

*Briefing to the OPTN Board of Directors on*

# Apply Transplant Notification Requirements for VCA Program Inactivation

*OPTN Vascularized Composite Allograft Transplantation Committee*

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# Apply Transplant Notification Requirements for VCA Program Inactivation

<i>Affected Bylaws:</i>	<i>Appendix J: Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs</i> <i>Appendix K: Transplant Program Inactivity, Withdrawal, and Termination</i>
<i>Sponsoring Committee:</i>	<i>Vascularized Composite Allograft Transplantation</i>
<i>Public Comment Period:</i>	<i>August 3, 2022-September 28, 2022</i>
<i>Board of Directors Meeting:</i>	<i>December 5, 2022</i>

## Executive Summary

The OPTN Vascularized Composite Allograft (VCA) Transplantation Committee (the Committee) is proposing changes to *OPTN Bylaw Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*. The proposal removes the exclusion of VCA programs from the requirement to notify their waitlisted patients in the event that a transplant program is placed under short or long-term inactive status, or can no longer transplant a subset of their patients.<sup>1</sup> This aligns VCA programs with the OPTN Final Rule requiring a transplant program "promptly to notify the OPTN and patients awaiting transplants if it becomes inactive."<sup>2</sup>

The Committee also proposes a change to Appendix J of the Bylaws to update the reference to eight VCA program types to ten VCA program types.<sup>3</sup> This addition reflects the OPTN Board of Directors' December 2021 approval of the proposal *Establish Membership Requirements for Uterus Transplant Programs*, which split the "genitourinary organ" VCA type into three VCA types (uterus, external male genitalia, and other genitourinary organ).<sup>4</sup>

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<sup>1</sup> OPTN Bylaws, accessed May 25, 2022, [https://optn.transplant.hrsa.gov/media/lgbmahi/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf).

<sup>2</sup> 42 CFR §121.9(a)(2)

<sup>3</sup> OPTN Bylaws, accessed October 7, 2022, [https://optn.transplant.hrsa.gov/media/lgbmahi/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf).

<sup>4</sup> *Establish Membership Requirements for Uterus Transplant Programs*, Policy and Bylaw Notice, accessed May 23, 2022, [https://optn.transplant.hrsa.gov/media/gapkr01m/policy-notice\\_establish-membership-requirements-for-uterus-transplant-programs\\_december-2021.pdf](https://optn.transplant.hrsa.gov/media/gapkr01m/policy-notice_establish-membership-requirements-for-uterus-transplant-programs_december-2021.pdf).

## Purpose

The purpose of this proposal is to remove the VCA exclusion from *OPTN Bylaw Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* so that the provisions of this Bylaw apply to VCA transplant programs. VCA transplant programs are currently excluded from provisions of the OPTN Bylaws Appendix K.1 through K.3 pertaining to transplant program inactivity, short-term inactive transplant program status, and long-term inactive transplant program status.<sup>5</sup> This exclusion was added when VCA was implemented as an organ under the purview of the OPTN in 2014.<sup>6,7</sup> The OPTN Final Rule requires transplant programs to notify the OPTN and patients if the program is inactive, and the procedures for these notifications are outlined in Appendix K.1 through K.3.<sup>8</sup> Though the bylaws do not require VCA transplant programs to follow these procedures currently, the programs voluntarily notify the OPTN when they are inactive and not receiving offers.

Additionally, this proposal includes a change to *OPTN Bylaw Appendix J: Membership and Personnel Requirements for VCA Transplant Programs* to update the reference of eight VCA program types to ten VCA program types.<sup>9</sup> This update aims to split the "genitourinary organ" VCA type into three VCA types (uterus, external male genitalia, and other genitourinary organ) as approved by the OPTN Board of directors in December 2021 as part of the proposal entitled *Establish Membership Requirements for Uterus Transplant Programs*.<sup>10</sup>

