OPTN | UNOS

Public Comment Proposal

Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs

OPTN/UNOS Vascularized Composite Allograft Transplantation Committee

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Align VCA Transplant Program Membership Requirements with Requirements of Other Solid Organ Transplant Programs

Affected Policies:	*OPTN Bylaws, Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs), and Appendix J (Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs)*
Sponsoring Committee:	*Vascularized Composite Allograft Transplantation Committee*
Public Comment Period:	*January 22, 2018 to March 23, 2018*

Executive Summary

In December 2015, the OPTN/UNOS Board of Directors approved changes to the Bylaws to remove the ambiguous term “foreign equivalent” from the transplant program key personnel requirements. Members and the Membership and Professional Standards Committee found it difficult to determine if a board certification or case experience performed outside the United States should be considered equivalent. In lieu of accepting foreign board certification, the Board approved continuing education pathways in order for individuals who were foreign board certified or U.S. board ineligible to continue to be considered for key personnel positions at solid organ transplant programs. These changes were not made to the membership requirements for key personnel at vascularized composite allograft (VCA) transplant programs due to feedback from professional transplant societies concerned about the impact of such changes on the nascent developmental stage of the VCA transplant field.

The current membership requirements for VCA transplant programs in the OPTN Bylaws include a pathway for non-board certified individuals to qualify as a primary VCA transplant surgeon. However, this pathway will sunset on September 1, 2018. The VCA Committee feels the implications of this sunset would:

- be overly restrictive
- result in membership requirements that were dissimilar to the membership requirements for all other solid organ transplant programs
- prohibit a surgeon who is U.S. board ineligible, but otherwise well qualified by training and experience, to qualify as a primary VCA transplant surgeon

This proposal addresses this gap for surgeons who wish to apply to be a primary VCA transplant surgeon. This proposal is not intended to reduce the rigor of the training and experience requirements for key personal at VCA transplant programs. Rather, it is intended to add an option for these surgeons that is consistent with the of membership requirements for all other solid organ transplant programs.

The Committee feels this proposal is in keeping with Goal 4 of the OPTN Strategic Plan by ensuring consistency between the requirements between key personnel at solid organ and VCA transplant programs. It will also address a problem posed by the increased burden for individuals to qualify as a primary VCA transplant surgeon if the sunset provision is not amended.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee encourages all interested individuals to comment on the proposal in its entirety. The Committee requests feedback on the following three items:

1. When considering the addition of a continuing medical education (CME) pathway, the Committee felt select elements of the pathways were broad and this may lead to lack of clarity for OPTN members. Should "category-one" CME and "self-assessments" be more specifically defined?
2. The Committee discussed whether "foreign board certification" should remain in Appendix J to ensure some level of advanced certification, should a surgeon be U.S. board ineligible. This concept would be to require foreign board certification in addition to a prescribed CME pathway for U.S. board ineligible persons. Do you feel this is an appropriate approach, or would this inclusion have unintended impact (e.g.: potentially exclude well qualified surgeons from being considered)?
3. Should the language for the primary VCA transplant surgeon include a similar allowance as it does the primary VCA transplant physician such that a primary transplant surgeon or physician of any solid organ transplant program could qualify to be the primary transplant surgeon of a VCA transplant program? Would such an allowance diminish the rigor of the membership requirements for the primary transplant surgeon of head and neck, or upper limb transplant program?

What problem will this proposal address?

In December 2015, the OPTN/UNOS Board of Directors (Board) approved changes to the OPTN Bylaws to remove the ambiguous term "foreign equivalent" from the transplant program key personnel requirements (herein referred to as the "MPSC foreign equivalent proposal").[1] OPTN members and the OPTN/UNOS Membership and Professional Standards Committee (MPSC) found it difficult to determine if a board certification or case experience performed outside the United States should be considered equivalent. In lieu of accepting foreign board certification, the Board approved continuing medical education (CME) pathways in order for individuals who were U.S. board ineligible to continue to be considered for key personnel positions at solid organ transplant programs. These changes did not apply to the membership requirements for key personnel at VCA transplant programs (OPTN Bylaws, Appendix J) due to feedback from professional transplant societies concerned that such changes could be onerous at this nascent developmental stage of VCA transplantation.

The current membership requirements for VCA transplant programs were approved by the Board in June 2015 (herein referred to as the "VCA membership proposal). These membership requirements include a pathway for non-board certified individuals to qualify as a primary transplant surgeon. However, this pathway will sunset on September 1, 2018 resulting in membership requirements that will only permit board certified individuals to qualify as a primary transplant surgeon for VCA programs. The VCA Committee (Committee) feels the implications of this sunset provision would:

- be overly restrictive by exclude pioneering surgeons who are U.S. board ineligible who helped develop the field
- be dissimilar to membership requirements for all other solid organ transplant programs

The Committee also feels the MPSC's proposal resulted in two different standards for transplant program key personnel to meet. Key personnel at VCA transplant programs would be required to meet one,

[1] https://optn.transplant.hrsa.gov/governance/public-comment/foreign-equivalent-in-bylaws/

potentially more restrictive standard for minimum training and experience, and key personnel at solid organ transplant programs would be required to be a different standard.

Why should you support this proposal?

