

Public Comment Proposal

Apply Transplant Notification Requirements for VCA Program Inactivation


OPTN Vascularized Composite Allograft Transplantation Committee

Prepared by: Krissy Laurie

UNOS Policy and Community Relations Department

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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>

Executive Summary

The OPTN Vascularized Composite Allograft (VCA) Transplantation Committee (VCA 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.¹ 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".² The Committee also proposes a correction to Appendix J of the Bylaws to update the reference to eight VCA program types to ten VCA program types. 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).³

¹ OPTN Bylaws, accessed May 25, 2022, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

² 42 CFR §121.9(a)(2)

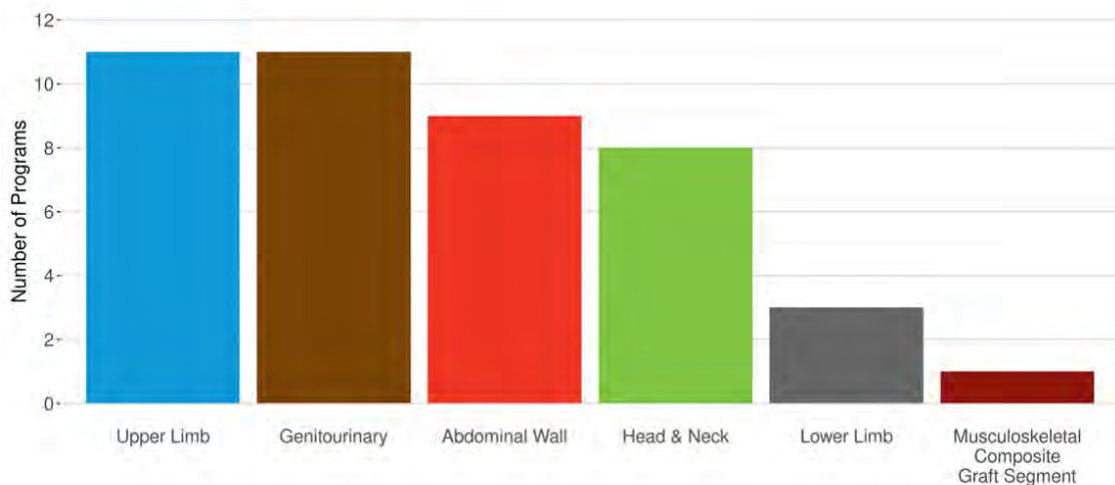
³ *Establish Membership Requirements for Uterus Transplant Programs*, Policy and Bylaw Notice, accessed May 23, 2022, https://optn.transplant.hrsa.gov/media/gapkr01m/policy-notice_establish-membership-requirements-for-uterus-transplant-programs_december-2021.pdf.

Background

This proposed bylaw change is 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.

Vascularized composite allografts (VCA) were designated as organs under the purview of the OPTN effective July 3, 2014.^{4,5} At that time, the OPTN Board of Directors approved changes to OPTN Bylaws requiring transplant programs to submit a letter of notification to the OPTN if they intended to perform VCA transplants.⁶ After this designation, the OPTN Board of Directors approved more detailed VCA membership requirements in 2015, 2016, and 2018.⁷ 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 2021.⁸ In December 2021, the OPTN Board of Directors approved further changes to the OPTN Bylaws to Establish Membership Requirements for Uterus Transplant Programs which will further separate the current genitourinary organ programs into uterus, external male genitalia, and other genitourinary programs.⁹ **Figure 1** shows the number of OPTN approved VCA programs as of April 2022.

Figure 1: Number of OPTN Approved VCA Programs¹⁰



⁴ 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>.

⁵ “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.

⁶ “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.

⁷ “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.

⁸ “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.

⁹ *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.

¹⁰ Current Number of OPTN Approved VCA programs as of April 6, 2022.

Currently, all other designated 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.¹¹ 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.¹² 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.

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. The proposed changes would be part of the continued effort to align VCA programs with all other organs in OPTN policy by requiring them to notify patients in the event that the program becomes short-term or long-term inactive.¹³ 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.^{14,15} 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".¹⁶

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 and the Committee also recognized the importance of informing patients.¹⁷

Purpose

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,

¹¹ OPTN Bylaws, Appendix K, accessed May 25, 2022, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

¹² OPTN Bylaws, Appendix K, accessed June 23, 2022, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf

¹³ Appendix K.1 explains that there are multiple reasons for which a designated transplant program may need to voluntarily inactivate, including The inability to meet functional activity requirements; The inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days; Temporarily lacking required physician or surgeon coverage; or A substantial change in operations that requires an interruption in transplantation. Functional inactivity is defined in Bylaw D.11, which details the number of transplants a designated transplant program for a specific organ type must perform in order to remain functionally active. No functional inactivity definitions have been established for VCA, islets, or intestinal organs, and this current proposal does not seek to change Bylaw D.11 at this time.

¹⁴ *Appendix K.1.A: Program Component Cessation*, OPTN Bylaw, accessed May 26, 2022,

https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

¹⁵ "Policy Notices," OPTN, accessed May 26, 2022, <https://optn.transplant.hrsa.gov/governance/policy-notice/>. See "Combined Policy Notice for VCA Membership Requirements" and "Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts" for details.

¹⁶ 42 CFR §121.9(a)(2).

¹⁷ 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.

and long-term inactive transplant program status. This exclusion was added when VCA was implemented as an organ under the purview of the OPTN in 2014. 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. 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.

The purpose of this project is to remove the exclusion so that these provisions of the Bylaws apply to VCA transplant programs. This project includes a correction to Appendix J of the Bylaws to update the reference of eight VCA program types to ten 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*.¹⁸

Overview of Proposal

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

NOTA and Final Rule Analysis

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.^{19,20} This proposal applies patient notification requirements to designated VCA transplant programs in the event that the program becomes inactive.

Implementation Considerations

Member Operations

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.

¹⁸ *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-programs_december-2021.pdf.

¹⁹ 42 U.S.C. §274(b)(2)(B)

²⁰ 42 CFR §121.9(a)(2)

This proposal is not anticipated to affect the operations of organ procurement organizations or histocompatibility laboratories.

Operations affecting Transplant Hospitals

This proposal would require that VCA transplant programs become familiar with the requirements outlined in Appendix K should they either short-term or long-term inactivate their program so they properly meet those requirements as necessary.

Operations affecting the OPTN

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.²¹

Projected Fiscal Impact

There is no expected fiscal impact on organ procurement organizations (OPOs), transplant hospitals, or histocompatibility laboratories.

Projected Impact on Transplant Hospitals

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.

Projected Impact on the OPTN

There is no expected fiscal impact on the OPTN.

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

This proposal aims to remove the exclusion of VCA from Appendix K.1 through K.3 and require VCA 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. The Committee also proposes a correction 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*.²²

²¹ *Programming VCA Allocation in UNetSM*, Policy Notice, accessed May 25, 2022, https://optn.transplant.hrsa.gov/media/4246/policy-notice_vca-in-unet_december-2020.pdf.

²² *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.

Consideration for the Community

The Committee is seeking public comment feedback on the removal of the VCA exclusion from transplant program inactivity patient and OPTN notification bylaw requirements.

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 [...]