

OPTN/UNOS Policy Notice - Subspecialty Board Certification for Primary Liver and Heart Transplant Physicians

Sponsoring Committee:	Membership and Professional Standards
Bylaws Affected:	OPTN Bylaws Appendices F.4 (Primary Liver Transplant Physician Requirements), F.4.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.4.D (Pediatric Transplant Hepatology Fellowship Pathway), F.4.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway), and H.3 (Primary Heart Transplant Physician Requirements)
Public Comment:	August – October 2016
Effective Date:	March 1, 2017

Problem Statement

OPTN/UNOS Bylaws require a liver transplant program's designated primary physician applicants to be board certified in gastroenterology. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) is increasingly receiving key personnel applications from liver programs where a proposed primary transplant physician meets all the Bylaws' requirements but is board certified in transplant hepatology and their gastroenterology board certification has lapsed. Although all other requirements are met, because these individuals do not fulfill the requirements in the Bylaws the MPSC is obligated to reject these applications. The MPSC is also aware of a subspecialty board certification for cardiologists- advanced heart failure and transplant cardiology. When this subspecialty board certification becomes more prevalent in the community, it will create a similar problem for primary heart transplant physician applicants if the current Bylaws are not modified.

Summary of Changes

The Bylaws now include the following additional options for board certification for the liver and heart primary transplant physicians:

- Primary liver transplant physician – can hold current board certification in either gastroenterology or transplant hepatology.
- Primary heart transplant physician – can have current certification in adult or pediatric cardiology or advanced heart failure and transplant cardiology.

What Members Need to Do

No immediate action will be required of members upon the implementation of when we implement these changes. From the implementation date forward, however, we will evaluate all primary liver physician and primary heart physician membership applications based on the new requirements.

Affected Policy Language:

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

1 **Appendix F:**

2 **Membership and Personnel Requirements for Liver** 3 **Transplant Programs**

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

5 A designated liver transplant program must have a primary physician who meets *all* the following
6 requirements:

- 7
- 8 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
9 license to practice medicine in the hospital's state or jurisdiction.
- 10 2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
- 11 3. The physician must have documentation from the hospital credentialing committee that it has verified
12 the physician's state license, board certification, training, and transplant continuing medical education
13 and that the physician is currently a member in good standing of the hospital's medical staff.
- 14 4. The physician must have current board certification in gastroenterology, current board certification in
15 transplant hepatology, or a current pediatric transplant hepatology certification of added qualification
16 by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College
17 of Physicians and Surgeons of Canada.

18
19 In place of current certification in ~~gastroenterology~~ by the American Board of Internal Medicine, the
20 American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the
21 physician must:

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

39
40 If the physician has not adhered to the plan for maintaining continuing education or has not obtained
41 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
42 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-
43 month grace period, and a key personnel change application has not been submitted, then the
44 transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of

45 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been
46 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be
47 given any grace period and will be referred to the MPSC for appropriate action according to *Appendix*
48 *L* of these Bylaws.

- 49
- 50 5. The physician must have completed at least one of pathways listed below:
- 51 a. The 12-month transplant hepatology fellowship pathway, as described in *Section F.4.A. 12-month*
52 *Transplant Hepatology Fellowship Pathway* below.
 - 53 b. The clinical experience pathway, as described in *Section F.4.B. Clinical Experience Pathway*
54 below.
 - 55 c. The 3-year pediatric gastroenterology fellowship pathway, as described in *Section F.4.C. Three-*
56 *year Pediatric Gastroenterology Fellowship Pathway* below.
 - 57 d. The 12-month pediatric transplant hepatology fellowship pathway, as described in *Section F.4.D.*
58 *Pediatric Transplant Hepatology Fellowship Pathway* below.
 - 59 e. The combined pediatric gastroenterology or transplant hepatology training and experience
60 pathway, as described in *Section F.4.E. Combined Pediatric Gastroenterology/Transplant*
61 *Hepatology Training and Experience Pathway* below.
 - 62 f. The conditional approval pathway, as described in *Section F.3.F. Conditional Approval for*
63 *Primary Transplant Physician* below, if the primary liver transplant physician changes at an
64 approved liver transplant program.