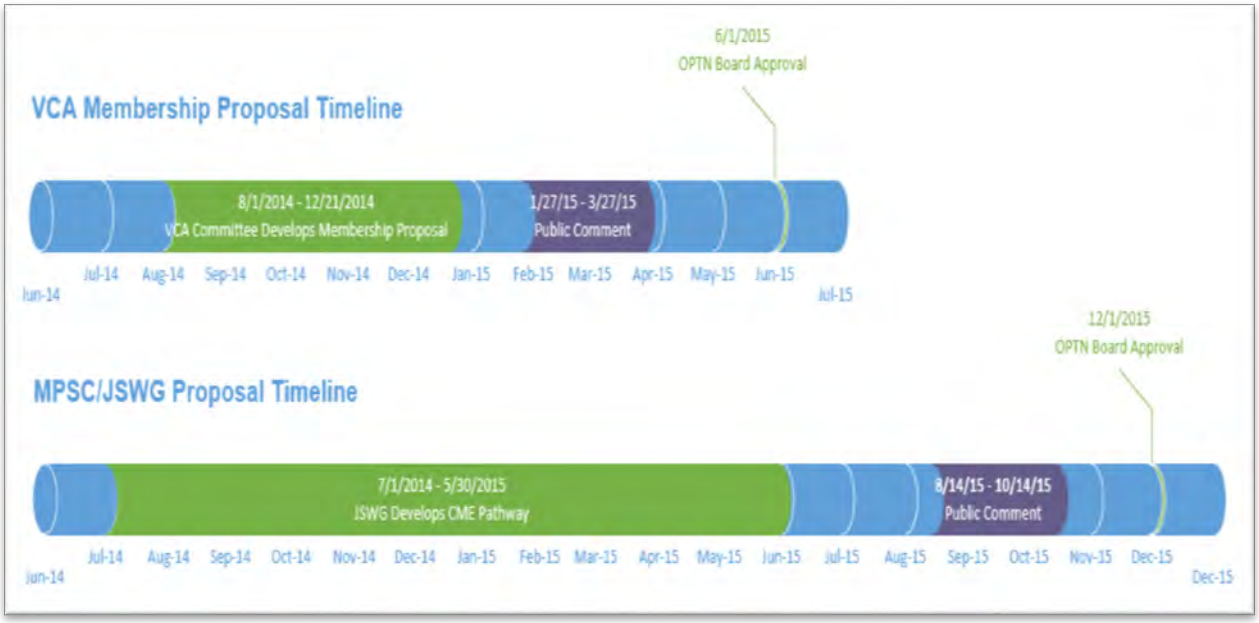
This proposal addresses a gap that will exist for surgeons who wish to apply as the primary transplant surgeon of a VCA transplant program after September 1, 2018. This proposal is not intended to reduce the rigor of the training and experience requirements for key personal at VCA transplant programs. Rather, it is intended to add an option for these surgeons that is consistent with the of membership requirements for all other solid organ transplant programs.

How was this proposal developed?

Two membership proposals affecting the OPTN Bylaws were developed by separate OPTN committees during 2014 and 2015. The Committee developed detailed training and experience requirements for key personnel at VCA transplant programs in mid-2014. These requirements were approved by the Board in June 2015.

During the same period, the MPSC and a Joint Society Working Group (JSWG) [2] collaborated on amendments to the OPTN Bylaws to remove the option for foreign board certified individuals to qualify as transplant program key personnel. Figure 1 below depicts the development timeline of the MPSC and Committee proposals in 2014 and 2015.

Figure 1: Development timelines for MPSC and VCA Committee membership proposals



During the development of the MPSC foreign equivalent proposal shown in Figure 1, the working group recommended to not make changes to the membership requirements for key personnel at VCA transplant programs due to feedback from members of the JSWG. The concern cited was that such changes could

[2] Joint Society Working Group members include representatives from the American Society for Transplantation (AST), and the American Society for Transplant Surgeons (ASTS), and NATCO.

be place unreasonable constraints on the nascent developmental stage of VCA transplantation by limiting the number of individuals who would qualify for key personnel positions at VCA transplant programs.[3] The Committee reviewed the Board's action on the MPSC foreign equivalent proposal in early 2016. The MPSC's proposal appeared to result in two different standards for transplant program key personnel to meet (between solid organ and VCA transplant programs):

- Solid organ transplant programs – board certified and U.S. board ineligible individuals would qualify for key personnel positions.
- VCA transplant programs – board certified and non-board certified individuals would qualify for key personnel positions. However, only board certified individuals would qualify after September 1, 2018.

The Committee was also concerned that the approaching sunset provision in the requirements for the primary VCA transplant surgeon for head and neck, and upper limb programs would limit the number of surgeons who would qualify for key personnel positions. Additionally, this sunset provision would exclude from leadership positions those VCA transplant surgeons who were experienced and well-qualified that helped develop the field.

The Committee considered two alternatives; 1) leave the VCA membership requirements unchanged to allow foreign board certified individuals to qualify for key personnel positions at VCA transplant programs, and only allow board certified individuals to qualify for the primary VCA transplant surgeon after September 1, 2018, or 2) modify the VCA membership requirements to adopt content of the 2015 MPSC foreign equivalent proposal (striking "foreign equivalent" and adding a CME pathway for U.S. board ineligible individuals). Early sentiments of the Committee were adopt content of the 2015 MPSC foreign equivalent proposal in order to achieve close alignment with the requirements for solid organ transplant programs. The Subcommittee felt this approach was a better alternative than the risk of excluding experienced and well-qualified surgeons who helped develop the VCA field due to the sunset provision. Adopting these changes would ensure key personnel at VCA transplant programs were evaluated against the same rigorous standards as their solid organ counterparts.

