

Notice of OPTN Bylaw Changes

Apply Transplant Notification Requirements for VCA Program Inactivation

Sponsoring Committee:	Vascularized Composite Allograft Transplantation
Bylaws Affected:	<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>
Public Comment:	August 3, 2022-September 28, 2022
Board Approved:	December 5, 2022
Effective Date:	Pending implementation and notice to OPTN members

Purpose of Bylaw Changes

This bylaw change removes the VCA exclusion from *OPTN Bylaw Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*. VCA transplant programs will be required to abide by 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.¹

The bylaw change also updates the reference of eight VCA program types to ten VCA program types in *OPTN Bylaw Appendix J: Membership and Personnel Requirements for VCA Transplant Programs*.² This bylaw update splits the "genitourinary organ" VCA type into three VCA types (uterus, external male genitalia, and other genitourinary organ) which aligns to the *Establish Membership Requirements for Uterus Transplant Programs* proposal that was approved by the OPTN Board of directors in December 2021.³

Proposal History

The proposed OPTN Bylaw changes are part of continued efforts to align VCA with all organ types in OPTN Policy, Bylaws, and procedures, including updates to data collection and implementing VCA allocation in the OPTN Computer System.

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

² OPTN Bylaws, accessed May 25, 2022, https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf.

³ 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

Summary of Changes

Remove VCA exclusion from *OPTN Bylaw Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*. This bylaw change will require VCA transplant programs to abide by the following requirements:

- VCA programs that voluntarily inactivate on a short-term basis are required to provide candidates with a written summary of its Program Coverage Plan
- VCA programs that long-term inactivate must notify the OPTN and follow requirements should the program seek reactivation or extension of that long-term inactive status
- VCA programs that have a cessation in their ability to transplant a subset of their patient population are required to notify patients
 - This proposal would not establish functional inactivity requirements for VCA

Update *OPTN Bylaw Appendix J: Membership and Personnel Requirements for VCA Transplant Programs*. This bylaw change will:

- Update the reference to eight VCA program types to ten VCA program types to reflect 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)⁴

Implementation

Upon implementation, VCA programs will be responsible for modifying their current procedures and reporting:

- If their program is under short-term or long-term inactivation status or can no longer transplant a subset of patients
- If their program is seeking to reactivate after long-term inactivation or to extend their long-term inactivation status

These bylaw changes will not require action from Organ Procurement Organizations (OPOs) or histocompatibility laboratories.

The OPTN is responsible for updates to the OPTN Computer System, education and training on the changes, and communication efforts about the changes.

Affected Bylaws Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

Appendix J:

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

[...]

⁴ 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

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

[...]

Appendix K:
Transplant Program Inactivity, Withdrawal, and Termination

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

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

- ~~■ *K.1: Transplant Program Inactivity*~~
- ~~■ *K.2: Short term Inactive Transplant Program Status*~~
- ~~■ *K.3: Long term Inactive Transplant Program Status*~~

[...]