

# **OPTN/UNOS Policy Notice**

## **Clarification to Remove Donor Location from Required Procurement Log Information**

<b>Sponsoring Committee:</b>	<b>Membership and Professional Standards</b>
<b>Policy/Bylaws Affected:</b>	<b>OPTN Bylaw Appendices E.2 (Primary Kidney Transplant Surgeon Requirements), E.3 (Primary Kidney Transplant Physician Requirements), E.5.C (Conditional Approval for a Pediatric Component), F.3 (Primary Liver Transplant Surgeon Requirements), F.4 (Primary Liver Transplant Physician Requirements), F.7.C (Conditional Approval for a Pediatric Component), F.11.(Primary Intestine Transplant Surgeon Requirements), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.2.B (Clinical Experience Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.3.B (Clinical Experience Pathway), G.3.D (Conditional Approval for Primary Transplant Physician), H.2 (Primary Heart Transplant Surgeon Requirements), H.3 (Primary Heart Transplant Physician Requirements), I.2 (Primary Lung Transplant Surgeon Requirements), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B. (Clinical Experience Pathway), and I.3.D (Conditional Approval for Primary Transplant Physician)</b>
<b>Public Comment:</b>	<b>No</b>
<b>Effective Date:</b>	<b>March 1, 2017</b>

### **Problem Statement**

The Bylaws currently require primary physician and primary surgeon applicants to include donor location information on procurement logs when they submit their application. Neither UNOS staff nor the MPSC use this information to process or evaluate applications.

### **Summary of Changes**

We have removed the requirement to submit the donor location on procurement logs for both the primary transplant surgeon and the primary transplant physician sections of the Bylaws.

### **What Members Need to Do**

No actions are required of members to implement this proposal. From the implementation date forward, however, the MPSC will evaluate all primary physician and primary surgeon membership applications based on the new requirements. Affected Policy Language:

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

## 1 E.2 Primary Kidney Transplant Surgeon Requirements

### 2 A. Formal 2-year Transplant Fellowship Pathway

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

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

Surgeons can meet the requirements for primary kidney transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated kidney transplant program. The transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. The log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.
2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first assistant. At least 10 of these procurements must be from deceased donors. These cases must be documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor ID.
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. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the transplant program and Chairman of the department or hospital credentialing committee verifying that the surgeon has met the above qualifications and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon 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 compliance protocols, 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.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

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

### **A. Twelve-month Transplant Nephrology Fellowship Pathway**

Physicians can meet the training requirements for a primary kidney transplant physician during a separate 12-month transplant nephrology fellowship if the following conditions are met:

- 90 1. The physician completed 12 consecutive months of specialized training in transplantation  
91 under the direct supervision of a qualified kidney transplant physician and along with a kidney  
92 transplant surgeon at a kidney transplant program that performs 30 or more transplants each  
93 year. The training must have included at least 6 months of clinical transplant service. The  
94 remaining time must have consisted of transplant-related experience, such as experience in a  
95 tissue typing laboratory, on another solid organ transplant service, or conducting basic or  
96 clinical transplant research.
- 97 2. During the fellowship period, the physician was directly involved in the primary care of 30 or  
98 more newly transplanted kidney recipients and continued to follow these recipients for a  
99 minimum of 3 months from the time of transplant. The care must be documented in a log that  
100 includes the date of transplant and the recipient medical record number or other unique  
101 identifier that can be verified by the OPTN Contractor. This recipient log must be signed by  
102 the director of the training program or the transplant program's primary transplant physician.
- 103 3. The physician has maintained a current working knowledge of kidney transplantation, defined  
104 as direct involvement in kidney transplant care in the last 2 years. This includes the  
105 management of patients with end stage renal disease, the selection of appropriate recipients  
106 for transplantation, donor selection, histocompatibility and tissue typing, immediate  
107 postoperative patient care, the use of immunosuppressive therapy including side effects of  
108 the drugs and complications of immunosuppression, differential diagnosis of renal  
109 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,  
110 interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The  
111 curriculum for obtaining this knowledge should be approved by the Residency Review  
112 Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical  
113 Education (ACGME).
- 114 4. The physician must have observed at least 3 kidney procurements, including at least 1  
115 deceased donor and 1 living donor. The physician must have observed the evaluation,  
116 donation process, and management of these donors. These observations must be  
117 documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor  
118 ID.
- 119 5. The physician must have observed at least 3 kidney transplants. The observation of these  
120 transplants must be documented in a log that includes the transplant date, donor type, and  
121 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 122 6. The following letters are submitted directly to the OPTN Contractor:
  - 123 a. A letter from the director of the training program and the supervising qualified kidney  
124 transplant physician verifying that the physician has met the above requirements and is  
125 qualified to direct a kidney transplant program.
  - 126 b. A letter of recommendation from the fellowship training program's primary physician and  
127 transplant program director outlining the physician's overall qualifications to act as a  
128 primary transplant physician, as well as the physician's personal integrity, honesty, and  
129 familiarity with and experience in adhering to OPTN obligations and compliance  
130 protocols, and any other matters judged appropriate. The MPSC may request additional  
131 recommendation letters from the primary physician, primary surgeon, director, or others  
132 affiliated with any transplant program previously served by the physician, at its discretion.
  - 133 c. A letter from the physician that details the training and experience the physician has  
134 gained in kidney transplantation.

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136 The training requirements outlined above are in addition to other clinical requirements for general  
137 nephrology training.  
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**B. Clinical Experience Pathway**

A physician can meet the requirements for a primary kidney transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program. The care must be documented in a log that includes the date of transplant and recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. The recipient log should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over 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, immediate postoperative patient 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.
3. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor ID.
4. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified transplant physician or the kidney transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, 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 physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

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

A physician can meet the requirements for primary kidney transplant physician by completion of 3 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics

187 in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the  
188 ACGME. The training must contain at least 6 months of clinical care for transplant patients, and the  
189 following conditions must be met:

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191 1. During the 3-year training period the physician was directly involved in the primary care of 10  
192 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney  
193 recipients for at least 6 months from the time of transplant, under the direct supervision of a  
194 qualified kidney transplant physician and in conjunction with a qualified kidney transplant  
195 surgeon. The pediatric nephrology program director may elect to have a portion of the  
196 transplant experience completed at another kidney transplant program in order to meet these  
197 requirements. This care must be documented in a log that includes the date of transplant,  
198 and the recipient medical record number or other unique identifier that can be verified by the  
199 OPTN Contractor. This recipient log must be signed by the training program's director or the  
200 primary physician of the transplant program.
- 201 2. The experience caring for pediatric patients occurred with a qualified kidney transplant  
202 physician and surgeon at a kidney transplant program that performs an average of at least 10  
203 pediatric kidney transplants a year.
- 204 3. The physician has maintained a current working knowledge of kidney transplantation, defined  
205 as direct involvement in kidney transplant patient care over the last 2 years. This includes the  
206 management of pediatric patients with end-stage renal disease, the selection of appropriate  
207 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,  
208 immediate post-operative care including those issues of management unique to the pediatric  
209 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the  
210 pediatric recipient including side-effects of drugs and complications of immunosuppression,  
211 the effects of transplantation and immunosuppressive agents on growth and development,  
212 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection  
213 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of  
214 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft  
215 recipients including management of hypertension, nutritional support, and drug dosage,  
216 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must  
217 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
- 218 4. The physician must have observed at least 3 kidney procurements, including at least 1  
219 deceased donor and 1 living donor. The physician must have observed the evaluation,  
220 donation process and management of these donors. These observations must be  
221 documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor  
222 ID.
- 223 5. The physician must have observed at least 3 kidney transplants involving a pediatric  
224 recipient. The observation of these transplants must be documented in a log that includes the  
225 transplant date, donor type, and medical record number or other unique identifier that can be  
226 verified by the OPTN Contractor.
- 227 6. The following letters are submitted directly to the OPTN Contractor:
  - 228 a. A letter from the director and the supervising qualified transplant physician and surgeon  
229 of the fellowship training program verifying that the physician has met the above  
230 requirements and is qualified to direct a kidney transplant program.
  - 231 b. A letter of recommendation from the fellowship training program's primary physician and  
232 transplant program director outlining the physician's overall qualifications to act as a  
233 primary transplant physician, as well as the physician's personal integrity, honesty, and  
234 familiarity with and experience in adhering to OPTN obligations, and any other matters  
235 judged appropriate. The MPSC may request additional recommendation letters from the

- 236 primary physician, primary surgeon, director, or others affiliated with any transplant  
237 program previously served by the physician, at its discretion.  
238 c. A letter from the physician that details the training and experience the physician has  
239 gained in kidney transplantation.

240 **D. Twelve-month Pediatric Transplant Nephrology Fellowship**  
241 **Pathway**  
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243 The requirements for the primary kidney transplant physician can be met during a separate  
244 pediatric transplant nephrology fellowship if the following conditions are met:

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- 246 1. The physician has current board certification in pediatric nephrology by the American Board  
247 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by  
248 the American Board of Pediatrics to take the certifying exam.
  - 249 2. During the fellowship, the physician was directly involved in the primary care of 10 or more  
250 newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for  
251 at least 6 months from the time of transplant, under the direct supervision of a qualified  
252 kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The  
253 pediatric nephrology program director may elect to have a portion of the transplant  
254 experience completed at another kidney transplant program in order to meet these  
255 requirements. This care must be documented in a recipient log that includes the date of  
256 transplant, and the recipient medical record number or other unique identifier that can be  
257 verified by the OPTN Contractor. This log must be signed by the training program director or  
258 the primary physician of the transplant program.
  - 259 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a  
260 qualified kidney transplant physician and surgeon that performs an average of at least 10  
261 pediatric kidney transplants a year.
  - 262 4. The physician has maintained a current working knowledge of kidney transplantation, defined  
263 as direct involvement in kidney transplant patient care in the past 2 years. This includes the  
264 management of pediatric patients with end-stage renal disease, the selection of appropriate  
265 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,  
266 immediate post-operative care including those issues of management unique to the pediatric  
267 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the  
268 pediatric recipient including side-effects of drugs and complications of immunosuppression,  
269 the effects of transplantation and immunosuppressive agents on growth and development,  
270 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection  
271 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of  
272 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft  
273 recipients including management of hypertension, nutritional support, and drug dosage,  
274 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must  
275 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
  - 276 5. 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, ~~location of the donor,~~ and Donor  
280 ID.
  - 281 6. The physician must have observed at least 3 kidney transplants involving a pediatric  
282 recipient. The observation of these transplants must be documented in a log that includes the

283 transplant date, donor type, and medical record number or other unique identifier that can be  
284 verified by the OPTN Contractor.

