

Mini-Brief

Clarification to Remove Donor Location from Required Procurement Log Information

OPTN/UNOS Membership and Professional Standards Committee

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Clarification to Remove Donor Location from Required Procurement Log Information

Affected Policies:

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), I.3.D (Conditional Approval for Primary Transplant Physician)

Sponsoring Committee:

Membership and Professional Standards

Executive Summary

The Bylaws unnecessarily require primary physician and primary surgeon applicants to include donor location information on procurement logs submitted with their application. Neither UNOS staff nor the MPSC require this information to process or evaluate applications. Removing the requirement from the bylaws will promote efficient management of the OPTN by ensuring the bylaws reflect current requirements and reducing the time members spend compiling information to submit with applications.

Because this clarification does not add any new member burdens, public comment is not required. Typically, policy clarifications are reviewed and approved by the Executive Committee however only the Board may approve changes to the Bylaws.

What problem will this proposal solve?

In response to an MPSC-sponsored public comment proposal to update the key personnel requirements for primary kidney transplant physicians, the American Society of Transplantation (AST) suggested that the MPSC remove the requirement for the “location of the donor” from the procurement log. AST noted that the information is very difficult to obtain once a fellow moves to a different transplant program. During its discussion of public comment responses, the MPSC agreed that the information is difficult to obtain and also noted that the information is not needed for their review of key personnel applications. The Committee supported removing “location of the donor” as it pertains to key personnel procurement logs not only in the applicable kidney physician sections, but also throughout the bylaws, including the applicable sections for the primary heart, liver, lung, intestine and pancreas physicians and surgeons. The MPSC felt that proposing this widespread change as a post public-comment change to the kidney physician proposal would be outside the intended scope of the kidney physician proposal and therefore inappropriate. Instead, the MPSC proposes this clarification for the OPTN/UNOS Board of Directors’ consideration. This clarification would ensure the bylaws do not include unnecessary requirements and would reduce the time and resources required for members to complete the application.

Why should you support this proposal?

During its discussions, the MPSC expressed its support for amending the bylaws through the clarification process. The MPSC Chair reviewed and approved the final language. Removing the requirement from the bylaws will promote efficient management of the OPTN by ensuring the bylaws reflect current requirements and reducing the time members spend compiling information to submit with applications.

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: There is no impact to this goal.
Improve equity in access to transplants: There is no impact to this goal.
Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.
Promote living donor and transplant recipient safety: There is no impact to this goal.
Promote the efficient management of the OPTN: This proposal will clarify which information members must obtain and submit with key personnel applications and will reduce the amount of time necessary for members to prepare application materials.

How will the OPTN implement this proposal?

Assuming the Board adopts these changes, members will be alerted through a policy notice. Staff will update the Frequently Asked Questions guide available for members completing key personnel applications to note that, for all applications received on or after the March 1, 2017, implementation date, donor location is no longer a required field. Staff will update the application forms to remove the donor location during the next regularly scheduled application form revision and approval process.

This proposal will not require programming in UNetSM.

How will members implement this proposal?

No actions are required of members to implement this proposal. Members that previously spent time researching donor location and including the information with key personnel applications will no longer need to do so.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection. Instead it lowers future data submission requirements.

How will members be evaluated for compliance with this proposal?

Members will not need to take any action to comply with this proposal. Members will be expected to review the applicable bylaws and to submit all information that continues to be required. For example, programs must continue to submit procurement logs containing the donor ID and procurement date for applicable primary physician and primary surgeon applications, even though donor location will no longer be required.

Policy or Bylaws Language

RESOLVED, that changes to 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), I.3.D (Conditional Approval for Primary Transplant Physician), as set forth below, are hereby approved, effective on March 1, 2017.

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.