65

66 Pediatric liver transplant programs should have a board certified pediatrician who meets the criteria
67 for primary liver transplant physician. If a qualified pediatric physician is not on staff at the program, a
68 physician meeting the criteria as a primary liver transplant physician for adults can function as the
69 primary liver transplant physician for the pediatric program, if a pediatric gastroenterologist is involved
70 in the care of the pediatric liver transplant recipients.

71 **C. Three-year Pediatric Gastroenterology Fellowship Pathway**

72

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

- 78 1. The physician has current board certification in pediatric gastroenterology or a pediatric
79 transplant hepatology certification of added qualification by the American Board of Pediatrics,
80 or the Royal College of Physicians and Surgeons of Canada.
 - 81 2. During the 3-year training period the physician was directly involved in the primary care of 10
82 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver
83 recipients for a minimum of 3 months from the time of transplant, under the direct supervision
84 of a qualified liver transplant physician along with a qualified liver transplant surgeon. The
85 physician was also directly involved in the preoperative, peri-operative and post-operative
86 care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology
87 program director may elect to have a portion of the transplant experience carried out at
88 another transplant service, to meet these requirements. This care must be documented in a
89 log that includes the date of transplant, the medical record number or other unique identifier
90 that can be verified by the OPTN Contractor. This recipient log must be signed by the training
91 program director or the transplant program's primary transplant physician.
 - 92 3. The experience caring for pediatric patients occurred at a liver transplant program with a
93 qualified liver transplant physician and a qualified liver transplant surgeon that performs an
94 average of at least 10 liver transplants on pediatric patients per year.
- 95

- 96 4. The physician must have observed at least 3 liver procurements. The physician must have
97 observed the evaluation, donation process, and management of these donors. These
98 observations must be documented in a log that includes the date of procurement, location of
99 the donor and Donor ID.
- 100 5. The physician must have observed at least 3 liver transplants. The observation of these
101 transplants must be documented in a log that includes the transplant date, donor type, and
102 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 103 6. The physician has maintained a current working knowledge of liver transplantation, defined
104 as direct involvement in liver transplant patient care within the last 2 years. This includes the
105 management of pediatric patients with end-stage liver disease acute liver failure, the
106 selection of appropriate pediatric recipients for transplantation, donor selection,
107 histocompatibility and tissue typing, immediate postoperative care including those issues of
108 management unique to the pediatric recipient, fluid and electrolyte management, the use of
109 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and
110 complications of immunosuppression, the effects of transplantation and immunosuppressive
111 agents on growth and development, differential diagnosis of liver dysfunction in the allograft
112 recipient, manifestation of rejection in the pediatric patient, histological interpretation of
113 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term
114 outpatient care of pediatric allograft recipients including management of hypertension,
115 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- 116 7. The following letters are submitted directly to the OPTN Contractor:
- 117 a. A letter from the director of the pediatric gastroenterology training program, and the
118 qualified liver transplant physician and surgeon of the fellowship training program
119 verifying that the physician has met the above requirements, and is qualified to act as a
120 liver transplant physician and direct a liver transplant program.
- 121 b. A letter of recommendation from the fellowship training program's primary physician and
122 transplant program director outlining the physician's overall qualifications to act as a
123 primary transplant physician, as well as the physician's personal integrity, honesty, and
124 familiarity with and experience in adhering to OPTN obligations, and any other matters
125 judged appropriate. The MPSC may request additional recommendation letters from the
126 primary physician, primary surgeon, director, or others affiliated with any transplant
127 program previously served by the physician, at its discretion.
- 128 c. A letter from the physician that details the training and experience the physician gained in
129 liver transplantation.