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

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

301 A physician can meet the requirements for primary kidney transplant physician if the following  
302 conditions are met:

- 303
- 304 1. The physician has current board certification in pediatric nephrology by the American Board  
305 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by  
306 the American Board of Pediatrics to take the certifying exam.
  - 307 2. The physician gained a minimum of 2 years of experience during or after fellowship, or  
308 accumulated during both periods, at a kidney transplant program.
  - 309 3. During the 2 or more years of accumulated experience, the physician was directly involved in  
310 the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly  
311 transplanted kidney recipients for at least 6 months from the time of transplant, under the  
312 direct supervision of a qualified kidney transplant physician, along with a qualified kidney  
313 transplant surgeon. This care must be documented in a recipient log that includes the date of  
314 transplant, and the recipient medical record number or other unique identifier that can be  
315 verified by the OPTN Contractor. This log must be signed by the training program director or  
316 the primary physician of the transplant program.
  - 317 4. The physician has maintained a current working knowledge of kidney transplantation, defined  
318 as direct involvement in kidney transplant patient care during the past 2 years. This includes  
319 the management of pediatric patients with end-stage renal disease, the selection of  
320 appropriate pediatric recipients for transplantation, donor selection, histocompatibility and  
321 tissue typing, immediate post-operative care including those issues of management unique to  
322 the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive  
323 therapy in the pediatric recipient including side-effects of drugs and complications of  
324 immunosuppression, the effects of transplantation and immunosuppressive agents on growth  
325 and development, differential diagnosis of renal dysfunction in the allograft recipient,  
326 manifestation of rejection in the pediatric patient, histological interpretation of allograft  
327 biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care  
328 of pediatric allograft recipients including management of hypertension, nutritional support,  
329 and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining



330 this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the  
331 ACGME or a Residency Review Committee.

- 332 5. The physician must have observed at least 3 kidney procurements, including at least 1  
333 deceased donor and 1 living donor. The physician must have observed the evaluation,  
334 donation process, and management of these donors. These observations must be  
335 documented in a log that includes the date of procurement, ~~location of the donor~~, and Donor  
336 ID.
- 337 6. The physician must have observed at least 3 kidney transplants involving a pediatric  
338 recipient. The observation of these transplants must be documented in a log that includes the  
339 transplant date, donor type, and medical record number or other unique identifier that can be  
340 verified by the OPTN Contractor.
- 341 7. The following letters are submitted directly to the OPTN Contractor:
- 342 a. A letter from the supervising qualified transplant physician and surgeon who were directly  
343 involved with the physician documenting the physician's experience and competence.
- 344 b. A letter of recommendation from the fellowship training program's primary physician and  
345 transplant program director outlining the physician's overall qualifications to act as a  
346 primary transplant physician, as well as the physician's personal integrity, honesty, and  
347 familiarity with and experience in adhering to OPTN obligations, and any other matters  
348 judged appropriate. The MPSC may request additional recommendation letters from the  
349 primary physician, primary surgeon, Director, or others affiliated with any transplant  
350 program previously served by the physician, at its discretion.
- 351 c. A letter from the physician that details the training and experience the physician has  
352 gained in kidney transplantation.

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## **F. Conditional Approval for Primary Transplant Physician**

355 If the primary kidney transplant physician changes at an approved Kidney transplant program, a  
356 physician can serve as the primary kidney transplant physician for a maximum of 12 months if the  
357 following conditions are met:

- 358
- 359 1. The physician has been involved in the primary care of 23 or more newly transplanted kidney  
360 recipients, and has followed these patients for at least 3 months from the time of their  
361 transplant. This care must be documented in a recipient log that includes the date of  
362 transplant and the medical record number or other unique identifier that can be verified by the  
363 OPTN Contractor. This log must be signed by the program director, division chief, or  
364 department chair from the transplant program where the experience was gained.
- 365 2. The physician has maintained a current working knowledge of kidney transplantation, defined  
366 as direct involvement in kidney transplant patient care during the last 2 years. This includes  
367 the management of patients with end stage renal disease, the selection of appropriate  
368 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate  
369 postoperative patient care, the use of immunosuppressive therapy including side effects of  
370 the drugs and complications of immunosuppression, differential diagnosis of renal  
371 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,  
372 interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
- 373 3. The physician has 12 months experience on an active kidney transplant service as the  
374 primary kidney transplant physician or under the direct supervision of a qualified kidney  
375 transplant physician and in conjunction with a kidney transplant surgeon at a designated  
376 kidney transplant program. These 12 months of experience must be acquired within a 2-year  
377 period.

- 378 4. The physician must have observed at least 3 kidney procurements, including at least 1  
379 deceased donor and 1 living donor. The physician must have observed the evaluation,  
380 donation process, and management of these donors. These observations must be  
381 documented in a log that includes the date of procurement, ~~location of the donor~~, and Donor  
382 ID.
- 383 5. The physician must have observed at least 3 kidney transplants. The observation of these  
384 transplants must be documented in a log that includes the transplant date, donor type, and  
385 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 386 6. The program has established and documented a consulting relationship with counterparts at  
387 another kidney transplant program.
- 388 7. The transplant program submits activity reports to the OPTN Contractor every 2 months  
389 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
390 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
391 efficient patient care at the program. The activity reports must also demonstrate that the  
392 physician is making sufficient progress to meet the required involvement in the primary care  
393 of 45 or more kidney transplant recipients, or that the program is making sufficient progress in  
394 recruiting a physician who meets all requirements for primary kidney transplant physician and  
395 who will be on site and approved by the MPSC to assume the role of primary physician by the  
396 end of the 12 month conditional approval period.
- 397 8. The following letters are submitted directly to the OPTN Contractor:
- 398 a. A letter from the supervising qualified transplant physician and surgeon who were directly  
399 involved with the physician documenting the physician's experience and competence.
- 400 b. A letter of recommendation from the primary physician and director at the transplant  
401 program last served by the physician outlining the physician's overall qualifications to act  
402 as a primary transplant physician, as well as the physician's personal integrity, honesty,  
403 and familiarity with and experience in adhering to OPTN obligations, and any other  
404 matters judged appropriate. The MPSC may request additional recommendation letters  
405 from the primary physician, primary surgeon, director, or others affiliated with any  
406 transplant program previously served by the physician, at its discretion.
- 407 c. A letter from the physician that details the training and experience the physician has  
408 gained in kidney transplantation.

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410 The 12-month conditional approval period begins on the initial approval date granted to the  
411 personnel change application, whether it is interim approval granted by the MPSC subcommittee,  
412 or approval granted by the full MPSC. The conditional approval period ends 12 months after the  
413 first approval date of the personnel change application.

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415 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
416 program that provides substantial evidence of progress toward fulfilling the requirements but is  
417 unable to complete the requirements within one year.

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419 If the program is unable to demonstrate that it has an individual on site who can meet the  
420 requirements as described in *Sections E.3.A through E.3.F* above at the end of the conditional  
421 approval period, it must inactivate. The requirements for program inactivation are described in  
422 *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.  
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## E.5 Kidney Transplant Programs that Register Candidates Less than 18 Years Old

### C. Conditional Approval for a Pediatric Component

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

1. The program has a qualified primary pediatric kidney physician who meets *all* of the requirements described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements* and a surgeon who meets *all* of the following requirements:
  - a. The surgeon meets all of the requirements described in Section E.2 Primary Kidney Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
    - The formal 2-year transplant fellowship pathway as described in *Section E.2.A. Formal 2-year Transplant Fellowship Pathway*
    - The kidney transplant program clinical experience pathway, as described in *Section E.2.B. Clinical Experience Pathway*
  - b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care in the last 2 years. This includes the management of pediatric patients with end stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, performing the pediatric 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.
2. The program has a qualified primary pediatric kidney surgeon who meets *all* of the requirements described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements* and a physician who meets *all* of the following requirements:
  - a. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
  - b. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.
  - c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted kidney recipients and followed 15 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient

- 476 log that includes the date of transplant and the recipient medical record number or other  
477 unique identifier that can be verified by the OPTN Contractor. This log must be signed by  
478 the training program director or the primary physician of the transplant program.
- 479 d. The physician has maintained a current working knowledge of pediatric kidney  
480 transplantation, defined as direct involvement in kidney transplant patient care during the  
481 past 2 years. This includes the management of pediatric patients with end-stage renal  
482 disease, the selection of appropriate pediatric recipients for transplantation, donor  
483 selection, histocompatibility and HLA typing, immediate post-operative care including  
484 those issues of management unique to the pediatric recipient, fluid and electrolyte  
485 management, the use of immunosuppressive therapy in the pediatric recipients including  
486 side-effects of drugs and complications of immunosuppression, the effects of  
487 transplantation and immunosuppressive agents on growth and development, differential  
488 diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the  
489 pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary  
490 tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients  
491 including management of hypertension, nutritional support, and drug dosage, including  
492 antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be  
493 approved by the Residency Review Committee (RRC) – Ped of the ACGME or a  
494 Residency Review Committee.
  - 495 e. The physician should have observed at least 3 organ procurements and 3 pediatric  
496 kidney transplants. The physician should also have observed the evaluation, the donation  
497 process, and management of at least 3 multiple organ donors who donated a kidney. If  
498 the physician has completed these observations, they must be documented in a log that  
499 includes the date of procurement, ~~location of the donor,~~ and Donor ID.
  - 500 f. The following letters are submitted directly to the OPTN Contractor:
    - 501 i. A letter from the supervising qualified transplant physician and surgeon who were  
502 directly involved with the physician documenting the physician's experience and  
503 competence.
    - 504 ii. A letter of recommendation from the fellowship training program's primary physician  
505 and transplant program director outlining the physician's overall qualifications to act  
506 as a primary transplant physician, as well as the physician's personal integrity,  
507 honesty, and familiarity with and experience in adhering to OPTN obligations, and  
508 any other matters judged appropriate. The MPSC may request additional  
509 recommendation letters from the primary pediatric surgeon, Director, or others  
510 affiliated with any transplant program previously served by the physician, at its  
511 discretion.
    - 512 iii. A letter from the physician that details the training and experience the physician has  
513 gained in kidney transplantation.

514  
515 A designated kidney transplant program's conditional approval for a pediatric component is  
516 valid for a maximum of 24 months.  
517

## 518 **F.3 Primary Liver Transplant Surgeon Requirements**

### 519 **A. Formal 2-year Transplant Fellowship Pathway**

520 Surgeons can meet the training requirements for primary liver transplant surgeon by completing a  
521 2-year transplant fellowship if the following conditions are met:  
522

- 523 1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant  
524 during the 2-year fellowship period. These transplants must be documented in a log that  
525 includes the date of transplant, the role of the surgeon in the procedure, and the medical  
526 record number or other unique identifier that can be verified by the OPTN Contractor. This log  
527 must be signed by the director of the training program.

- 528 2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant.  
529 These procurements must have been performed anytime during the surgeon's fellowship and  
530 the two years immediately following fellowship completion. These procedures must be  
531 documented in a log that includes the date of procurement, ~~location of the donor~~, and Donor  
532 ID. This log must be signed by the director of the training program.
- 533 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as  
534 direct involvement in liver transplant patient care within the last 2 years. This includes the  
535 management of patients with end stage liver disease, the selection of appropriate recipients  
536 for transplantation, donor selection, histocompatibility and tissue typing, performing the  
537 transplant operation, immediate postoperative and continuing inpatient care, the use of  
538 immunosuppressive therapy including side effects of the drugs and complications of  
539 immunosuppression, differential diagnosis of liver allograft dysfunction, histologic  
540 interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and  
541 long term outpatient care.
- 542 4. The training was completed at a hospital with a transplant training program approved by the  
543 Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal  
544 College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as  
545 described in *Section F.6. Approved Liver Surgeon Transplant Fellowship Programs* that  
546 follows.
- 547 5. The following letters are submitted directly to the OPTN Contractor:
- 548 a. A letter from the director of the training program verifying that the surgeon has met the  
549 above requirements, and is qualified to direct a liver transplant program.
- 550 b. A letter of recommendation from the fellowship training program's primary surgeon and  
551 transplant program director outlining the surgeon's overall qualifications to act as primary  
552 transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with  
553 and experience in adhering to OPTN obligations, and other matters judged appropriate.  
554 The MPSC may request additional recommendation letters from the primary physician,  
555 primary surgeon, director, or others affiliated with any transplant program previously  
556 served by the surgeon, at its discretion.
- 557 c. A letter from the surgeon that details his or her training and experience in liver  
558 transplantation.