The Committee acknowledged much of the pioneering work in VCA transplantation occurred outside the U.S.[4] Much of this work was performed by individuals who trained extensively in the involved surgical disciplines, but have not attained board certification in the U.S. or Canada. The Committee also believed that excluding a CME pathway from the VCA membership requirements would not be in alignment with the requirements for all other transplant programs in the OPTN Bylaws, and would reduce the number of VCA transplant programs in the U.S. Further, this could reduce patient access to VCA transplantation. The Committee believes these would be critical set-backs as increasing VCA transplants is consistent with Goal One of the OPTN Strategic Plan.[5]

The central tenet of this proposal is to address a gap that exists for individuals who wish to apply as the primary transplant surgeon of a VCA transplant program. Table 1 below illustrates the options available for individuals who wish to apply for key personnel positions at kidney transplant programs as compared to the options available for individuals who wish to apply for key personnel at VCA transplant programs.

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[3] From the 2015 MPSC Briefing Paper – *The proposed changes* [2015] *clarify the current Bylaws and address the problem by deleting the ambiguous term "foreign equivalent," and all its derivatives, from the Bylaws. The one exception is the usage of this term in the vascularized composite allograft (VCA) transplant program requirements. This change was not applied to VCA transplant program key personnel requirements per ASTS feedback, and considering the relative infancy of VCA and the OPTN/UNOS membership requirements for VCA transplant programs. Many VCA surgeons and physicians acquire transplant expertise outside of the United States, and the United States does not yet have VCA transplant fellowship programs or certifications.*

[4] Brandacher, G, "Composite Tissue Transplantation", In *Transplantation Immunology*, eds Zachary, A, Leffell, M, (Totowa: Humana Press 2013), 103-115.

[5] https://optn.transplant.hrsa.gov/governance/strategic-plan/

Table 1: Comparison of key personnel requirements for kidney and VCA transplant programs

Requirement	Primary Transplant Surgeon – Kidney	Primary Transplant Surgeon – VCA	Primary Transplant Physician – Kidney	Primary Transplant Physician - VCA
Medical Degree (MD or DO)	✓	✓	✓	✓
On hospital's medical staff	✓	✓	✓	✓
Reviewed by hospital's credentialing committee	✓	✓	✓	✓
U.S. or Canadian board certification	✓	✓	✓	✓
Accepts foreign board certification		✓		
Continuing education pathway in lieu of board certification	✓		✓	✓
Fellowship training	✓	✓	✓	✓
Experience pathway in lieu of fellowship training	✓	✓	✓	✓

As Table 1 shows, this proposal is not intended to reduce the rigor of the training and experience requirements for key personal at VCA transplant programs by altering the existing six components of VCA membership requirements (denoted by the blue checks). Rather, the proposal is intended to add an option for these individuals that is consistent with the membership requirements for all other solid organ transplant programs (denoted by the red highlighted area).

A Membership Subcommittee (Subcommittee) was formed with representatives of the VCA Committee and MPSC to develop amendments to Appendix J. The Subcommittee met by conference call over several months and discussed numerous elements of this proposal. This included addressing concerns of membership requirements being overly restrictive (in light of the sunset provision), and the dissimilar nature of VCA membership requirements as compared to solid organ requirements.

Reduce forthcoming constraint from the sunset provision

When the Committee created the 2015 VCA membership requirements, the rational was to allow both board certified and non-board certified/U.S. board ineligible individuals to qualify for key personnel positions at VCA transplant programs. This came from the desire to be inclusive of current VCA program leaders and to not place constraints on a developing field. If a surgeon was not board certified or U.S. board ineligible, this individual may qualify as the primary transplant surgeon of a head and neck, or upper limb VCA transplant program if they meet a prescribed clinical experience pathway.[6] This clinical experience pathway includes minimum case volumes for:

- VCA procurements as the first-assistant or primary surgeon
- pre-transplant evaluations of potential VCA transplant candidates
- VCA transplants as the primary surgeon
- post-operative follow-up of VCA transplant recipients
- observation of multi-organ procurements

After the sunset on September 1, 2018, only board certified individuals will qualify as the primary VCA transplant surgeon.

The Committee's early rationale for the sunset was to initially have broad membership requirements that would allow VCA programs to continue operating after the implementation of the requirements. After a

[6] https://optn.transplant.hrsa.gov/governance/public-comment/membership-requirements-for-vca-transplant-programs/

period of three years, the Committee thought it would be appropriate to only allow board certified key personnel. The implication of the sunset is that if a primary VCA transplant surgeon who was board ineligible left an approved VCA program, this individual would no longer qualify as a primary VCA transplant surgeon at another OPTN member transplant hospital. The index VCA transplant program would be required to recruit a board certified individual as a replacement.[7] There would be inherent challenges recruiting someone qualified to serve as the primary transplant surgeon because fewer people would be eligible based on the post-September 1, 2018 membership requirements. The passage of time, delays implementing the membership requirements outside the OPTN's control, and the MPSC's foreign equivalent proposal have demonstrated that the construct of only allowing board certified individuals to qualify for VCA key personnel positions represents a more restrictive standard to meet as compared to solid organ key personnel. Subcommittee members felt strongly that there was not a compelling reason for this difference between VCA and solid organ membership requirements, and the VCA transplant community should be held to the same rigorous standard as their solid organ transplant counterparts. Unless this current proposal is approved, there will not be a CME pathway for non-board certified or U.S. board ineligible individuals to lead VCA transplant programs.

