

At-a-Glance

Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18

- **Affected/Proposed Policy:** 9.1 (Status and Score Assignments); 9.1.B (Pediatric Status 1A Requirements); 9.1.C (Pediatric Status 1B); 9.3.A (Pediatric Status Exception for Candidates 18 Years or Older)

- **Pediatric Transplantation Committee**

Most organ candidates automatically retain pediatric priority if they turn 18 while waiting for a transplant. Under current liver policy, if a candidate turns 18 years old while waiting in a MELD score (i.e., not Status 1A, Status 1B, or inactive status), the candidate does not automatically retain pediatric classification. Rather the registering transplant program is responsible for requesting a pediatric classification exception from the Regional Review Board (RRB). Additionally, if a candidate was ever registered as a pediatric patient and was subsequently removed from the waiting list, but returns to the waiting list as an adult, the registering transplant program has the ability to apply to the RRB for a pediatric classification exception for this candidate. Both of these exception processes are inconsistent with allocation policy for most other organs. The RRBs have been consistent in their decision-making on these applications, making review of these applications unnecessary and easily automated. The Pediatric Transplantation Committee proposes the automatic transfer of pediatric classification for all candidates who turn 18 while waiting for a liver transplant. Further, the Pediatric Transplantation Committee seeks to eliminate the pediatric classification exception process for an adult candidate who was ever on the waiting list prior to age 18 but has since been removed and reregistered.

- **Affected Groups**

Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
Transplant Program Directors
Organ Candidates

- **Number of Potential Candidates Affected**

Since June 2013, the RRBs have reviewed and approved 12 pediatric classification exceptions. As of June 20, 2014, 38 liver candidates that would qualify for automatic pediatric classification under this proposal, but not under current policy, were actively waiting.

- **Compliance with OPTN Strategic Goals and Final Rule**

This proposal seeks to increase pediatric access to transplant, fulfilling the charge of the Final Rule that the OPTN develop equitable allocation policy that especially considers the unique health care needs of children (Code of Federal Regulations, title 10, sec. 121.8¹; 42 USC Sec. 274 (b)(2)(M)). This proposal also promotes the efficient management of the OPTN, which is a goal of the OPTN Strategic Plan.

¹ Code of Federal Regulations, Organ Procurement and Transplantation Network, title 42, sec. 121.8.

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Affected/Proposed Policy: 9.1 (Status and Score Assignments); 9.1.B (Pediatric Status 1A Requirements); 9.1.C (Pediatric Status 1B); 9.3.A (Pediatric Status Exception for Candidates 18 Years or Older)

Pediatric Transplantation Committee

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

Most organ candidates automatically retain pediatric priority if they turn 18 while waiting for a transplant^{2,3,4,5}. Under current liver policy, if a candidate turns 18 years old while waiting in a MELD score (i.e., not Status 1A, Status 1B, or inactive status), the candidate does not automatically retain pediatric classification. Rather the registering transplant program is responsible for requesting a pediatric classification exception from the Regional Review Board (RRB). Currently only Status 1A and Status 1B liver candidates turning 18 years old while waiting automatically retain pediatric classification. Additionally, if a candidate was ever registered as a pediatric patient and was subsequently removed from the waiting list, but returns to the waiting list as an adult, the registering transplant program has the ability to apply to the RRB for a pediatric classification exception for this candidate. Pediatric classification for an affected candidate operationally means prioritization as a 12 to 17 year old candidate on the liver match run. Both of these exception processes are inconsistent with allocation policy for most other organs. The RRBs have been consistent in their decision-making on these applications; candidates that turn 18 while waiting for liver transplant have been approved for pediatric classification, while adult candidates that were ever registered as pediatric candidates but have since been removed and reregistered were denied. The Pediatric Transplantation Committee believes that current policy historically has not been well-understood in the community. Requests to the RRBs have only recently become more frequent. Of the 15 exceptions that have been requested since May 24, 2004, 12 were requested after the OPTN published an informational article on June 13, 2013 regarding current policy. The Pediatric Transplantation Committee proposes that pediatric classification be automatically transferred for all candidates who turn 18 while waiting for a liver transplant. Further, the Pediatric Transplantation Committee seeks to eliminate the pediatric classification exception process for an adult candidate who was ever on the waiting list prior to age 18 but has since been removed and reregistered. These changes would make liver policy consistent with that of most other organs in regards to how candidates turning 18 while waiting are classified.