## 559 **B. Clinical Experience Pathway**

561 Surgeons can meet the requirements for primary liver transplant surgeon through clinical  
562 experience gained post-fellowship, if the following conditions are met:

- 563
- 564 1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary  
565 surgeon or first assistant at a designated liver transplant program. These transplants must be  
566 documented in a log that includes the date of transplant, the role of the surgeon in the  
567 procedure, and medical record number or other unique identifier that can be verified by the  
568 OPTN Contractor. This log should be signed by the program director, division chief, or  
569 department chair from the program where the experience was gained. Each year of the  
570 surgeon's experience must be substantive and relevant and include pre-operative  
571 assessment of liver transplant candidates, transplants performed as primary surgeon or first  
572 assistant, and post-operative management of liver recipients.
- 573 2. The surgeon has performed at least 30 liver procurements as primary surgeon or first  
574 assistant. These procedures must be documented in a log that includes the date of  
575 procurement, ~~location of the donor~~, and Donor ID.

- 576 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as  
577 direct involvement in liver transplant patient care within the last 2 years. This includes the  
578 management of patients with end stage liver disease, the selection of appropriate recipients  
579 for transplantation, donor selection, histocompatibility and tissue typing, performing the  
580 transplant operation, immediate postoperative and continuing inpatient care, the use of  
581 immunosuppressive therapy including side effects of the drugs and complications of  
582 immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient,  
583 histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver  
584 dysfunction, and long term outpatient care.
- 585 4. The following letters are sent directly to the OPTN Contractor:
- 586 a. A letter from the director of the transplant program and chairman of the department or  
587 hospital credentialing committee verifying that the surgeon has met the above  
588 requirements, and is qualified to direct a liver transplant program.
- 589 b. A letter of recommendation from the primary surgeon and transplant program director at  
590 the transplant program last served by the surgeon outlining the surgeon's overall  
591 qualifications to act as primary transplant surgeon, as well as the surgeon's personal  
592 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and  
593 other matters judged appropriate. The MPSC may request additional recommendation  
594 letters from the primary physician, primary surgeon, director, or others affiliated with any  
595 transplant program previously served by the surgeon, at its discretion.
- 596 c. A letter from the surgeon that details the training and experience the surgeon gained in  
597 liver transplantation.  
598

## 599 **F.4 Primary Liver Transplant Physician Requirements**

### 600 **A. 12-month Transplant Hepatology Fellowship Pathway**

601 Physicians can meet the training requirements for a primary liver transplant physician during a  
602 separate 12-month transplant hepatology fellowship if the following conditions are met:  
603

- 604 1. The physician completed 12 consecutive months of specialized training in transplantation  
605 under the direct supervision of a qualified liver transplant physician and in conjunction with a  
606 liver transplant surgeon at a liver transplant program. The training must have included at least  
607 3 months of clinical transplant service. The remaining time must have consisted of transplant-  
608 related experience, such as experience in a tissue typing laboratory, on another solid organ  
609 transplant service, or conducting basic or clinical transplant research.
- 610 2. During the fellowship period, the physician was directly involved in the primary care of 30 or  
611 more newly transplanted liver recipients, and continued to follow these recipients for a  
612 minimum of 3 months from the time of transplant. The care must be documented in a log that  
613 includes the date of transplant and the medical record number or other unique identifier that  
614 can be verified by the OPTN Contractor. This log must be signed by the director of the  
615 training program or the transplant program's primary transplant physician.
- 616 3. The physician has maintained a current working knowledge of liver transplantation, defined  
617 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
618 management of patients with end stage liver disease, acute liver failure, the selection of  
619 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
620 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
621 including side effects of the drugs and complications of immunosuppression, differential

- 622 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,  
623 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- 624 4. The physician must have observed at least 3 liver procurements. The physician must have  
625 observed the evaluation, donation process, and management of these donors. These  
626 observations must be documented in a log that includes the date of procurement, ~~location of~~  
627 ~~the donor~~, and Donor ID.
  - 628 5. The physician must have observed at least 3 liver transplants. The observation of these  
629 transplants must be documented in a log that includes the transplant date, donor type, and  
630 medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - 631 6. The following letters are submitted directly to the OPTN Contractor:
    - 632 a. A letter from the director of the training program and the supervising liver transplant  
633 physician verifying that the physician has met the above requirements and is qualified  
634 to direct a liver transplant program.
    - 635 b. A letter of recommendation from the fellowship training program's primary physician  
636 and transplant program director outlining the physician's overall qualifications to act  
637 as a primary transplant physician, as well as the physician's personal integrity,  
638 honesty, and familiarity with and experience in adhering to OPTN obligations, and  
639 any other matters judged appropriate. The MPSC may request additional  
640 recommendation letters from the primary physician, primary surgeon, director, or  
641 others affiliated with any transplant program previously served by the physician, at its  
642 discretion.
    - 643 c. A letter from the physician writes that details the training and experience the  
644 physician gained in liver transplantation.

645  
646 The training requirements outlines above are in addition to other clinical requirements for general  
647 gastroenterology training.

## 648 **B. Clinical Experience Pathway**

649  
650 A physician can meet the requirements for a primary liver transplant physician through acquired  
651 clinical experience if the following conditions are met:

- 652  
653 1. The physician has been directly involved in the primary care of 50 or more newly transplanted  
654 liver recipients and continued to follow these recipients for a minimum of 3 months from the  
655 time of transplant. This patient care must have been provided over a 2 to 5-year period on an  
656 active liver transplant service as the primary liver transplant physician or under the direct  
657 supervision of a qualified liver transplant physician and in conjunction with a liver transplant  
658 surgeon at a designated liver transplant program. This care must be documented in a log that  
659 includes the date of transplant and the medical record number or other unique identifier that  
660 can be verified by the OPTN Contractor. This recipient log should be signed by the program  
661 director, division chief, or department chair from the program where the physician gained this  
662 experience.
- 663 2. The physician has maintained a current working knowledge of liver transplantation, defined  
664 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
665 management of patients with end stage liver disease, acute liver failure, the selection of  
666 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
667 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
668 including side effects of the drugs and complications of immunosuppression, differential  
669 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,  
670 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.

- 671 3. The physician must have observed at least 3 liver procurements. The physician must have  
672 observed the evaluation, donation process, and management of these donors. These  
673 observations must be documented in a log that includes the date of procurement, ~~the location~~  
674 ~~of the donor~~, and Donor ID.
- 675 4. The physician must have observed at least 3 liver transplants. The observation of these  
676 transplants must be documented in a log that includes the transplant date, donor type, and  
677 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 678 5. The following letters are submitted directly to the OPTN Contractor:
- 679 a. A letter from the qualified transplant physician or the liver transplant surgeon who has  
680 been directly involved with the proposed physician documenting the physician's  
681 experience and competence.
- 682 b. A letter of recommendation from the primary physician and transplant program director at  
683 the transplant program last served by the physician outlining the physician's overall  
684 qualifications to act as a primary transplant physician, as well as the physician's personal  
685 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
686 and any other matters judged appropriate. The MPSC may request additional  
687 recommendation letters from the primary physician, primary surgeon, director, or others  
688 affiliated with any transplant program previously served by the physician, at its discretion.
- 689 c. A letter from the physician that details the training and experience the physician gained in  
690 liver transplantation.

### 691 **C. Three-year Pediatric Gastroenterology Fellowship Pathway**

693 A physician can meet the requirements for primary liver transplant physician by completion of 3  
694 years of pediatric gastroenterology fellowship training as required by the American Board of  
695 Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped)  
696 of the Accreditation Council for Graduate Medical Education (ACGME). The training must contain  
697 at least 6 months of clinical care for transplant patients, and meet the following conditions:

- 698
- 699 1. The physician has current board certification in pediatric gastroenterology by the American  
700 Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.
- 701 2. During the 3-year training period the physician was directly involved in the primary care of 10  
702 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver  
703 recipients for a minimum of 3 months from the time of transplant, under the direct supervision  
704 of a qualified liver transplant physician along with a qualified liver transplant surgeon. The  
705 physician was also directly involved in the preoperative, peri-operative and post-operative  
706 care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology  
707 program director may elect to have a portion of the transplant experience carried out at  
708 another transplant service, to meet these requirements. This care must be documented in a  
709 log that includes the date of transplant, the medical record number or other unique identifier  
710 that can be verified by the OPTN Contractor. This recipient log must be signed by the training  
711 program director or the transplant program's primary transplant physician.
- 712 3. The experience caring for pediatric patients occurred at a liver transplant program with a  
713 qualified liver transplant physician and a qualified liver transplant surgeon that performs an  
714 average of at least 10 liver transplants on pediatric patients per year.
- 715 4. The physician must have observed at least 3 liver procurements. The physician must have  
716 observed the evaluation, donation process, and management of these donors. These  
717 observations must be documented in a log that includes the date of procurement, ~~location of~~  
718 ~~the donor~~ and Donor ID.



- 719 5. The physician must have observed at least 3 liver transplants. The observation of these  
720 transplants must be documented in a log that includes the transplant date, donor type, and  
721 medical record number or other unique identifier that can be verified by the OPTN Contractor.  
722 6. The physician has maintained a current working knowledge of liver transplantation, defined  
723 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
724 management of pediatric patients with end-stage liver disease acute liver failure, the  
725 selection of appropriate pediatric recipients for transplantation, donor selection,  
726 histocompatibility and tissue typing, immediate postoperative care including those issues of  
727 management unique to the pediatric recipient, fluid and electrolyte management, the use of  
728 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and  
729 complications of immunosuppression, the effects of transplantation and immunosuppressive  
730 agents on growth and development, differential diagnosis of liver dysfunction in the allograft  
731 recipient, manifestation of rejection in the pediatric patient, histological interpretation of  
732 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term  
733 outpatient care of pediatric allograft recipients including management of hypertension,  
734 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.  
735 7. The following letters are submitted directly to the OPTN Contractor:  
736 a. A letter from the director of the pediatric gastroenterology training program, and the  
737 qualified liver transplant physician and surgeon of the fellowship training program  
738 verifying that the physician has met the above requirements, and is qualified to act as a  
739 liver transplant physician and direct a liver transplant program.  
740 b. A letter of recommendation from the fellowship training program's primary physician and  
741 transplant program director outlining the physician's overall qualifications to act as a  
742 primary transplant physician, as well as the physician's personal integrity, honesty, and  
743 familiarity with and experience in adhering to OPTN obligations, and any other matters  
744 judged appropriate. The MPSC may request additional recommendation letters from the  
745 primary physician, primary surgeon, director, or others affiliated with any transplant  
746 program previously served by the physician, at its discretion.  
747 c. A letter from the physician that details the training and experience the physician gained in  
748 liver transplantation.

