

**OPTN/UNOS Executive Committee  
Report to the Board of Directors  
December 1-2, 2015  
Richmond, Virginia**

**Betsy Walsh, JD, Chair**

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**Betsy Walsh, JD, Chair**

*This report reflects the work of the OPTN/UNOS Executive Committee from June 1-November 18, 2015.*

**Action Items**

1. Approval of Minutes from the June 1-2, 2015 Board of Directors Meeting

The Board is asked to approve the minutes of the June 1-2, 2015 meeting of the OPTN/UNOS Board of Directors convened in Atlanta, Georgia. The draft meeting minutes have been distributed to the Board of Directors for its review via SharePoint. The following resolution is recommended for consideration by the Board:

**RESOLVED, that the minutes of the June 1-2, 2015 meeting of the Board of Directors in Atlanta, Georgia as set forth in the materials distributed to the Board of Directors on November 18, 2015, are hereby approved.**

2. Consideration of Changes to the VCA membership requirements

The Board is asked to decide whether to delay implementation of some or all of the VCA membership requirements approved at the June 2015 Board meeting in Atlanta, Georgia.

**RESOLVED, that changes to OPTN Bylaws Appendix J (Membership Requirements for VCA Transplant Program), as set forth in Exhibit A of the Executive Committee's report to the Board, are hereby approved, effective pending programming and notice to OPTN members.**

**Executive Committee Actions on Policy**

3. Changes to implementation date for new definition of pancreas graft failure

In June 2015, the Board approved changes to OPTN policy regarding the definition of pancreas graft failure. The resolution approved by the Board contained an incorrect effective date of September 1, 2015. The proposal requires form approval by the federal Office of Management and Budget (OMB). The change also involves computer programming. Therefore, the resolution should have said that it was effective pending programming and notice to the OPTN membership.

On June 29, 2015, the Executive Committee considered the Pancreas Committee's request to approve a new resolution making the proposal effective pending and notice to the OPTN membership. The vote was unanimous (9-Y, 0-N, 0-A).

4. Changes to implementation date for new ABO policies

In June 2015, the OPTN/UNOS Board approved changes to OPTN policies regarding blood type verifications. The changes were approved with an effective date of February 1, 2016. UNOS IT is currently working to program computer system tools that will support member compliance with the new policy. These system enhancements were originally expected to be complete in Fall 2016. UNOS IT leadership recently re-assessed the IT Road Map (comprehensive schedule of IT work to complete) and determined it is possible to deliver the

system tools earlier in the year (it is estimated that completion will be in the 2nd quarter of 2016).

On a September 21, 2015 conference call, UNOS staff requested and the Executive Committee approved (by vote of 10-Y, 0-N, 0-A) a change in the implementation date for this project. The new rules will become effective once the system tools are in place.

5. Clarifications to Policy 9.1 MELD Score

In June 2014, the Board of Directors approved a new policy to incorporate serum sodium into the MELD score calculation. At the time of Executive Committee consideration, the policy was pending computer programming and expected to become effective upon implementation. Upon implementation, the system automatically calculates candidates' new MELD score. The Committee requested that the Executive Committee approve changes to provide a 7-day "grace period" during implementation for those candidates whose scores would be moved from one certification to another, and may as a result require immediate re-certification (i.e., the candidates would face an immediate "downgrade" of their MELD score). As proposed, if the center had not re-certified these candidates on the 8<sup>th</sup> day after implementation, the candidates would be downgraded to their previous lower MELD score as is done currently when certification expires.

On July 20, 2015 the Liver Committee requested that the Executive Committee approve clarifying changes to policy 9.1 MELD Score for the purposes of implementing changes to the MELD score. The Committee unanimously (9-Y, 0-N, 0-A) approved these changes.

6. Clarifications to Policy 13.5.B Antibody Screening Requirements for OPTN KPD Candidates

In November 2014, the OPTN/UNOS Board of Directors approved changes to (KPD) histocompatibility testing requirements for programs participating in the OPTN/UNOS KPD program. Included in these policies is a requirement for candidate transplant hospitals to test KPD candidates for antibodies "at least once every 90 days (+/- 20 days) from the date of the first antibody test." The new rules are currently being programmed into the KPD computer system.

During implementation meetings, UNOS staff found that although the policy specifically mentions that candidates must be tested every 90 days from the date of the first antibody test, the intent of the policy was to prohibit a candidate from going longer than 90 days without being retested. However, if the candidate was more recently tested due to a potentially sensitizing event or unacceptable positive crossmatch, the candidate should not have to be re-tested again within that 90 day timeframe. The Kidney Transplantation Committee requested that the Executive Committee approve clarifying changes to the policy that would tie the 90 day antibody testing requirement to the most recent antibody test date and to modify the 40 day window created by the +/- 20 days language.

On an October 19, 2015 conference call, the Executive Committee unanimously (11-Y, 0-N, 0-A) approved these changes. The changes will allow transplant hospitals to test KPD candidates within 110 days from the most recent test date, in order to reduce the number of potentially unnecessary tests.

7. Clarifications to Policy 18.1 Data Submission Requirements

In June 2015, the Board approved numerous proposals that affected OPTN *Policy 18.1: Data Submission Requirements*. All five resolutions made changes to the language in this policy:

- Resolution 18 (VCA)

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- Resolution 23 (Living Donation)
- Resolution 27 (VCA)
- Resolution 33 (OPO), as amended
- Resolution 35 (POC)

Upon updating the policy language for the September 1 implementation date, staff discovered that there was one line in Policy 18.1, Table 18.1 where the Board-approved language was in conflict. This conflict resulted in slight differences in phrasing in Resolution #27 and Resolution #33 as presented and approved at the June 2015 Board meeting. UNOS staff requested that the Executive Committee approve the resolved language, which corrects differences in language approved by the Board but does not make substantive changes to either proposal's language.

