

OPTN/UNOS Policy Notice

Revisions to Pediatric Emergency Membership Exception Pathway

Sponsoring Committee:	Pediatric Transplantation
Policy/Bylaws Affected:	OPTN Bylaws Appendices F.7.E (Emergency Pediatric Membership Exceptions for Candidates Less than 18 Years Old), and H.4.E (Emergency Pediatric Membership Exceptions for Candidates Less than 18 Years Old)
Public Comment:	July 31, 2017 – October 2, 2017
Effective Date:	Pending Programming and Notice to Members

Problem Statement

If an adult heart or liver transplant program wants to register a candidate less than 18 years old, the emergency membership exception requires programs to show:

1. The transplant was necessary to prevent a serious and imminent threat to the patient's health or safety
2. It was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated heart or liver transplant program with an approved pediatric component

As currently written, the emergency membership exception pathways require the MPSC to retrospectively review a transplant team's clinical decisions. A transplant team making the decision would have no frame of reference for how much risk is considered acceptable because the requirements are subjective. For example, the listing transplant program must demonstrate that it "believes" the patient must be transplanted, and that transfer to a pediatric hospital is "medically inadvisable or commercially impractical." Less specific member obligations like these are vulnerable to inconsistent interpretation and application.

Summary of Changes

This proposal only modifies the emergency membership exception pathways for heart and liver transplant programs without an approved pediatric component.

Heart Transplant Programs without an approved pediatric component may register a pediatric transplant candidate on the waiting list if the patient:

- Is less than 18 years old
- Is admitted to the transplant hospital and is supported by either a surgically implanted, non-endovascular ventricular assist device (VAD) that is not FDA-approved for out of hospital use for any age group, or by veno-arterial extracorporeal membrane oxygenator (VA ECMO)
- Meets the requirements for pediatric status 1A according to OPTN *Policy 6.2.A: Pediatric Heart Status 1A Requirements*

The primary pediatric physician or primary pediatric surgeon at an approved pediatric heart component must confirm that it is not medically advisable to transport this patient to a heart transplant program with an approved pediatric component.

Liver Transplant Programs without an approved pediatric component may register a pediatric transplant candidate if the patient:

- Is less than 18 years old
- Meets the requirements for pediatric status 1A for fulminant hepatic failure, acute decompensated Wilson's disease, primary non-function of a transplanted liver, or hepatic artery thrombosis following a liver transplant

The primary pediatric physician or primary pediatric surgeon at an approved pediatric liver component must confirm that it is not medically advisable to transport this patient to a liver transplant program with an approved pediatric component.

What Members Need to Do

We will implement the changes to the pathways along with the 2015 membership requirements for pediatric transplant programs. Once implemented, heart and liver transplant programs without an approved pediatric component will need to become familiar with new justification forms in UNetsm. If you elect to use the emergency membership exception pathway:

- You will need to maintain documentation
- The candidate's clinical status must be continually met
- Recertification is allowed according to OPTN Policies 6.1.D: *Pediatric Heart Status 1A Requirements*, and 9.2: *Status and Laboratory Values Update Schedule*

Affected Policy Language

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

Appendix F: Membership and Personnel Requirements for Liver Transplant Programs

F.7.E. Emergency Pediatric Membership Exceptions for Candidates Less than 18 Years Old

A designated liver transplant program that does not have an approved pediatric component may register a patient less than 18 years old on the waiting list if ~~all~~ both of the following conditions are met:

- ~~1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety~~
- ~~2. The patient is pediatric Status 1A according to *Policy 9: Allocation of Livers and Liver-Intestines*.~~
 1. The patient meets the requirements for pediatric status 1A according to OPTN Policy 9.1.B: *Pediatric Status 1A Requirements*. This does not include a patient who meets the status 1A requirements by exception according to OPTN Policy 9.3: *Status Exceptions*.
 2. The primary pediatric physician or primary pediatric surgeon at an approved pediatric liver component confirms that it is not medically advisable to transport this patient to a liver transplant program with an approved pediatric component. The transplant program that registers the candidate must document this confirmation.

If at any time the candidate no longer meets these criteria, the transplant program must remove the candidate from their waiting list within 24 hours, and may not transplant the candidate. The transplant program must assist candidates in transferring to other designated transplant programs.

Registration of a candidate less than 18 years old through an emergency exception does not grant the transplant program pediatric component approval.

~~The transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.~~

~~The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate *all* the following:~~

- ~~1. That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety~~
- ~~2. That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated liver transplant program with an approved pediatric component~~
- ~~3. The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant~~

~~If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.~~

~~Approval of an emergency pediatric membership exception request does not grant the transplant program approval of the pediatric component.~~

Appendix H: Membership and Personnel Requirements for Heart Transplant Programs

H.4.E. Emergency Pediatric Membership Exceptions for Candidates Less than 18 Years Old

A designated heart transplant program that does not have an approved pediatric component may register a patient less than 18 years old on the waiting list if *all* of the following conditions are met:

- ~~1. The transplant program believes it must transplant the pediatric patient to prevent a serious and imminent threat to the patient's health or safety~~
- ~~2. 1. The patient has one of the following conditions: The patient is pediatric Status 1A according to Policy 6: Allocation of Heart and Heart-Lungs~~
 - ~~a. Is admitted to the transplant hospital and is supported by a surgically implanted, non-endovascular ventricular assist device (VAD) that is not FDA-approved for out of hospital use for any age group.~~
 - ~~b. Is admitted to the transplant hospital and is supported by veno-arterial extracorporeal membrane oxygenator (VA ECMO).~~
- ~~2. The patient meets the requirements for pediatric status 1A according to OPTN Policy 6.2.A: Pediatric Heart Status 1A Requirements.~~
- ~~3. The primary pediatric physician or primary pediatric surgeon at an approved pediatric heart component confirms that it is not medically advisable to transport this patient to a heart transplant program with an approved pediatric component. The transplant program that registers the candidate must document this confirmation.~~

If at any time the candidate no longer meets these criteria, the transplant program must remove the candidate from their waiting list within 24 hours, and may not transplant the candidate. The transplant program must assist candidates in transferring to other designated transplant programs.

Registration of a candidate less than 18 years old through an emergency exception does not grant the transplant program pediatric component approval.

~~The transplant program must submit a pediatric membership exception request to the OPTN Contractor within 72 hours of the candidate's registration on the waiting list.~~

~~The MPSC will retrospectively review pediatric membership exception requests. As part of this review, the MPSC will consult with the Pediatric Transplantation Committee. In submitting the pediatric membership exception request, the transplant program must demonstrate *all* the following:~~

- ~~1. That the transplant was necessary to prevent a serious and imminent threat to the patient's health or safety~~
- ~~2. That it was medically inadvisable or commercially impractical for the transplant program to transport the candidate to a designated heart transplant program with an approved pediatric component~~
- ~~3. The candidate was registered as pediatric Status 1A and remained pediatric Status 1A until the time of transplant~~

~~If the member fails to demonstrate the criteria for this emergency exception, any listing made thereunder will be a violation of OPTN obligations and will be referred to the MPSC.~~

~~Approval of an emergency pediatric membership exception request does not grant the transplant program approval of the pediatric component.~~

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