43 **B. Clinical Experience Pathway**

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

- 47
- 48 1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as
49 primary surgeon or first assistant at a designated kidney transplant program. The transplants
50 must be documented in a log that includes the date of transplant, the role of the surgeon in
51 the procedure, and medical record number or other unique identifier that can be verified by
52 the OPTN Contractor. The log should be signed by the program director, division chief, or
53 department chair from the program where the experience was gained. Each year of the
54 surgeon's experience must be substantive and relevant and include pre-operative
55 assessment of kidney transplant candidates, performance of transplants as primary surgeon
56 or first assistant, and post-operative care of kidney recipients.
- 57 2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first
58 assistant. At least 10 of these procurements must be from deceased donors. These cases
59 must be documented in a log that includes the date of procurement, ~~location of the donor,~~
60 and Donor ID.
- 61 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
62 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
63 management of patients with end stage renal disease, the selection of appropriate recipients
64 for transplantation, donor selection, histocompatibility and tissue typing, performing the
65 transplant operation, immediate postoperative and continuing inpatient care, the use of
66 immunosuppressive therapy including side effects of the drugs and complications of
67 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
68 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
69 dysfunction, and long term outpatient care.
- 70 4. The following letters are submitted directly to the OPTN Contractor:
 - 71 a. A letter from the director of the transplant program and Chairman of the department or
72 hospital credentialing committee verifying that the surgeon has met the above
73 qualifications and is qualified to direct a kidney transplant program.
 - 74 b. A letter of recommendation from the primary surgeon and transplant program director at
75 the transplant program last served by the surgeon outlining the surgeon's overall
76 qualifications to act as a primary transplant surgeon, as well as the surgeon's personal
77 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
78 and compliance protocols, and any other matters judged appropriate. The MPSC may
79 request additional recommendation letters from the primary physician, primary surgeon,

- 80 director, or others affiliated with any transplant program previously served by the
81 surgeon, at its discretion.
82 c. A letter from the surgeon that details the training and experience the surgeon has gained
83 in kidney transplantation.
84

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

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

87 Physicians can meet the training requirements for a primary kidney transplant physician during a
88 separate 12-month transplant nephrology fellowship if the following conditions are met:
89

- 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.

135
136 The training requirements outlined above are in addition to other clinical requirements for general
137 nephrology training.

138
139 **B. Clinical Experience Pathway**

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

- 142
143 1. The physician has been directly involved in the primary care of 45 or more newly transplanted
144 kidney recipients and continued to follow these recipients for a minimum of 3 months from the
145 time of transplant. This patient care must have been provided over a 2 to 5-year period on an
146 active kidney transplant service as the primary kidney transplant physician or under the direct
147 supervision of a qualified transplant physician and in conjunction with a kidney transplant
148 surgeon at a designated kidney transplant program. The care must be documented in a log
149 that includes the date of transplant and recipient medical record number or other unique
150 identifier that can be verified by the OPTN Contractor. The recipient log should be signed by
151 the program director, division Chief, or department Chair from the program where the
152 physician gained this experience.
- 153 2. The physician has maintained a current working knowledge of kidney transplantation, defined
154 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
155 management of patients with end stage renal disease, the selection of appropriate recipients
156 for transplantation, donor selection, histocompatibility and tissue typing, immediate
157 postoperative patient care, the use of immunosuppressive therapy including side effects of
158 the drugs and complications of immunosuppression, differential diagnosis of renal
159 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
160 interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
- 161 3. The physician must have observed at least 3 kidney procurements, including at least 1
162 deceased donor and 1 living donor. The physician must have observed the evaluation,
163 donation process, and management of these donors. These observations must be
164 documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor
165 ID.
- 166 4. The physician must have observed at least 3 kidney transplants. The observation of these
167 transplants must be documented in a log that includes the transplant date, donor type, and
168 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 169 5. The following letters are submitted directly to the OPTN Contractor:
- 170 a. A letter from the qualified transplant physician or the kidney transplant surgeon who has
171 been directly involved with the proposed physician documenting the physician's
172 experience and competence.
- 173 b. A letter of recommendation from the primary physician and transplant program director at
174 the transplant program last served by the physician outlining the physician's overall

175 qualifications to act as a primary transplant physician, as well as the physician's personal
176 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
177 and compliance protocols, and any other matters judged appropriate. The MPSC may
178 request additional recommendation letters from the primary physician, primary surgeon,
179 director, or others affiliated with any transplant program previously served by the
180 physician, at its discretion.

181 c. A letter from the physician that details the training and experience the physician has
182 gained in kidney transplantation.