The Executive Committee unanimously (11-Y, 0-N, 0-A) approved these changes.

### 8. Changes to policy regarding the HIV Organ Policy Equity (HOPE) Act

The Organ Procurement Organization (OPO) Committee has requested several policy changes regarding the HOPE Act. See below for an explanation of changes made by topic.

#### *Allocating HIV+ organs to recipients who do not appear on the match run.*

During the June 2015 Board of Directors meeting the Board approved policy changes to create a variance for the allocation and transplantation of HIV positive organs into HIV positive recipients. However, a Board member expressed concern that the language addressing the allocation of HIV+ organs to HIV+ recipients not appearing on the match run did not clearly limit the practice to directed donations. During the development of the policy language, it was the OPO Committee's intent to only allow for an exception in cases where an HIV positive donor or legal next of kin wishes to directly donate organs to an HIV positive candidate, even if the candidate does not appear on the match run due to the candidate having a blood type that is not identical or permissible in OPTN policy.

The Executive Committee unanimously (11-Y, 0-N, 0-A) approved modifications to this policy to clarify that an HIV+ organ can only be allocated to HIV+ recipient who does not appear on the match run in the event of a directed donation.

#### HOPE Act research reporting.

The HOPE Act states that "not later than 4 years after the date of enactment and annually thereafter, the Secretary shall review the results of scientific research in conjunction with the Organ Procurement and Transplant Network to determine whether the results warrant revision of the standards of quality." UNOS leadership discussed the OPTN's role in this review and how to best meet the statutory requirements. These discussions resulted in a recommended modification to the variance to require members participating in a HOPE Act research study to provide periodic reports from their data safety monitoring boards to the OPTN.

The Executive Committee unanimously (11-Y, 0-N, 0-A) approved this request but agreed that this is the type of substantive change was contemplated with the creation of the new emergency policy development track created by the Board earlier this year. Therefore, the Committee elected to adopt a sunset date for this change and distribute this policy change for public comment during the January-March 2016 public comment period.

#### Clarifications to Policy 2.7 HIV Screening of Potential Deceased Donors.

In preparation for the implementation of the HOPE Act on November 21, 2015, UNOS staff identified a proposed policy change that was not submitted to the Board of Directors in June

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2015 as part of the HOPE Act proposal. This policy change was distributed for public comment during the September-December 2014 period; the policy had strong support during public comment and was approved by the OPO Committee. This policy change is necessary to remove the existing prohibition on the recovery and transplantation of organs from deceased donors known to be infected with HIV, and to allow for the conduct of research as outlined in OPTN Policy 15.6, the HOPE Act, and the OPTN Final Rule, and necessary for the successful implementation of the HOPE Act.

The Executive Committee unanimously approved this change (9-Y, 0-N, 0-A) on its November 16, 2015 conference call.

### 9. Retrospective review of clerical policy changes

In November 2014, the Board of Directors approved a change to the OPTN Bylaws that permits UNOS staff to make clerical, non-substantive changes to the bylaws and policies. The Bylaws specifies that the Executive Committee must retrospectively review any corrections made. The Committee reviewed and approved unanimously changes made to policy in the last six months.

Clerical changes criteria: The new rule allows UNOS staff to make the following types of clerical changes:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited.

The UNOS policy department staff presented a number of clerical changes that had been made since the new policy became effective on February 1, 2015.

Clerical Change	Reason
Bylaws D.5 Transplant Program Key Personnel	Deleted obsolete reference to <i>Appendix J: Membership and Personnel Requirements for Joint Heart and Lung Programs</i> , which no longer exists as of June 2014.
Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination	Corrected typo that said “The following provisions of Appendix D do not apply to VCA transplant programs,” with the correct reference to Appendix K.
Policy 14.4.B: Living Donor Medical Evaluation Requirements, Table 14-6: Requirements for Living Donor Medical Evaluations	Removed unnecessary period.
Policy 14.4.B: Living Donor Medical Evaluation Requirements, Table 14-6: Requirements for Living Donor Medical Evaluations	Corrected typo from <i>preventative</i> to <i>preventive</i> in “U.S. Preventive Services Task Force”
Policy 14.4.C, Table 14-7: Additional Requirements for Medical Evaluation of Living Kidney Donors	Deleted repeated language that introduces list of items required for the kidney-specific person history. Removed the first colon to combine the two lead clauses to only one, using a comma between. This also required making the letter “A” before <i>kidney-specific</i> a small “a.”

On an August 11, 2015 conference call, the Committee approved these changes unanimously (12-yes, 0-no, 0-abstain).

## **Oversight of Committee Project Portfolio, Public Comment Proposals, Board Approved IT Projects**

### **10. Committee Project Portfolio Review**

In June, the Committee met to consider recommendations from the Policy Oversight Committee (POC) regarding the committee project portfolio for the upcoming year and how those projects aligned with the resource allocation benchmarks in the OPTN strategic plan. Because there is a new 2015-2018 OPTN strategic plan and new resource allocation benchmarks, the POC recommended that 12 committee projects be put “on hold” to free up some resources for projects intended to impact the strategic goal to increase the number of transplants.

