

OPTN/UNOS Policy Notice

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

Sponsoring Committee:	Vascularized Composite Allograft Transplantation Committee
Policy/Bylaws Affected:	OPTN Bylaws Appendices D.7 (Transplant Program Key Personnel), and J (Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs), J.1 (Program Director, Primary Transplant Physician, and Primary Transplant Surgeon), J.3 (Primary VCA Transplant Surgeon Requirements), and J.2 (Primary VCA Transplant Physician Requirements)
Public Comment:	January 22, 2018 to March 23, 2018
Board Approval Date:	June 12, 2018
Effective Date:	Pending implementation and notice to OPTN members

Problem Statement

In December 2015, the Board approved changes to the OPTN Bylaws to remove the term “foreign equivalent” from the transplant program key personnel qualification requirements. These changes did not apply to the requirements for key personnel at VCA transplant programs, resulting in two different standards.

Summary of Changes

These changes provide options for non-board certified or U.S. board ineligible individuals applying for key personnel positions at VCA transplant programs, including the option to qualify under a continuing medical education (CME) pathway. The changes are consistent with options available to applicants for key personnel positions at other organ transplant programs. The Board also approved changes to Appendices D and J for clarity, style, and consistency.

What Members Need to Do

At the time of implementation, all key personnel at VCA transplant programs in the U.S. will be required to reapply to the OPTN. UNOS will send a 30-day notice to all currently approved VCA transplant programs that new applications will be coming and must be completed. 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. 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.

Affected Policy Language

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

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 (Program Coverage Plan)*.

J.32 Primary VCA Transplant Surgeon Requirements

~~Each~~ A 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 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.32* 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 ~~42~~16-month ~~period~~ extension.~~

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 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.

In addition to experience above, a surgeon without current or pending 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 must also:

- 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.

~~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.~~

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.32 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 1216-month period extension.

In place of 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, the Royal College of Physicians and Surgeons of Canada, or a pending 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 head and neck 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 head and neck 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.

In addition to experience above, a surgeon without current or pending 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 must also:

- 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.

~~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 at 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.~~

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

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.32 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 that is specific for the 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.23 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.~~

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

- Is currently the primary transplant surgeon or primary transplant physician at a designated transplant program
- Fulfills the requirements of a primary transplant surgeon or primary transplant physician at a designated transplant program according to the OPTN Bylaws
- Is a physician 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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