



**OPTN**

*Public Comment Proposal*

# **Proposal to Revise the OPTN Charter**

*OPTN Executive Committee*

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## Proposal to Revise the OPTN Charter

*Affected Document:* OPTN Charter  
*Sponsoring Committee:* Executive  
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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.”<sup>1</sup> 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.

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<sup>1</sup> Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HSH250201900001C, November 1, 2018.

## Purpose

The OPTN Charter governs the structure and operations of the OPTN.<sup>2</sup> 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.”<sup>3</sup>

## 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.<sup>4</sup> 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.<sup>5</sup>

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.<sup>6</sup>

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<sup>2</sup> OPTN Charter. <https://optn.transplant.hrsa.gov/about/optn-charter/>. (Accessed on December 10, 2021).

<sup>3</sup> Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HSH250201900001C, November 1, 2018.

<sup>4</sup> 42 U.S.C. §274

<sup>5</sup> 42 C.F.R. §121

<sup>6</sup> 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.<sup>7</sup>

## 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.<sup>8</sup> The OPTN Final Rule provides more granular detail about the composition of the OPTN Board.<sup>9</sup> 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.<sup>10</sup> However, the Board is also tasked with selecting an Executive Director.<sup>11</sup>

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<sup>7</sup> 42 U.S.C. §274(b)(2)(A)-(O)

<sup>8</sup> 42 U.S.C. §274(b)(1)(B)(i)

<sup>9</sup> 42 C.F.R. §121.3(a)(1)

<sup>10</sup> 42 U.S.C. §274(b)(1)(B)(ii); 42 C.F.R. §121.3(a)(2)

<sup>11</sup> 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.<sup>12</sup> 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 in 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."<sup>13</sup> 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..."<sup>14</sup> The OPTN Contract requires the OPTN Contractor to review the OPTN Charter with the OPTN Executive Committee to determine.<sup>15</sup> As described throughout the proposal, the proposed changes are consistent with applicable provisions of NOTA and the OPTN Final Rule.

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<sup>12</sup> 42 C.F.R. §121.3(b)

<sup>13</sup> Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HHS250201900001C, November 1, 2018.

<sup>14</sup> 42 U.S.C. §274(a)

<sup>15</sup> Performance Work Statement Task 3.2.2: Perform BOD review of the OPTN Charter; Organ Procurement and Transplantation Network; HHS250201900001C, 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.

## Charter Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

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

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

### 13                                  **ARTICLE I. ORGANIZATION**

14                                  The OPTN is authorized by the National Organ Transplant Act of 1984, as amended, 42 U.S.C.  
15                                  273 et seq. ~~The OPTN is a private, not-for-profit nonprofit entity with that has an expertise in~~  
16                                  ~~organ procurement and transplantation. The OPTN Contractor serves as the OPTN by contract~~  
17                                  ~~with the Department of Health and Human Services (HHS). The OPTN is a part of the OPTN~~  
18                                  ~~Contractor’s organization and operations. The OPTN Contractor is United Network for Organ~~  
19                                  ~~Sharing (UNOS), a Virginia non-stock, not-for-profit corporation which is qualified as a tax-~~  
20                                  ~~exempt public charity under Section 501(c)(3) of the Internal Revenue Code.~~

### 21                                  **ARTICLE II. PURPOSE**

22                                  The purpose of the OPTN is to carry out the statutory functions listed in NOTA at 42 U.S.C.  
23                                  §274(b)(2)(A)-(O)). ~~The primary purposes of the OPTN are to operate and monitor an equitable~~  
24                                  ~~system for allocating organs donated for transplantation; maintain a waiting list of potential~~  
25                                  ~~recipients; match potential recipients with organ donors according to established medical~~  
26                                  ~~criteria for allocation of organs and, to the extent feasible, for listing and de-listing transplant~~  
27                                  ~~patients; facilitate the efficient, effective placement of organs for transplantation; and increase~~  
28                                  ~~organ donation. To accomplish these purposes, the OPTN:~~

29                                  ~~(a) Establishes, maintains, and monitors compliance with voluntary and mandatory membership~~  
30                                  ~~criteria/policies and procedures for institutions and interested parties and training and~~  
31                                  ~~experience criteria as consistent with Federal regulations for primary personnel at transplant~~  
32                                  ~~programs. Policies may become mandatory through a process involving consideration and~~  
33                                  ~~recommendation as a mandatory policy by the OPTN and official adoption by the Secretary of~~  
34                                  ~~the Department of Health and Human Services (HHS) of the policy as mandatory.~~

