

OPTN/UNOS Policy Notice

Updating Primary Kidney Transplant Physician Requirements

Sponsoring Committee: Membership and Professional Standards
Policy/Bylaws Affected: E.3 (Primary Kidney Transplant Physician Requirements)
Public Comment: August 2016
Effective Date: Pending implementation and notice to members

Problem Statement

Although fellowship training requirements generally serve as the foundation for key personnel requirements in the OPTN/UNOS Bylaws, the primary transplant kidney physician pathways do not reflect some options and standards currently associated with transplant nephrology fellowships.

Summary of Changes

These Bylaws changes will align primary kidney transplant physician requirements with transplant nephrology fellowship requirements. With the exception of requiring a certain number of kidney biopsies and observing a living donor kidney transplant, the changes incorporate all other relevant requirements that transplant programs must continually meet to be accredited by the Transplant Nephrology Fellowship Training Accreditation Program. The most significant element of these changes is modifying Appendix E.3.A so that it will accommodate transplant nephrology fellows who opt to complete their fellowship through the Transplant Nephrology Fellowship Training Accreditation Program's alternative pathway.

What Members Need to Do

No immediate action will be required of members when we implement these changes. After implementation, we will evaluate any membership and key personnel change applications we receive from kidney programs based on the changes.

Affected Policy Language:

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

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

2 A designated kidney transplant program must have a primary physician who meets *all* the following
3 requirements:

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5 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
6 license to practice medicine in the hospital's state or jurisdiction.

7 2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.

8 3. The physician must have documentation from the hospital credentialing committee that it has verified
9 the physician's state license, board certification, training, and transplant continuing medical education
10 and that the physician is currently a member in good standing of the hospital's medical staff.

- 11 4. The physician must have current certification in nephrology by the American Board of Internal
12 Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of
13 Canada.

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15 In place of current certification in nephrology by the American Board of Internal Medicine, the
16 American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the
17 physician must:

- 18
19 a. Be ineligible for American board certification.
20 b. Provide a plan for continuing education that is comparable to American board maintenance of
21 certification. This plan must at least require that the physician obtains 60 hours of Category I
22 continuing medical education (CME) credits with self-assessment that are relevant to the
23 individual's practice every three years. Self-assessment is defined as a written or electronic
24 question-and-answer exercise that assesses understanding of the material in the CME program.
25 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
26 an acceptable self-assessment score are allowed. The transplant hospital must document
27 completion of this continuing education.
28 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
29 transplant programs not employed by the applying hospital. These letters must address:
30 i. Why an exception is reasonable.
31 ii. The physician's overall qualifications to act as a primary kidney transplant physician.
32 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
33 OPTN obligations and compliance protocols.
34 iv. Any other matters judged appropriate.

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

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46 5. The physician must have completed at least one of the pathways listed below:
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48 a. The ~~12-month~~ transplant nephrology fellowship pathway, as described in *Section E.3.A. Twelve-*
49 *month Transplant Nephrology Fellowship Pathway* below.
50 b. The clinical experience pathway, as described in *Section E.3.B. Clinical Experience Pathway*
51 below.
52 c. The 3-year pediatric nephrology fellowship pathway, as described in *Section E.3.C. Three-year*
53 *Pediatric Nephrology Fellowship Pathway* below.
54 d. The 12-month pediatric transplant nephrology fellowship pathway, as described in *Section E.3.D.*
55 *Twelve-month Pediatric Transplant Nephrology Fellowship Pathway* below.
56 e. The combined pediatric nephrology training and experience pathway, as described in *Section*
57 *E.3.E. Combined Pediatric Nephrology Training and Experience Pathway* below.
58 f. The conditional approval pathway, as described in *Section E.3.F. Conditional Approval for*
59 *Primary Transplant Physician* below, if the primary kidney transplant physician changes at an
60 approved kidney transplant program.
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A. ~~Twelve-month~~ Transplant Nephrology Fellowship Pathway

Physicians can meet the training requirements for a primary kidney transplant physician during a separate ~~42-month~~ transplant nephrology fellowship if the following conditions are met:

1. The physician completed at least 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 or more transplants each year. The training must have included at least 6 months of clinical inpatient 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.
2. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued ~~to~~ the outpatient follow-up of these recipients for a minimum of 3 months from the time of transplant. If the physician's fellowship was longer than 12 months, the physician also must have been directly involved in the outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive months. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
3. During the fellowship period, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program's primary transplant physician.
4. During the fellowship period, the physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the director of the training program or the transplant program's primary transplant physician.
- ~~3-5.~~ The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
- 4~~6~~. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