131 **D. Pediatric Transplant Hepatology Fellowship Pathway**

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

- 134
- 135 1. The physician has current board certification in pediatric gastroenterology or a current
136 pediatric transplant hepatology certification of added qualification by the American Board of
137 Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the
138 American Board of Pediatrics to take the certifying exam.
- 139 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
140 newly transplanted pediatric liver recipients and followed 20 newly transplanted liver
141 recipients for at least 3 months from the time of transplant, under the direct supervision of a
142 qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon.
143 The physician must have been directly involved in the pre-operative, peri-operative and post-

- 144 operative care of 10 or more liver transplants in pediatric patients. The pediatric
145 gastroenterology program director may elect to have a portion of the transplant experience
146 completed at another liver transplant program in order to meet these requirements. This care
147 must be documented in a log that includes the date of transplant and the medical record
148 number or other unique identifier that can be verified by the OPTN Contractor. This recipient
149 log must be signed by the training program director or the transplant program primary
150 transplant physician.
- 151 3. The experience in caring for pediatric liver patients occurred at a liver transplant program with
152 a qualified liver transplant physician and surgeon that performs an average of at least 10
153 pediatric liver transplants a year.
 - 154 4. The physician has maintained a current working knowledge of liver transplantation, defined
155 as direct involvement in liver transplant patient care within the last 2 years. This includes the
156 management of pediatric patients with end-stage liver disease, acute liver failure, the
157 selection of appropriate pediatric recipients for transplantation, donor selection,
158 histocompatibility and tissue typing, immediate postoperative care including those issues of
159 management unique to the pediatric recipient, fluid and electrolyte management, the use of
160 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and
161 complications of immunosuppression, the effects of transplantation and immunosuppressive
162 agents on growth and development, differential diagnosis of liver dysfunction in the allograft
163 recipient, manifestation of rejection in the pediatric patient, histological interpretation of
164 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term
165 outpatient care of pediatric allograft recipients including management of hypertension,
166 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
 - 167 5. The physician must have observed at least 3 liver procurements. The physician must have
168 observed the evaluation, donation process, and management of these donors. These
169 observations must be documented in a log that includes the date of procurement, location of
170 the donor and Donor ID.
 - 171 6. The physician must have observed at least 3 liver transplants. The observation of these
172 transplants must be documented in a log that includes the transplant date, donor type, and
173 medical record number or other unique identifier that can be verified by the OPTN Contractor.
 - 174 7. The following letters are submitted directly to the OPTN Contractor:
 - 175 a. A letter from the director of the pediatric transplant hepatology training program, and the
176 qualified liver transplant physician and surgeon of the fellowship training program
177 verifying that the physician has met the above requirements, and is qualified to act as a
178 liver transplant physician and direct a liver transplant program.
 - 179 b. A letter of recommendation from the fellowship training program's primary physician and
180 transplant program director outlining the physician's overall qualifications to act as a
181 primary transplant physician, as well as the physician's personal integrity, honesty, and
182 familiarity with and experience in adhering to OPTN obligations, and any other matters
183 judged appropriate. The MPSC may request additional recommendation letters from the
184 primary physician, primary surgeon, director, or others affiliated with any transplant
185 program previously served by the physician, at its discretion.
 - 186 c. A letter from the physician that details the training and experience the physician gained in
187 liver transplantation.
- 188

189 **E. Combined Pediatric Gastroenterology/Transplant Hepatology**
190 **Training and Experience Pathway**

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

- 193
- 194 1. The physician has current board certification in pediatric gastroenterology or a current
195 pediatric transplant hepatology certification of added qualification by the American Board of
196 Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the
197 American Board of Pediatrics to take the certifying exam.
 - 198 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
199 accumulated during both periods, at a liver transplant program.
 - 200 3. During the 2 or more years of accumulated experience, the physician was directly involved in
201 the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20
202 newly transplanted liver recipients for a minimum of 6 months from the time of transplant,
203 under the direct supervision of a qualified liver transplant physician and along with a qualified
204 liver transplant surgeon. The physician must have been directly involved in the pre-operative,
205 peri-operative and post-operative care of 10 or more pediatric liver transplants recipients.
206 This care must be documented in a log that includes at the date of transplant and the medical
207 record number or other unique identifier that can be verified by the OPTN Contractor. This
208 recipient log must be signed by the training program director or the transplant program
209 primary transplant physician.
 - 210 4. The individual has maintained a current working knowledge of liver transplantation, defined
211 as direct involvement in liver transplant patient care within the last 2 years. This includes the
212 management of pediatric patients with end-stage liver disease, the selection of appropriate
213 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
214 immediate post-operative care including those issues of management unique to the pediatric
215 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
216 pediatric recipient including side-effects of drugs and complications of immunosuppression,
217 the effects of transplantation and immunosuppressive agents on growth and development,
218 differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in
219 the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary
220 tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients
221 including management of hypertension, nutritional support, and drug dosage, including
222 antibiotics, in the pediatric patient.
 - 223 5. The physician must have observed at least 3 liver procurements. The physician must have
224 observed the evaluation, the donation process, and the management of these donors. These
225 observations must be documented in a log that includes the date of procurement, location of
226 the donor, and Donor ID.
 - 227 6. The physician must have observed at least 3 liver transplants. The observation of these
228 transplants must be documented in a log that includes the transplant date, donor type, and
229 medical record number or other unique identifier that can be verified by the OPTN Contractor.
 - 230 7. The following letters are submitted directly to the OPTN Contractor:
 - 231 a. A letter from the qualified liver transplant physician and surgeon who have been directly
232 involved with the physician documenting the physician's experience and competence.
 - 233 b. A letter of recommendation from the primary physician and transplant program director at
234 the fellowship training program or transplant program last served by the physician
235 outlining the physician's overall qualifications to act as a primary transplant physician, as
236 well as the physician's personal integrity, honesty, and familiarity with and experience in