The Subcommittee discussed the cautious sentiment of some Committee members of allowing non-board certified key personnel to qualify over concerns of potential untoward events due to unqualified leadership. Their position was such an untoward event in a VCA transplant could detrimentally impact the entire VCA field. The Subcommittee and OPTN are not aware of any untoward events due to unqualified key personnel at VCA transplant programs in the U.S. since the first VCA transplant in 1998. Further, non-board certified or board ineligible surgeons could lead VCA transplant programs in the 17 years prior to the VCA membership proposal. This was due, in part, to the lack of national consensus on minimum training and experience requirements, and the lack of formalized training programs in VCA transplantation. Based on the possibility for non-board certified or board ineligible surgeons to lead VCA transplant teams prior to the VCA membership proposal and the lack of data to support such a restriction, the Subcommittee felt strongly that the sunset provision for non-board certified individuals should be struck. Further, U.S board ineligible individuals should continue to qualify as the primary transplant surgeon of a head and neck, or upper limb transplant program by way of satisfying a CME pathway and other case experience requirements.

Similarity of Membership Requirements

The Subcommittee discussed several items related to the similarity between membership requirements of solid organ and VCA transplant programs. These included whether to strike the requirement for foreign board certification, adopt continuing education requirements, to limit the applicable board certifications to certain credentialing bodies, required letters of recommendation, the role of credentials from member organizations, the feasibility of a written examination for U.S. board ineligible individuals, and if it was appropriate to allow the primary transplant physician or surgeon of a solid organ program to be the primary transplant surgeon of a VCA transplant program.[8]

The Subcommittee first discussed the MPSC's rationale to remove foreign board certification from the solid organ membership requirements. Members agreed with the challenged expressed by the MPSC to determine if a board certification or case experience performed outside the United States should be considered equivalent to U.S. board certification and training. As a result, the Subcommittee favored removing references to foreign board certification from the VCA membership requirements. Some Committee members did express interest in feedback during public comment if there was some benefit to

[7] From the 2015 VCA Briefing Paper - *Qualifying under an experience pathway can only be used once by an individual VCA program. If a primary surgeon at a VCA program qualified under the experience pathway (in lieu of board certification) leaves a transplant hospital prior to the "expiration date" [September 1, 2018], the transplant hospital must identify a replacement who is board certified in an appropriate discipline outlined in Appendix J.*

[8] Case experience requirements are outlined in the 2015 VCA membership proposal and are not being changed in the current proposal (https://optn.transplant.hrsa.gov/governance/public-comment/membership-requirements-for-vca-transplant-programs/).

retaining the requirement of foreign board certification in addition the CME pathway in order to ensure some level of advanced certification for a U.S. board ineligible surgeon.

Second, the Subcommittee discussed the role of continuing education requirements for U.S. board ineligible individuals. The MPSC foreign equivalent proposal outlined that CME and self-assessments for U.S. board ineligible individuals were critical to demonstrate commitment to the field and lifelong learning.[9] The Subcommittee agreed with this sentiment and discussed whether to limit the scope of practice for CME credits. Members discussed the advantages and disadvantages of requiring CME credits from a board specific to the member's area of expertise and relevant to the VCA programs they lead. Members felt that allowing CME from organizations that were germane to the area of practice, e.g.: infectious disease, immunosuppression, etc., is appropriate. It was noted that the requirements for key personnel utilizing the CME pathways for solid organ transplant programs did not specify details regarding subject areas for CME credits. As a result, the Subcommittee felt comfortable allowing broad CMEs that were germane to the individual's scope of practice. Some Committee members did express interest in feedback during public comment if "continuing medical education" and "self-assessments" should be more objectively defined.

Third, the Subcommittee discussed a concern from the Committee to only allow board certification from American Board of Medical Specialty (AMBS) member-boards. One Committee member noted there are a handful of unaffiliated organizations in existence that refer to themselves as "medical boards", and the general public was likely unaware of the distinction between AMBS-affiliated or unaffiliated boards. UNOS staff shared with the Subcommittee that the membership requirements for solid organ transplant programs set precedents by allowing individuals with either an M.D. or D.O. degree, and allowing board certification by the American Osteopathic Association (AOA) e.g.: primary kidney transplant surgeon.[10] The Subcommittee members felt strongly that it was important to maintain alignment with the solid organ membership requirements by allowing individuals with certifications from any U.S. board credentialing body should be allowed to qualify for key personnel positions at VCA program. Subcommittee members noted that board certification was not the only criteria that a surgeon would need to meet in order to qualify as the primary VCA transplant surgeon. A companion requirement the Subcommittee felt was a more critical indicator of true readiness to serve as the primary transplant surgeon were fellowship training or relevant clinical case volume.