- 110 57. The physician must have observed at least 3 kidney transplants. The observation of these
111 transplants must be documented in a log that includes the transplant date, donor type, and
112 medical record number or other unique identifier that can be verified by the OPTN Contractor.
113 68. The following letters are submitted directly to the OPTN Contractor:
114 a. A letter from the director of the training program and the supervising qualified kidney
115 transplant physician verifying that the physician has met the above requirements and is
116 qualified to direct a kidney transplant program.
117 b. A letter of recommendation from the fellowship training program's primary physician and
118 transplant program director outlining the physician's overall qualifications to act as a
119 primary transplant physician, as well as the physician's personal integrity, honesty, and
120 familiarity with and experience in adhering to OPTN obligations and compliance
121 protocols, and any other matters judged appropriate. The MPSC may request additional
122 recommendation letters from the primary physician, primary surgeon, director, or others
123 affiliated with any transplant program previously served by the physician, at its discretion.
124 c. A letter from the physician that details the training and experience the physician has
125 gained in kidney transplantation.

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

131 A physician can meet the requirements for a primary kidney transplant physician through
132 acquired clinical experience if the following conditions are met:
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- 134 1. The physician has been directly involved in the primary care of 45 or more newly transplanted
135 kidney recipients and continued ~~to~~ the outpatient follow-up of these recipients for a minimum
136 of 3 months from the time of transplant. This patient care must have been provided over a 2
137 to 5-year period on an active kidney transplant service as the primary kidney transplant
138 physician or under the direct supervision of a qualified transplant physician and in conjunction
139 with a kidney transplant surgeon at a designated kidney transplant program. The care must
140 be documented in a log that includes the date of transplant and recipient medical record
141 number or other unique identifier that can be verified by the OPTN Contractor. The recipient
142 log should be signed by the program director, division Chief, or department Chair from the
143 program where the physician gained this experience.
144 2. The physician was directly involved in the evaluation of 25 potential kidney recipients,
145 including participation in selection committee meetings. These potential kidney recipient
146 evaluations must be documented in a log that includes each evaluation date and is signed by
147 the program director, division Chief, or department Chair from the program where the
148 physician gained this experience.
149 3. The physician was directly involved in the evaluation of 10 potential living kidney donors,
150 including participation in selection committee meetings. These potential living kidney donor
151 evaluations must be documented in a log that includes each evaluation date and the potential
152 living kidney donor's medical record number or other unique identifier than can be verified by
153 the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the
154 program director, division Chief, or department Chair from the program where the physician
155 gained this experience.
156 24. The physician has maintained a current working knowledge of kidney transplantation, defined
157 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
158 management of patients with end stage renal disease, the selection of appropriate recipients

- 159 for transplantation, donor selection, histocompatibility and tissue typing, immediate
160 postoperative patient care, the use of immunosuppressive therapy including side effects of
161 the drugs and complications of immunosuppression, differential diagnosis of renal
162 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
163 interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
- 164 35. The physician must have observed at least 3 kidney procurements, including at least 1
165 deceased donor and 1 living donor. The physician must have observed the evaluation,
166 donation process, and management of these donors. These observations must be
167 documented in a log that includes the date of procurement, location of the donor, and Donor
168 ID.
- 169 46. The physician must have observed at least 3 kidney transplants. The observation of these
170 transplants must be documented in a log that includes the transplant date, donor type, and
171 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 172 57. The following letters are submitted directly to the OPTN Contractor:
- 173 a. A letter from the qualified transplant physician or the kidney transplant surgeon who has
174 been directly involved with the proposed physician documenting the physician's
175 experience and competence.
- 176 b. A letter of recommendation from the primary physician and transplant program director at
177 the transplant program last served by the physician outlining the physician's overall
178 qualifications to act as a primary transplant physician, as well as the physician's personal
179 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
180 and compliance protocols, and any other matters judged appropriate. The MPSC may
181 request additional recommendation letters from the primary physician, primary surgeon,
182 director, or others affiliated with any transplant program previously served by the
183 physician, at its discretion.
- 184 c. A letter from the physician that details the training and experience the physician has
185 gained in kidney transplantation.