183
184

C. Three-year Pediatric Nephrology Fellowship Pathway

185 A physician can meet the requirements for primary kidney transplant physician by completion of 3
186 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:

190

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**
242

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:

- 245
- 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.

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.

353
354 **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.

409
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.

414
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.

418
 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.
 423

424 **E.5 Kidney Transplant Programs that Register Candidates** 425 **Less than 18 Years Old**

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

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

- 429
- 430 1. The program has a qualified primary pediatric kidney physician who meets *all* of the
 431 requirements described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician*
 432 *Requirements* and a surgeon who meets *all* of the following requirements:
 433
 - 434 a. The surgeon meets all of the requirements described in Section E.2 Primary Kidney
 435 Transplant Surgeon Requirements, including completion of at least one of the following
 436 training or experience pathways:
 - 437 ■ The formal 2-year transplant fellowship pathway as described in *Section E.2.A.*
 438 *Formal 2-year Transplant Fellowship Pathway*
 - 439 ■ The kidney transplant program clinical experience pathway, as described in *Section*
 440 *E.2.B. Clinical Experience Pathway*
 - 441 b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first
 442 assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these
 443 kidney transplants must have been in recipients less than 6 years old or weighing less
 444 than 25 kilograms at the time of transplant. These transplants must have been performed
 445 during or after fellowship, or across both periods. These transplants must be documented
 446 in a log that includes the date of transplant, the recipient's date of birth, the recipient's
 447 weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure,
 448 and the medical record number or other unique identifier that can be verified by the
 449 OPTN Contractor.
 - 450 c. The surgeon has maintained a current working knowledge of pediatric kidney
 451 transplantation, defined as direct involvement in pediatric kidney transplant patient care in
 452 the last 2 years. This includes the management of pediatric patients with end stage renal
 453 disease, the selection of appropriate pediatric recipients for transplantation, donor
 454 selection, histocompatibility and HLA typing, performing the pediatric transplant
 455 operation, immediate postoperative and continuing inpatient care, the use of
 456 immunosuppressive therapy including side effects of the drugs and complications of
 457 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
 458 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
 459 dysfunction, and long term outpatient care.
 - 460 2. The program has a qualified primary pediatric kidney surgeon who meets *all* of the
 461 requirements described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon*
 462 *Requirements* and a physician who meets *all* of the following requirements:
 463
 - 464 a. The physician has current board certification in pediatric nephrology by the American
 465 Board of Pediatrics or the foreign equivalent, or is approved by the American Board of
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- 468 Pediatrics to take the certifying exam.
- 469 b. The physician gained a minimum of 2 years of experience during or after fellowship, or
- 470 accumulated during both periods, at a kidney transplant program.
- 471 c. During the 2 or more years of accumulated experience, the physician was directly
- 472 involved in the primary care of 5 or more newly transplanted kidney recipients and
- 473 followed 15 newly transplanted kidney recipients for at least 6 months from the time of
- 474 transplant, under the direct supervision of a qualified kidney transplant physician, along
- 475 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 A designated kidney transplant program's conditional approval for a pediatric component is

515 valid for a maximum of 24 months.

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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:

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1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated liver 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 liver transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative management of liver recipients.
 2. The surgeon has performed at least 30 liver procurements as primary surgeon or first assistant. 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 liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver 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 liver dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
 4. The following letters are sent 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 requirements, and is qualified to direct a liver 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 primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and 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 gained in liver transplantation.

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:
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1. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program. The training must have included at least 3 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ 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**

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**

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

- 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.

749
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

861 **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:
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- 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.

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 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.

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.

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

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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:

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- 1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel and composite grafts and must perform 3 or more intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine 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 must be signed by the program director, division chief, or department chair from the program where the experience or training was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.

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- 2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first assistant. These procurements must include at least 1 procurement of a graft that includes a liver. This procedure must be documented in a log that includes the date of procurement, ~~location of the donor,~~ and Donor ID.

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- 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 dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
- 4. The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.

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- 5. The following letters are sent to the OPTN Contractor:
 - a. A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine transplant program.

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- 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 primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician, 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 gained in intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
 - d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

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G.2 Primary Pancreas Transplant Surgeon Requirements

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A. Formal 2-year Transplant Fellowship Pathway

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

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1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant. 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 must be signed by the director of the 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.