#### 750 **D. Pediatric Transplant Hepatology Fellowship Pathway**

751 The requirements for primary liver transplant physician can be met during a separate pediatric  
752 transplant hepatology fellowship if the following conditions are met:  
753

- 754 1. The physician has current board certification in pediatric gastroenterology by the American  
755 Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved  
756 by the American Board of Pediatrics to take the certifying exam.  
757 2. During the fellowship, the physician was directly involved in the primary care of 10 or more  
758 newly transplanted pediatric liver recipients and followed 20 newly transplanted liver  
759 recipients for at least 3 months from the time of transplant, under the direct supervision of a  
760 qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon.  
761 The physician must have been directly involved in the pre-operative, peri-operative and post-  
762 operative care of 10 or more liver transplants in pediatric patients. The pediatric  
763 gastroenterology program director may elect to have a portion of the transplant experience  
764 completed at another liver transplant program in order to meet these requirements. This care  
765 must be documented in a log that includes the date of transplant and the medical record  
766 number or other unique identifier that can be verified by the OPTN Contractor. This recipient

- 767 log must be signed by the training program director or the transplant program primary  
768 transplant physician.
- 769 3. The experience in caring for pediatric liver patients occurred at a liver transplant program with  
770 a qualified liver transplant physician and surgeon that performs an average of at least 10  
771 pediatric liver transplants a year.
- 772 4. The physician has maintained a current working knowledge of liver transplantation, defined  
773 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
774 management of pediatric patients with end-stage liver disease, acute liver failure, the  
775 selection of appropriate pediatric recipients for transplantation, donor selection,  
776 histocompatibility and tissue typing, immediate postoperative care including those issues of  
777 management unique to the pediatric recipient, fluid and electrolyte management, the use of  
778 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and  
779 complications of immunosuppression, the effects of transplantation and immunosuppressive  
780 agents on growth and development, differential diagnosis of liver dysfunction in the allograft  
781 recipient, manifestation of rejection in the pediatric patient, histological interpretation of  
782 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term  
783 outpatient care of pediatric allograft recipients including management of hypertension,  
784 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- 785 5. The physician must have observed at least 3 liver procurements. The physician must have  
786 observed the evaluation, donation process, and management of these donors. These  
787 observations must be documented in a log that includes the date of procurement, ~~location of~~  
788 ~~the donor~~ and Donor ID.
- 789 6. The physician must have observed at least 3 liver transplants. The observation of these  
790 transplants must be documented in a log that includes the transplant date, donor type, and  
791 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 792 7. The following letters are submitted directly to the OPTN Contractor:
- 793 a. A letter from the director of the pediatric transplant hepatology training program, and the  
794 qualified liver transplant physician and surgeon of the fellowship training program  
795 verifying that the physician has met the above requirements, and is qualified to act as a  
796 liver transplant physician and direct a liver transplant program.
- 797 b. A letter of recommendation from the fellowship training program's primary physician and  
798 transplant program director outlining the physician's overall qualifications to act as a  
799 primary transplant physician, as well as the physician's personal integrity, honesty, and  
800 familiarity with and experience in adhering to OPTN obligations, and any other matters  
801 judged appropriate. The MPSC may request additional recommendation letters from the  
802 primary physician, primary surgeon, director, or others affiliated with any transplant  
803 program previously served by the physician, at its discretion.
- 804 c. A letter from the physician that details the training and experience the physician gained in  
805 liver transplantation.

806  
807 **E. Combined Pediatric Gastroenterology/Transplant Hepatology**  
808 **Training and Experience Pathway**

809 A physician can meet the requirements for primary liver transplant physician if the following  
810 conditions are met:

- 811
- 812 1. The physician has current board certification in pediatric gastroenterology by the American  
813 Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved  
814 by the American Board of Pediatrics to take the certifying exam.

- 815 2. The physician gained a minimum of 2 years of experience during or after fellowship, or  
816 accumulated during both periods, at a liver transplant program.
- 817 3. During the 2 or more years of accumulated experience, the physician was directly involved in  
818 the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20  
819 newly transplanted liver recipients for a minimum of 6 months from the time of transplant,  
820 under the direct supervision of a qualified liver transplant physician and along with a qualified  
821 liver transplant surgeon. The physician must have been directly involved in the pre-operative,  
822 peri-operative and post-operative care of 10 or more pediatric liver transplants recipients.  
823 This care must be documented in a log that includes at the date of transplant and the medical  
824 record number or other unique identifier that can be verified by the OPTN Contractor. This  
825 recipient log must be signed by the training program director or the transplant program  
826 primary transplant physician.
- 827 4. The individual has maintained a current working knowledge of liver transplantation, defined  
828 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
829 management of pediatric patients with end-stage liver disease, the selection of appropriate  
830 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,  
831 immediate post-operative care including those issues of management unique to the pediatric  
832 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the  
833 pediatric recipient including side-effects of drugs and complications of immunosuppression,  
834 the effects of transplantation and immunosuppressive agents on growth and development,  
835 differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in  
836 the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary  
837 tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients  
838 including management of hypertension, nutritional support, and drug dosage, including  
839 antibiotics, in the pediatric patient.
- 840 5. The physician must have observed at least 3 liver procurements. The physician must have  
841 observed the evaluation, the donation process, and the management of these donors. These  
842 observations must be documented in a log that includes the date of procurement, ~~location of~~  
843 ~~the donor~~, and Donor ID.
- 844 6. The physician must have observed at least 3 liver transplants. The observation of these  
845 transplants must be documented in a log that includes the transplant date, donor type, and  
846 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 847 7. The following letters are submitted directly to the OPTN Contractor:
- 848 a. A letter from the qualified liver transplant physician and surgeon who have been directly  
849 involved with the physician documenting the physician's experience and competence.
- 850 b. A letter of recommendation from the primary physician and transplant program director at  
851 the fellowship training program or transplant program last served by the physician  
852 outlining the physician's overall qualifications to act as a primary transplant physician, as  
853 well as the physician's personal integrity, honesty, and familiarity with and experience in  
854 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC  
855 may request additional recommendation letters from the primary physician, primary  
856 surgeon, director, or others affiliated with any transplant program previously served by  
857 the physician, at its discretion.
- 858 c. A letter from the physician that details the training and experience the physician gained in  
859 liver transplantation.

## 860 **F. Conditional Approval for Primary Transplant Physician**

862 If the primary liver transplant physician changes at an approved liver transplant program, a

863 physician can serve as the primary liver transplant physician for a maximum of 12 months if the  
864 following conditions are met:

- 865  
866 1. The physician has been involved in the primary care of 25 or more newly transplanted liver  
867 recipients, and has followed these patients for at least 3 months from the time of their  
868 transplant. This care must be documented in a recipient log that includes the date of  
869 transplant and the medical record number or other unique identifier that can be verified by the  
870 OPTN Contractor. This log must be signed by the program director, division chief, or  
871 department chair from the transplant program where the experience was gained.
- 872 2. The physician has maintained a current working knowledge of liver transplantation, defined  
873 as direct involvement in liver transplant patient care during the last 2 years. This includes the  
874 management of patients with end stage liver disease, acute liver failure, the selection of  
875 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
876 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
877 including side effects of the drugs and complications of immunosuppression, differential  
878 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,  
879 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- 880 3. The physician has 12 months experience on an active liver transplant service as the primary  
881 liver transplant physician or under the direct supervision of a qualified liver transplant  
882 physician along with a liver transplant surgeon at a designated liver transplant program.  
883 These 12 months of experience must be acquired within a 2-year period.
- 884 4. The physician must have observed at least 3 liver procurements. The physician must have  
885 observed the evaluation, donation process, and management of these donors. These  
886 observations must be documented in a log that includes the date of procurement, ~~location of~~  
887 ~~the donor,~~ and Donor ID.
- 888 5. The physician must have observed at least 3 liver transplants. The observation of these  
889 transplants must be documented in a log that includes the transplant date, donor type, and  
890 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 891 6. The transplant program submits activity reports to the OPTN Contractor every 2 months  
892 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
893 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
894 efficient patient care at the program. The activity reports must also demonstrate that the  
895 physician is making sufficient progress to meet the required involvement in the primary care  
896 of 50 or more liver transplant recipients, or that the program is making sufficient progress in  
897 recruiting a physician who meets all requirements for primary liver transplant physician and  
898 who will be on site and approved by the MPSC to assume the role of primary physician by the  
899 end of the 12 month conditional approval period.
- 900 7. The program has established and documented a consulting relationship with counterparts at  
901 another liver transplant program.
- 902 8. The following letters are submitted directly to the OPTN Contractor:
  - 903 a. A letter from the qualified liver transplant physician and surgeon who were directly  
904 involved with the physician verifying that the physician has satisfactorily met the above  
905 requirements to become the primary transplant physician of a liver transplant program.
  - 906 b. A letter of recommendation from the primary physician and transplant program director at  
907 the transplant program last served by the physician outlining the physician's overall  
908 qualifications to act as a primary transplant physician, as well as the physician's personal  
909 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
910 and any other matters judged appropriate. The MPSC may request additional

- 911 recommendation letters from the primary physician, primary surgeon, director, or others  
912 affiliated with any transplant program previously served by the physician, at its discretion.  
913 c. A letter from the physician sends that details the training and experience the physician  
914 gained in liver transplantation.

915  
916 The 12-month conditional approval period begins on the first approval date granted to the personnel  
917 change application, whether it is interim approval granted by the MPSC subcommittee, or approval  
918 granted by the full MPSC. The conditional approval period ends 12 months after the first approval  
919 date of the personnel change application.

920  
921 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
922 program that provides substantial evidence of progress toward fulfilling the requirements but is  
923 unable to complete the requirements within one year.

924  
925 If the program is unable to demonstrate that it has an individual on site who can meet the  
926 requirements as described in *Sections F.4.A through F.4.F* above at the end of the conditional  
927 approval period, it must inactivate. The requirements for program inactivation are described in  
928 *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

### 929 930 **F.7.C. Conditional Approval for a Pediatric Component**

931 A designated liver transplant program can obtain conditional approval for a pediatric component if  
932 either of the following conditions is met:

- 933  
934 1. The program has a qualified primary pediatric liver physician who meets *all* of the  
935 requirements described in *Section F.7.B. Primary Pediatric Liver Transplant Physician*  
936 *Requirements* and a surgeon who meets *all* of the following requirements:  
937 a. The surgeon meets *all* of the requirements described in *Section F.3 Primary Liver*  
938 *Transplant Surgeon Requirements*, including completion of at least *one* of the following  
939 training or experience pathways:  
940 ■ The formal 2-year transplant fellowship pathway as described in *Section F.3.A.*  
941 *Formal 2-year Transplant Fellowship Pathway*  
942 ■ The liver transplant program clinical experience pathway, as described in *Section*  
943 *F.3.B. Clinical Experience Pathway*  
944  
945 b. The surgeon has performed at least 7 liver transplants, as the primary surgeon or first  
946 assistant, in recipients less than 18 years old at the time of transplant. At least 2 of these  
947 liver transplants must have been in recipients less than 6 years old or weighing less than  
948 25 kilograms at the time of transplant. These transplants must have been performed  
949 during or after fellowship, or across both periods. These transplants must be documented  
950 in a log that includes the date of transplant, the recipient's date of birth, the recipient's  
951 weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure,  
952 and the medical record number or other unique identifier that can be verified by the  
953 OPTN Contractor.  
954 c. The surgeon has maintained a current working knowledge of pediatric liver  
955 transplantation, defined as direct involvement in pediatric liver transplant patient care  
956 within the last 2 years. This includes the management of pediatric patients with end stage  
957 liver disease, the selection of appropriate pediatric recipients for transplantation, donor  
958 selection, histocompatibility and HLA typing, performing the transplant operation,  
959 immediate postoperative and continuing inpatient care, the use of immunosuppressive  
960 therapy including side effects of the drugs and complications of immunosuppression,  
961 differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft  
962 biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient  
963 care.

