

Public Comment Proposal

Addressing Approved Transplant Fellowship Training Programs Bylaws

OPTN/UNOS Membership and Professional Standards Committee

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Addressing Approved Transplant Fellowship Training Programs Bylaws

Affected Bylaws:

OPTN Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship Pathway), E.3.A (Transplant Nephrology Fellowship Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.4.A (Transplant Surgeon Fellowship Training Programs), E.4.B (Transplant Physician Fellowship Training Programs), E.5.C (Conditional Approval for a Pediatric Component), E.6.D (Primary Open Living Donor Kidney Surgeon), F.3.A (Formal 2-year Transplant Fellowship Pathway), F.6 (Approved Liver Surgeon Transplant Fellowship Programs), F.11.A (Full Intestine Surgeon Approval Pathway), F.14 (Approved Intestine Surgeon Transplant Fellowship Programs), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.7 (Approved Pancreas Transplant Surgeon Fellowship Training Programs), J.3.A (Additional Primary Surgeon Requirements for Upper Limb Transplant Programs), and J.3.B (Additional Primary Surgeon Requirements for Head and Neck Transplant Programs)

*Sponsoring Committee:
Public Comment Period:*

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Executive Summary

A number of abdominal key personnel training pathways in the Bylaws require that the training occurred at a fellowship program “approved by the MPSC,” and that the Membership and Professional Standards Committee (MPSC) will review training programs “every five years or any time the program director changes.” The MPSC does not regularly review or formally approve transplant training programs, nor has it done so historically. This proposal recommends deleting Bylaws that reference the MPSC’s “approval” and routine review of transplant fellowship programs to address this discrepancy, while retaining language that validates the rigor of the training program cited by a key personnel applicant applying through one of the Bylaws’ “training pathways.” The proposal also recommends some clerical changes to simplify these Bylaws sections. Making these proposed changes to the Bylaws supports the OPTN strategic plan goal of promoting the efficient management of the OPTN.

What problem will this proposal address?

There is disparity between what is stated in the Bylaws and what the MPSC actually does when considering the transplant training program of key personnel applicants who apply through one of the Bylaws' "training pathways." Some of the abdominal key personnel training pathways in the Bylaws require that the training occurred at a fellowship program "approved by the MPSC," and that the MPSC will review training programs "every five years or any time the program director changes." Although the MPSC does review where a key personnel applicant applying through one of the training pathways gained their fellowship experience, the MPSC does not formally approve or regularly review transplant training programs, nor has it done so historically.

Why should you support this proposal?

This proposal addresses longstanding Bylaws (the OPTN/UNOS Board of Directors adopted the earliest version of these requirements in November 1987) that establish MPSC actions that have never been formally undertaken by the MPSC. This proposal eliminates this discrepancy between the Bylaws and how the MPSC functionally operates, while retaining language to define what types of transplant fellowship training programs are acceptable for the purposes of evaluating prospective primary transplant surgeons or primary transplant physicians who apply through one of the Bylaws key personnel "training pathways." Adopting this proposal will effectively align the Bylaws with how the MPSC currently operates when reviewing transplant fellowship programs during the evaluation of key personnel applicants who apply through one of the training pathways in the Bylaws.

How was this proposal developed?

The Bylaws addressed in this proposal evolved directly from language that the OPTN/UNOS Board of Directors originally adopted in November 1987. The Board adopted these Bylaws to define what constituted an accepted training program for evaluating individuals' qualifications to serve as transplant program key personnel. Prior to the Board's decision in November 1987, key personnel requirements were rather basic; for example, primary transplant surgeons needed to be board certified and have one year of "formal training" and one year of experience at a designated transplant program, or three years of experience at a designated transplant program. In processing these early membership applications, the MPSC recognized a need to develop operational guidelines for defining what constituted "formal training." Subsequent to the development and usage of these operational guidelines, the MPSC recommended their incorporation in the Bylaws. The Board heeded this recommendation, and adopted the MPSC's "formal training" operational guidelines as Bylaws in November 1987.

The Board originally adopted these basic membership requirements to establish a standard that every transplant program is led by experienced individuals. As the field of transplantation began to develop, little distinction was made between training and experience because transplantation was a new field in which new experiences facilitated new knowledge and training. As transplantation became more commonplace and mature as a medical specialty, it was necessary to distinguish appropriate experience gained through training as compared to experience gained during clinical practice for the purpose of recognizing well-qualified key personnel. During the initial development of these Bylaws in the late eighties, extensive, closely-supervised training was provided through programs approved by the American Society of Transplant Surgeons (ASTS). This is reflected in the "formal training" criteria adopted by the OPTN/UNOS Board of Directors in 1987, which includes automatic approval of programs approved for training by ASTS.

Although it is well accepted that ASTS is the leader in establishing surgical transplant training curriculums and certifying transplant surgery training programs, the OPTN is prohibited from endorsing a single entity or business due to anti-competitive legal considerations. To avoid these concerns, the Bylaws also include explicit requirements that detail necessary components of a non-ASTS approved surgical training program. These Bylaws provide a means other than through an ASTS-approved fellowship program to qualify as a transplant program's primary surgeon through an OPTN Bylaws training pathway.

As transplantation has grown and evolved, so have the requirements in the key personnel Bylaws. Key personnel Bylaws now include organ specific considerations and a number of more detailed requirements. Although the key personnel requirements have increased in number and rigor, the Bylaws originally adopted in November 1987 that detail what “formal training” entails are quite similar to current Bylaws, including an expectation that transplant training programs are reviewed every five years, or when the program director changes.

The MPSC has raised questions about the requirement to review transplant training programs, recognizing that the MPSC does not perform such reviews, nor has it done so historically. Furthermore, the MPSC believes that the logistics and resources necessary to regularly monitor fellowship training program requirements would be significant, and likely duplicative of fellowship evaluations and accreditations performed by other organizations. The disparity between what is required in the Bylaws and how the MPSC actually operates prompted the Committee to review the Bylaws pertaining to transplant fellowship program approval by the MPSC.

As the majority of the problematic Bylaws regarding transplant fellowship approval pertain to abdominal primary transplant surgeons, and considering ASTS’ role in developing surgical transplant fellowship curriculum, the MPSC engaged ASTS representatives to provide its feedback and recommendations for modifying these Bylaws. Discussion yielded agreement that the scope of the proposed changes should be focused on the elimination of problematic Bylaws language regarding the MPSC review and approval process, and other changes that would streamline these sections of the Bylaws. The proposed Bylaws changes to those sections that pertain to primary kidney transplant surgeons, primary open living donor kidney surgeons, primary liver transplant surgeons, primary pancreas transplant surgeons, and primary intestine transplant surgeons provided at the end of this proposal are the product of the recommendations provided by ASTS.

Of these proposed edits, the most significant is the elimination of the problematic language regarding MPSC review and approval of fellowship programs. The remaining proposed deletions reflect the elimination of duplicative requirements found elsewhere in the Bylaws or requirements that are arbitrary and thus unenforceable. The few instances of proposed new language reflects an attempt to communicate more clearly the remaining requirements in these Bylaws pertaining to surgical transplant fellowships.

Following the review of those Bylaws focused on surgical transplant fellowships, the MPSC proceeded to engage representatives from the American Society of Transplantation (AST) to address similar problematic language found in OPTN Bylaws Appendix E.4.B (Transplant Physician Fellowship Training Programs), which addresses fellowship experience cited by primary kidney transplant physician applicants. Conversations with AST yielded similar changes: elimination of the problematic language regarding MPSC review and approval of transplant nephrology fellowships; elimination of requirements that are arbitrary to evaluate or duplicative of requirements established elsewhere in the Bylaws; and addition of language intended to make the remaining requirements clearer (included in these additions are formatting changes to align the structure of Appendix E.4.B with what is proposed for the those sections that focus on abdominal surgical transplant fellowships).