## Background

The proposed OPTN Bylaw changes are part of continued efforts to align VCA with all organ types in OPTN Policy, Bylaw, and procedures, including updates to data collection and implementing VCA allocation in the OPTN Computer System. VCAs were designated as organs under the purview of the OPTN effective July 3, 2014.<sup>11,12</sup> At this time the OPTN Board of Directors also approved changes to OPTN Bylaws requiring transplant programs to submit a letter of notification to the OPTN if they intended to perform VCA transplants.<sup>13</sup>

### *OPTN Bylaw Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*

Due to the novelty of the field resulting in relatively low transplant volume in 2014, VCA was originally excluded from the requirements found in Appendix K.1 through K.3. Currently, all other designated

<sup>5</sup> OPTN Bylaws, Appendix K, accessed May 25, 2022, [https://optn.transplant.hrsa.gov/media/lgbmahi/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf)

<sup>6</sup> U.S. Department of Health and Human Services, Final Rule, "Organ Procurement and Transplantation Network." *Federal Register* 78, no. 128 (July 3, 2013): 40033, <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf>.

<sup>7</sup> "Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)," Public Comment Proposal, OPTN, accessed April 1, 2021, [https://optn.transplant.hrsa.gov/media/1118/05\\_vca\\_implementation.pdf](https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf).

<sup>8</sup> 42 CFR §121.9(a)(2).

<sup>9</sup> OPTN Bylaws, accessed May 25, 2022, [https://optn.transplant.hrsa.gov/media/lgbmahi/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf).

<sup>10</sup> Establish Membership Requirements for Uterus Transplant Programs, Policy and Bylaw Notice, accessed May 23, 2022, [https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice\\_establish-membership-requirements-for-uterus-transplant](https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice_establish-membership-requirements-for-uterus-transplant)

<sup>11</sup> U.S. Department of Health and Human Services, Final Rule, "Organ Procurement and Transplantation Network." *Federal Register* 78, no. 128 (July 3, 2013): 40033, <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf>.

<sup>12</sup> "Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)," Public Comment Proposal, OPTN, accessed April 1, 2021, [https://optn.transplant.hrsa.gov/media/1118/05\\_vca\\_implementation.pdf](https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf).

<sup>13</sup> "Executive Summary of the OPTN Board of Directors Meeting," June 23-24, 2014, OPTN, accessed April 1, 2021, [https://optn.transplant.hrsa.gov/media/1794/executive\\_summary\\_06-2014.pdf](https://optn.transplant.hrsa.gov/media/1794/executive_summary_06-2014.pdf).

organ transplant programs, under the purview of the OPTN, are required to follow all aspects of *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* which outlines requirements for patient notification and notification to the OPTN if a transplant program becomes inactive.<sup>14</sup> The OPTN Bylaws state that transplant programs must remain active in transplantation to maintain membership in the OPTN and identify two types of member inactivity, short-term inactive transplant program status and long-term inactive transplant program status.<sup>15</sup> Short-term program inactivity is defined as a transplant program that is inactive for no more than 14 consecutive days. Transplant programs may voluntarily inactivate for not more than 14 days by changing their waiting list status to inactive in the OPTN Computer System. When a program intends to voluntarily inactivate on a short-term basis, notification to the OPTN is not required but the program must provide candidates with a written summary of its Program Coverage Plan. VCA programs that long-term inactivate would also be required to notify the OPTN and follow the outlined requirements should the program seek reactivation or extension of that long-term inactive status. Additionally, there are requirements for patient notification if a program has a cessation in their ability to transplant a subset of their patient population (i.e., infants within a pediatric transplant program) which may also apply to VCA programs such as a Head and Neck program no longer able to perform trachea transplants.<sup>16,17</sup> This would also align VCA programs with the OPTN Final Rule requiring a transplant program "promptly to notify the OPTN and patients awaiting transplants if it becomes inactive".<sup>18</sup>

It was noted that VCA programs may be more affected by their limited number of transplant surgeons and physicians on site, but the Committee ultimately felt that VCA transplant programs should adhere to the already established time frames that designate both short-term and long-term inactivation since this does not differ greatly from single surgeon/physician programs. The Committee also recognized the importance of informing patients.<sup>19</sup>