- 964 2. The program has a qualified primary pediatric liver surgeon who meets *all* of the  
965 requirements described in *Section F.7.A: Primary Pediatric Liver Transplant Surgeon*  
966 *Requirements* and a physician who meets *all* of the following requirements:  
967 a. The physician has current board certification in pediatric gastroenterology by the  
968 American Board of Pediatrics or the foreign equivalent, or is approved by the American  
969 Board of Pediatrics to take the certifying exam.  
970 b. The physician gained a minimum of 2 years of experience during or after fellowship, or  
971 accumulated during both periods, at a liver transplant program.  
972 c. During the 2 or more years of accumulated experience, the physician was directly  
973 involved in the primary care of 5 or more newly transplanted pediatric liver recipients and  
974 followed 10 newly transplanted liver recipients for a minimum of 6 months from the time  
975 of transplant, under the direct supervision of a qualified liver transplant physician along  
976 with a qualified liver transplant surgeon. The physician must have been directly involved  
977 in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver  
978 transplants recipients. This care must be documented in a log that includes at the date of  
979 transplant and the medical record number or other unique identifier that can be verified  
980 by the OPTN Contractor. This recipient log must be signed by the training program  
981 director or the transplant program primary transplant physician.  
982 d. The individual has maintained a current working knowledge of pediatric liver  
983 transplantation, defined as direct involvement in pediatric liver transplant patient care  
984 within the last 2 years. This includes the management of pediatric patients with end-stage  
985 liver disease, the selection of appropriate pediatric recipients for transplantation, donor  
986 selection, histocompatibility and tissue typing, immediate post-operative care including  
987 those issues of management unique to the pediatric recipient, fluid and electrolyte  
988 management, the use of immunosuppressive therapy in the pediatric recipient including  
989 side-effects of drugs and complications of immunosuppression, the effects of  
990 transplantation and immunosuppressive agents on growth and development, differential  
991 diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the  
992 pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary  
993 tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients  
994 including management of hypertension, nutritional support, and drug dosage, including  
995 antibiotics, in the pediatric patient.  
996 e. The physician should have observed at least 3 organ procurements and 3 liver  
997 transplants. In addition, the physician should have observed the evaluation of donor, the  
998 donation process, and the management of at least 3 multiple organ donors who donated  
999 a liver. If the physician has completed these observations, they must be documented in a  
1000 log that includes the date of procurement, ~~location of the donor,~~ and Donor ID.  
1001 f. The following letters are submitted directly to the OPTN Contractor:  
1002 i. A letter from the qualified liver transplant physician and surgeon who have been  
1003 directly involved with the physician documenting the physician's experience and  
1004 competence.  
1005 ii. A letter of recommendation from the primary physician and transplant program  
1006 director at the fellowship training program or transplant program last served by the  
1007 physician outlining the physician's overall qualifications to act as a primary transplant  
1008 physician, as well as the physician's personal integrity, honesty, and familiarity with  
1009 and experience in adhering to OPTN obligations, and any other matters judged  
1010 appropriate. The MPSC may request additional recommendation letters from the  
1011 primary physician, primary surgeon, director, or others affiliated with any transplant  
1012 program previously served by the physician, at its discretion.  
1013 iii. A letter from the physician that details the training and experience the physician  
1014 gained in liver transplantation.  
1015

1016 A designated liver transplant program's conditional approval for a pediatric component is valid for  
1017 a maximum of 24 months.  
1018

1019 **F.11 Primary Intestine Transplant Surgeon Requirements**

1020 **A. Full Intestine Surgeon Approval Pathway**

1021 Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal  
1022 transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of  
1023 the following conditions are met:  
1024

1. The surgeon performed 7 or more intestine transplants at a designated intestine transplant program, to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in 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 from the program where the experience or training was gained.
2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include 1 or more organ recovery that includes a liver. These procedures must be documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, 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 intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The training was completed at a hospital with a transplant training program approved by the American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as described in *Section F.13 Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows.
5. The following letters are submitted to the OPTN Contractor:
  - a. A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon 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 surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

1025

1026 **B. Conditional Intestine Surgeon Approval Pathway**

1027 Surgeons can meet the requirements for conditional approval as primary intestine transplant  
1028 surgeon through experience gained during or post-fellowship, if *all* of the following conditions are  
1029 met:  
1030

1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel  
1031 and composite grafts and must perform 3 or more intestine transplants over the next 3  
1032

1033 consecutive years as primary surgeon or first assistant at a designated intestine transplant  
1034 program. These transplants must be documented in a log that includes the date of transplant,  
1035 the role of the surgeon in the procedure, and medical record number or other unique identifier  
1036 that can be verified by the OPTN Contractor. This log must be signed by the program  
1037 director, division chief, or department chair from the program where the experience or training  
1038 was gained. Each year of the surgeon's experience must be substantive and relevant and  
1039 include pre-operative assessment of intestine transplant candidates, transplants performed  
1040 as primary surgeon or first assistant and post-operative management of intestine recipients.

- 1041 2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first  
1042 assistant. These procurements must include at least 1 procurement of a graft that includes a  
1043 liver. This procedure must be documented in a log that includes the date of procurement,  
1044 ~~location of the donor,~~ and Donor ID.
- 1045 3. The surgeon has maintained a current working knowledge of intestine transplantation,  
1046 defined as direct involvement in intestine transplant patient care within the last 5 years. This  
1047 includes the management of patients with short bowel syndrome or intestinal failure, the  
1048 selection of appropriate recipients for transplantation, donor selection, histocompatibility and  
1049 tissue typing, performing the transplant operation, immediate postoperative and continuing  
1050 inpatient care, the use of immunosuppressive therapy including side effects of the drugs and  
1051 complications of immunosuppression, differential diagnosis of intestine dysfunction in the  
1052 allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests  
1053 for intestine dysfunction, and long term outpatient care.
- 1054 4. The surgeon develops a formal mentor relationship with a primary intestine transplant  
1055 surgeon at another approved intestine transplant program. The mentor will discuss program  
1056 requirements, patient and donor selection, recipient management, and be available for  
1057 consultation as required until full approval conditions are all met.
- 1058 5. The following letters are sent to the OPTN Contractor:
  - 1059 a. A letter from the director of the transplant program and chair of the department or hospital  
1060 credentialing committee verifying that the surgeon has met the above requirements and  
1061 is qualified to direct an intestine transplant program.
  - 1062 b. A letter of recommendation from the primary surgeon and transplant program director at  
1063 the transplant program last served by the surgeon, outlining the surgeon's overall  
1064 qualifications to act as primary transplant surgeon, as well as the surgeon's personal  
1065 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and  
1066 other matters judged appropriate. The MPSC may request additional recommendation  
1067 letters from the primary surgeon, primary physician, director, or others affiliated with any  
1068 transplant program previously served by the surgeon, at its discretion.
  - 1069 c. A letter from the surgeon that details the training and experience the surgeon gained in  
1070 intestine transplantation as well as detailing the plan for obtaining full approval within the  
1071 3-year conditional approval period.
  - 1072 d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed  
1073 by the surgeon to obtain full approval.

1074

## 1075 **G.2 Primary Pancreas Transplant Surgeon Requirements**

### 1076 **A. Formal 2-year Transplant Fellowship Pathway**

1077 Surgeons can meet the training requirements for primary pancreas transplant surgeon by  
1078 completing a 2-year transplant fellowship if the following conditions are met:

- 1079 1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant.  
1080 These transplants must be documented in a log that includes the date of transplant, the role  
1081 of the surgeon in the procedure, and medical record number or other unique identifier that  
1082 can be verified by the OPTN Contractor. This log must be signed by the director of the  
1083 training program.  
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2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These cases must be documented in a log that includes the date of procurement, ~~location of the donor~~, and Donor ID. This log must be signed by the director of the training program.
  3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in patient care within the last 2 years. This includes the management of patients with diabetes mellitus, 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 pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
  4. The training was completed at a hospital with a pancreas 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 accepted by the OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon 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 fellow has met the above requirements and is qualified to direct a pancreas 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 primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

## **B. Clinical Experience Pathway**

1119 Surgeons can meet the requirements for primary pancreas transplant surgeon through clinical  
1120 experience gained post-fellowship if the following conditions are met:

- 1121  
1122  
1123  
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1130
1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon or first assistant, at a designated pancreas transplant program. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.

- 1131 2. The surgeon has performed at least 10 pancreas procurements as primary surgeon or first  
1132 assistant. These procurements must be documented in a log that includes the date of  
1133 procurement, ~~location of the donor,~~ and Donor ID.
- 1134 3. The surgeon has maintained a current working knowledge of pancreas transplantation,  
1135 defined as direct involvement in pancreas transplant patient care within the last 2 years. This  
1136 includes the management of patients with diabetes mellitus, the selection of appropriate  
1137 recipients for transplantation, donor selection, histocompatibility and tissue typing, performing  
1138 the transplant operation, immediate postoperative and continuing inpatient care, the use of  
1139 immunosuppressive therapy including side effects of the drugs and complications of  
1140 immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient,  
1141 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic  
1142 dysfunction, and long term outpatient care.
- 1143 4. The following letters are submitted directly to the OPTN Contractor:  
1144 a. A letter from the director of the transplant program and chairman of the department or  
1145 hospital credentialing committee verifying that the surgeon has met the above  
1146 requirements and is qualified to direct a pancreas transplant program.  
1147 b. A letter of recommendation from the primary surgeon and director at the transplant  
1148 program last served by the surgeon outlining the surgeon's overall qualifications to act as  
1149 primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity  
1150 with and experience in adhering to OPTN obligations, and any other matters judged  
1151 appropriate. The MPSC may request similar letters of recommendation from the primary  
1152 physician, primary surgeon, director, or others affiliated with any transplant program  
1153 previously served by the individual, at its discretion.  
1154 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1155 in pancreas transplantation.  
1156

### 1157 **G.3 Primary Pancreas Transplant Physician Requirements**

#### 1158 **A. Twelve-month Transplant Medicine Fellowship Pathway**

1159 Physicians can meet the training requirements for a primary pancreas transplant physician during  
1160 a separate 12-month transplant medicine fellowship if the following conditions are met:

- 1161 1. The physician completed 12 consecutive months of specialized training in pancreas  
1162 transplantation at a pancreas transplant program under the direct supervision of a qualified  
1163 pancreas transplant physician along with a pancreas transplant surgeon. The training must  
1164 have included at least 6 months on the clinical transplant service. The remaining time must  
1165 have consisted of transplant-related experience, such as experience in a tissue typing  
1166 laboratory, on another solid organ transplant service, or conducting basic or clinical transplant  
1167 research.
- 1168 2. During the fellowship period, the physician was directly involved in the primary care of 8 or  
1169 more newly transplanted pancreas recipients and followed these recipients for a minimum of  
1170 3 months from the time of transplant. The care must be documented in a log that includes the  
1171 date of transplant and medical record number or other unique identifier that can be identified  
1172 by the OPTN Contractor. This recipient log must be signed by the director of the training  
1173 program or the transplant program's primary transplant physician.
- 1174 3. The physician has maintained a current working knowledge of pancreas transplantation,  
1175 defined as direct involvement in pancreas transplant patient care within the last 2 years. This  
1176 includes the management of patients with end stage pancreas disease, the selection of  
1177

- 1178 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
1179 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
1180 including side effects of the drugs and complications of immunosuppression, differential  
1181 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of  
1182 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term  
1183 outpatient care.
- 1184 4. The physician must have observed at least 3 pancreas procurements. The physician must  
1185 have also observed the evaluation, donation process, and management of these donors.  
1186 These observations must be documented in a log that includes the date of procurement,  
1187 ~~location of the donor,~~ and Donor ID.
  - 1188 5. The physician must have observed at least 3 pancreas transplants. The observation of these  
1189 transplants must be documented in a log that includes the transplant date and medical record  
1190 number or other unique identifier that can be verified by the OPTN Contractor.
  - 1191 6. The curriculum of this transplant medicine fellowship should be approved by the Residency  
1192 Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate  
1193 Medical Education (ACGME).
  - 1194 7. The following letters are submitted directly to the OPTN Contractor:
    - 1195 a. A letter from director of the training program and supervising qualified pancreas  
1196 transplant physician send a letter directly to the OPTN Contractor verifying that the fellow  
1197 has met the above requirements and is qualified to direct a pancreas transplant program.
    - 1198 b. A letter of recommendation from the fellowship training program's primary physician and  
1199 transplant program director outlining the physician's overall qualifications to act as  
1200 primary transplant physician as well as the physician's personal integrity, honesty,  
1201 familiarity with and experience in adhering to OPTN obligations, and any other matters  
1202 judged appropriate. The MPSC may request similar letters of recommendation from the  
1203 primary physician, primary surgeon, director, or others affiliated with any transplant  
1204 program that the physician previously served, at its discretion.
    - 1205 c. A letter from the physician that details the training and experience the physician has  
1206 gained in pancreas transplantation.

1207  
1208 The above training is in addition to other clinical requirements for general nephrology,  
1209 endocrinology, or diabetology training.

## 1210 1211 **B. Clinical Experience Pathway**

1212 A physician can meet the requirements for a primary transplant physician through acquired  
1213 clinical experience if the following conditions are met:

- 1214 1. The physician has been directly involved in the primary care of 15 or more newly transplanted  
1215 pancreas recipients and continued to follow these recipients for a minimum of 3 months from  
1216 the time of transplant. This patient care must have been provided over a 2 to 5-year period on  
1217 an active pancreas transplant service as the primary pancreas transplant physician or under  
1218 the direct supervision of a qualified pancreas transplant physician along with a pancreas  
1219 transplant surgeon at a designated pancreas transplant program. The care must be  
1220 documented in a log that includes the date of transplant and the medical record number or  
1221 other unique identifier that can be verified by the OPTN Contractor. This recipient log should  
1222 be signed by the program director, division chief, or department chair from the program  
1223 where the physician gained this experience.
- 1224 2. The physician has maintained a current working knowledge of pancreas transplantation,  
1225 defined as direct involvement in pancreas transplant patient care within the last 2 years. This  
1226

- 1227 includes the management of patients with end stage pancreas disease, the selection of  
1228 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
1229 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
1230 including side effects of the drugs and complications of immunosuppression, differential  
1231 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of  
1232 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term  
1233 outpatient care.
- 1234 3. The physician must have observed at least 3 pancreas procurements. The physician must  
1235 have observed the evaluation, donation process, and management of these donors. These  
1236 observations must be documented in a log that includes the date of procurement, ~~location of~~  
1237 ~~the donor,~~ and Donor ID.
- 1238 4. The physician must have observed at least 3 pancreas transplants. The observation of these  
1239 transplants must be documented in a log that includes the transplant date and medical record  
1240 number or other unique identifier that can be verified by the OPTN Contractor.
- 1241 5. The following letters are submitted directly to the OPTN Contractor:
- 1242 a. A letter from the qualified pancreas transplant physician or surgeon who has been  
1243 directly involved with the physician documenting the physician's experience and  
1244 competence.
- 1245 b. A letter of recommendation from the primary physician and director at the transplant  
1246 program last served by the physician outlining the physician's overall qualifications to act  
1247 as primary transplant physician as well as the physician's personal integrity, honesty,  
1248 familiarity with and experience in adhering to OPTN obligations, and any other matters  
1249 judged appropriate. The MPSC may request similar letters of recommendation from the  
1250 primary physician, primary surgeon, director, or others affiliated with any transplant  
1251 program the physician previously served, at its discretion.
- 1252 c. A letter from the physician that details the training and experience the physician has  
1253 gained in pancreas transplantation.
- 1254

#### 1255 **D. Conditional Approval for Primary Transplant Physician**

1256 If the primary pancreas transplant physician changes at an approved pancreas transplant  
1257 program, a physician can serve as the primary pancreas transplant physician for a maximum of  
1258 12 months if the following conditions are met:

- 1259
- 1260 1. The physician has been involved in the primary care of 8 or more newly transplanted  
1261 pancreas recipients, and has followed these patients for at least 3 months from the time of  
1262 their transplant. This care must be documented in a recipient log that includes the date of  
1263 transplant and the medical record number or other unique identifier that can be verified by the  
1264 OPTN Contractor. This log should be signed by the program director, division chief, or  
1265 department chair from the transplant program where the experience was gained.
- 1266 2. The physician has maintained a current working knowledge of pancreas transplantation,  
1267 defined as direct involvement in pancreas transplant patient care within the last 2 years. This  
1268 includes the management of patients with end stage pancreas disease, the selection of  
1269 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
1270 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
1271 including side effects of the drugs and complications of immunosuppression, differential  
1272 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of  
1273 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term  
1274 outpatient care.

- 1275 3. The physician has 12 months experience on an active pancreas transplant service as the  
1276 primary pancreas transplant physician or under the direct supervision of a qualified pancreas  
1277 transplant physician along with a pancreas transplant surgeon at a designated pancreas  
1278 transplant program. This 12-month period of experience on the transplant service must have  
1279 been acquired over a maximum of 2 years.
- 1280 4. The physician must have observed at least 3 pancreas procurements. The physician must  
1281 have observed the evaluation, donation process, and management of these donors. These  
1282 observations must be documented in a log that includes the date of procurement, ~~location of~~  
1283 ~~the donor,~~ and Donor ID.
- 1284 5. The physician must have observed at least 3 pancreas transplants. The observation of these  
1285 transplants must be documented in a log that includes the transplant date and medical record  
1286 number or other unique identifier that can be verified by the OPTN Contractor.
- 1287 6. The program has established and documented a consulting relationship with counterparts at  
1288 another pancreas transplant program.
- 1289 7. The transplant program submits activity reports to the OPTN Contractor every 2 months  
1290 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
1291 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
1292 efficient patient care at the program. The activity reports must also demonstrate that the  
1293 physician is making sufficient progress in meeting the required involvement in the primary  
1294 care of 15 or more pancreas transplant recipients, or that the program is making sufficient  
1295 progress in recruiting a physician who will be on site and approved by the MPSC to assume  
1296 the role of Primary Physician by the end of the 12 month conditional approval period.
- 1297 8. The following letters are submitted directly to the OPTN Contractor:
- 1298 a. A letter from the qualified pancreas transplant physician and surgeon who were directly  
1299 involved with the physician documenting the physician's experience and competence.
- 1300 b. A letter of recommendation from the primary physician and director at the transplant  
1301 program last served by the physician outlining the physician's overall qualifications to act  
1302 as a primary transplant physician, as well as the physician's personal integrity, honesty,  
1303 and familiarity with and experience in adhering to OPTN obligations, and any other  
1304 matters judged appropriate. The MPSC may request additional recommendation letters  
1305 from the primary physician, primary surgeon, director, or others affiliated with any  
1306 transplant program previously served by the physician, at its discretion.
- 1307 c. A letter from the physician that details the training and experience the physician has  
1308 gained in pancreas transplantation.

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1310 The 12-month conditional approval period begins on the initial approval date granted to the  
1311 personnel change application, whether it is interim approval granted by the MPSC subcommittee,  
1312 or approval granted by the full MPSC. The conditional approval period ends 12 months after the  
1313 first approval date of the personnel change application.

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1315 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
1316 program that provides substantial evidence of progress toward fulfilling the requirements but is  
1317 unable to complete the requirements within one year.

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1319 If the transplant program is unable to demonstrate that it has an individual on site who can meet  
1320 the requirements as described in *Sections G.3.A through G.3.C* above at the end of the conditional  
1321 approval period, it must inactivate. The requirements for program inactivation are described in  
1322 *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

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## H.2 Primary Heart Transplant Surgeon Requirements

### A. Cardiothoracic Surgery Residency Pathway

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a cardiothoracic surgery residency if *all* the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the cardiothoracic surgery residency. These transplants must be documented in a log that includes the date of transplant, role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procurements must have been performed anytime during the surgeon's cardiothoracic surgery residency and the two years immediately following cardiothoracic surgery residency completion. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as 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.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### B. Twelve-month Heart Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a 12-month heart transplant fellowship if the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in 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 director of the training program.