A few of the proposed changes to OPTN Bylaws Appendix E.4.B cannot be appropriately labeled with any of these general themes, and are detailed further here. First, the volume of kidney transplants that the training program must perform has been modified to align with what is currently required by the AST Adult Transplant Nephrology Fellowship Training Accreditation Program (a similar change is also proposed in OPTN Bylaws Appendix E.3.A).¹ Additionally, it is proposed that the biopsy requirement in Appendix E.4.B.5 be eliminated. This section focuses on fellowship program requirements, not individual fellow requirements, and the MPSC believes fellow-specific requirements should be removed from this section. This proposal does not include this requirement elsewhere in the Bylaws, as the inclusion of a biopsy requirement was specifically considered, and ultimately not proposed, with the MPSC’s proposal to

¹ <http://www.txnephaccreditation.org/list-eligibility-criteria>

update the primary kidney transplant physician Bylaws that it distributed for public comment during fall 2016, and that the OPTN/UNOS Board of Directors adopted in December 2016.²

Review of these Bylaws by AST also prompted questions about language that requires transplant medicine fellowship curriculum to be approved by the respective Residency Review Committee (RRC) of the Accreditation Council for Graduate Medical Education (ACGME). Nephrologists representing AST indicated that the RRC/ACGME do not have a role in setting transplant fellowship curriculum, to the extent outlined in these Bylaws, for either nephrology or pancreas physicians. Feedback requested from pediatric transplant nephrologists echoed this sentiment as it pertains to pediatric transplant nephrology fellowships. Considering this guidance, the proposal recommends deleting these references to RRC/ACGME curriculum approval in OPTN Bylaws Appendices E.3.A, E.3.D, E.3.E, E.5.C, and G.3.A. It is important to note that this proposal does not include changes to RRC/ACGME program accreditation requirements found in OPTN Bylaws Appendix E.3.C and F.3.C (one reference is deleted in E.3.C, but only because it is duplicative of similar language found earlier in that section that will remain). These sections of the Bylaws establish a “training pathway” for individuals who completed a three-year pediatric nephrology fellowship and a three-year pediatric gastroenterology fellowship, respectively. As the RRC/ACGME does establish fellowship program requirements for these specialties, the MPSC believes that it is appropriate to retain these references in these sections of the Bylaws.^{3,4}

Finally, although Appendix J (Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs) does not include language regarding periodic MPSC review of approved fellowship programs, it does reference fellowship programs that are “approved by the MPSC.” For consistency throughout the Bylaws, edits are proposed to OPTN Bylaws Appendices J.3.A.2.A and J.3.B.2.A to remove references to “MPSC approved” fellowship programs. With these edits, these sections now just focus on what is required of VCA key personnel applicants without additional qualifiers reiterating that fellowship programs meeting these requirements will be accepted/approved by the MPSC.

How well does this proposal address the problem statement?

This proposal completely addresses the disparity between how the MPSC functionally operates and the process currently established in the Bylaws regarding the MPSC’s ongoing review and approval of transplant fellowship programs. Further, the proposed changes preserve the Bylaws’ recognition of ASTS and AST transplant fellowships while still providing a list of transplant fellowship program minimal requirements to accommodate the possibility of other non-ASTS/non-AST transplant fellowships, and with respects to federal anti-competitive statutes.

This proposal could be criticized for proposing the deletion of Bylaws that differ from normal MPSC operations rather than changing the MPSC’s operations such that it adheres to the process established in the Bylaws. The MPSC opted to modify the Bylaws as it did not believe it would be worthwhile for the OPTN to expend the significant resources that would be needed to review transplant fellowship programs regularly. To do so would unnecessarily duplicate the considerable effort and resources that other organizations already invest in this process.

Which populations are impacted by this proposal?

This proposal addresses Bylaws that establish an MPSC operational action that has historically not been performed. Adopting this proposal will effectively align the Bylaws with how the MPSC currently operates with respects to evaluating key personnel applicants applying through one of the Bylaws’ training pathways. As such, there will be no impact to any part of the transplant community.

² https://optn.transplant.hrsa.gov/media/1998/mpsc_brief_kimd_201612.pdf#page=4

³ http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/328_nephrology_peds_2016.pdf

⁴ http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/332_gastroenterology_peds_2016.pdf

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* The efficient management of the OPTN is supported through these proposed changes by aligning the Bylaws with how the MPSC functionally operates with regards to the focus of this proposal and by increasing the consistency of key personnel requirements across all transplant program types.

How will the OPTN implement this proposal?

If public comment on this proposal is favorable, the MPSC would likely present these changes for the OPTN/UNOS Board of Directors' consideration at its December 2017 meeting. Assuming the Board adopts these changes, they would be effective on March 1, 2018.

Implementing the changes detailed in this proposal will align the Bylaws with how the MPSC currently operates when evaluating key personnel applicants who have applied through a "fellowship pathway." As such, the OPTN's implementation effort will primarily consist of updating the Bylaws found on the OPTN website on the effective date of these changes.

How will members implement this proposal?

No action will be required of members upon the implementation of these proposed Bylaws changes.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

This proposal primarily eliminates Bylaws that pertain to MPSC approval of fellowship training programs. Compliance with remaining Bylaws will be expected, but there are no member compliance considerations that directly result from these changes.

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

Considering the primary problem driving these proposed changes is operational in nature, deleting Bylaws as recommended in this proposal will successfully address this problem. Nevertheless, the MPSC will monitor if these changes yield consequences that it did not anticipate. Should any unanticipated negative consequences be realized, the MPSC would work towards another solution that corrects those.

Policy or Bylaws Language

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

E.2 Primary Kidney Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant. At least 10 of these procurements must be from deceased donors. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. This training was completed at a hospital with a kidney transplant training program approved by ~~the Fellowship Training Committee~~ of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized surgical fellowship training program accepted by the OPTN Contractor as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows.
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
 - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- 43 c. A letter from the surgeon that details the training and experience the surgeon has gained
44 in kidney transplantation.
45

46 **E.3 Primary Kidney Transplant Physician Requirements**

47 **A. Transplant Nephrology Fellowship Pathway**

48 Physicians can meet the training requirements for a primary kidney transplant physician during a
49 separate transplant nephrology fellowship if the following conditions are met:

- 50
- 51 1. The physician completed at least 12 consecutive months of specialized training in
52 transplantation under the direct supervision of a qualified kidney transplant physician and
53 along with a kidney transplant surgeon at a kidney transplant program that performs ~~30~~ 50 or
54 more transplants each year. The training must have included at least 6 months of clinical
55 inpatient transplant service. The remaining time must have consisted of transplant-related
56 experience, such as experience in a tissue typing laboratory, on another solid organ
57 transplant service, or conducting basic or clinical transplant research.
 - 58 2. During the fellowship period, the physician was directly involved in the primary care of 30 or
59 more newly transplanted kidney recipients and continued the outpatient follow-up of these
60 recipients for a minimum of 3 months from the time of transplant. If the physician's fellowship
61 was longer than 12 months, the physician also must have been directly involved in the
62 outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive
63 months. The care must be documented in a log that includes the date of transplant and the
64 recipient medical record number or other unique identifier that can be verified by the OPTN
65 Contractor. This recipient log must be signed by the director of the training program or the
66 transplant program's primary transplant physician.
 - 67 3. During the fellowship period, the physician was directly involved in the evaluation of 25
68 potential kidney recipients, including participation in selection committee meetings. These
69 potential kidney recipient evaluations must be documented in a log that includes each
70 evaluation date and is signed by the director of the training program or the transplant
71 program's primary transplant physician.
 - 72 4. During the fellowship period, the physician was directly involved in the evaluation of 10
73 potential living kidney donors, including participation in selection committee meetings. These
74 potential living kidney donor evaluations must be documented in a log that includes each
75 evaluation date and the potential living kidney donor's medical record number or other unique
76 identifier than can be verified by the OPTN Contractor. This potential living kidney donor
77 evaluation log must be signed by the director of the training program or the transplant
78 program's primary transplant physician.
 - 79 5. The physician has maintained a current working knowledge of kidney transplantation, defined
80 as direct involvement in kidney transplant care in the last 2 years. This includes the
81 management of patients with end stage renal disease, the selection of appropriate recipients
82 for transplantation, donor selection, histocompatibility and tissue typing, immediate
83 postoperative patient care, the use of immunosuppressive therapy including side effects of
84 the drugs and complications of immunosuppression, differential diagnosis of renal
85 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
86 interpretation of ancillary tests for renal dysfunction, and long term outpatient care. ~~The~~
87 ~~curriculum for obtaining this knowledge should be approved by the Residency Review~~
88 ~~Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical~~
89 ~~Education (ACGME).~~

- 90 6. The physician must have observed at least 3 kidney procurements, including at least 1
91 deceased donor and 1 living donor. The physician must have observed the evaluation,
92 donation process, and management of these donors. These observations must be
93 documented in a log that includes the date of procurement and Donor ID.
- 94 7. The physician must have observed at least 3 kidney transplants. The observation of these
95 transplants must be documented in a log that includes the transplant date, donor type, and
96 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 97 8. The following letters are submitted directly to the OPTN Contractor:
- 98 a. A letter from the director of the training program and the supervising qualified kidney
99 transplant physician verifying that the physician has met the above requirements and is
100 qualified to direct a kidney transplant program.
- 101 b. A letter of recommendation from the fellowship training program's primary physician and
102 transplant program director outlining the physician's overall qualifications to act as a
103 primary transplant physician, as well as the physician's personal integrity, honesty, and
104 familiarity with and experience in adhering to OPTN obligations and compliance
105 protocols, and any other matters judged appropriate. The MPSC may request additional
106 recommendation letters from the primary physician, primary surgeon, director, or others
107 affiliated with any transplant program previously served by the physician, at its discretion.
- 108 c. A letter from the physician that details the training and experience the physician has
109 gained in kidney transplantation.

110
111 The training requirements outlined above are in addition to other clinical requirements for general
112 nephrology training.
113

114 **C. Three-year Pediatric Nephrology Fellowship Pathway**

115 A physician can meet the requirements for primary kidney transplant physician by completion of 3
116 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics
117 in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the
118 ACGME. The training must contain at least 6 months of clinical care for transplant patients, and
119 the following conditions must be met:

- 120
- 121 1. During the 3-year training period the physician was directly involved in the primary care of 10
122 or more newly transplanted kidney recipients for at least 6 months from the time of transplant
123 and followed 30 transplanted kidney recipients for at least 6 months, under the direct
124 supervision of a qualified kidney transplant physician and in conjunction with a qualified
125 kidney transplant surgeon. The pediatric nephrology program director may elect to have a
126 portion of the transplant experience completed at another kidney transplant program in order
127 to meet these requirements. This care must be documented in a log that includes the date of
128 transplant, and the recipient medical record number or other unique identifier that can be
129 verified by the OPTN Contractor. This recipient log must be signed by the training program's
130 director or the primary physician of the transplant program.
- 131 2. The experience caring for pediatric patients occurred with a qualified kidney transplant
132 physician and surgeon at a kidney transplant program that performs an average of at least 10
133 pediatric kidney transplants a year.
- 134 3. During the fellowship period, the physician was directly involved in the evaluation of 25
135 potential kidney recipients, including participation in selection committee meetings. These
136 potential kidney recipient evaluations must be documented in a log that includes each
137 evaluation date and is signed by the director of the training program or the transplant
138 program's primary transplant physician.

- 139 4. The physician has maintained a current working knowledge of kidney transplantation, defined
140 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
141 management of pediatric patients with end-stage renal disease, the selection of appropriate
142 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
143 immediate post-operative care including those issues of management unique to the pediatric
144 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
145 pediatric recipient including side-effects of drugs and complications of immunosuppression,
146 the effects of transplantation and immunosuppressive agents on growth and development,
147 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
148 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
149 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
150 recipients including management of hypertension, nutritional support, and drug dosage,
151 including antibiotics, in the pediatric patient. ~~The curriculum for obtaining this knowledge must
152 be approved by the Residency Review Committee (RRC)–Ped of the ACGME.~~
- 153 5. The physician must have observed at least 3 kidney procurements, including at least 1
154 deceased donor and 1 living donor. The physician must have observed the evaluation,
155 donation process and management of these donors. These observations must be
156 documented in a log that includes the date of procurement and Donor ID.
- 157 6. The physician must have observed at least 3 kidney transplants involving a pediatric
158 recipient. The observation of these transplants must be documented in a log that includes the
159 transplant date, donor type, and medical record number or other unique identifier that can be
160 verified by the OPTN Contractor.
- 161 7. The following letters are submitted directly to the OPTN Contractor:
- 162 a. A letter from the director and the supervising qualified transplant physician and surgeon
163 of the fellowship training program verifying that the physician has met the above
164 requirements and is qualified to direct a kidney transplant program.
- 165 b. A letter of recommendation from the fellowship training program's primary physician and
166 transplant program director outlining the physician's overall qualifications to act as a
167 primary transplant physician, as well as the physician's personal integrity, honesty, and
168 familiarity with and experience in adhering to OPTN obligations, and any other matters
169 judged appropriate. The MPSC may request additional recommendation letters from the
170 primary physician, primary surgeon, director, or others affiliated with any transplant
171 program previously served by the physician, at its discretion.
- 172 c. A letter from the physician that details the training and experience the physician has
173 gained in kidney transplantation.

174
175 **D. Twelve-month Pediatric Transplant Nephrology Fellowship**
176 **Pathway**

177 The requirements for the primary kidney transplant physician can be met during a separate
178 pediatric transplant nephrology fellowship if the following conditions are met:

- 179
- 180 1. The physician has current board certification in pediatric nephrology by the American Board
181 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
182 the American Board of Pediatrics to take the certifying exam.
- 183 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
184 newly transplanted kidney recipients for at least 6 months from the time of transplant and
185 followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision
186 of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant

- 187 surgeon. The pediatric nephrology program director may elect to have a portion of the
188 transplant experience completed at another kidney transplant program in order to meet these
189 requirements. This care must be documented in a recipient log that includes the date of
190 transplant, and the recipient medical record number or other unique identifier that can be
191 verified by the OPTN Contractor. This log must be signed by the training program director or
192 the primary physician of the transplant program.
- 193 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a
194 qualified kidney transplant physician and surgeon that performs an average of at least 10
195 pediatric kidney transplants a year.
- 196 4. During the four years that include the physician's three-year pediatric nephrology fellowship
197 and twelve-month pediatric transplant nephrology fellowship, the physician was directly
198 involved in the evaluation of 25 potential kidney recipients, including participation in selection
199 committee meetings. These potential kidney recipient evaluations must be documented in a
200 log that includes each evaluation date and is signed by the director of the training program or
201 the transplant program's primary transplant physician.
- 202 5. The physician has maintained a current working knowledge of kidney transplantation, defined
203 as direct involvement in kidney transplant patient care in the past 2 years. This includes the
204 management of pediatric patients with end-stage renal disease, the selection of appropriate
205 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
206 immediate post-operative care including those issues of management unique to the pediatric
207 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
208 pediatric recipient including side-effects of drugs and complications of immunosuppression,
209 the effects of transplantation and immunosuppressive agents on growth and development,
210 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
211 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
212 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
213 recipients including management of hypertension, nutritional support, and drug dosage,
214 including antibiotics, in the pediatric patient. ~~The curriculum for obtaining this knowledge must
215 be approved by the Residency Review Committee (RRC)–Ped of the ACGME.~~
- 216 6. The physician must have observed at least 3 kidney procurements, including at least 1
217 deceased donor and 1 living donor. The physician must have observed the evaluation,
218 donation process, and management of these donors. These observations must be
219 documented in a log that includes the date of procurement and Donor ID.
- 220 7. The physician must have observed at least 3 kidney transplants involving a pediatric
221 recipient. The observation of these transplants must be documented in a log that includes the
222 transplant date, donor type, and medical record number or other unique identifier that can be
223 verified by the OPTN Contractor.
- 224 8. The following letters are submitted directly to the OPTN Contractor:
- 225 a. A letter from the director and the supervising qualified transplant physician and surgeon
226 of the fellowship training program verifying that the physician has met the above
227 requirements and is qualified to become the primary transplant physician of a designated
228 kidney transplant program.
- 229 b. A letter of recommendation from the fellowship training program's primary physician and
230 transplant program director outlining the physician's overall qualifications to act as a
231 primary transplant physician, as well as the physician's personal integrity, honesty, and
232 familiarity with and experience in adhering to OPTN obligations, and any other matters
233 judged appropriate. The MPSC may request additional recommendation letters from the
234 primary physician, primary surgeon, director, or others affiliated with any transplant
235 program previously served by the physician, at its discretion.

- 236 c. A letter from the physician that details the training and experience the physician has
237 gained in kidney transplantation.
238

239 **E. Combined Pediatric Nephrology Training and Experience Pathway**

240 A physician can meet the requirements for primary kidney transplant physician if the following
241 conditions are met:
242

- 243 1. The physician has current board certification in pediatric nephrology by the American Board
244 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
245 the American Board of Pediatrics to take the certifying exam.
- 246 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
247 accumulated during both periods, at a kidney transplant program.
- 248 3. During the 2 or more years of accumulated experience, the physician was directly involved in
249 the primary care of 10 or more newly transplanted kidney recipients for at least 6 months
250 from the time of transplant and followed 30 transplanted kidney recipients for at least 6
251 months, under the direct supervision of a qualified kidney transplant physician, along with a
252 qualified kidney transplant surgeon. This care must be documented in a recipient log that
253 includes the date of transplant, and the recipient medical record number or other unique
254 identifier that can be verified by the OPTN Contractor. This log must be signed by the training
255 program director or the primary physician of the transplant program.
- 256 4. The physician was directly involved in the evaluation of 25 potential kidney recipients,
257 including participation in selection committee meetings. These potential kidney recipient
258 evaluations must be documented in a log that includes each evaluation date and be signed by
259 the program director, division Chief, or department Chair from the program where the
260 physician gained this experience.
- 261 5. The physician has maintained a current working knowledge of kidney transplantation, defined
262 as direct involvement in kidney transplant patient care during the past 2 years. This includes
263 the management of pediatric patients with end-stage renal disease, the selection of
264 appropriate pediatric recipients for transplantation, donor selection, histocompatibility and
265 tissue typing, immediate post-operative care including those issues of management unique to
266 the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive
267 therapy in the pediatric recipient including side-effects of drugs and complications of
268 immunosuppression, the effects of transplantation and immunosuppressive agents on growth
269 and development, differential diagnosis of renal dysfunction in the allograft recipient,
270 manifestation of rejection in the pediatric patient, histological interpretation of allograft
271 biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care
272 of pediatric allograft recipients including management of hypertension, nutritional support,
273 and drug dosage, including antibiotics, in the pediatric patient. ~~The curriculum for obtaining
274 this knowledge must be approved by the Residency Review Committee (RRC) – Ped of the
275 ACGME or a Residency Review Committee.~~
- 276 6. The physician must have observed at least 3 kidney procurements, including at least 1
277 deceased donor and 1 living donor. The physician must have observed the evaluation,
278 donation process, and management of these donors. These observations must be
279 documented in a log that includes the date of procurement and Donor ID.
- 280 7. The physician must have observed at least 3 kidney transplants involving a pediatric
281 recipient. The observation of these transplants must be documented in a log that includes the
282 transplant date, donor type, and medical record number or other unique identifier that can be
283 verified by the OPTN Contractor.

- 284 8. The following letters are submitted directly to the OPTN Contractor:
285 a. A letter from the supervising qualified transplant physician and surgeon who were directly
286 involved with the physician documenting the physician's experience and competence.
287 b. A letter of recommendation from the fellowship training program's primary physician and
288 transplant program director outlining the physician's overall qualifications to act as a
289 primary transplant physician, as well as the physician's personal integrity, honesty, and
290 familiarity with and experience in adhering to OPTN obligations, and any other matters
291 judged appropriate. The MPSC may request additional recommendation letters from the
292 primary physician, primary surgeon, Director, or others affiliated with any transplant
293 program previously served by the physician, at its discretion.
294 c. A letter from the physician that details the training and experience the physician has
295 gained in kidney transplantation.
296

297 **E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training**
298 **Programs**

299 **A. Transplant Surgeon Fellowship Training Programs**

300 Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year formal
301 surgical transplant fellowship must complete their training at a fellowship program approved by
302 the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of
303 Canada, or another recognized fellowship training program accepted by the OPTN Contractor
304 MPSC. Any program approved for training by the Fellowship Training Committee of the American
305 Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program
306 that meets the following criteria:

- 307
308 1. The program is at a transplant hospital that transplants one or more organs, including
309 kidneys.
310 2. The program is at an institution that has ACGME approved training in general surgery-a
311 proven commitment to graduate medical education.
312 ~~3. The program director is a board-certified surgeon who meets the OPTN Contractor~~
313 ~~requirements for primary kidney transplant surgeon.~~
314 ~~4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets~~
315 ~~the OPTN Contractor requirements for histocompatibility laboratories.~~
316 ~~5. The program is at a hospital that is affiliated with an organ procurement organization (OPO)~~
317 ~~that meets the OPTN Contractor requirements for OPOs.~~
318 63. The program performs at least 60 kidney transplants during each year of the fellowship
319 training from deceased or living donors.
320 ~~7. The program has the resources, including adequate clinical facilities, laboratory research~~
321 ~~facilities, and appropriately trained faculty and staff, to provide research experience.~~

322
323 ~~Training programs are reviewed by the MPSC every 5 years or any time the program director~~
324 ~~changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a~~
325 ~~new program.~~
326

327 **B. Transplant Physician Fellowship Training Programs**

328 A formal training program for primary kidney transplant physicians requires that training must be
329 completed at a program approved by the MPSC. Any training program approved by the AST

330 ~~Adult Renal Transplant Training Accreditation Program is automatically accepted by the MPSC,~~
331 ~~as well as any program that meets the following criteria:~~
332 ~~Physicians qualifying as primary transplant physician based on completion of a formal transplant~~
333 ~~fellowship must complete their training at a fellowship program approved by the American Society~~
334 ~~of Transplantation Adult Transplant Nephrology Fellowship Training Program, the Royal College~~
335 ~~of Physicians and Surgeons of Canada, or another recognized fellowship training program~~
336 ~~accepted by the OPTN Contractor that meets the following criteria:~~