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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.

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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.

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5. The following letters are submitted directly to the OPTN Contractor:

- 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.
- 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.
- A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

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B. Clinical Experience Pathway

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Surgeons can meet the requirements for primary pancreas 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 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.
 2. The surgeon has performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements 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 pancreas transplantation, defined as direct involvement in pancreas transplant 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 pancreatic dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic 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 requirements and is qualified to direct a pancreas transplant program.
 - b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon 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 individual, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

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:

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

- 1167 laboratory, on another solid organ transplant service, or conducting basic or clinical transplant
1168 research.
- 1169 2. During the fellowship period, the physician was directly involved in the primary care of 8 or
1170 more newly transplanted pancreas recipients and followed these recipients for a minimum of
1171 3 months from the time of transplant. The care must be documented in a log that includes the
1172 date of transplant and medical record number or other unique identifier that can be identified
1173 by the OPTN Contractor. This recipient log must be signed by the director of the training
1174 program or the transplant program's primary transplant physician.
- 1175 3. The physician has maintained a current working knowledge of pancreas transplantation,
1176 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
1177 includes the management of patients with end stage pancreas disease, the selection of
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.

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:

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

1309
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.

1318

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

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A. Cardiothoracic Surgery Residency Pathway

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Surgeons can meet the training requirements for primary heart transplant surgeon by completing
1327 a cardiothoracic surgery residency if *all* the following conditions are met:

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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.

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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.
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:

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

- 1409 was gained. Transplants performed during board qualifying surgical residency or fellowship
1410 do not count.
- 1411 2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon
1412 or first assistant under the supervision of a qualified heart transplant surgeon. These
1413 procedures must be documented in a log that includes the date of procurement, ~~location of~~
1414 ~~the donor,~~ and Donor ID.
- 1415 3. The surgeon has maintained a current working knowledge of all aspects of heart
1416 transplantation, defined as a direct involvement in heart transplant patient care within the last
1417 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.
1433

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

1478 A physician can meet the requirements for primary heart transplant physician through acquired
1479 clinical experience if the following conditions are met.
1480

- 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
1518 **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

- 1523 1. The physician has 12 months experience on an active heart transplant service as the primary
1524 heart transplant physician or under the direct supervision of a qualified heart transplant
1525 physician and in conjunction with a heart transplant surgeon at a designated heart transplant
1526 program. These 12 months of experience must be acquired within a 2-year period.
1527 2. The physician has maintained a current working knowledge of heart transplantation, defined
1528 as direct involvement in heart transplant patient care within the last 2 years. This includes
1529 knowledge of acute and chronic heart failure, donor selection, the use of mechanical
1530 circulatory support devices, recipient selection, pre- and post-operative hemodynamic care,
1531 post-operative immunosuppressive therapy, histological interpretation in grading of
1532 myocardial biopsies for rejection, and long-term outpatient follow-up.
1533 3. The physician has been involved in the primary care of 10 or more newly transplanted heart
1534 or heart/lung transplant recipients as the heart transplant physician or under the direct
1535 supervision of a qualified heart transplant physician or in conjunction with a heart transplant
1536 surgeon at a designated heart transplant program. The physician will have followed these
1537 patients for a minimum of 3 months from the time of transplant. This care must be
1538 documented in a log that includes the date of transplant and medical record or other unique
1539 identifier that can be verified by the OPTN Contractor. This recipient log should be signed by
1540 the program director or the primary transplant physician at the transplant program where the
1541 physician gained experience.
1542 4. The physician must have observed at least 3 heart procurements. The physician must have
1543 observed the evaluation, donation process, and management of these donors. These
1544 observations must be documented in a log that includes the date of procurement, ~~location of~~
1545 ~~the donor,~~ and Donor ID.
1546 5. The physician must have observed at least 3 heart transplants. The observation of these
1547 transplants must be documented in a log that includes the transplant date and medical record
1548 number or other unique identifier that can be verified by the OPTN Contractor.
1549 6. The program has established and documented a consulting relationship with counterparts at
1550 another heart transplant program.
1551 7. The transplant program submits activity reports to the OPTN Contractor every 2 months
1552 describing the transplant activity, transplant outcomes, physician recruitment efforts, and

1553 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
1554 efficient patient care at the program. The activity reports must also demonstrate that the
1555 physician is making sufficient progress to meet the required involvement in the primary care
1556 of 20 or more heart transplant recipients, or that the program is making sufficient progress in
1557 recruiting a physician who meets all requirements for primary heart transplant physician by
1558 the end of the 12 month conditional approval period.