² Policy 6.1: Status Assignments, Organ Procurement and Transplantation (OPTN) Policies

³ Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%, Organ Procurement and Transplantation (OPTN) Policies (pending implementation)

⁴ Policy 8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 20% but Less Than 35%, Organ Procurement and Transplantation (OPTN) Policies (pending implementation)

⁵ Policy 11.4.A: Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old, Organ Procurement and Transplantation (OPTN) Policies (pending implementation)

Background and Significance of the Proposal:

In spring 2013, the Pediatric Transplantation Committee requested that staff publish an article explaining the pediatric classification exception process for liver candidates. Committee members did not believe that the current policy was well-understood in the community. This speculation was verified when 12 applications were submitted after the June 13, 2013 article was published, when only 3 had been requested in the previous 9 years.

In reviewing the exception applications, the Pediatric Transplantation Committee learned that the RRBs have been consistent in their decision-making; candidates that turn 18 while waiting for liver transplant have been approved for pediatric classification, while adult candidates that were ever registered as pediatric candidates but have since been removed and reregistered were denied. Pediatric Transplantation Committee members proposed the automatic transfer of pediatric classification for all candidates who turn 18 while waiting for a liver transplant. They also proposed eliminating the pediatric classification exception process for an adult candidate who was ever on the waiting list prior to age 18, but has since been removed and reregistered. These proposed changes would make liver policy consistent with that of most other organs in regards to how candidates in these specific situations are classified. They would also contribute to the fair and efficient management of the OPTN by eliminating two unnecessary exception processes.

The Pediatric Transplantation Committee sent the Liver and Intestinal Organ Transplantation Committee a memorandum on December 12, 2013, requesting its feedback on the proposed policy changes. On a February 14, 2014 conference call, the Liver and Intestinal Organ Transplantation Committee indicated their general support for the proposed changes with the suggestion that the Pediatric Transplantation Committee specify an age after which a candidate would no longer qualify for pediatric classification, also referred to as a cap. The Pediatric Transplantation Committee considered but ultimately decided against the Liver and Intestinal Organ Transplantation Committee's suggestion, since a cap is inconsistent with other organ allocation policies. Furthermore, Pediatric Transplantation Committee members could not propose an evidence-based cap due to the small number of pediatric liver candidates that turn 18 while waiting. The Pediatric Transplantation Committee affirmed that, as with any allocation policy, adequate and appropriate registration of patients and good waiting list management is always necessary.

The Pediatric Transplantation Committee voted to approve final policy language on July 9, 2014 (14 yes, 0 no, 0 abstentions). The Liver and Intestinal Organ Transplantation Committee considered this proposal on an August 6, 2014 conference call and unanimously voted to support it.

Supporting Evidence and/or Modeling:

The Pediatric Transplantation Committee reviewed a descriptive data analysis of candidates currently waiting that would qualify for automatic pediatric classification under this proposed policy. Thirty-eight candidates aged 18 or older, who had been registered prior to turning 18, were still waiting with a MELD score on June 20, 2014. Over 70% (27) of these candidates were 15 to 17 years old at registration. Registered at 22 different centers, the candidate age ranged from 18 to 33 years, though only 11% (4/38) were currently older than 25. Time spent on the waiting list ranged from less than 1 to 17 years. Most of the candidates had a MELD score less than 13. Five candidates had re-certifications that were past due, so they had been assigned a MELD score of 6. None of the candidates had a previous liver transplant. Most had received at

least one offer, and the most common refusal reason was donor age or quality. There was not a prevalent diagnosis among candidates. After careful consideration of the data, the Pediatric Transplantation Committee decided to proceed with the proposed policy. As with any allocation policy, adequate and appropriate registration of patients and good waiting list management is always necessary.

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Populations:

This proposal eliminates the need for transplant programs to petition the RRB on behalf of candidates turning 18 while waiting for a liver transplant in order to retain pediatric classification. In contrast to an automatic transfer of pediatric classification, an exception process is less efficient and the outcome of these applications is not guaranteed. Furthermore, evidence suggests that historically more candidates could have benefitted from a pediatric classification exception than applications were submitted, most likely because this policy is inconsistent with that of other organs and not well-understood.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal seeks to increase pediatric access to transplant, fulfilling the charge of the National Organ Transplant Act (NOTA) and the Final Rule that the OPTN develop equitable allocation policy that especially considers the unique health care needs of children (Code of Federal Regulations, title 10, sec. 121.8⁶; 42 USC Sec. 274 (b)(2)(M)). Eliminating the pediatric classification exception process for liver candidates also promotes the efficient management of the OPTN, which is a goal of the OPTN Strategic Plan. The RRBs have been consistent in their decision-making on these applications, making review of these applications unnecessary and easily automated.