- 337
- 338 1. ~~The program is at a transplant hospital that transplants one or more organs, including~~
339 ~~kidneys. must be OPTN approved as a kidney transplant program and be affiliated with an~~
340 ~~ACGME approved nephrology program. Transplant programs that are not OPTN approved or~~
341 ~~affiliated with an ACGME approved nephrology program will be evaluated on a case-by-case~~
342 ~~basis.~~
 - 343 2. ~~The program is at a hospital that has an ACGME approved nephrology program.~~
 - 344 23. ~~The program performs at least 50 kidney transplants per year if the program is training one~~
345 ~~transplant nephrology fellow, and performs at least 30 additional kidney transplants per year~~
346 ~~for each additional fellow it trains. The program must perform at least 10 kidney transplants~~
347 ~~per year for each first year, general nephrology fellow in training and an additional 30~~
348 ~~transplants per year for each kidney transplant fellow to be trained.~~
 - 349 34. ~~The program's must have a full-time faculty member or members capable of teaching a~~
350 ~~curriculum with a broad base of knowledge in transplant medicine. The curriculum must~~
351 ~~include training and experience in end-stage renal disease, training in the selection of~~
352 ~~appropriate transplant recipients and donors, experience in the immediate and long term care~~
353 ~~of the transplant recipient, and training in the performance of kidney transplant biopsies.~~
354 ~~Additionally there must be an emphasis on the management of immunosuppressive agents~~
355 ~~and the evaluation of kidney transplant dysfunction. Combined surgical and medical rounds~~
356 ~~should be conducted on a regular basis.~~
 - 357 45. ~~The program must provide patient co-management responsibility with transplant surgeons~~
358 ~~from the peri-operative through the outpatient period. The kidney trainee must primarily~~
359 ~~manage the transplant recipient's medical care including hypertension, diabetes, and dialytic~~
360 ~~problems. Trainees must also serve as a primary member of the transplant team and~~
361 ~~participate in making decisions about immunosuppression. The transplant renal fellow must~~
362 ~~be primarily responsible for 30 in-patient renal transplant recipients and 30 outpatient~~
363 ~~recipients over a period of 12 months. Outpatient follow up must be continuous for a~~
364 ~~minimum of at least 3 months. Training must be completed within 12 continuous months; a~~
365 ~~minimum of 6 months of training must be performed in inpatient clinical service.~~
 - 366 5. ~~The transplant nephrology fellow must perform a minimum of 10 transplant biopsies during~~
367 ~~the training period.~~
 - 368 6. ~~The transplant nephrology fellow must observe at least 3 kidney transplants and at least 3~~
369 ~~procurement procedures.~~

370

371 **E.5 Kidney Transplant Programs that Register Candidates Less than 18 Years** 372 **Old**

373 **C. Conditional Approval for a Pediatric Component**

374 A designated kidney transplant program can obtain conditional approval for a pediatric
375 component if *either* of the following conditions is met:

376

- 377 1. The program has a qualified primary pediatric kidney physician who meets *all* of the

- 378 requirements described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician*
379 *Requirements* and a surgeon who meets *all* of the following requirements:
380
- 381 a. The surgeon meets all of the requirements described in *Section E.2: Primary Kidney*
382 *Transplant Surgeon Requirements*, including completion of at least one of the following
383 training or experience pathways:
- 384 ■ The formal 2-year transplant fellowship pathway as described in *Section E.2.A:*
385 *Formal 2-year Transplant Fellowship Pathway*
 - 386 ■ The kidney transplant program clinical experience pathway, as described in *Section*
387 *E.2.B: Clinical Experience Pathway*
388
- 389 b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first
390 assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these
391 kidney transplants must have been in recipients less than 6 years old or weighing less
392 than 25 kilograms at the time of transplant. These transplants must have been performed
393 during or after fellowship, or across both periods. These transplants must be documented
394 in a log that includes the date of transplant, the recipient's date of birth, the recipient's
395 weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure,
396 and the medical record number or other unique identifier that can be verified by the
397 OPTN Contractor.
- 398 c. The surgeon has maintained a current working knowledge of pediatric kidney
399 transplantation, defined as direct involvement in pediatric kidney transplant patient care in
400 the last 2 years. This includes the management of pediatric patients with end stage renal
401 disease, the selection of appropriate pediatric recipients for transplantation, donor
402 selection, histocompatibility and HLA typing, performing the pediatric transplant
403 operation, immediate postoperative and continuing inpatient care, the use of
404 immunosuppressive therapy including side effects of the drugs and complications of
405 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
406 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
407 dysfunction, and long term outpatient care.
408
- 409 2. The program has a qualified primary pediatric kidney surgeon who meets *all* of the
410 requirements described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon*
411 *Requirements* and a physician who meets *all* of the following requirements:
412
- 413 a. The physician has current board certification in pediatric nephrology by the American
414 Board of Pediatrics or the foreign equivalent, or is approved by the American Board of
415 Pediatrics to take the certifying exam.
 - 416 b. The physician gained a minimum of 2 years of experience during or after fellowship, or
417 accumulated during both periods, at a kidney transplant program.
 - 418 c. During the 2 or more years of accumulated experience, the physician was directly
419 involved in the primary care of 5 or more newly transplanted kidney recipients and
420 followed 15 newly transplanted kidney recipients for at least 6 months from the time of
421 transplant, under the direct supervision of a qualified kidney transplant physician, along
422 with a qualified kidney transplant surgeon. This care must be documented in a recipient
423 log that includes the date of transplant and the recipient medical record number or other
424 unique identifier that can be verified by the OPTN Contractor. This log must be signed by
425 the training program director or the primary physician of the transplant program.
 - 426 d. The physician has maintained a current working knowledge of pediatric kidney
427 transplantation, defined as direct involvement in kidney transplant patient care during the
428 past 2 years. This includes the management of pediatric patients with end-stage renal
429 disease, the selection of appropriate pediatric recipients for transplantation, donor
430 selection, histocompatibility and HLA typing, immediate post-operative care including
431 those issues of management unique to the pediatric recipient, fluid and electrolyte
432 management, the use of immunosuppressive therapy in the pediatric recipients including

433 side-effects of drugs and complications of immunosuppression, the effects of
434 transplantation and immunosuppressive agents on growth and development, differential
435 diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the
436 pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary
437 tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients
438 including management of hypertension, nutritional support, and drug dosage, including
439 antibiotics, in the pediatric patient. ~~The curriculum for obtaining this knowledge must be
440 approved by the Residency Review Committee (RRC) — Ped of the ACGME or a
441 Residency Review Committee.~~

- 442 e. The physician should have observed at least 3 organ procurements and 3 pediatric
443 kidney transplants. The physician should also have observed the evaluation, the donation
444 process, and management of at least 3 multiple organ donors who donated a kidney. If
445 the physician has completed these observations, they must be documented in a log that
446 includes the date of procurement and Donor ID.
- 447 f. The following letters are submitted directly to the OPTN Contractor:
- 448 i. A letter from the supervising qualified transplant physician and surgeon who were
449 directly involved with the physician documenting the physician's experience and
450 competence.
- 451 ii. A letter of recommendation from the fellowship training program's primary physician
452 and transplant program director outlining the physician's overall qualifications to act
453 as a primary transplant physician, as well as the physician's personal integrity,
454 honesty, and familiarity with and experience in adhering to OPTN obligations, and
455 any other matters judged appropriate. The MPSC may request additional
456 recommendation letters from the primary pediatric surgeon, Director, or others
457 affiliated with any transplant program previously served by the physician, at its
458 discretion.
- 459 iii. A letter from the physician that details the training and experience the physician has
460 gained in kidney transplantation.