Fourth, the Subcommittee discussed requirement for letters of recommendation for an individual applying in lieu of board certification. Two alternatives were discussed; requiring letters from directors of the same type of VCA, or letters from *any* VCA transplant program director. The Subcommittee felt there was no value requiring letters from directors of the same VCA type. Further, this requirement would be nearly impossible for novel VCA types with very low numbers of approved transplant programs, e.g.: genitourinary organs. The Subcommittee felt program directors of VCA transplant programs would have an understanding of the requirements to be leaders of VCA transplant programs. However, the Subcommittee was in wide agreement that recommendation letters needed to be from VCA program directors, not program directors of solid organ transplant programs. Thus, the Subcommittee felt requiring two letters of reference from VCA transplant program directors, consistent with the number of letters for the solid organ CME pathways, was appropriate.

Fifth, the Subcommittee discussed whether it was important for non-board certified/board ineligible individuals to complete (and pass with a minimum score) a continuing education written exam from a U.S medical board related to their clinical practice. Members felt this was a good idea, but such exams are not consistently offered by all medical boards. Further, it would not be possible for a board ineligible individual

[9] From the 2015 MPSC Briefing Paper – *The JSWG discussed the limitations of continuing medical education (CME) credits (obtaining CMEs is sometimes perfunctory, and not really reflective of ongoing learning; rising costs to obtain necessary CMEs; and legal questions about maintenance of certification that have recently been pursued), but ultimately it agreed that CMEs are expected to maintain American board certification, and the best tool available to the OPTN for clinicians without American or Canadian board certification to demonstrate ongoing, lifelong learning.*

[10] https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Appendix_E

to have access to this type of exam. The Subcommittee acknowledged that such a requirement was not in place for solid organ transplant programs, and requiring such an exam was not possible at this time.

Lately, the Committee discussed the idea to allow the primary transplant physician or surgeon to qualify as the primary transplant surgeon of a VCA program. This stemmed from the VCA membership proposal which included language that the primary transplant surgeon or physician of a solid organ transplant program can qualify as the primary transplant *physician* of a VCA transplant program. The Committee's prior rationale for this allowance was the primary transplant surgeon or physician of a solid organ transplant program may have the knowledge, skills, and abilities to oversee the medical care of a VCA candidate or recipient (e.g. medical or immunosuppression management). Some Committee members felt such an allowance should be included for the primary transplant surgeon of a VCA program for consistency. Some Committee members did express interest in feedback during public comment if the language for the primary VCA transplant surgeon should include to allow a primary transplant surgeon or physician of any solid organ transplant program to qualify to be the primary transplant surgeon of a VCA transplant program.

One of the items discussed by the Committee was the issue of transition from the 2014 membership requirements to new, more detailed membership requirements. Some Committee members verbalized the desire for the OPTN to automatically approve legacy personnel currently leading VCA transplant programs upon implementation. UNOS staff expressed that automatic approval of key personnel, often referred to as "grandfathering", is not practiced by the OPTN. Individuals applying for key personnel positions at <u>any</u> organ transplant program are vetted upon 1) a new transplant program applying at an OPTN member transplant hospital, and 2) changes in key personnel, e.g.: the departure of a primary transplant physician or surgeon. Further, it would be inappropriate to automatically accept key personnel based on approval under the 2014 VCA membership requirements.[11] These requirements did not contain any objective minimum training and experience for key personnel at VCA transplant programs. The Subcommittee felt the construct of the current proposal would be inclusive of current VCA transplant program key personnel. This approach to how the OPTN will implement the 2015 and proposed membership requirements was detailed in the 2015 public comment proposal and materials considered by the Board.

Information regarding the qualifications of potential transplant program key personnel are used to assess if the applicant meets or exceeds the minimum training and experience requirements to lead organ transplant programs. Further, this proposal assists the OPTN to fulfill requirements of the OPTN Final Rule.[12] This proposal is consistent with the OPTN Principles of Data Collection.

The Committee feels the current proposal addresses concerns over the VCA membership requirements being overly restrictive (in light of the approaching sunset for non-board certified/U.S. board ineligible surgeons), and the dissimilar nature of VCA membership requirements as compared to solid organ requirements. The Committee voted during their October 2017 meeting to solicit public comment on the proposal (Yes – 11, No – 0, Abstain – 3).

How well does this proposal address the problem statement?

The current proposal addresses an area of concern identified in the MPSC foreign equivalent proposal.[13] The current proposal will effectively address the last remaining ambiguous use of "foreign equivalent" by proposing that it be deleted from Appendix J.

[11] https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Appendix_J

[12] https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5

[13] From the 2015 MPSC Briefing Paper - *Another weakness of this proposal is that the term "foreign equivalent" is still included in the VCA program key personnel requirements. This was felt to be necessary because of the infancy of VCA transplantation, but the problems that prompted this proposal will continue to impact VCA program applications.*

The 2014 VCA membership requirements currently in effect require the transplant hospital to identify the primary transplant physician and primary transplant surgeon for each type of VCA the hospital intends to transplant.[14] However, there are no minimum training and experience requirements embedded in these requirements. As a result, the Committee and OPTN do not have an assessment of how many individuals currently serving in key personnel positions at VCA programs may be impacted by this change.

Which populations are impacted by this proposal?