- 1559 8. The following letters are submitted directly to the OPTN Contractor:
- 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.

1572
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.

1581
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:

- 1591 1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or
1592 heart/lung transplants as primary surgeon or first assistant under the direct supervision of a
1593 qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung
1594 transplant program. At least half of these transplants must be lung procedures. These
1595 transplants must be documented in a log that includes the date of transplant, role of the
1596 surgeon in the procedure, and medical record number or other unique identifier that can be
1597 verified by the OPTN Contractor. This log must be signed by the director of the training
1598 program.
- 1599 2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant
1600 under the supervision of a qualified lung transplant surgeon. These procurements must have
1601

- 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.

1628

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:

- 1632
- 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.
- 1666
- 1667

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:

1670

- 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.
1702

1703 **1.3 Primary Lung Transplant Physician Requirements**

1704 **A. Twelve-month Transplant Pulmonary Fellowship Pathway**

1705 Physicians can meet the training requirements for primary lung transplant physician during a 12-
1706 month transplant pulmonary fellowship if the following conditions are met:
1707

- 1708 1. The physician was directly involved in the primary and follow-up care of at least 15 newly
1709 transplanted lung or heart/lung recipients. This training will have been under the direct
1710 supervision of a qualified lung transplant physician and in conjunction with a lung transplant
1711 surgeon. At least half of these patients must be single or double-lung transplant recipients.
1712 This care must be documented in a log that includes the date of transplant and the medical
1713 record number or other unique identifier that can be verified by the OPTN Contractor. This
1714 recipient log must be signed by the director of the training program or the primary transplant
1715 physician at the transplant program.
- 1716 2. The physician has maintained a current working knowledge of all aspects of lung
1717 transplantation, defined as a direct involvement in lung transplant patient care within the last
1718 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
1719 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
1720 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
1721 rejection, and long-term outpatient follow-up.
- 1722 3. The physician must have observed at least 3 lung or heart/lung procurements. The physician
1723 must have observed the evaluation, donation process, and management of these donors.
1724 These observations must be documented in a log that includes the date of procurement,
1725 ~~location of the donor,~~ and Donor ID.
- 1726 4. The physician must have observed at least 3 lung transplants. The observation of these
1727 transplants must be documented in a log that includes the transplant date and medical record
1728 number or other unique identifier that can be verified by the OPTN Contractor.
- 1729 5. This training was completed at a hospital with an American Board of Internal Medicine
1730 certified fellowship training program in adult pulmonary medicine, an American Board of
1731 Pediatrics-certified fellowship training program in pediatric medicine, or a pulmonary medicine
1732 training program approved by the Royal College of Physicians and Surgeons of Canada.
- 1733 6. The following letters are submitted directly to the OPTN Contractor:
 - 1734 a. A letter from the director of the training program verifying that the physician has met the
1735 above requirements and is qualified to direct a lung transplant program.
 - 1736 b. A letter of recommendation from the training program's primary physician and transplant
1737 program director outlining the physician's overall qualifications to act as primary
1738 transplant physician, as well as the physician's personal integrity, honesty, and familiarity
1739 with and experience in adhering to OPTN obligations, and any other matters judged
1740 appropriate. The MPSC may request additional recommendation letters from the primary
1741 physician, primary surgeon, director, or others affiliated with any transplant program
1742 previously served by the physician, at its discretion.

- 1743 c. A letter from the physician that details the training and experience the physician has
1744 gained in lung transplantation.

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1746

B. Clinical Experience Pathway

1747 A physician can meet the requirements for primary lung transplant physician through acquired
1748 clinical experience if the following conditions are met.

1749

- 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.

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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
1849 the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the conditional
1850 approval period, it must inactivate. The requirements for transplant program inactivation are
1851 described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these
1852 Bylaws.

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