## *OPTN Bylaw Appendix J: Membership and Personnel Requirements for VCA Transplant Programs*

After the designation in 2014, the OPTN Board of Directors approved more detailed VCA membership requirements in 2015, 2016, and 2018.<sup>20</sup> These included tailored requirements for head and neck, upper limb, and abdominal wall transplant programs. The updates to the Bylaws also included general requirements for "other VCA" transplant programs, which included genitourinary organ as well as gland, lower limb, musculoskeletal composite graft segment, and spleen VCA transplant programs. These requirements were implemented in June 2021.<sup>21</sup>

In December 2021, the OPTN Board of Directors approved further changes to the OPTN Bylaws to *Establish Membership Requirements for Uterus Transplant Programs* which further separate the current

<sup>14</sup> OPTN Bylaws, Appendix K, accessed May 25, 2022, [https://optn.transplant.hrsa.gov/media/lgbbmahioptn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbbmahioptn_bylaws.pdf).

<sup>15</sup> OPTN Bylaws, Appendix K, accessed June 23, 2022, [https://optn.transplant.hrsa.gov/media/lgbbmahioptn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbbmahioptn_bylaws.pdf).

<sup>16</sup> *Appendix K.1.A: Program Component Cessation*, OPTN Bylaw, accessed May 26, 2022,

[https://optn.transplant.hrsa.gov/media/lgbbmahioptn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbbmahioptn_bylaws.pdf).

<sup>17</sup> "Policy Notices," OPTN, accessed May 26, 2022, <https://optn.transplant.hrsa.gov/governance/policy-notices/>. See "Combined Policy Notice for VCA Membership Requirements" and "Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts" for details.

<sup>18</sup> 42 CFR §121.9(a) (2).

<sup>19</sup> OPTN Vascularized Composite Allograft Transplantation Committee, Meeting Summary, March 9, 2022, accessed May 25, 2022,

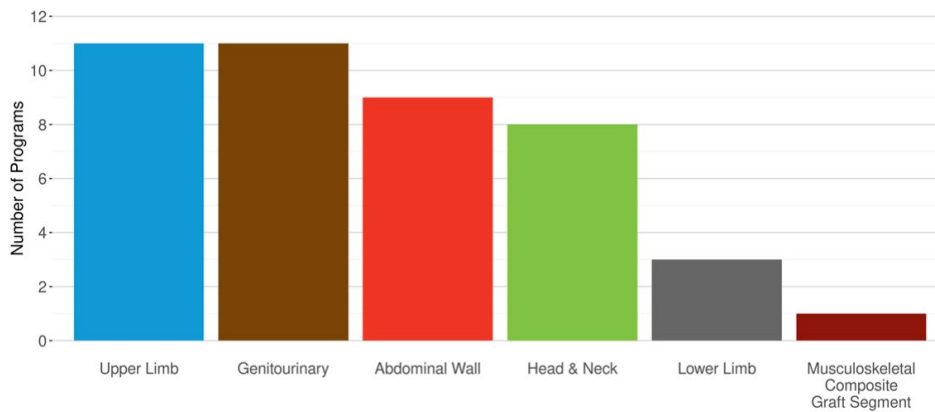
[https://optn.transplant.hrsa.gov/media/m2pncbxb/20220309\\_vca-committee-meeting-summary\\_final.pdf](https://optn.transplant.hrsa.gov/media/m2pncbxb/20220309_vca-committee-meeting-summary_final.pdf).

<sup>20</sup> "Policy Notices," OPTN, accessed June 24, 2021, <https://optn.transplant.hrsa.gov/governance/policy-notices/>. See "Combined Policy Notice for VCA Membership Requirements" for details.

<sup>21</sup> "Policy Notices," OPTN, accessed June 24, 2021, <https://optn.transplant.hrsa.gov/governance/policy-notices/>. See "Combined Policy Notice for VCA Membership Requirements" and "Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts" for details.

genitourinary organ programs into uterus, external male genitalia, and other genitourinary programs.<sup>22</sup> **Figure 1** shows the number of OPTN approved VCA programs as of April 2022.