This proposal will impact VCA transplant programs currently in operation with U.S. board ineligible key personnel, and future VCA transplant programs. However, the Committee feels the amendments herein will be inclusive of these key personnel currently leading VCA transplant programs in the U.S. Table 2 below illustrates the number of approved VCA transplant programs in the U.S.

Table 2: OPTN Approved VCA Transplant Programs in the U.S.

VCA Program Type	N
Upper Limb	18
Head and Neck	17
Abdominal Wall	14
Other Specify: Uterine	3
Other Specify: Lower Limb	2
Other Specify: Penile	2
Other Specify: Chest Wall Nerve, Vessel, Vascular	1
Other Specify: Genitourinary	1
Other Specify: Urogenital	1
Other Specify: Genitourinary (Excluding Lines)	1
Other Specify: Uterus	1
Total	61

Based on most recent available information provided by members to the OPTN as of November 24, 2017
Data subject to change based on future data submission or correction.

Table 2 above lists the type and number of approved VCA transplant programs in the U.S as of November 24, 2017. However, there are only 14 transplant hospitals in the U.S. with case experience in VCA transplants since July 3, 2014. There are nine VCA transplant programs in the U.S. with candidates awaiting a transplant.[15] Given the small number of VCA programs in the U.S., the Committee feels the risk is minimal for a VCA transplant program inactivating, and therefore should continue to promote the access that VCA transplant candidates currently have to transplant programs.

There is no expected impact on organ procurement organizations or histocompatibility laboratories.

[14] https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Appendix_J

[15] Based on OPTN data as of November 24, 2017.

How does this proposal impact the OPTN Strategic Plan?

4. *Increase the number of transplants:* VCA transplantation is in the early stages of development and the number of programs and transplants is currently low. Following the history and lessons from solid organ transplantation, the establishment of programs with qualified key personnel is imperative for growth of the field.
5. *Improve equity in access to transplants:* By aligning membership requirements of VCA transplant program with the membership requirements with solid organ transplant programs within the OPTN, this will continue implementing VCA as other transplants and will potentially allow for the establishment of additional VCA transplant programs improving the access to VCA transplantation.
6. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
7. *Promote living donor and transplant recipient safety:* The primary goal of this proposal is to amend the training and experience requirements for the primary transplant surgeon of VCA transplant programs to be similar with membership requirements for other solid organ transplant programs. It will address the problem posed by the increased burden for individuals to qualify as key personnel at VCA transplant programs as compared to their solid organ counterparts. It will also ensure consistency between the requirements for key personnel across all VCA transplant programs, specifically, between the primary transplant surgeons and primary transplant physician.
8. *Promote the efficient management of the OPTN:* By aligning the VCA membership requirements, bylaw language would be standardized as much as possible across all OPTN membership requirements. This is consistent with the original intent and spirit of the bylaw modifications approved by the Board in 2015: to reduce the risk associated with reviewing applications for key personnel, and the inconsistent and poorly understood nature of "foreign equivalent". Consistency in membership requirements will also improve the efficiency of OPTN membership operations.

How will the OPTN implement this proposal?

If approved by the Board, changes will be made to the OPTN Bylaws in two phases. The first phase of language changes would include amendments striking the sunset provision for the primary VCA transplant surgeons of head and neck, and upper limb transplant programs on lines 105-107 and 225-227 of the proposal below. The rationale for the phase one amendments is to ensure these individuals will continue to qualify for key personnel positions until such time as the full membership requirements are implemented in 2019.

The second phase of language changes would include not only the elements of the CME pathways, but also amendments to Appendices D and J for clarity, style, and consistency. This second phase of amendments would be implemented in tandem with the VCA membership proposal in 2019. As a result, all key personnel at VCA transplant programs in the U.S. will be required to reapply. This is consistent with the implementation plan outlined in the VCA membership proposal. This is also consistent with the Committee's desire that the amendments herein would apply to any U.S. board ineligible key personnel currently leading VCA transplant programs.

UNOS staff will send a 30-day notice to all currently approved VCA transplant programs of forthcoming applications. Once applications are sent to members, VCA transplant programs will need to indicate their desire to "opt out", or will need to submit a completed application within 120 days. The MPSC will review these VCA program applications with collaboration from the Committee, and may offer interim approval. Final approval will be at the discretion of the Board.

The OPTN will communicate any amendments to the VCA membership requirements through a policy notice, media releases on the OPTN and TransplantPro websites, and a future webinar.

Although changes of this nature would typically require review and approved by the U.S. Office of Management and Budget (OMB), this approval process may not be applicable to this proposal going forward. The OPTN anticipated the revisions to Appendix J related to requirements of continuing education and letters of recommendation for proposed personnel without American or Canadian Board certification and previously submitted amended membership applications for VCA transplant programs to OMB in January 2017. OMB approved these changes in July 2017.

This proposal will require programming in OPTN internal-facing databases. This proposal will not require programming in UNet^{SM}.

How will members implement this proposal?

If approved by the Board, transplant hospitals with approved VCA transplant programs will be responsible for proposing individuals who will qualify for key personnel positions. If these key personnel are U.S. board ineligible, these individuals will be responsible for adhering to the requirements of the CME pathway identified in their application. Consistent with the implementation plan for the MPSC foreign equivalent proposal, the OPTN will not regularly monitor adherence to this plan, but may request documentation of this adherence as deemed necessary.

Will this proposal require members to submit additional data?