461
462 A designated kidney transplant program's conditional approval for a pediatric component is
463 valid for a maximum of 24 months.
464

465 **E.6 Kidney Transplant Programs that Perform Living Donor Recovery**

466 **D. Primary Open Living Donor Kidney Surgeon**

467 A kidney donor surgeon who performs open living donor nephrectomies must be on site and must
468 meet *one* of the following criteria:
469

- 470 ■ ~~Completion of an accredited American Society of Transplant Surgeons (ASTS) a formal 2-~~
471 ~~year surgical transplant fellowship with in kidney certification at a fellowship program~~
472 approved by the American Society of Transplant Surgeons, the Royal College of Physicians
473 and Surgeons of Canada, or other recognized fellowship training program accepted by the
474 OPTN Contractor as described in *Section E.4.A: Transplant Surgeon Fellowship Training*
475 *Programs.*
- 476 ■ Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or
477 the removal of diseased kidneys, as primary surgeon, co-surgeon, or first assistant. At least 5
478 of these open nephrectomies must have been performed as the primary surgeon or co-
479 surgeon. The open nephrectomies must be documented in a log that includes the date of
480 recovery, the role of the surgeon in the procedure, the type of procedure (open or
481 laparoscopic), and the medical record number or Donor ID.
482

483 **F.3 Primary Liver Transplant Surgeon Requirements**

484 **A. Formal 2-year Transplant Fellowship Pathway**

485 Surgeons can meet the training requirements for primary liver transplant surgeon by completing a
486 formal 2-year surgical transplant fellowship if the following conditions are met:
487

- 488 1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant
489 during the 2-year fellowship period. These transplants must be documented in the surgeon's
490 fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the
491 medical record number or other unique identifier that can be verified by the OPTN Contractor,
492 and the fellowship director's signature must be provided with this log.
- 493 2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant.
494 These procurements must have been performed anytime during the surgeon's fellowship and
495 the two years immediately following fellowship completion. These procedures must be
496 documented in the surgeon's fellowship operative log. The date of procurement and Donor ID
497 must be provided with this log.
- 498 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
499 direct involvement in liver transplant patient care within the last 2 years. This includes the
500 management of patients with end stage liver disease, the selection of appropriate recipients
501 for transplantation, donor selection, histocompatibility and tissue typing, performing the
502 transplant operation, immediate postoperative and continuing inpatient care, the use of
503 immunosuppressive therapy including side effects of the drugs and complications of
504 immunosuppression, differential diagnosis of liver allograft dysfunction, histologic
505 interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and
506 long term outpatient care.
- 507 4. The training was completed at a hospital with a liver transplant training program approved by
508 the ~~Fellowship Training Committee~~ of the American Society of Transplant Surgeons, the
509 Royal College of Physicians and Surgeons of Canada, or another recognized fellowship
510 training program accepted by the OPTN Contractor as described in *Section F.6: Approved*
511 *Liver Surgeon Transplant Fellowship Programs* that follows.
- 512 5. The following letters are submitted directly to the OPTN Contractor:
- 513 a. A letter from the director of the training program verifying that the surgeon has met the
514 above requirements, and is qualified to direct a liver transplant program.
- 515 b. A letter of recommendation from the fellowship training program's primary surgeon and
516 transplant program director outlining the surgeon's overall qualifications to act as primary
517 transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with
518 and experience in adhering to OPTN obligations, and other matters judged appropriate.
519 The MPSC may request additional recommendation letters from the primary physician,
520 primary surgeon, director, or others affiliated with any transplant program previously
521 served by the surgeon, at its discretion.
- 522 c. A letter from the surgeon that details his or her training and experience in liver
523 transplantation.
524

525 **F.6 Approved Liver Surgeon Transplant Fellowship Programs**

526 Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year formal surgical
527 transplant fellowship must complete their training at a fellowship program approved by the American
528 Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another
529 recognized fellowship training program accepted by the OPTN Contractor ~~MPSC. Any program approved~~

530 ~~for training by the Fellowship Training Committee of the American Society of Transplant Surgeons is~~
531 ~~automatically accepted by the MPSC, as well as any program that meets the following criteria:~~

- 532
- 533 1. ~~The program is at a transplant hospital that transplants one or more organs, including livers.~~
 - 534 2. ~~The program is at an institution that has ACGME approved training in general surgery a ~~proven~~~~
 - 535 ~~commitment to graduate medical education.~~
 - 536 3. ~~The program director is a board-certified surgeon who meets the OPTN Contractor requirements for~~
537 ~~primary liver transplant surgeon.~~
 - 538 4. ~~The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN~~
539 ~~Contractor requirements for histocompatibility laboratories.~~
 - 540 5. ~~The program is at a hospital that is affiliated with an organ procurement organization (OPO) that~~
541 ~~meets the OPTN Contractor requirements for OPOs.~~
 - 542 6. ~~The program performs at least 50 liver transplants during each year of the fellowship training from~~
543 ~~deceased or living donors.~~
 - 544 7. ~~The program has the resources, including adequate clinical facilities, laboratory research facilities,~~
545 ~~and appropriately trained faculty and staff, to provide research experience.~~

546
547 ~~Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If~~
548 ~~a program has no fellows during the 5 years between reviews, it must re-apply as a new program.~~
549

550 **F.11 Primary Intestine Transplant Surgeon Requirements**

551 **A. Full Intestine Surgeon Approval Pathway**

552 Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal
553 surgical transplant fellowship or by completing clinical experience at an intestine transplant
554 program if *all* of the following conditions are met:
555

- 556 1. The surgeon performed 7 or more intestine transplants at a designated intestine transplant
557 program, to include the isolated bowel and composite grafts, as primary surgeon or first
558 assistant within the last 10 years. These transplants must be documented in a log that
559 includes the date of transplant, the role of the surgeon in the procedure, and the medical
560 record number or other unique identifier that can be verified by the OPTN Contractor. This log
561 must be signed by the program director, division chief, or department chair from the program
562 where the experience or training was gained.
- 563 2. The surgeon performed 3 or more intestine procurements as primary surgeon or first
564 assistant. These procurements must include 1 or more organ recovery that includes a liver.
565 These procedures must be documented in a log that includes the date of procurement and
566 Donor ID. This log must be signed by the program director, division chief, or department chair
567 from the program where the experience or training was gained.
- 568 3. The surgeon has maintained a current working knowledge of intestine transplantation,
569 defined as direct involvement in intestine transplant patient care within the last 5 years. This
570 includes the management of patients with short bowel syndrome or intestinal failure, the
571 selection of appropriate recipients for transplantation, donor selection, histocompatibility and
572 tissue typing, performing the transplant operation, immediate postoperative and continuing
573 inpatient care, the use of immunosuppressive therapy including side effects of the drugs and
574 complications of immunosuppression, differential diagnosis of intestine allograft dysfunction,
575 histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine
576 dysfunction, and long term outpatient care.