**Figure 1: Number of OPTN Approved VCA Programs<sup>23</sup>**



## Proposal for Board Consideration

- Update Appendix K to remove the VCA exclusion from transplant program inactivity patient and OPTN notification requirements
  - This proposal would not establish functional inactivity requirements for VCA
- Update Appendix J to reflect OPTN Board of Directors approved changes to types of VCA transplant programs

This proposal was generally supported during public comment. The majority of feedback agreed that *OPTN Bylaw, Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* should be applied to VCA programs in order to contribute to continued efforts to align VCA programs with all organ types in OPTN Policy, Bylaws, and Procedures. There was little discussion regarding the proposed change to *OPTN Bylaws, Appendix J: Membership and Personnel Requirements for VCA Transplant Programs*, but this portion of the proposal did not receive any feedback indicating opposition. The minority of public comment respondents including the American Society of Transplant Surgeons (ASTS), expressed concern that the proposed removal of the Appendix K exclusion which, would require VCA programs to notify patient and/or the OPTN based upon short or long-term inactivation status, is too prescriptive and has potential to overly complicate VCA program operations. When the Committee carefully considered the feedback from ASTS they discussed the importance of communication and transparency with VCA candidates related to programs being unable to perform transplants on a short or long-term basis. The Committee determined that the benefit of removing the Appendix K exclusion, which advances the goal to align VCA organs with other organ types and the Final Rule, outweighed the expressed concerns regarding potential additional burden for VCA programs. At the conclusion of this discussion, the Committee determined that the wide majority of public sentiment supports sending the proposal to the Board with no changes.

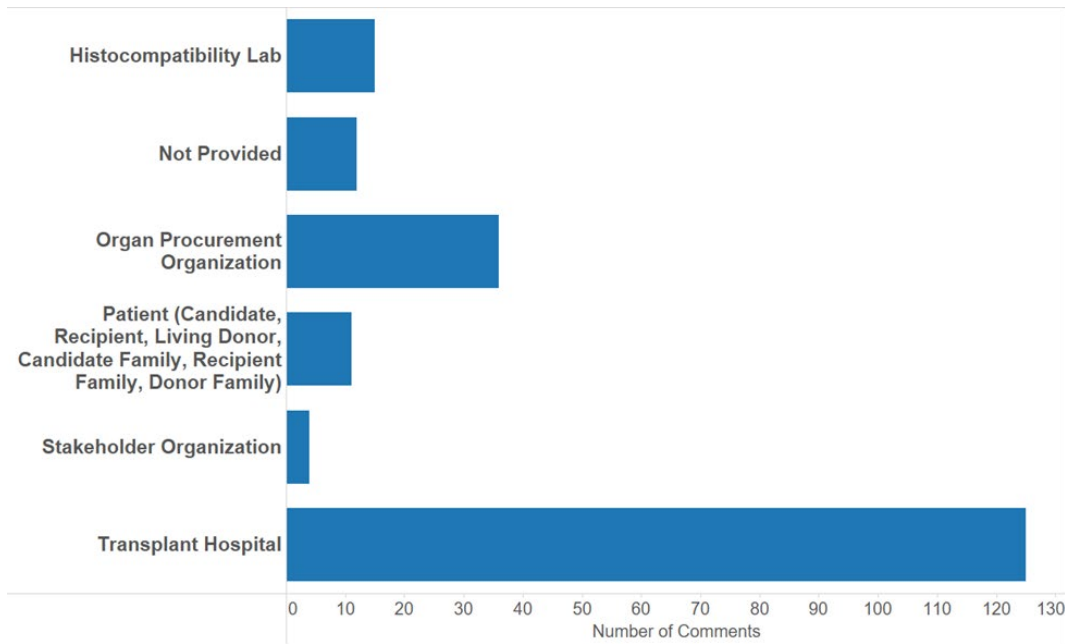
<sup>22</sup> *Establish Membership Requirements for Uterus Transplant Programs*, Policy and Bylaw Notice, accessed May 23, 2022, [https://optn.transplant.hrsa.gov/media/gapkr01m/policy-notice\\_establish-membership-requirements-for-uterus-transplant-programs\\_december-2021.pdf](https://optn.transplant.hrsa.gov/media/gapkr01m/policy-notice_establish-membership-requirements-for-uterus-transplant-programs_december-2021.pdf).