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2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. 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 a log that includes the date of procurement, ~~location of the donor~~, and Donor ID. This log must be signed by the director of the training program.
  3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
  4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
    - b. A letter of recommendation from the training program’s primary surgeon and transplant program director outlining the individual’s overall qualifications to act as 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.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

**C. Clinical Experience Pathway**

Surgeons can meet the requirements for primary heart transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

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1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from program where the experience was gained. Transplants performed during board qualifying surgical residency or fellowship do not count.
  2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procedures must be documented in a log that includes the date of procurement, ~~location of the donor~~, and Donor ID.
  3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of

- 1418 mechanical assist devices, recipient selection, post-operative hemodynamic care,  
1419 postoperative immunosuppressive therapy, and outpatient follow-up.
- 1420 4. The following letters are submitted directly to the OPTN Contractor:
- 1421 a. A letter from the director of the program where the surgeon acquired transplant  
1422 experience verifying that the surgeon has met the above requirements and is qualified to  
1423 direct a heart transplant program.
- 1424 b. A letter of recommendation from the primary surgeon and transplant program director at  
1425 the transplant program last served by the surgeon outlining the surgeon's overall  
1426 qualifications to act as primary transplant surgeon, as well as the surgeon's personal  
1427 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
1428 and any other matters judged appropriate. The MPSC may request additional  
1429 recommendation letters from the primary physician, primary surgeon, director, or others  
1430 affiliated with any transplant program previously served by the surgeon, at its discretion.
- 1431 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1432 in heart transplantation.  
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### 1434 H.3 Primary Heart Transplant Physician Requirements

#### 1435 A. Twelve-month Transplant Cardiology Fellowship Pathway

1436 Physicians can meet the training requirements for primary heart transplant physician during a 12-  
1437 month transplant cardiology fellowship if the following conditions are met:

- 1438
- 1439 1. During the fellowship period, the physician was directly involved in the primary care of at least  
1440 20 newly transplanted heart or heart/lung recipients. This training will have been under the  
1441 direct supervision of a qualified heart transplant physician and in conjunction with a heart  
1442 transplant surgeon. This care must be documented in a log that includes the date of  
1443 transplant and the medical record number or other unique identifier that can be verified by the  
1444 OPTN Contractor. This recipient log must be signed by the director of the training program or  
1445 the primary transplant physician at the transplant program.
- 1446 2. The physician has maintained a current working knowledge of heart transplantation, defined  
1447 as direct involvement in heart transplant patient care within the last 2 years. This includes the  
1448 care of acute and chronic heart failure, donor selection, the use of mechanical circulatory  
1449 support devices, recipient selection, pre- and post-operative hemodynamic care, post-  
1450 operative immunosuppressive therapy, histological interpretation and grading of myocardial  
1451 biopsies for rejection, and long-term outpatient follow-up.
- 1452 3. The physician must have observed at least 3 heart procurements. The physician must have  
1453 observed the evaluation, donation process, and management of these donors. These  
1454 observations must be documented in a log that includes the date of procurement, ~~location of~~  
1455 ~~the donor,~~ and Donor ID.
- 1456 4. The physician must have observed at least 3 heart transplants. The observation of these  
1457 transplants must be documented in a log that includes the transplant date and medical record  
1458 number or other unique identifier that can be verified by the OPTN Contractor.
- 1459 5. This training was completed at a hospital with an American Board of Internal Medicine  
1460 certified fellowship training program in adult cardiology, an American Board of Pediatrics  
1461 certified fellowship training program in pediatric cardiology, or a cardiology training program  
1462 approved by the Royal College of Physicians and Surgeons of Canada.
- 1463 6. The following letters are submitted directly to the OPTN Contractor:



- 1464 a. A letter from the director of the training program and the supervising qualified heart
- 1465 transplant physician verifying that the physician has met the above requirements and is
- 1466 qualified to direct a heart transplant program.
- 1467 b. A letter of recommendation from the training program's primary physician and transplant
- 1468 program director outlining the physician's overall qualifications to act as primary
- 1469 transplant physician, as well as the physician's personal integrity, honesty, and familiarity
- 1470 with and experience in adhering to OPTN obligations, and any other matters judged
- 1471 appropriate. The MPSC may request additional recommendation letters from the Primary
- 1472 Physician, primary surgeon, director, or others affiliated with any transplant program
- 1473 previously served by the physician, at its discretion.
- 1474 c. A letter from the physician that details the training and experience the physician has
- 1475 gained in heart transplantation.
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**B. Clinical Experience Pathway**

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

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- 1481 1. The physician has been directly involved in the primary care of 20 or more newly transplanted
- 1482 heart or heart/lung recipients and continued to follow these recipients for a minimum of 3
- 1483 months from transplant. This patient care must have been provided over a 2 to 5-year period
- 1484 on an active heart transplant service as the primary heart transplant physician or under the
- 1485 direct supervision of a qualified heart transplant physician and in conjunction with a heart
- 1486 transplant surgeon at a heart transplant program. This care must be documented in a log that
- 1487 includes the date of transplant and medical record number or other unique identifier that can
- 1488 be verified by the OPTN Contractor. This recipient log should be signed by the director or the
- 1489 primary transplant physician at the transplant program where the physician gained this
- 1490 experience.
- 1491 2. The physician has maintained a current working knowledge of heart transplantation, defined
- 1492 as direct involvement in heart transplant patient care within the last 2 years. This includes the
- 1493 care of acute and chronic heart failure, donor selection, use of mechanical circulatory support
- 1494 devices, recipient selection, pre- and post-operative hemodynamic care, post-operative
- 1495 immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for
- 1496 rejection, and long-term outpatient follow-up.
- 1497 3. The physician must have observed at least 3 heart procurements. The physician must have
- 1498 observed the evaluation, donation process, and management of these donors. These
- 1499 observations must be documented in a log that includes the date of procurement, ~~location of~~
- 1500 ~~the donor~~, and Donor ID.
- 1501 4. The physician must have observed at least 3 heart transplants. The observation of these
- 1502 transplants must be documented in a log that includes the transplant date and medical record
- 1503 number or other unique identifier that can be verified by the OPTN Contractor.
- 1504 5. The following letters are submitted directly to the OPTN Contractor:
- 1505 a. A letter from the heart transplant physician or the heart transplant surgeon who has been
- 1506 directly involved with the physician at the transplant program verifying the physician's
- 1507 competence.
- 1508 b. A letter of recommendation from the primary physician and transplant program director
- 1509 at the transplant program last served by the physician outlining the physician's overall
- 1510 qualifications to act as primary transplant physician, as well as the physician's personal
- 1511 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,

1512 and any other matters judged appropriate. The MPSC may request additional  
1513 recommendation letters from the primary physician, primary surgeon, director, or others  
1514 affiliated with any transplant program previously served by the physician, at its discretion.  
1515 c. A letter from the physician that details the training and experience the physician has  
1516 gained in heart transplantation.

### 1517 **C. Conditional Approval for Primary Transplant Physician**

1519 If the primary heart transplant physician changes at an approved heart transplant program, a  
1520 physician can serve as the primary heart transplant physician for a maximum of 12 months if the  
1521 following conditions are met:

- 1522 1. The physician has 12 months experience on an active heart transplant service as the primary  
1523 heart transplant physician or under the direct supervision of a qualified heart transplant  
1524 physician and in conjunction with a heart transplant surgeon at a designated heart transplant  
1525 program. These 12 months of experience must be acquired within a 2-year period.
- 1526 2. The physician has maintained a current working knowledge of heart transplantation, defined  
1527 as direct involvement in heart transplant patient care within the last 2 years. This includes  
1528 knowledge of acute and chronic heart failure, donor selection, the use of mechanical  
1529 circulatory support devices, recipient selection, pre- and post-operative hemodynamic care,  
1530 post-operative immunosuppressive therapy, histological interpretation in grading of  
1531 myocardial biopsies for rejection, and long-term outpatient follow-up.
- 1532 3. The physician has been involved in the primary care of 10 or more newly transplanted heart  
1533 or heart/lung transplant recipients as the heart transplant physician or under the direct  
1534 supervision of a qualified heart transplant physician or in conjunction with a heart transplant  
1535 surgeon at a designated heart transplant program. The physician will have followed these  
1536 patients for a minimum of 3 months from the time of transplant. This care must be  
1537 documented in a log that includes the date of transplant and medical record or other unique  
1538 identifier that can be verified by the OPTN Contractor. This recipient log should be signed by  
1539 the program director or the primary transplant physician at the transplant program where the  
1540 physician gained experience.
- 1541 4. The physician must have observed at least 3 heart procurements. The physician must have  
1542 observed the evaluation, donation process, and management of these donors. These  
1543 observations must be documented in a log that includes the date of procurement, ~~location of~~  
1544 ~~the donor,~~ and Donor ID.
- 1545 5. The physician must have observed at least 3 heart transplants. The observation of these  
1546 transplants must be documented in a log that includes the transplant date and medical record  
1547 number or other unique identifier that can be verified by the OPTN Contractor.
- 1548 6. The program has established and documented a consulting relationship with counterparts at  
1549 another heart transplant program.
- 1550 7. The transplant program submits activity reports to the OPTN Contractor every 2 months  
1551 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
1552 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
1553 efficient patient care at the program. The activity reports must also demonstrate that the  
1554 physician is making sufficient progress to meet the required involvement in the primary care  
1555 of 20 or more heart transplant recipients, or that the program is making sufficient progress in  
1556 recruiting a physician who meets all requirements for primary heart transplant physician by  
1557 the end of the 12 month conditional approval period.
- 1558 8. The following letters are submitted directly to the OPTN Contractor:
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- 1560 a. A letter from the heart transplant physician or the heart transplant surgeon who has been  
1561 directly involved with the physician at the transplant program verifying the physician's  
1562 competence.
- 1563 b. A letter of recommendation from the primary physician and director at the transplant  
1564 program last served by the physician outlining the physician's overall qualifications to act  
1565 as primary transplant physician, as well as the physician's personal integrity, honesty,  
1566 and familiarity with and experience in adhering to OPTN obligations, and any other  
1567 matters judged appropriate. The MPSC may request additional recommendation letters  
1568 from the primary physician, primary surgeon, director, or others affiliated with any  
1569 transplant program previously served by the physician, at its discretion.
- 1570 c. A letter from the physician that details the training and experience the physician has  
1571 gained in heart transplantation.

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1573 The 12-month conditional approval period begins on the first approval date granted to the personnel  
1574 change application, whether it is an interim approval granted by the MPSC subcommittee, or an  
1575 approval granted by the full MPSC. The conditional approval period ends exactly 12 months after  
1576 this first approval date of the personnel change application.

1577  
1578 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
1579 program that provides substantial evidence of progress toward fulfilling the requirements but is  
1580 unable to complete the requirements within one year.

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1582 If the program is unable to demonstrate that it has an individual on site who can meet the  
1583 requirements as described in *Sections H.3.A through H.3.B* above at the end of the conditional  
1584 approval period, it must inactivate. The requirements for program inactivation are described in  
1585 *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

## 1587 **I.2 Primary Lung Transplant Surgeon Requirements**

### 1588 **A. Cardiothoracic Surgery Residency Pathway**

1589 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a  
1590 cardiothoracic surgery residency if the following conditions are met:

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- 1592 1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or  
1593 heart/lung transplants as primary surgeon or first assistant under the direct supervision of a  
1594 qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung  
1595 transplant program. At least half of these transplants must be lung procedures. These  
1596 transplants must be documented in a log that includes the date of transplant, role of the  
1597 surgeon in the procedure, and medical record number or other unique identifier that can be  
1598 verified by the OPTN Contractor. This log must be signed by the director of the training  
1599 program.
  - 1600 2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant  
1601 under the supervision of a qualified lung transplant surgeon. These procurements must have  
1602 been performed anytime during the surgeon's cardiothoracic surgery residency and the two  
1603 years immediately following cardiothoracic surgery residency completion. These procedures  
1604 must be documented in a log that includes the date of procurement, ~~location of the donor,~~  
1605 and Donor ID.
  - 1606 3. The surgeon has maintained a current working knowledge of all aspects of lung  
1607 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1608 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,

- 1609 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
 1610 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
 1611 rejection, and long-term outpatient follow-up. This training must also include the other clinical  
 1612 requirements for thoracic surgery
- 1613 4. This training was completed at a hospital with a cardiothoracic training program approved by  
 1614 the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of  
 1615 Canada.
  - 1616 5. The following letters are submitted directly to the OPTN Contractor:  
 1617 a. A letter from the director of the training program verifying that the surgeon has met the  
 1618 above requirements and is qualified to direct a lung transplant program.  
 1619 b. A letter of recommendation from the program's primary surgeon and transplant program  
 1620 director outlining the individual's overall qualifications to act as primary transplant  
 1621 surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and  
 1622 experience in adhering to OPTN obligations and compliance protocols, and any other  
 1623 matters judged appropriate. The MPSC may request additional recommendation letters  
 1624 from the primary physician, primary surgeon, director, or others affiliated with any  
 1625 transplant program previously served by the surgeon, at its discretion.  
 1626 c. A letter from the surgeon that details the training and experience the surgeon has gained  
 1627 in lung transplantation.