The Committee voted unanimously to place the following 11 committee projects on hold:

- Consider if living donor recovery hospitals should be responsible for providing care for post-operative complications (Ethics Committee)
- Enhancing priority for DR matching in kidney allocation (Histocompatibility Committee)
- New requirements for the transport of living donor organs (Living Donor Committee)
- Consider primary surgeon qualifications-primary or first assistant on transplant cases (MPSC)
- Define working knowledge for primary physician qualification pathways (MPSC)
- Reassess currency requirements for primary surgeons and primary physicians (MPSC)
- Approved transplant fellowship training programs (MPSC)
- Consider requirement for primary physician observation of procurements (MPSC)
- Composite pre-transplant metrics (MPSC)
- Proposal to notify patients with extended inactive status (Transplant Coordinators Committee)

In addition, the Committee provided direction that the project, “Changes to KAS CPRA priority for kidney candidates undergoing desensitization” from the Histocompatibility Committee should be broken into two phases. The project is in the first phase of collecting data on how any changes being contemplated might impact candidate order and allocation. The Committee directed the second phase (policy development) be put on hold until this data has been collected.

### **11. Review of public comment proposals**

Before each public comment period, the Executive Committee reviews and approves which committee proposals will be distributed for community and public input. The Policy Oversight Committee (POC) performs an extensive review of the proposals and presents a recommendation to the Executive Committee prior to the vote. The POC reviews the proposals to ensure that each aligns with the OPTN strategic plan, the committee has collaborated with all the appropriate stakeholders, and the proposal is clearly written and explained. The Executive Committee reviews public comment proposals to ensure that all align with the OPTN strategic plan and the timing and level of resource allocation on each proposal is appropriate for the benchmarks outlined in the plan.

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POC chair Sue Dunn presented the POC recommendations to the Committee. The POC recommended that the following proposals be distributed for public comment for the August 14-October 14 comment period:

1. Pediatric Transplantation Committee—Establish pediatric training and experience requirements
2. Data Advisory Committee—Revise data release policies
3. Kidney Transplantation Committee—Simultaneous liver kidney allocation policy
4. Kidney Transplantation Committee—Revise KPD priority points
5. Histocompatibility Committee—Updates to the HLA Equivalency Tables
6. Living Donor Committee—Requirements for therapeutic organ donation
7. Membership and Professional Standards Committee—Foreign equivalent in Bylaws
8. Membership and Professional Standards Committee—Personnel Procurement Requirement
9. OPO Committee—Reduce documentation shipped with organs
10. Policy Oversight Committee—Increase committee member terms to three years
11. Thoracic Transplantation Committee—Modify pediatric lung allocation policy
12. Pancreas Transplantation Committee--Revise facilitated pancreas allocation policy

The Committee members unanimously approved the POC's recommendation (12-yes, 0-no, 0-abstain) but requested that the Spring 2016 public comment proposals include a more elaborate analysis of the cost v. benefit for each proposal. The Committee members also agreed that future consideration of public comment proposals will need to include an analysis of how the overall portfolio is aligned with the resource allocation benchmarks outlined in the OPTN strategic plan.

### 12. Endorsement of schedule of work for Board approved projects requiring IT programming

In June, the Executive Committee reviewed the UNOS IT Roadmap (the schedule of work for implementing Board approved projects requiring computer system programming). The Committee endorsed the schedule of work for the upcoming year.

## **Responses to Federal Issues and Other Proposed Rules**

### 13. OPTN response to federal NIH HOPE Act Criteria

In November 2013, the HIV Organ Policy Equity (HOPE) Act was signed into federal law. The law authorizes transplantation of HIV positive organs into HIV positive recipients. It also requires that the OPTN revise its policies no later than 2 years after the law takes effect. In June 2015, the Board approved new policies to implement these requirements. Under the next step of this process, the National Institute of Health (NIH) has developed research criteria for internal review boards (IRBs) to use in assessing whether a transplant program should be approved to participate in the HOPE Act variance. The proposed criteria was published in the Federal Register for a 60 day public comment period on June 18, 2015.

UNOS has an established 'Plan for Review of Federal Issues', as outlined in the OPTN contract. Under this process, the Executive Committee may provide an official response to federal issues on behalf of the OPTN. The OPTN's HOPE Act working group, which is comprised of several OPTN/UNOS committees drafted a proposed response for the Committee's review and consideration. Rich Pietroski, Chair of the HOPE Act working group and Executive Committee member, presented the draft response to the Committee.

The Committee discussed whether the proposed draft should be strengthened to highlight greater concerns about the inclusion of living donors into the research study. Mr. Pietroski reported that the working group had discussed this issue and there is no consensus within

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the transplant community about whether it is appropriate to include living donors. The federal statute, regulations, and research criteria are all silent on the issue. Ultimately, the working group recommends that the decision be made by each transplant center's IRB and that the OPTN not take an official stance on the issue.

The Committee also discussed whether the response should express concerns about the OPTN bearing responsibility for additional data collection as part of the research efforts. The Committee ultimately felt that this was not necessary because there was no explicit reference to the OPTN bearing this responsibility in the statute or NIH research criteria.

The Committee unanimously approved the response recommended by the HOPE Act working group (12-yes, 0-no, 0-abstain) for submission in the Federal Register.

### 14. Response to proposed ABIM certification requirements

In September 2015, the American Board of Internal Medicine reached out to request UNOS feedback on proposed changes to the current training and procedural requirements for certification in transplant hepatology.

In keeping with the OPTN/UNOS process for responding to these types of requests, the Liver and Intestinal Transplantation Committee reviewed the proposed changes and recommended that the Executive Committee endorse them.