35 ~~(b) Establishes, maintains, and monitors compliance with voluntary and mandatory~~  
36 ~~criteria/policies and procedures for the safe and efficient acquisition and transportation of~~  
37 ~~donor organs and for the allocation and distribution of these organs equitably among transplant~~  
38 ~~patients, consistent with Federal law and regulations. Policies may become mandatory through~~  
39 ~~a process involving consideration and recommendation as a mandatory policy by the OPTN and~~  
40 ~~official adoption by the Secretary of HHS of the policy as mandatory.~~

41 ~~(c) Collects, analyzes, and publishes data on pre-transplant and post-transplant events to~~  
42 ~~advance the fields of organ transplantation, organ procurement, organ preservation, and~~  
43 ~~immunogenetics.~~

### 44 **ARTICLE III. BOARD OF DIRECTORS**

45 The OPTN shall be governed by a Board of Directors ~~composed of not less than 34 nor more~~  
46 ~~than 42 members. In accordance with the OPTN Final Rule at §121.3(a), the~~ The Board of  
47 Directors shall include:

48 (a) Approximately 50% transplant surgeons ~~and~~ or transplant physicians;

49 (b) At least 25% transplant candidates, transplant recipients, organ donors, and family members  
50 representing the diversity of the population of transplant candidates, transplant recipients,  
51 organ donors, and family members served by the OPTN, including, to the extent practicable, the  
52 minority and gender diversity of this population. These members shall ~~be required to certify that~~  
53 ~~they are not~~ be employees of, ~~and do not~~ or have a similar relationship with Organ Procurement  
54 Organizations (OPOs) ~~(defined below), Transplant Hospitals (defined below),~~ voluntary health  
55 organizations, transplant coordinators, histocompatibility experts, or other non-physician  
56 transplant professionals. The Board of Directors may, however, waive this requirement for not  
57 more than 50% of this category of members;

58 (c) Representatives of OPOs, Transplant Hospitals, voluntary health associations, transplant  
59 coordinators, histocompatibility experts, non-physician transplant professionals, and the general  
60 public, as well as at least one member representing pediatric-specific interests; and

61 (d) ~~The Project Officer~~ Contracting Officer's Representative for the OPTN Contract and the  
62 Director of the Division of Transplantation, within the Health Resources and Services  
63 Administration, HHS, or their designees, as ex-officio, non-voting members.

64 The Board of Directors shall ~~elect an Executive Committee from the membership of the Board~~  
65 ~~and establish such other committees as are necessary to perform the duties of the OPTN.~~  
66 perform the duties detailed in, and in accordance with, NOTA and the OPTN Final Rule,  
67 including:

- 68 a) Electing an Executive Committee from the membership of the Board;  
69 b) Appointing an Executive Director of the OPTN  
70 c) Establishing such other committees as are necessary to perform the duties of the  
71 OPTN.

72 The OPTN Board of Directors shall ~~be elected in parallel with and using the same processes as~~  
73 ~~the OPTN Contractor's Board of Directors, resulting in identical memberships, if the OPTN~~  
74 ~~Contract provides for such an arrangement. This will enable the OPTN Contractor to perform~~  
75 ~~tasks required by the OPTN Contract under the governance of the OPTN Board of Directors.~~



76 Activities of the Board of Directors, while constituted as the OPTN Board, shall be limited to  
77 activities of the OPTN (i.e., those activities for which costs are reimbursed under the OPTN  
78 Contract). To accomplish this, separate agendas or sections within combined agendas shall  
79 identify OPTN versus OPTN Contractor business. The Board of Directors shall convene as the  
80 OPTN Board for purposes of conducting OPTN affairs and the OPTN Contractor Board for  
81 purposes of conducting OPTN Contractor affairs. Consistent with this framework, OPTN  
82 Committees are appointed in parallel with OPTN Contractor Committees and operate under  
83 these same procedures.

#### 84 **ARTICLE IV. MEMBERSHIP**

85 There shall be five three categories of members of the OPTN. These are: Institutional Members,  
86 Medical/Scientific Members, Public Organization Members, Business Members, and Individual  
87 Members. By amendment to the Bylaws of the OPTN, the Board of Directors may establish  
88 additional categories of Members in order to conform to requirements of law and regulations  
89 applicable to the OPTN. 1) transplant hospitals participating in the Medicare or Medicaid  
90 programs; 2) all organ procurement organizations (OPO), and 3) other organizations,  
91 institutions, and individuals that have an interest in the fields of organ donation or  
92 transplantation, including transplant hospitals that do not participate in the Medicare or  
93 Medicaid programs, medical/scientific members, public organization members, business  
94 members, and Individual Members. The OPTN Bylaws shall specify the requirements for  
95 applying to be an OPTN member and the responsibilities of an OPTN member.