- 237 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC
238 may request additional recommendation letters from the primary physician, primary
239 surgeon, director, or others affiliated with any transplant program previously served by
240 the physician, at its discretion.
- 241 c. A letter from the physician that details the training and experience the physician gained in
242 liver transplantation.
- 243

244 **Appendix H:**

245 **Membership and Personnel Requirements for Heart**

246 **Transplant Programs**

247 **H.3 Primary Heart Transplant Physician Requirements**

248 A designated heart transplant program must have a primary physician who meets *all* the following
249 requirements:

- 250
- 251 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
252 license to practice medicine in the hospital's state or jurisdiction.
 - 253 2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this
254 hospital.
 - 255 3. The physician must have documentation from the hospital credentialing committee that it has verified
256 the physician's state license, board certification, training, and transplant continuing medical education
257 and that the physician is currently a member in good standing of the hospital's medical staff.
 - 258 4. The physician must have current certification in adult or pediatric cardiology or current board
259 certification in advanced heart failure and transplant cardiology by the American Board of Internal
260 Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of
261 Canada.

262

263 In place of current board certification ~~in adult or pediatric cardiology~~ by the American Board of Internal
264 Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of
265 Canada, the physician must:

- 266
- 267 a. Be ineligible for American board certification.
 - 268 b. Provide a plan for continuing education that is comparable to American board maintenance of
269 certification. This plan must at least require that the physician obtains 60 hours of Category I
270 continuing medical education (CME) credits with self-assessment that are relevant to the
271 individual's practice every three years. Self-assessment is defined as a written or electronic
272 question-and-answer exercise that assesses understanding of the material in the CME program.
273 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
274 an acceptable self-assessment score are allowed. The transplant hospital must document
275 completion of this continuing education.
 - 276 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
277 transplant programs not employed by the applying hospital. These letters must address:
 - 278 i. Why an exception is reasonable.
 - 279 ii. The physician's overall qualifications to act as a primary heart transplant physician.
 - 280 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
281 OPTN obligations and compliance protocols.
 - 282 iv. Any other matters judged appropriate.

283

284 If the physician has not adhered to the plan for maintaining continuing education or has not obtained
285 the necessary CME credits with self-assessment, the transplant program will have a six-month grace

286 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-
287 month grace period, and a key personnel change application has not been submitted, then the
288 transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of
289 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been
290 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be
291 given any grace period and will be referred to the MPSC for appropriate action according to *Appendix*
292 *L* of these Bylaws.

- 293
- 294 5. The physician must have completed at least *one* of the pathways listed below:
- 295
- 296 a. The 12-month transplant cardiology fellowship pathway, as described in *Section*
297 *H.3.A. Twelve-month Transplant Cardiology Fellowship Pathway* below.
 - 298 b. The clinical experience pathway, as described in *Section H.3.B. Clinical Experience Pathway*
299 below.
 - 300 c. The conditional approval pathway, as described in *Section H.3.C. Conditional Approval for*
301 *Primary Transplant Physician* below, if the primary heart transplant physician changes at an
302 approved heart transplant program.

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