On an October 19, 2015 conference call, the Executive Committee voted unanimously (11-Y, 0-N, 0-A) to endorse the proposed changes.

## Other Actions

### 15. Approval of IT strategic plan

On a June 29 conference call, the Committee reviewed and endorsed the IT strategic plan, which explains the technology direction for OPTN/UNOS systems and the strategic goals that are driving that direction. The IT Strategic Plan also serves as the Application and Technology Roadmap which is an OPTN Contract Deliverable (Delivery Item 39) and must be submitted to Health Resources and Services Administration (HRSA) within 30 days following OPTN Board of Directors approval.

### 16. Approval of changes to social security numbers (SSN) and date of birth (DOB) data entry

On the June 29 conference call, UNOS staff requested that the Committee endorse a new requirement for double entry of SSN and DOBs entered into UNet<sup>SM</sup>. In the process of adding or editing a candidate record in UNet<sup>SM</sup>, transplant programs sometimes enter an inaccurate SSN and/or DOB for a candidate. These data are critical, as the UNet<sup>SM</sup> system uses them to make decisions for medical urgency and allocation order. As one example, an incorrect SSN for a candidate could lead to an incorrect assessment of multi-organ listings. In addition, some allocation priority is based on factors determined by this data (i.e. age or whether the candidate had a prior transplant). In these ways, these errors can have a direct negative impact on candidate allocation order.

There are also indirect impacts associated with these errors. The UNOS research department uses these data to prepare data sets for the committees, and the Board and committees use these data analyses to make policy decisions. When these errors are identified (either internally by UNOS staff or externally by transplant programs), staff time must be spent on correcting these errors.

The UNOS research department staff presented the following statistics on these errors.

In the 5 year period from Oct 2009 – Oct 2014:

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- Staff internally identified 12,693 potential discrepancies involving SSN and/or DOB. This constituted 2815 staff hours (roughly .25 FTE annually)
- Members generated 778 requests to maintain/correct discrepancies involving SSN and/or DOB
- There were a total of 6,900 SSN and DOB changes, an average of 26 corrections made per week
- The majority (> 76%) were due to minor transcription errors

The Committee approved this change, which required some computer system programming.

### **Other Committee Work**

#### **17. Feedback to Liver and Intestinal Organ Transplantation Committee (“Liver Committee”) on Liver Redistricting project**

On a September 21, 2015 conference call, the Liver Committee provided the Executive Committee with a status update on two projects that originated from OPTN/UNOS Board directives: 1) Liver redistricting; and 2) National Liver Review Board (“NLRB”).

The Liver Committee leadership explained that the NLRB project is on track to be released for public comment ahead of the redistricting project and the NLRB changes (along with others that could be addressed within this proposal) are appropriate to be addressed in advance of a liver redistricting proposal. Members of the Executive Committee agreed that this timing was appropriate and provided direction that the Liver Committee should prioritize OPTN committee resources on projects that will directly impact further consensus on the liver redistricting project.

#### **18. Feedback to Pediatric Transplantation Committee on pediatric experience requirements in the Bylaws**

On an October 19 conference call, the Committee received an update from the Pediatric Transplantation Committee on the project to create new pediatric training and experience requirements in the Bylaws.

Dr. Eileen Brewer, chair of the Pediatric Committee, reviewed the public comments with the Committee and explained that the Committee was considering two post-public comment changes at this time:

- 1) Remove any new requirements for pediatric lung key personnel (because many have expressed concerns about the ability to meet the volume requirements and there are very small numbers of these transplants done each year).
- 2) Establish an emergency exception for liver and heart candidates with status 1A if the program certifies that the exception is needed to address an immediate threat to the patient’s health.

Several members of the Committee raised concerns about the adolescent patient population and whether access was going to be constrained for this group of patients. It was suggested by one member that the Pediatric Committee consider an amendment that would allow for a pathway other than pediatric board certification for programs treating older pediatric patients.

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### **Meeting Summaries**

The committee held meetings on the following dates:

- June 29, 2015
- July 20, 2015
- August 11, 2015
- September 21, 2015
- October 19, 2015
- November 16, 2015

Meetings summaries for this Committee are available on the OPTN website at:  
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=17>.

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# Modifications to OPTN Bylaws, Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

*Committee Liaison  
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UNOS Policy Department*

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# Modifications to OPTN Bylaws, Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

*Mini-Brief*

## Executive Summary

In June 2015, the OPTN/UNOS Board of Directors (Board) approved amendments to the OPTN Bylaws, Appendix J that established detailed membership requirements for vascularized composite allograft (VCA) transplant programs. These changes outlined membership requirements for upper limb, head and neck, abdominal wall, and “other” VCA transplant program types. Additionally, the Board approved the previous, more general, membership requirements be effective until the detailed membership requirements are implemented. Following the Board meeting, the OPTN/UNOS Executive Committee approved the implementation of the Membership Requirements for VCA Transplant Programs for the second quarter of 2016.

Just prior to the June 2015 Board meeting, representatives from the Health Resources and Services Administration (HRSA) Division of Transplantation notified UNOS staff and leadership of the VCA Committee that the HRSA Office of General Counsel noted an inconsistency between the OPTN Final Rule and OPTN Policy/Bylaw language pertaining to VCAs. Specifically, the OPTN Final Rule directs the OPTN to identify covered body parts in any policies specific to vascularized composite allografts<sup>1</sup>. As written, the OPTN Policies and Bylaws do not consistently specify the covered body parts that are VCAs. The VCA Committee has begun work on policy and bylaw language amendments to be consistent with the OPTN Final Rule.