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

97 (i) An organization designated as an organ procurement organization by the Secretary of the  
98 Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security  
99 Act or an organization that meets all requirements for such designation, other than OPTN  
100 membership (OPO).

101 (ii) A hospital (a) that aspires to perform organ transplants, as evidenced by submission of an  
102 active application for designated transplant program status for at least one organ type, or in  
103 which organ transplantation is performed, and (b) that participates in the Medicare or Medicaid  
104 programs (Transplant Hospital).

105 (iii) An independent histocompatibility laboratory that serves at least one Transplant Hospital  
106 that is active in the field of human organ transplantation within its service area  
107 (Histocompatibility Laboratory). For purposes of the OPTN Charter and Bylaws, independence  
108 from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing  
109 body for the Histocompatibility Laboratory that is separate and not under the direct or indirect  
110 control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals  
111 or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's  
112 Transplant Hospitals.

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

115 (i) An established, non-profit organization or institution with at least one year of operating  
116 history that has an interest in the fields of organ donation or transplantation, defined as:

- 117 (a) An organization or institution that serves as a medical or scientific membership organization  
118 and includes within its membership professional members who are involved in organ  
119 transplantation, or
- 120 (b) An organization or institution that is supported by letters of recommendation for OPTN  
121 membership from at least three other organizations or institutions, each of which meets the  
122 criteria for Institutional Membership listed in Article IV(a) above, Medical/Scientific Membership  
123 listed in Article IV(b)(i)(a) above, or Public Organization Membership listed in Articles IV(c)(i)(a)  
124 or IV(c)(ii) below.
- 125 (c) Public Organization Members. A Public Organization Member shall meet the following  
126 criteria:
- 127 (i) An established, non-profit organization or institution with at least one year of operating  
128 history that has an interest in the fields of organ donation or transplantation, defined as:
- 129 (a) An organization or institution that engages in organ donation activities or represents or  
130 provides direct support or services to transplant recipients, transplant candidates, or their  
131 families, or
- 132 (b) An organization or institution that is supported by letters of recommendation for OPTN  
133 membership from at least three other organizations or institutions, each of which meets the  
134 criteria for Institutional Membership listed in Article IV(a) above, Medical/Scientific Membership  
135 listed in Article IV(b)(i)(a) above, or Public Organization Membership listed in Article IV(c)(i)(a)  
136 above or Article IV(c)(ii) below, or
- 137 (ii) A hospital with at least one year of operating history that participates in the Medicare or  
138 Medicaid programs and has an interest in the fields of organ donation or transplantation,  
139 defined by the referral of at least one potential organ or tissue donor per year for donation.  
140 The Board of Directors shall from time to time review these criteria and establish as part of the  
141 Bylaws of the OPTN, additional membership requirements for Institutional Members, Public  
142 Organization Members, and Medical/Scientific Members.
- 143 (d) Business Members. A Business Member shall be an established organization or institution  
144 with at least one year of operating history that has an interest in the fields of organ donation or  
145 transplantation, defined as engaging in commercial activities with two or more active  
146 Institutional Members.
- 147 (e) Individual Members. An Individual Member shall be a person with an interest and/or  
148 expertise in the fields of organ donation or transplantation, defined to include one or more of  
149 the following:
- 150 (i) Individuals who have served or are presently serving on the OPTN Board of Directors, or an  
151 OPTN Committee.
- 152 (ii) Individuals who are themselves or are family members of: a transplant candidate, transplant  
153 recipient, or organ or tissue donor.
- 154 (iii) Individuals who are presently employed by or are independent contractors with OPOs,  
155 Transplant Hospitals, or Histocompatibility Laboratories
- 156 (iv) Individuals who were formerly employed by or were formerly independent contractors with  
157 OPOs, Transplant Hospitals, or Histocompatibility Laboratories and individuals formerly

158 ~~employed by Federal or State government agencies involved in the field of organ donation and~~  
159 ~~transplantation, who demonstrate continued active interest in and involvement with the fields~~  
160 ~~of organ donation or transplantation.~~

161 ~~(v) Individuals who otherwise have an active interest in and involvement with the fields of organ~~  
162 ~~donation or transplantation demonstrated by letters of recommendation for OPTN membership~~  
163 ~~from at least three persons, each of whom meets the criteria for Individual Membership listed in~~  
164 ~~Article IV(e) (i)-(iv) above.~~