<sup>23</sup> Current Number of OPTN Approved VCA programs as of April 6, 2022.

## Overall Sentiment from Public Comment

The Committee welcomed all feedback on the proposed changes to OPTN Bylaws, Appendices J and K.<sup>24</sup> Due to the non-controversial nature of OPTN Bylaw changes, the proposal was on the non-discussion agenda for summer 2022 regional meetings. **Figure 1** shows *Apply Transplant Notification Requirements for VCA Program Inactivation* received 185 comments. Of these comments 6 were substantive, including 3 submitted by organizations and 3 submitted by regions. Comments received represent all member types, with the greatest participation coming from transplant programs, which is similar to other OPTN proposals.

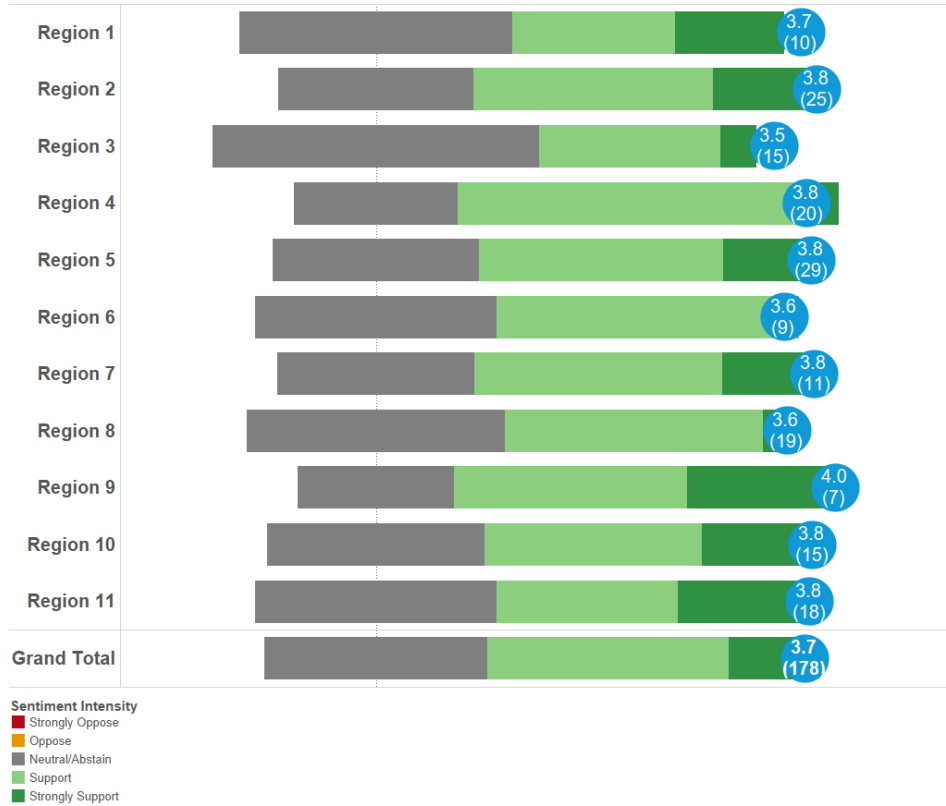
**Figure 1: Public Comment participation by member type, *Apply Transplant Notification Requirements for VCA Program Inactivation***



**Figure 2** shows sentiment received during regional meetings. All regions indicated neutral, supportive or strongly supportive sentiment on the proposal indicated by the green and grey. Regions 7 and 10 submitted substantive comments supporting the removal of the VCA exclusion as proposed, including requiring notification to the OPTN for long-term inactivity, and support for the inactivity timelines. There was also support expressed for updating eight VCA types to ten VCA types. Although no opposing or strongly opposing sentiment was received during regional meetings, members from region 2 expressed concern that this proposal may place unnecessary regulation on VCA programs.