Plan for Evaluating the Proposal:

The following data will be provided to the Pediatric Transplantation Committee after the policy has been in place for at least 6 months:

- The number of candidates who are still waiting in a MELD score after turning 18 but were registered prior to turning 18 by candidate age after policy implementation.
- The number of non-Status 1A and non-Status 1B deceased donor liver transplants by recipient age group at registration (0-11, 12-17, 18+) and donor age group (0-10, 11-17, 18+) before and after policy implementation.

The data will be provided on an annual basis for up to three years after policy implementation.

Additional Data Collection:

No additional data collection is required.

⁶ Code of Federal Regulations, Organ Procurement and Transplantation Network, title 42, sec. 121.8.

Expected Implementation Plan:

This policy will be implemented upon Board approval using a manual solution. Programming in UNetSM will eventually be required to fully automate transfer of pediatric classification. This policy will not require any changes to the Liver Regional Review Board Operational Guidelines. No action is required of liver programs.

Communication and Education Plan:

The OPTN will follow established protocols to inform members of the Public Comment period and educate them on any policy changes through Policy Notices. Upon implementation, the OPTN will publish an article informing the community that transplant hospitals no longer have to petition the RRB for continued pediatric classification for candidates turning 18 while waiting for a liver transplant. Once programming is complete, UNOS will update UNetSM Help Documentation and distribute a System Notice to UNetSM users.

Compliance Monitoring:

This proposal will not affect monitoring of liver programs.

Policy or Bylaw Proposal:

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

9.1 Status and Score Assignments

Each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric End Stage Liver Disease (PELD) scoring system. Liver candidates can also be assigned a priority status if the candidate meets the requirements for that status.

Liver candidates at least 18 years old at the time of registration may be assigned *any* of the following:

- Adult status 1A
- ~~Inactive status~~
- Calculated MELD score
- Exception MELD score
- Inactive status
- ~~Pediatric status 1A or 1B with pediatric classification, if the candidate is registered on the waiting list when less than 18 years old and remains on the waiting list, or registers again after turning 18 years old or older and meets the requirements for that status.~~

Liver candidates less than 18 years old at the time of registration may be assigned *any* of the following:

- Pediatric status 1A
- Pediatric status 1B
- ~~Inactive status~~
- Calculated MELD or PELD score
- Exception MELD or PELD score
- Inactive status

Liver candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, will be classified as a 12 to 17 year old for the purposes of allocation in:

- Policy 9.6.F: Allocation of Livers from Deceased Donors 11 to 17 Years Old
- Policy 9.6.G: Allocation of Livers from Deceased Donors Less than 11 Years Old
- Policy 9.6.J: Allocation of Liver-Intestines from Donors Less than 11 Years Old

If the candidate is removed from the waiting list at any time and returns to the waiting list after turning 18 years old, the candidate must then be registered as an adult.

9.1.B Pediatric Status 1A Requirements

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of ~~initial~~ registration. This includes candidates ~~who are currently 18 years old and greater but remain on the waiting list, or have returned to the waiting list after initial registration~~ less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.
 2. The candidate has at least *one* of the following conditions:
 - a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease and has at least *one* of the following criteria:
 - i. Is ventilator dependent
 - ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iii. Has an international normalized ratio (INR) greater than 2.0
 - b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
 - i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
 - ii. INR greater than or equal to 2.5
 - iii. Total bilirubin greater than or equal to 10 mg/dL
 - iv. Acidosis, defined as *one* of the following:
 - Arterial pH less than or equal to 7.30
 - Venous pH less than or equal to 7.25
 - Lactate greater than or equal to 4 mmol/L
- All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.
- c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant
 - d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN Contractor. A candidate is not registered as status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of ~~initial~~ registration. This includes candidates ~~who are currently 18 years old and greater but remain on the waiting list or have returned to the waiting list after initial registration less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.~~
2. The candidate has *one* of the following conditions:
 - a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.
 - b. The candidate has an organic acidemia or urea cycle defect and a MELD or PELD exception score of 30 points for at least 30 days.
 - c. Chronic liver disease with a MELD greater than 25 for adolescent candidates 12 to 17 years old, or a PELD greater than 25 for candidates less than 12 years old, and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.
 - d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
 - i. Is on a mechanical ventilator
 - ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
 - iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
 - iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

~~9.3.A Pediatric Status Exception for Candidates 18 Years or Older~~

~~Liver candidates with a MELD score initially registered on the waiting list when less than 18 years old who remain on the waiting list or are registered again after turning 18 years old may be assigned the appropriate pediatric classification by exception. The transplant hospital must apply for the exception and include justification to the applicable RRB that the candidate is considered, by consensus medical judgment and using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having pediatric classification.~~

9.3.BA MELD/PELD Exception Applications

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]