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

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

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- 194 1. During the 3-year training period the physician was directly involved in the primary care of 10
195 or more newly transplanted kidney recipients for at least 6 months from the time of transplant
196 and followed 30 ~~newly~~ transplanted kidney recipients for at least 6 months ~~from the time of~~
197 ~~transplant~~, under the direct supervision of a qualified kidney transplant physician and in
198 conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program
199 director may elect to have a portion of the transplant experience completed at another kidney
200 transplant program in order to meet these requirements. This care must be documented in a
201 log that includes the date of transplant, and the recipient medical record number or other
202 unique identifier that can be verified by the OPTN Contractor. This recipient log must be
203 signed by the training program's director or the primary physician of the transplant program.
- 204 2. The experience caring for pediatric patients occurred with a qualified kidney transplant
205 physician and surgeon at a kidney transplant program that performs an average of at least 10
206 pediatric kidney transplants a year.

- 207 3. During the fellowship period, the physician was directly involved in the evaluation of 25
208 potential kidney recipients, including participation in selection committee meetings. These
209 potential kidney recipient evaluations must be documented in a log that includes each
210 evaluation date and is signed by the director of the training program or the transplant
211 program's primary transplant physician.
- 212 34. The physician has maintained a current working knowledge of kidney transplantation, defined
213 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
214 management of pediatric patients with end-stage renal disease, the selection of appropriate
215 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
216 immediate post-operative care including those issues of management unique to the pediatric
217 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
218 pediatric recipient including side-effects of drugs and complications of immunosuppression,
219 the effects of transplantation and immunosuppressive agents on growth and development,
220 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
221 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
222 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
223 recipients including management of hypertension, nutritional support, and drug dosage,
224 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
225 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
- 226 45. The physician must have observed at least 3 kidney procurements, including at least 1
227 deceased donor and 1 living donor. The physician must have observed the evaluation,
228 donation process and management of these donors. These observations must be
229 documented in a log that includes the date of procurement, location of the donor, and Donor
230 ID.
- 231 56. The physician must have observed at least 3 kidney transplants involving a pediatric
232 recipient. The observation of these transplants must be documented in a log that includes the
233 transplant date, donor type, and medical record number or other unique identifier that can be
234 verified by the OPTN Contractor.
- 235 67. The following letters are submitted directly to the OPTN Contractor:
- 236 a. A letter from the director and the supervising qualified transplant physician and surgeon
237 of the fellowship training program verifying that the physician has met the above
238 requirements and is qualified to direct a kidney transplant program.
- 239 b. A letter of recommendation from the fellowship training program's primary physician and
240 transplant program director outlining the physician's overall qualifications to act as a
241 primary transplant physician, as well as the physician's personal integrity, honesty, and
242 familiarity with and experience in adhering to OPTN obligations, and any other matters
243 judged appropriate. The MPSC may request additional recommendation letters from the
244 primary physician, primary surgeon, director, or others affiliated with any transplant
245 program previously served by the physician, at its discretion.
- 246 c. A letter from the physician that details the training and experience the physician has
247 gained in kidney transplantation.

249 **D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway**

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

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- 253 1. The physician has current board certification in pediatric nephrology by the American Board
254 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
255 the American Board of Pediatrics to take the certifying exam.
- 256 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
257 newly transplanted kidney recipients for at least 6 months from the time of transplant and
258 followed 30 ~~newly~~ transplanted kidney recipients for at least 6 months ~~from the time of~~
259 ~~transplant~~, under the direct supervision of a qualified kidney transplant physician and in
260 conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program
261 director may elect to have a portion of the transplant experience completed at another kidney
262 transplant program in order to meet these requirements. This care must be documented in a
263 recipient log that includes the date of transplant, and the recipient medical record number or
264 other unique identifier that can be verified by the OPTN Contractor. This log must be signed
265 by the training program director or the primary physician of the transplant program.
- 266 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a
267 qualified kidney transplant physician and surgeon that performs an average of at least 10
268 pediatric kidney transplants a year.
- 269 4. During the four years that include the physician's three-year pediatric nephrology fellowship
270 and twelve-month pediatric transplant nephrology fellowship, the physician was directly
271 involved in the evaluation of 25 potential kidney recipients, including participation in selection
272 committee meetings. These potential kidney recipient evaluations must be documented in a
273 log that includes each evaluation date and is signed by the director of the training program or
274 the transplant program's primary transplant physician.
- 275 45. The physician has maintained a current working knowledge of kidney transplantation, defined
276 as direct involvement in kidney transplant patient care in the past 2 years. This includes the
277 management of pediatric patients with end-stage renal disease, the selection of appropriate
278 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
279 immediate post-operative care including those issues of management unique to the pediatric
280 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
281 pediatric recipient including side-effects of drugs and complications of immunosuppression,
282 the effects of transplantation and immunosuppressive agents on growth and development,
283 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
284 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
285 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
286 recipients including management of hypertension, nutritional support, and drug dosage,
287 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
288 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
- 289 56. The physician must have observed at least 3 kidney procurements, including at least 1
290 deceased donor and 1 living donor. The physician must have observed the evaluation,
291 donation process, and management of these donors. These observations must be
292 documented in a log that includes the date of procurement, location of the donor, and Donor
293 ID.
- 294 67. The physician must have observed at least 3 kidney transplants involving a pediatric
295 recipient. The observation of these transplants must be documented in a log that includes the
296 transplant date, donor type, and medical record number or other unique identifier that can be
297 verified by the OPTN Contractor.
- 298 78. The following letters are submitted directly to the OPTN Contractor:
299 a. A letter from the director and the supervising qualified transplant physician and surgeon
300 of the fellowship training program verifying that the physician has met the above