<sup>24</sup> OPTN Public Comment, *Apply Transplant Notification Requirements for VCA Program Inactivation*, accessed October 7, 2022' <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/apply-transplant-notification-requirements-for-vca-program-inactivation/>

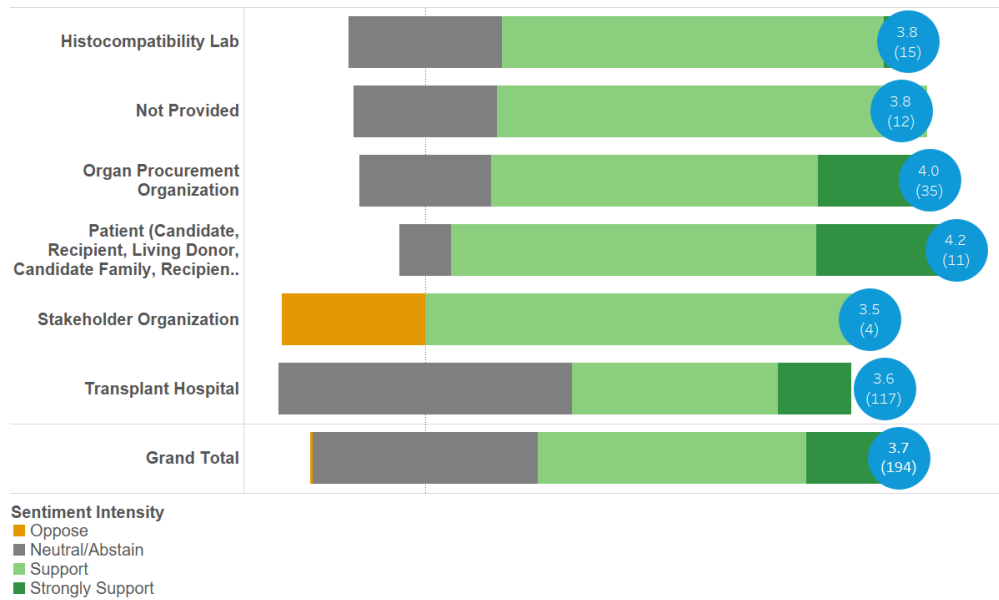
**Figure 2: Sentiment by Region, Apply Transplant Notification Requirements for VCA Program Inactivation<sup>25</sup>**



**Figure 3** shows sentiment received from all respondents by their indicated member type. All but one member type indicated neutral, supportive or strongly supportive sentiment on the proposal indicated by the green and grey. The American Society of Transplantation (AST) and The Organization for Donation and Transplant Professionals (NATCO) expressed support for the proposal. NATCO’s remarks included the following, *“Since VCAs were designated organs under the purview of the OPTN in July 2014 it would seem appropriate that VCA programs should notify their patients if they were to be on a short or long-term inactive period...”*. The American Society of Transplant Surgeons (ASTS) reported concerns similar to those heard during the region 2 meeting. Part of the public comment by ASTS expressed that, *“...The increased complexity of the approval process of VCA programs combined with new inactivity requirements could foreseeably decrease the number of active VCA programs and continue to decrease the availability and patient access to specific VCA programs.”*

<sup>25</sup> This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses

**Figure 3: Sentiment by member type, Apply Transplant Notification Requirements for VCA Program Inactivation<sup>26</sup>**



## Compliance Analysis

### NOTA and OPTN Final Rule

The VCA Committee submits this project under the authority of NOTA, which requires the OPTN to "establish membership criteria... and provide to members of the public an opportunity to comment with respect to such criteria," and the OPTN Final Rule requiring a transplant program "promptly to notify the OPTN and patients awaiting transplants if it becomes inactive" in order to receive organs for transplantation. This proposal applies patient notification requirements to designated VCA transplant programs in the event that the program becomes inactive.

## Implementation Considerations

### Transplant Programs

#### Operational Considerations

Transplant hospitals that perform covered VCA transplants would need to modify their current procedures and reporting in the event that their program is under short-term or long-term inactivation status or can no longer transplant a subset of patients. Programs seeking to reactivate after long-term inactivation or to extend their long-term inactivation status would also need to update their processes to meet those requirements.

