is to carry out the statutory functions listed in NOTA at 42 U.S.C. §274(b)(2)(A)-(O). 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 42 members. In accordance with the OPTN Final Rule at §121.3(a), the Board of
Directors shall include:

(a) Approximately 50% transplant surgeons and/or transplant 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 or 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 Contracting Officer’s Representative 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,
perform the duties detailed in, and in accordance with, NOTA and the OPTN Final Rule,
including:

a) Electing an Executive Committee from the membership of the Board;
b) Appointing an Executive Director of the OPTN;
c) Establishing 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 three 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. 1) transplant hospitals participating in the Medicare or Medicaid programs; 2) all organ procurement organizations (OPO), and 3) other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation, including transplant hospitals that do not participate in the Medicare or Medicaid programs, medical/scientific members, public organization members, business members, and Individual Members. The OPTN Bylaws shall specify the requirements for applying to be an OPTN member and the responsibilities of an OPTN member.

(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.