The anticipated implementation of the Membership Requirements for VCA Transplant Programs (second quarter 2016) conflicts with the timeline for the VCA Committee’s work on amendments to policy and bylaw language. As a result, the Executive Committee is asking the Board to delay the implementation of the detailed membership requirements for “other” VCA program types until policy and bylaw language addressing VCA specificity are resolved.

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<sup>1</sup> §42 CFR 121.4(e)(3) <http://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5>

# Modifications to OPTN Bylaws, Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

*Affected Policies:* OPTN Bylaws, Appendix J (Membership Requirements for VCA Transplant Programs – J.1, J.1.A-J.1.F, and J.2)

*Sponsoring Committee:* OPTN/UNOS Executive Committee

## What problem will this proposal solve?

In June 2015, the OPTN/UNOS Board of Directors (Board) approved amendments to the OPTN Bylaws, Appendix J that established detailed membership requirements for vascularized composite allograft (VCA) transplant programs. These changes outlined membership requirements for upper limb, head and neck, abdominal wall, and “other” VCA transplant program types. Additionally, the Board approved the previous, more general, membership requirements be effective until the detailed membership requirements are implemented. Following the Board meeting, the OPTN/UNOS Executive Committee approved the implementation of the Membership Requirements for VCA Transplant Programs for the second quarter of 2016.

Just prior to the June 2015 Board meeting, representatives from the Health Resources and Services Administration (HRSA) Division of Transplantation notified UNOS staff and leadership of the VCA Committee that the HRSA Office of General Counsel noted an inconsistency between the OPTN Final Rule and OPTN Policy/Bylaw language pertaining to VCAs. Specifically, the OPTN Final Rule directs the OPTN to identify covered body parts in any policies specific to vascularized composite allografts. As written, the OPTN Policies and Bylaws do not consistently specify the covered body parts that are VCAs. The VCA Committee has begun work on policy and bylaw language amendments to be consistent with the OPTN Final Rule.

The anticipated implementation of the Membership Requirements for VCA Transplant Programs (second quarter 2016) conflicts with the timeline for the VCA Committee’s work on amendments to policy and bylaw language.

## Why should you support this proposal?

Implementing membership requirements is a resource-intensive project for the OPTN. This involves creation of membership applications, review by the U.S. Office of Management and Budget, and expenditure of IT resources for programming. UNOS leadership believes it premature to implement membership requirements for “Other” VCA transplant programs while the VCA Committee develops amendments to Appendix J. Additionally, these amendments are needed to ensure the OPTN Policies and Bylaws are consistent with the OPTN Final Rule. The Committee is therefore asking the Board to not implement Bylaws Appendix J.3.D: Additional Primary Surgeon Requirements for Other VCA Transplant Programs, until policy and bylaw language addressing VCA specificity is resolved. Once language

regarding VCA specificity is resolved, the VCA Committee will bring an updated proposal back to the Board.

In lieu of the language on membership requirements for “Other” VCA transplant programs approved in June 2015, the Committee is asking the Board to retain the existing general VCA membership requirements, outlined in the Policy and Bylaw section of the Mini-brief below. Procedurally, the Committee is asking to revert to the membership requirements previously approved by the Board. This proposal will allow currently approved “Other” VCA transplant programs to maintain their program designation. Additionally, this proposal will allow transplant hospitals that wish to perform VCA transplants other than upper limbs, head and necks, and abdominal walls, a mechanism to apply to OPTN.

## How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact on this goal.
2. *Improve equity in access to transplants:* There is no impact on this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* This specific proposal has no impact on this goal. However, the previously Board approved VCA membership proposal would establish objective requirements for the OPTN/UNOS to assess qualifications of key VCA transplant program personnel.
4. *Promote living donor and transplant recipient safety:* There is no impact on this goal.
5. *Promote the efficient management of the OPTN:* This proposal makes OPTN Policies and Bylaws consistent with the requirements of the Final Rule.

## How will the OPTN implement this proposal?

This proposal requests a delay in the implementation of Board-approved language and maintains the status quo (general membership requirements) regarding membership requirements for “Other” VCA transplant program types. Similar to the OPO Committee’s proposal to delay the implementation of Imminent and Eligible Death Data Definition, the Committee’s proposal to delay implementation of membership requirements for “Other” VCA transplant programs will not go out for public comment.

Only the Board is empowered to make amendments to the OPTN Bylaws as outlined in the Code of Virginia<sup>2</sup>, and OPTN/UNOS Bylaw Article X<sup>3</sup>. Because this proposal amends language in the OPTN Bylaws, the Committee is required to submit the proposal for Board consideration.

The OPTN will continue to direct new notification letters from transplant hospitals to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review. The OPTN will communicate the changes to Bylaws, Appendix J through a policy notice to the transplant community.

Although this proposal will not directly require programming in UNet<sup>SM</sup>, the proposal will be effective pending programming of the membership requirements approved by the Board in June 2015 and notice to OPTN members. This will avoid the circumstance of membership requirements being effective before programming is completed. There will be instructional support required for this proposal.