- 577 4. The training was completed at a hospital with an intestinal transplant training program
578 approved by the American Society of Transplant Surgeons, (ASTS) or the Royal College of
579 Physicians and Surgeons of Canada, or another recognized fellowship training program
580 accepted by the OPTN Contractor as described in *Section F.14: Approved Intestine*
581 *Transplant Surgeon Fellowship Training Programs* that follows.
- 582 5. The following letters are submitted to the OPTN Contractor:
- 583 a. A letter from the qualified intestine transplant physician and surgeon who have been
584 directly involved with the surgeon documenting the surgeon's experience and
585 competence.
- 586 b. A letter of recommendation from the primary surgeon and transplant program director at
587 the fellowship training program or transplant program last served by the surgeon outlining
588 the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the
589 surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
590 OPTN obligations, and any other matters judged appropriate. The MPSC may request
591 additional recommendation letters from the primary surgeon, primary physician surgeon,
592 director, or others affiliated with any transplant program previously served by the
593 physician, at its discretion.
- 594 c. A letter from the surgeon that details the training and experience the surgeon gained in
595 intestine transplantation.
- 596

597 **F.14 Approved Intestine Surgeon Transplant Fellowship Programs**

598 Surgeons qualifying as primary transplant surgeon ~~through~~ based on completion of a formal transplant
599 fellowship must complete their training at a fellowship program approved by the American Society of
600 Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized
601 fellowship training program accepted by the OPTN Contractor MPSC. Any program approved by the
602 Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted
603 by the MPSC, as well as any program that meets all of the following criteria:

- 604
- 605 1. The program is at a transplant hospital that transplants ~~one~~ two or more organs, including liver and
606 intestines.
 - 607 2. The program is at an institution that has ACGME approved training in general surgery ~~a proven~~
608 commitment to graduate medical education.
 - 609 ~~3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for~~
610 ~~primary intestine transplant surgeon.~~
 - 611 ~~4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN~~
612 ~~Contractor requirements for histocompatibility laboratories.~~
 - 613 ~~5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that~~
614 ~~meets the OPTN Contractor requirements for OPOs.~~
 - 615 6. The program performs at least 10 intestine transplants during each year of the fellowship training.
 - 616 ~~7. The program has the resources, including adequate clinical facilities, laboratory research facilities,~~
617 ~~and appropriately trained faculty and staff, to provide research experience.~~
- 618

619 **G.2 Primary Pancreas Transplant Surgeon Requirements**

620 **A. Formal 2-year Transplant Fellowship Pathway**

621 Surgeons can meet the training requirements for primary pancreas transplant surgeon by
622 completing a formal 2-year surgical transplant fellowship if the following conditions are met:
623

- 624 1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant.
625 These transplants must be documented in the surgeon's fellowship operative log. The date of
626 transplant, the role of the surgeon in the procedure, the medical record number or other
627 unique identifier that can be verified by the OPTN Contractor, and the fellowship director's
628 signature must be provided with this log.
- 629 2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first
630 assistant. These procurements must have been performed anytime during the surgeon's
631 fellowship and the two years immediately following fellowship completion. These cases must
632 be documented in the surgeon's fellowship operative log. The date of procurement, Donor ID,
633 and the fellowship director's signature must be provided with this log.
- 634 3. The surgeon has maintained a current working knowledge of pancreas transplantation,
635 defined as direct involvement in patient care within the last 2 years. This includes the
636 management of patients with diabetes mellitus, the selection of appropriate recipients for
637 transplantation, donor selection, histocompatibility and tissue typing, performing the
638 transplant operation, immediate postoperative and continuing inpatient care, the use of
639 immunosuppressive therapy including side effects of the drugs and complications of
640 immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient,
641 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic
642 dysfunction, and long term outpatient care.
- 643 4. The training was completed at a hospital with a pancreas transplant training program
644 approved by the ~~Fellowship Training Committee of the American Society of Transplant~~
645 ~~Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized~~
646 ~~fellowship training program~~ accepted by the OPTN Contractor as described in *Section G.7:*
647 *Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows.
- 648 5. The following letters are submitted directly to the OPTN Contractor:
- 649 a. A letter from the director of the training program and chairman of the department or
650 hospital credentialing committee verifying that the fellow has met the above requirements
651 and is qualified to direct a pancreas transplant program.
- 652 b. A letter of recommendation from the fellowship training program's primary surgeon and
653 transplant program director outlining the surgeon's overall qualifications to act as primary
654 transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with
655 and experience in adhering to OPTN obligations, and any other matters judged
656 appropriate. The MPSC may request similar letters of recommendation from the primary
657 physician, primary surgeon, director, or others affiliated with any transplant program
658 previously served by the surgeon, at its discretion.
- 659 c. A letter from the surgeon that details the training and experience the surgeon has gained
660 in pancreas transplantation.
- 661

662 **G.3 Primary Pancreas Transplant Physician Requirements**

663 **A. Twelve-month Transplant Medicine Fellowship Pathway**

664 Physicians can meet the training requirements for a primary pancreas transplant physician during
665 a separate 12-month transplant medicine fellowship if the following conditions are met:

- 666
- 667 1. The physician completed 12 consecutive months of specialized training in pancreas
668 transplantation at a pancreas transplant program under the direct supervision of a qualified
669 pancreas transplant physician along with a pancreas transplant surgeon. The training must
670 have included at least 6 months on the clinical transplant service. The remaining time must
671 have consisted of transplant-related experience, such as experience in a tissue typing

- 672 laboratory, on another solid organ transplant service, or conducting basic or clinical transplant
673 research.
- 674 2. During the fellowship period, the physician was directly involved in the primary care of 8 or
675 more newly transplanted pancreas recipients and followed these recipients for a minimum of
676 3 months from the time of transplant. The care must be documented in a log that includes the
677 date of transplant and medical record number or other unique identifier that can be identified
678 by the OPTN Contractor. This recipient log must be signed by the director of the training
679 program or the transplant program's primary transplant physician.
- 680 3. The physician has maintained a current working knowledge of pancreas transplantation,
681 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
682 includes the management of patients with end stage pancreas disease, the selection of
683 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
684 typing, immediate post-operative patient care, the use of immunosuppressive therapy
685 including side effects of the drugs and complications of immunosuppression, differential
686 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of
687 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term
688 outpatient care.
- 689 4. The physician must have observed at least 3 pancreas procurements. The physician must
690 have also observed the evaluation, donation process, and management of these donors.
691 These observations must be documented in a log that includes the date of procurement and
692 Donor ID.
- 693 5. The physician must have observed at least 3 pancreas transplants. The observation of these
694 transplants must be documented in a log that includes the transplant date and medical record
695 number or other unique identifier that can be verified by the OPTN Contractor.
- 696 ~~6. The curriculum of this transplant medicine fellowship should be approved by the Residency
697 Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate
698 Medical Education (ACGME).~~
- 699 76. The following letters are submitted directly to the OPTN Contractor:
- 700 a. A letter from director of the training program and supervising qualified pancreas
701 transplant physician send a letter directly to the OPTN Contractor verifying that the fellow
702 has met the above requirements and is qualified to direct a pancreas transplant program.
- 703 b. A letter of recommendation from the fellowship training program's primary physician and
704 transplant program director outlining the physician's overall qualifications to act as
705 primary transplant physician as well as the physician's personal integrity, honesty,
706 familiarity with and experience in adhering to OPTN obligations, and any other matters
707 judged appropriate. The MPSC may request similar letters of recommendation from the
708 primary physician, primary surgeon, director, or others affiliated with any transplant
709 program that the physician previously served, at its discretion.
- 710 c. A letter from the physician that details the training and experience the physician has
711 gained in pancreas transplantation.