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 1629 **B. Twelve-month Lung Transplant Fellowship Pathway**

1630 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a  
 1631 12-month lung transplant fellowship if the following conditions are met:  
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- 1633 1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct  
 1634 supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung  
 1635 transplant physician as primary surgeon or first assistant during the 12-month lung transplant  
 1636 fellowship. At least half of these transplants must be lung procedures. These transplants  
 1637 must be documented in a log that includes the date of transplant, the role of the surgeon in  
 1638 the procedure, and the medical record number or other unique identifier that can be verified  
 1639 by the OPTN Contractor. This log must be signed by the director of the program.
- 1640 2. The surgeon has performed at least 10 lung procurements as primary surgeon or first  
 1641 assistant under the supervision of a qualified lung transplant surgeon. These procurements  
 1642 must have been performed anytime during the surgeon's fellowship and the two years  
 1643 immediately following fellowship completion. These procedures must be documented in a log  
 1644 that includes the date of procurement, ~~location of the donor,~~ and Donor ID.
- 1645 3. The surgeon has maintained a current working knowledge of all aspects of lung  
 1646 transplantation, defined as a direct involvement in lung transplant patient care within the last  
 1647 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
 1648 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
 1649 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
 1650 rejection, and long-term outpatient follow-up.
- 1651 4. This training was completed at a hospital with a cardiothoracic training program approved by  
 1652 the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of  
 1653 Canada.
- 1654 5. The following letters are submitted directly to the OPTN Contractor:  
 1655 a. A letter from the director of the training program verifying that the surgeon has met the  
 1656 above requirements and is qualified to direct a lung transplant program.

- 1657 b. A letter of recommendation from the training program’s primary surgeon and transplant  
1658 program director outlining the individual’s overall qualifications to act as primary  
1659 transplant surgeon, as well as the surgeon’s personal integrity, honesty, and familiarity  
1660 with and experience in adhering to OPTN obligations, and any other matters judged  
1661 appropriate. The MPSC may request additional recommendation letters from the primary  
1662 physician, primary surgeon, director, or others affiliated with any transplant program  
1663 previously served by the surgeon, at its discretion.  
1664 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1665 in lung transplantation.  
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### C. Clinical Experience Pathway

1668 Surgeons can meet the requirements for primary lung transplant surgeon through clinical  
1669 experience gained post-fellowship if the following conditions are met:  
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- 1671 1. The surgeon has performed 15 or more lung or heart/lung transplants over a 2 to 5-year  
1672 period as primary surgeon or first assistant at a designated lung transplant program. At least  
1673 half of these transplants must be lung procedures, and at least 10 must be performed as the  
1674 primary surgeon. The surgeon must also have been actively involved with cardiothoracic  
1675 surgery. These transplants must be documented in a log that includes the date of transplant,  
1676 the role of the surgeon in the procedure, and medical record number or other unique identifier  
1677 that can be verified by the OPTN Contractor. This recipient log should be signed by the  
1678 program director, division chief, or department chair from program where the experience was  
1679 gained.  
1680 2. The surgeon has performed at least 10 lung procurements. These procedures must be  
1681 documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor  
1682 ID.  
1683 3. The surgeon has maintained a current working knowledge of all aspects of lung  
1684 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1685 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
1686 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
1687 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
1688 rejection, and long-term outpatient follow-up.  
1689 4. The following letters are submitted directly to the OPTN Contractor:  
1690 a. A letter from the director of the program where the surgeon gained experience verifying  
1691 that the surgeon has met the above requirements and is qualified to direct a lung  
1692 transplant program.  
1693 b. A letter of recommendation from the primary surgeon and director at the transplant  
1694 program last served by the surgeon outlining the surgeon’s overall qualifications to act as  
1695 primary transplant surgeon, as well as the surgeon’s personal integrity, honesty, and  
1696 familiarity with and experience in adhering to OPTN obligations, and any other matters  
1697 judged appropriate. The MPSC may request additional recommendation letters from the  
1698 primary physician, primary surgeon, director, or others affiliated with any transplant  
1699 program previously served by the surgeon, at its discretion.  
1700 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1701 in lung transplantation.  
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## 1.3 Primary Lung Transplant Physician Requirements

### A. Twelve-month Transplant Pulmonary Fellowship Pathway

Physicians can meet the training requirements for primary lung transplant physician during a 12-month transplant pulmonary fellowship if the following conditions are met:

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician must have observed at least 3 lung or heart/lung procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor ID.
4. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or a pulmonary medicine training program approved by the Royal College of Physicians and Surgeons of Canada.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician'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 physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

### B. Clinical Experience Pathway

A physician can meet the requirements for primary lung transplant physician through acquired clinical experience if the following conditions are met.

- 1750 1. The physician has been directly involved in the primary care of 15 or more newly transplanted  
 1751 lung or heart/lung recipients and continued to follow these recipients for a minimum of 3  
 1752 months from the time of transplant. At least half of these transplant must be lung transplants.  
 1753 This patient care must have been provided over a 2 to 5-year period at a designated lung  
 1754 transplant program. This care must have been provided as the lung transplant physician or  
 1755 directly supervised by a qualified lung transplant physician along with a lung transplant  
 1756 surgeon. This care must be documented in a log that includes the date of transplant and  
 1757 medical record number or other unique identifier that can be verified by the OPTN Contractor.  
 1758 This recipient log should be signed by the director or the primary transplant physician at the  
 1759 transplant program where the physician gained this experience.
- 1760 2. The physician has maintained a current working knowledge of all aspects of lung  
 1761 transplantation, defined as a direct involvement in lung transplant patient care within the last  
 1762 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
 1763 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
 1764 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
 1765 rejection, and long-term outpatient follow-up.
- 1766 3. The physician must observe at least 3 lung or heart/lung procurements. The physician must  
 1767 have observed the evaluation, donation process, and management of these donors. These  
 1768 observations must be documented in a log that includes the date of procurement, ~~location of~~  
 1769 ~~the donor,~~ and Donor ID.
- 1770 4. The physician must have observed at least 3 lung transplants. The observation of these  
 1771 transplants must be documented in a log that includes the transplant date and medical record  
 1772 number or other unique identifier that can be verified by the OPTN Contractor.
- 1773 5. The following letters are submitted directly to the OPTN Contractor:
- 1774 a. A letter from the lung transplant physician or surgeon of the training program who has  
 1775 been directly involved with the physician documenting the physician's competence.
- 1776 b. A letter of recommendation from the primary physician and transplant program director at  
 1777 the transplant program last served by the physician outlining the physician's overall  
 1778 qualifications to act as primary transplant physician, as well as the physician's personal  
 1779 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
 1780 and any other matters judged appropriate. The MPSC may request additional  
 1781 recommendation letters from the primary physician, primary surgeon, director, or others  
 1782 affiliated with any transplant program previously served by the physician, at its discretion.
- 1783 c. A letter from the physician that details the training and experience the physician has  
 1784 gained in lung transplantation.

1785  
 1786 **D. Conditional Approval for Primary Transplant Physician**

1787 If the primary lung transplant physician changes at an approved lung transplant program, a  
 1788 physician can serve as the primary lung transplant physician for a maximum of 12 months if the  
 1789 following conditions are met:

- 1790
- 1791 1. The physician has 12 months of experience on an active lung transplant service as the  
 1792 primary lung transplant physician or under the direct supervision of a qualified lung transplant  
 1793 physician and in conjunction with a lung transplant surgeon at a designated lung transplant  
 1794 program. These 12 months of experience must be acquired within a 2-year period.
- 1795 2. The physician has been involved in the primary care of 8 or more newly transplanted lung or  
 1796 heart/lung transplant recipients as the lung transplant physician or under the direct  
 1797 supervision of a qualified lung transplant physician and in conjunction with a lung transplant  
 1798 surgeon. At least half of these patients must be lung transplant recipients. This care must be

1799 documented in a recipient log that includes the date of transplant and medical record or other  
1800 unique identifier that can be verified by the OPTN Contractor. This log should be signed by  
1801 the program director or the primary transplant physician at the transplant program where the  
1802 physician gained experience.

- 1803 3. The physician has maintained a current working knowledge of all aspects of lung  
1804 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1805 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
1806 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
1807 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
1808 rejection, and long-term outpatient follow-up.
- 1809 4. The physician must have observed at least 3 lung or heart/lung procurements. The physician  
1810 must have observed the evaluation, donation process, and management of these donors.  
1811 These observations must be documented in a log that includes the date of procurement,  
1812 ~~location of the donor,~~ and Donor ID.
- 1813 5. The physician must have observed at least 3 lung transplants. The observation of these  
1814 transplants must be documented in a log that includes the transplant date and medical record  
1815 number or other unique identifier that can be verified by the OPTN Contractor.
- 1816 6. The program has established and documented a consulting relationship with counterparts at  
1817 another lung transplant program.
- 1818 7. The transplant program submits activity reports to the OPTN Contractor every 2 months  
1819 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
1820 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
1821 efficient patient care at the program. The activity reports must also demonstrate that the  
1822 physician is making sufficient progress to meet the required involvement in the primary care  
1823 of 20 or more lung transplant recipients, or that the program is making sufficient progress in  
1824 recruiting a physician who meets all requirements for primary lung transplant physician by the  
1825 end of the 12 month conditional approval period.
- 1826 8. The following letters are submitted directly to the OPTN Contractor:
  - 1827 a. A letter from the supervising lung transplant physician or surgeon of the training program  
1828 documenting the physician's competence.
  - 1829 b. A letter of recommendation from the training program's primary physician and director  
1830 outlining the physician's overall qualifications to act as primary transplant physician of the  
1831 transplant program last served by the physician, as well as the physician's personal  
1832 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
1833 and any other matters judged appropriate. The MPSC may request additional  
1834 recommendation letters from the primary physician, primary surgeon, director, or others  
1835 affiliated with any transplant program previously served by the physician, at its discretion.
  - 1836 c. A letter from the physician that details the training and experience the physician has  
1837 gained in lung transplantation.

1838  
1839 The 12-month conditional approval period begins on the first approval date granted to the personnel  
1840 change application, whether it is an interim approval granted by the MPSC subcommittee, or  
1841 approval granted by the full MPSC. The conditional approval period ends exactly 12 months after  
1842 this first approval date of the personnel change application.

1843  
1844 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
1845 program that provides substantial evidence of progress toward fulfilling the requirements but is  
1846 unable to complete the requirements within one year.

1847  
1848 If the program is unable to demonstrate that it has an individual practicing on site who can meet



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1850  
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1852

the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the conditional approval period, it must inactivate. The requirements for transplant program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

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