## How will members implement this proposal?

The currently approved “other” VCA transplant programs will not be impacted by this proposal. If this proposal is approved, transplant hospitals that wish to apply for a VCA program type, other than

<sup>2</sup> VA Code § 13.1-869 (2013) <http://law.lis.virginia.gov/vacode/title13.1/chapter10/section13.1-869/>

<sup>3</sup> OPTN Bylaws, Article X

[http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Bylaws.pdf#nameddest=Article\\_10](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Article_10)

abdominal wall, head and neck, and upper limb, will follow requirements already in existence. This process requires a letter of notification from the transplant hospital with the following:

1. The specific types of VCA transplant the hospital will perform.
2. If the member will perform deceased donor VCA transplants, assurance from the local OPO that it will provide the same type or types of VCA for transplantation.

The letter of notification from the transplant hospital must be signed by *all* of the following individuals:

1. The chief administrative officer for the institution.
2. The reconstructive surgeon for each type of VCA transplant with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction.
3. The transplant physician or transplant surgeon for each type of VCA transplant at an approved transplant program that has completed an approved transplant fellowship, or who qualifies by documented transplant experience in a medical or surgical specialty.

### Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

### How will members be evaluated for compliance with this proposal?

The MPSC will still plan to review VCA transplant program applications and key personnel change applications for head and neck, upper limb, and abdominal wall to determine compliance with the proposed Bylaws once implemented. For other VCA programs, the MPSC process for review will not change from the process as it exists today; the MPSC will review notification letters for new applicants and changes to identified individuals.

### Policy or Bylaw Language

**RESOLVED, that changes to OPTN Bylaws Appendix J (Membership Requirements for VCA Transplant Program), as set forth in Exhibit A of the Executive Committee’s report to the Board, are hereby approved, effective pending programming and notice to OPTN members.**

#### **Appendix J:**

#### **Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs**

~~This appendix describes the information and documentation transplant hospitals must provide when:~~  
This appendix describes the documentation transplant hospitals must provide when requesting approval as a designated VCA transplant program.

- ~~■ Submitting a completed membership application to apply for approval for each designated VCA transplant program.~~
- ~~■ Completing a Personnel Change Application for a change in key personnel at each designated VCA transplant program.~~

## **J.1 Membership Requirements for Abdominal Wall, Head and Neck, and Upper Limb VCA Transplant Programs**

Appendix J.1 applies only to abdominal wall, head and neck, and upper limb VCA transplant programs.

For approval as a designated VCA transplant program, transplant hospitals must ~~also~~:

1. Meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.
2. Have current approval for and maintain a designated kidney, liver, heart, lung, or pancreas transplant program.

For more information on the application and review process, see *Appendix A: Membership Application and Review*.

### **J.1.A Program Director, Primary Transplant Physician, and Primary Transplant Surgeon**

A VCA transplant program must identify at least one designated staff member to act as the VCA program director. The director must be a physician or surgeon who is a member of the transplant hospital staff. The same individual can serve as the program director for multiple VCA programs.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary transplant surgeon, primary transplant physician, and VCA program director for each designated VCA transplant program must submit a detailed Program Coverage Plan to the OPTN Contractor. For information about the Program Coverage Plan, see *Appendix D.6.B, Surgeon and Physician Coverage*.

### **J.21.B Primary VCA Transplant Physician Requirements**

Each designated VCA transplant program must have a primary transplant physician who is (1) currently designated as the primary transplant surgeon or primary transplant physician at an active solid organ transplant program, (2) meets the requirements of a primary transplant surgeon or primary transplant physician in the OPTN Bylaws, or (3) who meets *all* of the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. The physician must have documentation from the hospital's credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have completed an approved transplant fellowship in a medical or surgical specialty. Approved transplant fellowships for each organ are determined according to the requirements in OPTN Bylaws Appendices E through I.

### **J.31.C Primary VCA Transplant Surgeon Requirements**

Each designated VCA transplant program must have a primary transplant surgeon that meets *all*

59 of the following requirements:

60

61 1. The primary surgeon must have an M.D., D.O., or equivalent degree from another country,  
62 with a current license to practice medicine in the hospital's state or jurisdiction.

63 2. The primary surgeon must be accepted onto the hospital's medical staff, and be on-site at  
64 this hospital.

65 3. The primary surgeon must have documentation from the hospital's credentialing committee  
66 that it has verified the surgeon's state license, training, and continuing medical education,  
67 and that the surgeon is currently a member in good standing of the hospital's medical staff.

68 4. The primary surgeon must have observed at least 2 multi-organ procurements.

69

### 70 **J.3.A1.D Additional Primary Surgeon Requirements for Upper Limb** 71 **Transplant Programs**

72 In addition to the requirements as described in J.1.C above, the surgeon for an upper limb  
73 transplant program must meet the following:

74

- 75 1. Must meet at least *one* of the following:
- 76 a. Have current certification by the American Board of Plastic Surgery, the American Board  
77 of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the  
78 case of a surgeon who has just completed training and whose board certification is  
79 pending, the Membership and Professional Standards Committee (MPSC) may grant  
80 conditional approval for 24 months to allow time for the surgeon to complete board  
81 certification, with the possibility of renewal for an additional 12-month period.
  - 82 b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of  
83 the relevant clinical experience as outlined below. As of September 1, 2018, this pathway  
84 will no longer be available and all primary surgeons must meet the requirements of  
85 paragraph 1A.
    - 86 i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or  
87 primary surgeon on at least 1 VCA procurement.
    - 88 ii. Pre-operative evaluation of at least 3 potential upper limb transplant patients.
    - 89 iii. Acted as primary surgeon of a least 1 upper limb transplant.
    - 90 iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

91

92 The multi-organ procurement experience must be documented in a log that includes the  
93 Donor ID or other unique identifier that can be verified by the OPTN Contractor. The  
94 experience for upper limb transplant procedures must be documented in a log that includes  
95 the dates of procedures and evaluations, the role of the surgeon, and the medical record  
96 number or other unique identifier that can be verified by the OPTN Contractor. This log must  
97 be signed by the program director, division chief, or department chair where the experience  
98 was gained.