- 301 requirements and is qualified to become the primary transplant physician of a designated
302 kidney transplant program.
- 303 b. A letter of recommendation from the fellowship training program's primary physician and
304 transplant program director outlining the physician's overall qualifications to act as a
305 primary transplant physician, as well as the physician's personal integrity, honesty, and
306 familiarity with and experience in adhering to OPTN obligations, and any other matters
307 judged appropriate. The MPSC may request additional recommendation letters from the
308 primary physician, primary surgeon, director, or others affiliated with any transplant
309 program previously served by the physician, at its discretion.
- 310 c. A letter from the physician that details the training and experience the physician has
311 gained in kidney transplantation.

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

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

- 316
- 317 1. The physician has current board certification in pediatric nephrology by the American Board
318 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
319 the American Board of Pediatrics to take the certifying exam.
 - 320 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
321 accumulated during both periods, at a kidney transplant program.
 - 322 3. During the 2 or more years of accumulated experience, the physician was directly involved in
323 the primary care of 10 or more newly transplanted kidney recipients for at least 6 months
324 from the time of transplant and followed 30 ~~newly~~ transplanted kidney recipients for at least 6
325 months ~~from the time of transplant~~, under the direct supervision of a qualified kidney
326 transplant physician, along with a qualified kidney transplant surgeon. This care must be
327 documented in a recipient log that includes the date of transplant, and the recipient medical
328 record number or other unique identifier that can be verified by the OPTN Contractor. This log
329 must be signed by the training program director or the primary physician of the transplant
330 program.
 - 331 4. The physician was directly involved in the evaluation of 25 potential kidney recipients,
332 including participation in selection committee meetings. These potential kidney recipient
333 evaluations must is documented in a log that includes each evaluation date and be signed by
334 the program director, division Chief, or department Chair from the program where the
335 physician gained this experience.
 - 336 45. The physician has maintained a current working knowledge of kidney transplantation, defined
337 as direct involvement in kidney transplant patient care during the past 2 years. This includes
338 the management of pediatric patients with end-stage renal disease, the selection of
339 appropriate pediatric recipients for transplantation, donor selection, histocompatibility and
340 tissue typing, immediate post-operative care including those issues of management unique to
341 the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive
342 therapy in the pediatric recipient including side-effects of drugs and complications of
343 immunosuppression, the effects of transplantation and immunosuppressive agents on growth
344 and development, differential diagnosis of renal dysfunction in the allograft recipient,
345 manifestation of rejection in the pediatric patient, histological interpretation of allograft
346 biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care
347 of pediatric allograft recipients including management of hypertension, nutritional support,
348 and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining

- 349 this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the
350 ACGME or a Residency Review Committee.
- 351 56. The physician must have observed at least 3 kidney procurements, including at least 1
352 deceased donor and 1 living donor. The physician must have observed the evaluation,
353 donation process, and management of these donors. These observations must be
354 documented in a log that includes the date of procurement, location of the donor, and Donor
355 ID.
- 356 67. The physician must have observed at least 3 kidney transplants involving a pediatric
357 recipient. The observation of these transplants must be documented in a log that includes the
358 transplant date, donor type, and medical record number or other unique identifier that can be
359 verified by the OPTN Contractor.
- 360 78. The following letters are submitted directly to the OPTN Contractor:
- 361 a. A letter from the supervising qualified transplant physician and surgeon who were directly
362 involved with the physician documenting the physician's experience and competence.
- 363 b. A letter of recommendation from the fellowship training program's primary physician and
364 transplant program director outlining the physician's overall qualifications to act as a
365 primary transplant physician, as well as the physician's personal integrity, honesty, and
366 familiarity with and experience in adhering to OPTN obligations, and any other matters
367 judged appropriate. The MPSC may request additional recommendation letters from the
368 primary physician, primary surgeon, Director, or others affiliated with any transplant
369 program previously served by the physician, at its discretion.
- 370 c. A letter from the physician that details the training and experience the physician has
371 gained in kidney transplantation.