Yes, this proposal will require individuals who are U.S. board ineligible and applying to be the primary transplant surgeon of a VCA program to submit additional information to the OPTN. This will include a plan for continuing education that is comparable to American board maintenance of certification, and two letters of recommendation from directors of designated VCA transplant programs not employed by the applying transplant hospital. Application submission to the OPTN will be performed by using standardized application forms for key personnel.

If an individual chooses to apply for a key personnel position using one of these pathways, continuing education records and documentation of self-assessments will be submitted to the OPTN on an as-requested basis.

How will members be evaluated for compliance with this proposal?

The MPSC will review the VCA transplant program applications to determine compliance with these proposed amendments to Appendix J. Upon implementation, the OPTN will facilitate the key personnel change process, and the MPSC will review key personnel change applications to ensure ongoing compliance with the Bylaws when changes to a transplant program's primary surgeon or primary physician occur.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The MPSC will monitor the use of the CME pathways and provide a report one year following implementation to the VCA Committee. This report will contain aggregate data on the instances of approved personnel changes involving U.S. board ineligible surgeons applying for key personnel

positions at a VCA transplant program, instances when a U.S. board ineligible surgeon applies and is declined for a key personnel position at a VCA transplant program, and new VCA transplant programs applying with U.S. board ineligible surgeons applying for a key personnel position at a VCA transplant program.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

D.7 Transplant Program Key Personnel

Designated transplant programs must have certain key personnel on site. These key personnel include a qualified primary surgeon and primary physician that meet the requirements set forth in these Bylaws. For the detailed primary surgeon and primary physician requirements for specific organs, see the following appendices of these Bylaws:

- *Appendix E:Membership and Personnel Requirements for Kidney Transplant Programs*
- *Appendix F: Membership and Personnel Requirements for Liver Transplant Programs*
- *Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs*
- *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*
- *Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*
- *Appendix J: Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs*

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

This appendix describes the information and documentation transplant hospitals must provide when:

- 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.

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 approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

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

J.1 Program Director, Primary Transplant Surgeon ~~Physician~~, and Primary Transplant Physician ~~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 *Section D.7.B. Surgeon and Physician Coverage*.

J.~~3~~2 Primary VCA Transplant Surgeon Requirements

Each designated VCA transplant program must have a primary transplant surgeon that meets *all* of the following requirements:

1. The ~~primary~~ surgeon 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 ~~primary~~ surgeon must be accepted onto the hospital's medical staff, and be on-site at this hospital.
3. The ~~primary~~ surgeon must have documentation from the hospital's credentialing committee that it has verified the surgeon's state license, training, and continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The ~~primary~~ surgeon must have observed at least 2 multi-organ procurements. These 2 procurements must have been observed anytime during the previous two years. These observations must be documented in a log that includes the date of procurement and Donor ID.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

In addition to the requirements as described in *Section J.~~3~~2* above, the surgeon for an upper limb transplant program must meet *both of* the following:

1. ~~Must meet at least *one* of the following:~~
   ~~a.~~ Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of ~~renewal for an~~ one additional ~~12~~16-month ~~period~~ extension.

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

      ~~i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.~~
      ~~ii. Pre-operative evaluation of at least 3 potential upper limb transplant patients.~~
      ~~iii. Acted as primary surgeon of a least 1 upper limb transplant.~~

~~iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.~~

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

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

In place of current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or a pending certification, the surgeon must:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary upper limb transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

If the surgeon does not have board certification, the surgeon must demonstrate the following experience:

a. Acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
b. Participated in the pre-operative evaluation of at least 3 potential upper limb transplant patients.
c. Acted as primary surgeon of a least 1 upper limb transplant.
d. Participated in the post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

The upper limb procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier

that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

2. Completion of at least *one* of the following:
   a. ~~A fellowship program in hand surgery that is approved by the MPSC.~~ Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program in hand surgery~~is automatically accepted by the MPSC~~.
   b. A fellowship program in hand surgery that meets *all* of the following criteria ~~will also be accepted~~:
      i. The program is located at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
      ii. The program is located at an institution that has a proven commitment to graduate medical education.
      iii. The program director must have current certification in the sub-specialty by the American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or American Board of Surgery.
      iv. The program should have at least 2 physician faculty members with hand surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
      v. The program at a hospital that has affiliated rehabilitation medicine services.
      vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.
   c. ~~The surgeon must have a~~ At least 2 years of consecutive and independent practice of hand surgery and must have completed a minimum number of upper limb procedures as the primary surgeon shown in Table J-~~.~~1 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.

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 Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in J.~~3~~2 above, the transplant surgeon for a head and neck transplant program must meet *both* of the following:

1. ~~Must meet at least *one* of the following:~~
   ~~a.~~ Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, the American Board of Oral and Maxillofacial

Surgery, the American Board of Surgery, or the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of ~~renewal for an~~ one additional ~~12~~16-month ~~period~~ extension.