99

100 If a primary surgeon qualified under 1.b ends his involvement with the transplant program, the  
101 program must identify a primary transplant surgeon who meets the requirements under 1.a.

102

- 103 2. Completion of at least *one* of the following:
- 104 a. Completion of a fellowship program in hand surgery that is approved by the MPSC. Any  
105 Accreditation Council of Graduate Medical Education (ACGME) approved fellowship  
106 program is automatically accepted by the MPSC.

107

- 108 b. Completion of a fellowship program in hand surgery that meets *all* of the following criteria  
 109 will also be accepted:  
 110  
 111 i. The program is located at a hospital that has inpatient facilities, operative suites  
 112 and diagnostic treatment facilities, outpatient facilities, and educational resources.  
 113 ii. The program is located at an institution that has a proven commitment to graduate  
 114 medical education.  
 115 iii. The program director must have current certification in the sub-specialty by the  
 116 American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or  
 117 American Board of Surgery.  
 118 iv. The program should have at least 2 physician faculty members with hand surgery  
 119 experience and current medical licensure who are actively involved in the  
 120 instruction and supervision of fellows during the time of accredited education.  
 121 v. The program at a hospital that has affiliated rehabilitation medicine services.  
 122 vi. The program has the resources, including adequate clinical facilities, laboratory  
 123 research facilities, and appropriately trained faculty and staff, to provide research  
 124 experience.  
 125  
 126 c. The surgeon must have at least 2 years of consecutive and independent practice of hand  
 127 surgery and must have completed a minimum number of upper limb procedures as the  
 128 primary surgeon shown in *Table J-1* below. This includes completion of pre-operative  
 129 assessments and post-operative care for a minimum of 90 days after surgery. These  
 130 procedures must be documented in a log that includes the date of the procedure and the  
 131 medical record number or other unique identifier that can be verified by the OPTN  
 132 Contractor. This log must be signed by the program director, division chief, or department  
 133 chair where the experience was gained. Surgery of the hand includes only those  
 134 procedures performed on the upper limb below the elbow.  
 135  
 136

**Table J-1: Minimum Procedures for Upper Limb Primary Transplant Surgeons**

Type of Procedure	Minimum Number of Procedures
Bone	20
Nerve	20
Tendon	20
Skin or Wound Problems	14
Contracture or Joint Stiffness	10
Tumor	10
Microsurgical Procedures	10
Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

137  
 138 **J.3.B1.E Additional Primary Surgeon Requirements for Head and Neck**  
 139 **Transplant Programs**

140 In addition to the requirements as described in J.1.C above, the transplant surgeon for a  
 141 head and neck transplant program must meet at least *one* of the following:  
 142

- 143 1. Must meet at least *one* of the following:  
 144 a. Have current certification by the American Board of Plastic Surgery, the  
 145 American Board of Otolaryngology, American Board of Oral and Maxillofacial  
 146 Surgery, the American Board of Surgery, or the foreign equivalent. In the case of

147 a surgeon who has just completed training and whose board certification is  
 148 pending, the Membership and Professional Standards Committee (MPSC) may  
 149 grant conditional approval for 24 months to allow time for the surgeon to  
 150 complete board certification, with the possibility of renewal for an additional 12-  
 151 month period.

152  
 153 b. If the surgeon does not have board certification, the surgeon may qualify by  
 154 gaining all of the relevant clinical experience as outlined below. As of September  
 155 1, 2018, this pathway will no longer be available and all primary surgeons must  
 156 meet the requirements of paragraph 1.a.

- 157  
 158 i. Observe at least 2 multi-organ procurements and acted as the first-  
 159 assistant or primary surgeon on at least 1 VCA procurement.  
 160 ii. Pre-operative evaluation of at least 3 potential head and neck transplant  
 161 patients.  
 162 iii. Primary surgeon of a least 1 head and neck transplant.  
 163 iv. Post-operative follow up of at least 1 head and neck recipient for 1 year  
 164 post-transplant.

165 The multi-organ procurement experience must be documented in a log that  
 166 includes the Donor ID or other unique identifier that can be verified by the OPTN  
 167 Contractor. The experience for head and neck procedures must be documented  
 168 in a log that includes the dates of procedures and evaluations, the role of the  
 169 surgeon, and the medical record number or other unique identifier that can be  
 170 verified by the OPTN Contractor. This log must be signed by the program  
 171 director, division chief, or department chair where the experience was gained.

172  
 173 If a primary surgeon qualified under 1.b ends his involvement with the transplant  
 174 program, the program must identify a primary transplant surgeon who meets the  
 175 requirements under 1.a.

176  
 177 2. Completion of at least *one* of the following:

- 178 a. Completion of a fellowship program in otolaryngology, plastic, oral and  
 179 maxillofacial, or craniofacial surgery that is approved by the MPSC. Any  
 180 ACGME–approved fellowship program is automatically accepted by the MPSC.  
 181 b. Completion of a fellowship program in otolaryngology, plastic, oral and  
 182 maxillofacial, or craniofacial surgery that meets all of the following criteria:  
 183  
 184 i. The program is at a hospital that has inpatient facilities, operative suites  
 185 and diagnostic treatment facilities, outpatient facilities, and educational  
 186 resources.  
 187 ii. The program is at an institution that has a proven commitment to  
 188 graduate medical education.  
 189 iii. The program director must have current certification in the sub-specialty  
 190 by the American Board of Plastic Surgery, the American Board of  
 191 Otolaryngology, American Board of Oral and Maxillofacial Surgery.  
 192 iv. The program should have at least two physician faculty members with  
 193 head and neck surgery experience and current medical licensure who  
 194 are actively involved in the instruction and supervision of fellows during  
 195 the time of accredited education.  
 196 v. The program is at a hospital that has affiliated rehabilitation medicine  
 197 services.