<sup>26</sup> This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses



## *Fiscal Impact*

There is no expected fiscal impact for transplant hospitals generally, although individual VCA transplant programs will need to ensure they have processes in place for notifying candidates about program inactivation.

## Histocompatibility Laboratories

### *Operational Considerations*

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

### *Fiscal Impact*

There is no expected fiscal impact on histocompatibility laboratories.

## Organ Procurement Organizations

### *Operational Considerations*

This proposal is not anticipated to affect the operations of organ procurement organizations (OPOs).

### *Fiscal Impact*

There is no expected fiscal impact on OPOs.

## OPTN

### *Operational Considerations*

Since inactivity requirements are managed in the OPTN Computer System, the VCA Committee proposes implementing these changes concurrent with the implementation of VCA allocation in the OPTN Computer System.<sup>27</sup>

### *Resource Estimates*

The OPTN contractor estimates 50 hours for implementation. Implementation will involve updates to the OPTN Computer System to align with the previously approved Establish Membership Requirements for Uterus Transplant Programs body of work, education and training on the changes, and communication efforts about the changes. The OPTN contractor estimates 25 hours for ongoing support. Ongoing support may involve the OPTN requesting and processing documentation in the event of a transplant program inactivation, as well as answering member questions as necessary.

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<sup>27</sup> *Programming VCA Allocation in UNet<sup>SM</sup>*, Policy Notice, accessed May 25, 2022, [https://optn.transplant.hrsa.gov/media/4246/policy-notice\\_vca-in-unet\\_december-2020.pdf](https://optn.transplant.hrsa.gov/media/4246/policy-notice_vca-in-unet_december-2020.pdf).

## Post-implementation Monitoring

### Member Compliance

This proposal will not change current routine monitoring of OPTN members. The OPTN may review transplant program inactivation, and members must provide documentation as requested.

### Conclusion

Current OPTN policy excludes VCA from Appendix K.1 through K.3.<sup>28</sup> This proposal aims to remove that exclusion and require programs to notify their patients if they short-term inactivate, their patients and the OPTN if they long-term inactivate, and follow the requirements for reactivation after long-term inactivation or the requirements for extension of a long-term inactivation. This proposal also aims to make a change to Appendix J, of the Bylaws to update the reference to eight VCA program types to 10 VCA program types, reflecting that the OPTN Board of Directors approved splitting the "genitourinary organ" VCA type into three VCA types (uterus, external male genitalia, and other genitourinary organ) in December 2021 as part of the proposal entitled *Establish Membership Requirements for Uterus Transplant Programs*.

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<sup>28</sup> OPTN Bylaws, Appendix K, accessed May 25, 2022, [https://optn.transplant.hrsa.gov/media/lgbmahi/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf)

## Bylaws 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. The [...] signifies language in the current Policy that is not presented here for the purposes of brevity and will not be affected by the proposal.

1 **Appendix J:**

2 **Membership and Personnel Requirements for Vascularized Composite**  
3 **Allograft (VCA) Transplant Programs**

4  
5 [...]

6  
7 There are ~~eight~~ten types of VCA transplant programs: upper limb, head and neck, abdominal wall,  
8 ~~genitourinary organ, uterus, external male genitalia, other genitourinary organ,~~ vascularized gland, lower  
9 limb, musculoskeletal composite graft segment, and spleen. For approval as a designated VCA transplant  
10 program, transplant hospitals must also:

11  
12 [...]

13  
14 **Appendix K:**

15 **Transplant Program Inactivity, Withdrawal, and Termination**

16  
17 This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what  
18 members must do to be in compliance with OPTN obligations during these periods.

19  
20 The following provisions of Appendix K ~~do not apply to VCA transplant programs:~~

- 21  
22 ~~■ K.1: Transplant Program Inactivity~~  
23 ~~■ K.2: Short-term Inactive Transplant Program Status~~  
24 ~~■ K.3: Long-term Inactive Transplant Program Status~~

25  
26 [...]