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

~~i. Observe at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.~~

~~ii. Pre-operative evaluation of at least 3 potential head and neck transplant patients.~~

~~iii. Primary surgeon of a least 1 head and neck transplant.~~

~~iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-transplant.~~

~~The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. If a primary surgeon qualified under 1.b ends his involvement with the transplant program, the program must identify a primary transplant surgeon who meets the requirements under 1.a.~~

In place of current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or pending certification, the surgeon must:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
    i. Why an exception is reasonable.
    ii. The surgeon's overall qualifications to act as a primary head and neck transplant surgeon.
    iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
    iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

If the surgeon does not have board certification, the surgeon must demonstrate the following experience:

a. Acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
b. Participated in the pre-operative evaluation of at least 3 potential head and neck transplant patients.
c. Acted as primary surgeon of a least 1 upper limb transplant.
d. Participated in the post-operative follow-up of at least 1 head and neck recipient for 1 year post-transplant.

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

2. Completion of at least *one* of the following:
   a. ~~A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that is approved by the MPSC.~~ Any ACGME–approved fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery ~~is automatically accepted by the MPSC~~.
   b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets all of the following criteria:

      i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.
      ii. The program is at an institution that has a proven commitment to graduate medical education.
      iii. The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery.
      iv. The program should have at least two physician faculty members with head and neck surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.
      v. The program is at a hospital that has affiliated rehabilitation medicine services.
      vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

   c. At least 2 years of consecutive and independent practice of head and neck surgery. The surgeon must have completed at least 1 face transplant as primary

surgeon or first-assistant, or a minimum number of head and neck procedures as the primary surgeon as shown in Table J-2 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained.

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

C. Additional Primary Surgeon Requirements for Abdominal Wall Transplant Programs

The primary surgeon for an abdominal wall transplant program must meet the primary transplant surgeon requirements of a head and neck, intestine, kidney, liver, pancreas, or upper limb transplant program.

D. Additional Primary Surgeon Requirements for Other VCA Transplant Programs

This pathway is only for the primary transplant surgeon at a VCA program intending to transplant body parts other than those that will be transplanted at approved upper limb, head and neck, or abdominal wall transplant programs. In addition to the requirements as described in J.~~3~~2 above, the primary surgeon for other VCA transplant programs must meet *all* of the following:

~~1. Have current American Board of Medical Specialties certification or the foreign equivalent in a specialty relevant to the covered body part the surgeon will be transplanting.~~
~~2. Have gained *all* of the following relevant clinical experience:~~
~~a. Observation of at least 2 multi-organ procurements.~~
~~b. Participation in the multidisciplinary evaluations of at least 3 potential VCA transplant candidates.~~
~~3. Have at least 5 years of consecutive and independent practice the surgical specialty.~~
~~4. Have assembled a multidisciplinary surgical team that includes the primary surgeon with board certification in the relevant surgical specialty and other specialties necessary to complete the VCA transplant, such as plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must also include a member that has microvascular experience such as replantation, revascularization, free tissue transfer, or major flap surgery. These procedures must be documented in a log that includes the dates of procedures, the role of the surgeon, and the medical record number, Donor ID, or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. The team must have demonstrated detailed planning and cadaver rehearsals that are specific to the covered body part the VCA transplant program will perform.~~

~~A letter from the presiding executive of the transplant hospital where the VCA transplant will be performed must provide written notification that requirements 1-4 above have been met.~~

1. Specify to the OPTN Contractor the types of VCA transplant the surgeon will perform according to *OPTN Policy 1.2: Administrative Rules and Definitions, Vascularized Composite Allograft*.

2. Have current American Board of Medical Specialties or Royal College of Physicians and Surgeons of Canada certification in a specialty relevant to the type of VCA transplant the surgeon will be performing.

   In place of current certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada, the surgeon must:

   a. Be ineligible for American board certification.
   b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
   c. Provide to the OPTN Contractor two letters of recommendation from directors of designated VCA transplant programs not employed by the applying hospital. These letters must address:
      i. Why an exception is reasonable.
      ii. The surgeon's overall qualifications to act as a primary VCA transplant surgeon.
      iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
      iv. Any other matters judged appropriate.

      If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.
3. Have performed the pre-operative evaluation of at least 3 potential VCA transplant patients.
4. Have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period.
5. Have assembled a multidisciplinary surgical team that includes specialists necessary to complete the VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must include a team member that has microvascular experience such as replantation, revascularization, free tissue transfer, and major flap surgery. These

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

A letter from the presiding executive of the transplant hospital where the VCA will be performed must provide written verification that requirements 1 through 5 above have been met by the primary surgeon

J.2~~2~~3 Primary VCA Transplant Physician Requirements

Each designated VCA transplant program must have a primary transplant physician who meets at least *one* of the following requirements:

- i~~I~~s ~~(1)~~ currently ~~designated as~~ the primary transplant surgeon or primary transplant physician at a~~n active solid organ~~ designated transplant program~~,~~
- ~~(2)~~ Fulfills the requirements of a primary transplant surgeon or primary transplant physician at a designated transplant program ~~in~~ according to the OPTN Bylaws~~, or (3) who~~
- Is a ~~The~~physician ~~must have~~ with 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 and who meets *all* of the following additional requirements:
  1. The physician must be accepted onto the hospital's medical staff, and be on-site at this hospital.
  2. 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.
  3. 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*.
  4. The physician must have current board certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada.

     In place of current certification by the American Board of Medical Specialties or the Royal College of Physicians and Surgeons of Canada, the physician must:
     a. Be ineligible for American board certification.
     b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
     c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
        i. Why an exception is reasonable.
        ii. The physician's overall qualifications to act as a primary VCA transplant physician.
        iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
        iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

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