- 198 vi. The program has the resources, including adequate clinical facilities,
- 199 laboratory research facilities, and appropriately trained faculty and staff,
- 200 to provide research experience.
- 201
- 202 c. The surgeon must have at least 2 years of consecutive and independent practice
- 203 of head and neck surgery. The surgeon must have completed at least 1 face
- 204 transplant as primary surgeon or first-assistant, or a minimum number of head
- 205 and neck procedures as the primary surgeon as shown in *Table J-2* below. This
- 206 includes completion of pre-operative assessments and post-operative care for a
- 207 minimum of 90 days after surgery. These procedures must be documented in a
- 208 log that includes the dates of procedures and evaluations, the role of the surgeon
- 209 and the medical record number, Donor ID, or other unique identifier that can be
- 210 verified by the OPTN Contractor. This log must be signed by the program
- 211 director, division chief, or department chair where the experience was gained.
- 212
- 213

**Table J-2: Minimum Procedures for Head and Neck Primary Transplant Surgeons**

Type of Procedure	Minimum Number of Procedures
Facial trauma with bone fixation	10
Head or neck free tissue reconstruction	10

214

215 **J.3.C1.F Additional Primary Surgeon Requirements for Abdominal Wall**

216 **Transplant Programs**

217 The primary surgeon for an abdominal wall transplant program must meet the primary transplant

218 surgeon requirements of a head and neck, intestine, kidney, liver, pancreas, or upper limb

219 transplant program.

220 **~~D. Additional Primary Surgeon Requirements for Other VCA Transplant~~**

221 **~~Programs~~**

222 ~~This pathway is only for the primary transplant surgeon at a VCA program intending to transplant~~

223 ~~body parts other than those that will be transplanted at approved upper limb, head and neck, or~~

224 ~~abdominal wall transplant programs. In addition to the requirements as described in J.3 above,~~

225 ~~the primary surgeon for other VCA transplant programs must meet all of the following:~~

- 226 ~~1. Specify the type or types of VCA transplant the surgeon will perform.~~
- 227
- 228 ~~2. Have current American Board of Medical Specialties certification or the foreign equivalent in a~~
- 229 ~~specialty relevant to the type of VCA transplant the surgeon will be performing.~~
- 230 ~~3. Have gained all of the relevant clinical experience as outlined below:~~
- 231 ~~b. Observe at least 2 multi-organ procurements.~~
- 232 ~~c. Pre-operative evaluation of at least 3 potential VCA transplant patients.~~
- 233
- 234 ~~4. Have current working knowledge in the surgical specialty, defined as independent practice in~~
- 235 ~~the specialty over a consecutive five-year period.~~
- 236 ~~5. Assembled a multidisciplinary surgical team that includes the primary surgeon with board~~
- 237 ~~certification in the relevant surgical specialty and other specialists necessary to complete the~~
- 238 ~~VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics~~
- 239 ~~and gynecology, urology, or general surgery. This team must include a team member that~~
- 240 ~~has microvascular experience such as replantation, revascularization, free tissue transfer,~~
- 241

242 and major flap surgery. These procedures must be documented in a log that includes the  
 243 dates of procedures, the role of the surgeon, and the medical record number, Donor ID, or  
 244 other unique identifier that can be verified by the OPTN Contractor. This log must be signed  
 245 by the program director, division chief, or department chair where the experience was gained.  
 246 The team must have demonstrated detailed planning and cadaver rehearsals that are specific  
 247 to the type or types of VCA transplant the program will perform.

248  
 249 A letter from the presiding institutional executive of the institution where the VCA will be  
 250 performed must provide written notification that requirements 1-5 above have been met.  
 251

## 252 **J.2 Letter of Notification for VCA transplant programs, other than abdominal** 253 **wall, head and neck, and upper limb**

254  
 255 If a transplant hospital member commits to performing VCA transplants, other than abdominal wall, head  
 256 and neck, and upper limb, the hospital must send a written notification to the OPTN Contractor that  
 257 includes both of the following:

- 258  
 259 1. The specific types of VCA transplant the hospital will perform.  
 260 2. If the member will perform deceased donor VCA transplants, assurance from the local OPO that it will  
 261 provide the same type or types of VCA for transplantation.

262  
 263 The letter of notification from the transplant hospital must be signed by all of the following individuals:

- 264  
 265 1. The chief administrative officer for the institution.  
 266 2. The reconstructive surgeon for each type of VCA transplant with expertise in microsurgical  
 267 reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in  
 268 the applicable reconstructive procedure as required, such as hand replantation or facial  
 269 reconstruction.  
 270 3. The transplant physician or transplant surgeon for each type of VCA transplant at an approved  
 271 transplant program that has completed an approved transplant fellowship, or who qualifies by  
 272 documented transplant experience in a medical or surgical specialty.

273  
 274 The OPTN Contractor will then notify the transplant hospital member of the program designation for each  
 275 type of other VCA transplant.

276 #