

## Notice of OPTN Policy Change

# Expedited Placement of Livers

<b>Sponsoring Committee:</b>	<b>Organ Procurement Organization (OPO)</b>
<b>Policies Affected:</b>	<b><i>1.2: Definitions</i></b>
<b><i>5.3.D:</i></b>	<b><i>Liver Acceptance Criteria</i></b>
<b><i>5.6.B:</i></b>	<b><i>Time Limit for Review and Acceptance of Organ Offers</i></b>
<b><i>9.10.A:</i></b>	<b><i>Expedited Liver Placement Acceptance Criteria</i></b>
<b><i>9.10.B: Expedited Liver Offers</i></b>	
<b>Public Comment:</b>	<b>August 2 – October 2, 2019</b>
<b>Board Approved:</b>	<b>December 3, 2019</b>
<b>Effective Date:</b>	<b>Pending programming and notice to OPTN members</b>

### Purpose of Policy Changes

Current OPTN liver allocation policy does not address the expedited placement of organs. The absence of policy language creates a lack of transparency about how late turndowns are handled, and a lack of consistent guidance for OPOs and transplant hospitals. This could ultimately affect a candidate's access to a lifesaving liver transplant if they are bypassed on the match run. The purpose of these policy changes is to create standard requirements and practices for expedited placement of livers that are at risk of not being used for transplant.

### Proposal History

- The OPO Committee received input from the community with a concept paper distributed for public comment in 2018
- Draft policy language developed by a multi-committee workgroup in 2018-2019
- Initial public comment on policy proposals in early 2019. Common concerns from previous public comment cycle:
  - "In the donor OR" was too late in the process
  - 20 minutes is not enough time to respond
- Changes to the proposal based on feedback:
  - Programming changes to identify expedited placement candidates on the original liver match run intended to support OPO logistics/planning
  - Clarifying that expedited placements will use the original match run with additional screening applied (versus a new match run type)
  - Extends response time to 30 minutes
- Considerable support received during second public comment period in 2019

## Summary of Changes

The policy changes establish a system for the expedited placement of livers.

- Transplant hospitals will be required to “opt-in” to receive expedited liver offers
- Creates criteria for when OPOs can initiate expedited liver placement, as well as required information that needs to be entered by the OPO before sending electronic expedited livers offers
- Transplant hospitals must respond with a provisional “yes” to expedited offers within 30 minutes in order to be eligible to receive the liver for their candidate.
- After the 30 minute period, OPOs must place the liver with the candidate with a provisional “yes” that appears highest on the match run.

## Implementation

### Transplant Hospitals

- Transplant hospitals will have to be aware of the needed acceptance criteria for each candidate in order to be eligible to receive expedited liver offers for those candidates.
- Transplant hospitals will need to respond to expedited liver offers within 30 minutes in order to be eligible to receive the expedited placement liver.

### OPOs

- OPO staff will need to be aware that expedited liver candidates will be identified on the original liver match run. This will allow for advanced planning and communication for potential expedited offers.
- OPO staff will need to be aware of the criteria for initiating expedited placement.
- OPO staff will need to be aware of the information that needs to be submitted prior to sending electronic offers
- OPO staff will need to be aware of the requirement to place the liver with the candidate with a provisional “yes” response that appears highest on the expedited match run after the 30 minute acceptance period.

### OPTN

System programming changes include:

- New fields in Waitlist and DonorNet that allow transplant hospitals and OPOs to enter the required information
- New field on liver match run that will show expedited liver candidates
- When expedited placement initiated, new screening will be applied to the original liver match run

## Affected Policy Language

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

### 1.2 Definitions

#### Organ offer acceptance

When the transplant hospital notifies the host OPO that it ~~they~~ accepts the organ offer for an intended recipient, pending review of organ anatomy. For kidney, acceptance is also pending final crossmatch.

### 5.3.D Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN Contractor.

Liver transplant programs may also specify additional liver acceptance criteria, including any of the following:

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. Acceptance criteria for expedited offers as outlined in *Policy 9.10.A: Expedited Placement Acceptance Criteria*
- ~~3.~~ 4. If a blood type O candidate will accept a liver from a deceased donor with blood type A, non- A1
- ~~4.~~ 5. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
- ~~5.~~ 6. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
- ~~6.~~ 7. If a candidate will accept a liver for other methods of hepatic support
- ~~7.~~ 8. If a candidate is willing to accept a segmental graft
- ~~8.~~ 9. If a candidate is willing to accept an HIV positive liver as part of an institutional review board approved research protocol that meets the requirement in the OPTN Final Rule

### 5.6.B Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver Offers*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to Policy 2.11: Required Deceased Donor Information, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with either of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with either of the following:

- An organ offer acceptance
- An organ offer refusal

## 9.10 Expedited Placement of Livers

### 9.10.A Expedited Liver Placement Acceptance Criteria

In order for a liver candidate to receive expedited offers as outlined in *Policy 9.10.B: Expedited Liver Offers*, the transplant hospital must report *all* of the following information to the OPTN Contractor:

1. Agreement to accept a liver recovered by any procurement team
2. The following liver acceptance criteria:
  - Minimum and maximum age
  - Maximum body mass index (BMI)
  - Maximum distance from the donor hospital
  - Minimum and maximum height
  - Percentage of macrosteatosis
  - Minimum and maximum weight

### 9.10.B Expedited Liver Offers

The host OPO or the Organ Center is permitted to make expedited liver offers if *both* of the following conditions are met:

1. The donor has entered the operating room or, in the case of a DCD donor, withdrawal of life sustaining medical support has been initiated, whichever occurs first.
2. The host OPO or Organ Center is notified by the primary transplant hospital that the primary potential transplant recipient will no longer accept the liver.

Prior to sending expedited liver offers, the host OPO or Organ Center must report *all* of the following information to the OPTN Contractor:

1. Date and time donor entered the operating room or withdrawal of life sustaining medical support was initiated, whichever occurs first.
2. Date and time host OPO was notified by the primary transplant hospital that they will no longer accept the liver offer for the primary potential transplant recipient.
3. Reason for organ offer refusal by the primary potential transplant recipient.

Expedited liver offers will be made to potential transplant recipients on the match run who are eligible to receive expedited liver offers as described in *Policy 9.10.A: Expedited Liver Placement Acceptance Criteria*.

Transplant hospitals must accept an expedited offer within 30 minutes of notification to be eligible to receive the liver. Once this time limit has expired, the host OPO or Organ Center must place the liver with the potential transplant recipient with the provisional yes that appears highest on the match run.

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

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