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

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374 If the primary kidney transplant physician changes at an approved kidney transplant program, a
375 physician can serve as the primary kidney transplant physician for a maximum of 12 months if the
376 following conditions are met:

- 377
- 378 1. The physician has been involved in the primary care of 23 or more newly transplanted kidney
379 recipients, and has ~~followed~~ continued the outpatient follow-up of these patients for at least 3
380 months from the time of their transplant. This care must be documented in a recipient log that
381 includes the date of transplant and the medical record number or other unique identifier that
382 can be verified by the OPTN Contractor. This log must be signed by the program director,
383 division chief, or department chair from the transplant program where the experience was
384 gained.
 - 385 2. The physician was directly involved in the evaluation of 25 potential kidney recipients,
386 including participation in selection committee meetings. These potential kidney recipient
387 evaluations must be documented in a log that includes each evaluation date and is signed by
388 the program director, division Chief, or department Chair from the program where the
389 physician gained this experience.
 - 390 3. The physician was directly involved in the evaluation of 10 potential living kidney donors,
391 including participation in selection committee meetings. These potential living kidney donor
392 evaluations must be documented in a log that includes each evaluation date and the potential
393 living kidney donor's medical record number or other unique identifier than can be verified by
394 the OPTN Contractor. This potential living kidney donor log must and be signed by program
395 director, division Chief, or department Chair from the program where the physician gained
396 this experience.

- 397 24. The physician has maintained a current working knowledge of kidney transplantation, defined
398 as direct involvement in kidney transplant patient care during the last 2 years. This includes
399 the management of patients with end stage renal disease, the selection of appropriate
400 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate
401 postoperative patient care, the use of immunosuppressive therapy including side effects of
402 the drugs and complications of immunosuppression, differential diagnosis of renal
403 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
404 interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
- 405 35. The physician has 12 months experience on an active kidney inpatient transplant service as
406 the primary kidney transplant physician or under the direct supervision of a qualified kidney
407 transplant physician and in conjunction with a kidney transplant surgeon at a designated
408 kidney transplant program. These 12 months of experience must be acquired within a 2-year
409 period.
- 410 46. The physician must have observed at least 3 kidney procurements, including at least 1
411 deceased donor and 1 living donor. The physician must have observed the evaluation,
412 donation process, and management of these donors. These observations must be
413 documented in a log that includes the date of procurement, location of the donor, and Donor
414 ID.
- 415 57. The physician must have observed at least 3 kidney transplants. The observation of these
416 transplants must be documented in a log that includes the transplant date, donor type, and
417 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 418 68. The program has established and documented a consulting relationship with counterparts at
419 another kidney transplant program.
- 420 79. The transplant program submits activity reports to the OPTN Contractor every 2 months
421 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
422 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
423 efficient patient care at the program. The activity reports must also demonstrate that the
424 physician is making sufficient progress to meet the required involvement in the primary care
425 of 45 or more kidney transplant recipients, or that the program is making sufficient progress in
426 recruiting a physician who meets all requirements for primary kidney transplant physician and
427 who will be on site and approved by the MPSC to assume the role of primary physician by the
428 end of the 12 month conditional approval period.
- 429 810. The following letters are submitted directly to the OPTN Contractor:
- 430 a. A letter from the supervising qualified transplant physician and surgeon who were directly
431 involved with the physician documenting the physician's experience and competence.
- 432 b. A letter of recommendation from the primary physician and director at the transplant
433 program last served by the physician outlining the physician's overall qualifications to act
434 as a primary transplant physician, as well as the physician's personal integrity, honesty,
435 and familiarity with and experience in adhering to OPTN obligations, and any other
436 matters judged appropriate. The MPSC may request additional recommendation letters
437 from the primary physician, primary surgeon, director, or others affiliated with any
438 transplant program previously served by the physician, at its discretion.
- 439 c. A letter from the physician that details the training and experience the physician has
440 gained in kidney transplantation.

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

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

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections E.3.A through E.3.F* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

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