712
713 The above training is in addition to other clinical requirements for general nephrology,
714 endocrinology, or diabetology training.
715

716 **G.7 Approved Pancreas Transplant Surgeon Fellowship Training Programs**

717 Surgeons qualifying as primary transplant surgeons based on completion of a formal 2-year surgical
718 transplant fellowship must complete their training at a fellowship program approved by Fellowship training
719 programs accredited by the Fellowship Training Committee of the American Society of Transplant

720 Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship
721 training program accepted by ~~are acceptable to the OPTN Contractor or all programs that meets~~ the
722 following criteria:

723

724 1. The program ~~must be~~ is located at a transplant hospital that transplants one or more organs,
725 including pancreas.

726 ~~2. The program must be reviewed every 5 years by the OPTN Contractor.~~

727 ~~3. The program must be~~ is at an institution that has ACGME approved training in general surgery with a
728 proven commitment to graduate medical education.

729 ~~4. The program director must be a board certified surgeon who meets the requirements of a primary~~
730 ~~transplant surgeon.~~

731 ~~5. The program must be at an institution affiliated with a histocompatibility laboratory member.~~

732 ~~6. The program must be at an institution affiliated with an organ procurement organization member.~~

733 ~~7. The program must~~ performs at least 20 pancreas transplants during each year of fellowship training
734 to qualify for pancreas transplantation training.

735 ~~8. The training program must have adequate clinical and laboratory research facilities.~~

736 ~~9. The training program should have adequate faculty with appropriate training to provide proper~~
737 ~~research experience.~~

738

739 ~~Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If~~
740 ~~a program has no fellows during the 5 years between reviews, it must re-apply as a new training program.~~

741

742 **J.3 Primary VCA Transplant Surgeon Requirements**

743 **A. Additional Primary Surgeon Requirements for Upper Limb** 744 **Transplant Programs**

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

747 1. Must meet at least *one* of the following:

748 a. Have current certification by the American Board of Plastic Surgery, the American Board
749 of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the
750 case of a surgeon who has just completed training and whose board certification is
751 pending, the Membership and Professional Standards Committee (MPSC) may grant
752 conditional approval for 24 months to allow time for the surgeon to complete board
753 certification, with the possibility of renewal for an additional 12-month period.

754 b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of
755 the following relevant clinical experience:

756 i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or
757 primary surgeon on at least 1 VCA procurement.

758 ii. Pre-operative evaluation of at least 3 potential upper limb transplant candidates.

759 iii. Acted as primary surgeon of a least 1 upper limb transplant.

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

761

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

767 be signed by the program director, division chief, or department chair where the experience
 768 was gained.

769
 770 If a primary surgeon qualified under 1.b leaves the transplant program, the replacement for
 771 this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway 1.b will
 772 no longer be available and all primary surgeons must meet the requirements of 1.a.

773
 774 2. Completion of at least *one* of the following:

775 a. ~~A fellowship program in hand surgery that is approved by the MPSC. Any Accreditation~~
 776 ~~Council of Graduate Medical Education (ACGME) approved fellowship program in hand~~
 777 ~~surgery is automatically accepted by the MPSC.~~

778 b. A fellowship program in hand surgery that meets *all* of the following criteria ~~will also be~~
 779 ~~accepted:~~

780 i. The program is at a hospital that has inpatient facilities, operative suites and
 781 diagnostic treatment facilities, outpatient facilities, and educational resources.

782 ii. The program is at an institution that has a proven commitment to graduate medical
 783 education.

784 iii. The program director must have current certification in the sub-specialty by the
 785 American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or
 786 American Board of Surgery.

787 iv. The program should have at least 2 physician faculty members with hand surgery
 788 experience and current medical licensure who are actively involved in the instruction
 789 and supervision of fellows during the time of accredited education.

790 v. The program is at a hospital that has affiliated rehabilitation medicine services.

791 vi. The program has the resources, including adequate clinical facilities, laboratory
 792 research facilities, and appropriately trained faculty and staff, to provide research
 793 experience.

794 c. At least 2 years of consecutive and independent practice of hand surgery and must have
 795 completed a minimum number of upper limb procedures as the primary surgeon shown in
 796 *Table J-1* below. This includes completion of pre-operative assessments and post-
 797 operative care for a minimum of 90 days after surgery. These procedures must be
 798 documented in a log that includes the date of the procedure and the medical record
 799 number or other unique identifier that can be verified by the OPTN Contractor. This log
 800 must be signed by the program director, division chief, or department chair where the
 801 experience was gained. Surgery of the hand includes only those procedures performed
 802 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	10
Free flaps	10
Non-surgical management	6
Replantation or Transplant	5

805

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

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

- 810
- 811 1. Must meet at least *one* of the following:
 - 812 a. Have current certification by the American Board of Plastic Surgery, the American Board
813 of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American
814 Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just
815 completed training and whose board certification is pending, the Membership and
816 Professional Standards Committee (MPSC) may grant conditional approval for 24 months
817 to allow time for the surgeon to complete board certification, with the possibility of
818 renewal for an additional 12-month period.
 - 819 b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of
820 the following relevant clinical experience:
 - 821 i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or
822 primary surgeon on at least 1 VCA procurement.
 - 823 ii. Pre-operative evaluation of at least 3 potential head and neck transplant candidates.
 - 824 iii. Acted as primary surgeon of a least 1 head and neck transplant.
 - 825 iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-
826 transplant.
 - 827

828 The multi-organ procurement experience must be documented in a log that includes the
829 Donor ID or other unique identifier that can be verified by the OPTN Contractor. The
830 experience for head and neck procedures must be documented in a log that includes the
831 dates of procedures and evaluations, the role of the surgeon, and the medical record
832 number or other unique identifier that can be verified by the OPTN Contractor. This log
833 must be signed by the program director, division chief, or department chair where the
834 experience was gained.
835

836 If a primary surgeon qualified under 1.b leaves the transplant program, the replacement
837 for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway
838 1.b will no longer be available and all primary surgeons must meet the requirements of
839 1.a.
840

- 841
- 842 2. Completion of at least *one* of the following:
 - 843 a. ~~A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial~~
844 ~~surgery that is approved by the MPSC. Any ACGME-approved fellowship program in~~
845 ~~otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery is automatically~~
846 ~~accepted by the MPSC.~~
 - 847 b. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial
848 surgery that meets all of the following criteria:
 - 849 i. The program is at a hospital that has inpatient facilities, operative suites and
850 diagnostic treatment facilities, outpatient facilities, and educational resources.
 - 851 ii. The program is at an institution that has a proven commitment to graduate medical
852 education.
 - 853 iii. The program director must have current certification in the sub-specialty by the
854 American Board of Plastic Surgery, the American Board of Otolaryngology, American
855 Board of Oral and Maxillofacial Surgery.
 - 856 iv. The program should have at least two physician faculty members with head and neck
857 surgery experience and current medical licensure who are actively involved in the
858 instruction and supervision of fellows during the time of accredited education.
 - 859 v. The program is at a hospital that has affiliated rehabilitation medicine services.

- 860 vi. The program has the resources, including adequate clinical facilities, laboratory
 861 research facilities, and appropriately trained faculty and staff, to provide research
 862 experience.
- 863 c. At least 2 years of consecutive and independent practice of head and neck surgery. The
 864 surgeon must have completed at least 1 face transplant as primary surgeon or first-
 865 assistant, or a minimum number of head and neck procedures as the primary surgeon as
 866 shown in *Table J-2* below. This includes completion of pre-operative assessments and
 867 post-operative care for a minimum of 90 days after surgery. These procedures must be
 868 documented in a log that includes the dates of procedures and evaluations, the role of
 869 the surgeon and the medical record number, Donor ID, or other unique identifier that can
 870 be verified by the OPTN Contractor. This log must be signed by the program director,
 871 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