

## *Notice of OPTN Policy Change*

# Updates to Candidate Data during 2020 COVID-19 Emergency

<b>Sponsoring Committee:</b>	<b>Executive Committee</b>
<b>Policy Affected:</b>	<b><i>Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency</i></b>
<b>Executive Committee Approved:</b>	<b>March 17, 2020</b>
<b>Effective Date:</b>	<b>March 17, 2020</b>

### **Purpose of Policy Change**

The current COVID-19 crisis has created unprecedented challenges for the nation's health care system. The transplant network is facing several actual and projected disruptions to normal operations. One of the many effects of the national emergency is the inability to conduct routine clinical testing that is needed to obtain data required for transplant candidates. Several OPTN organ allocation policies require periodic refreshing of clinical data to establish and maintain waitlist priority. If deadlines for refreshing these data are not met, candidates' urgency, eligibility, or status can be automatically "downgraded." The scope and scale of the COVID-19 crisis necessitates providing an emergency policy solution so that candidates waiting for lifesaving organ transplants are not adversely affected solely because they are unable to undergo testing.

### **Proposal History**

COVID-19 was declared a national emergency on March 13, 2020 by the President of the United States. In response to multiple concerns expressed to the OPTN by the transplant community, this proposal was developed to assist with helping candidates not lose current allocation priority due to COVID-19 outbreak impacts. The proposal was discussed emergently with leadership from the Data Advisory, Liver, Membership and Professional Standards, Policy Oversight, Transplant Administrators, Transplant Coordinators, and Thoracic OPTN Committees. The Executive Committee considered the action pursuant to OPTN Bylaw *11.7: Emergency Actions* which allows the OPTN to create policy required due to an emergent public health issue. The Executive Committee, on behalf of the OPTN Board of Directors, met and approved the policy action on March 17, 2020.

### **Summary of Changes**

This emergency policy will allow transplant programs to refresh candidate clinical data with data obtained through previous testing in order to maintain current waitlist priority when obtaining updated clinical data is not feasible or advisable in the transplant program's medical judgment due to the current COVID-19 crisis.

## Implementation

Transplant programs will need to educate staff to this policy allowance. When data cannot be collected and updated in accordance with regular OPTN policy due to issues related to the COVID-19 outbreak, then transplant programs may enter the same values from the most recent previously provided clinical data. Data used for the most recent prior qualification or extension can be used for the required update in order to ensure that candidates will not be disadvantaged due to the national public health emergency.

The date on which the most recent previously provided clinical data are resubmitted pursuant to this emergency policy must be used for the test date field. Using the date that the data is being reported to the OPTN for the date required in UNet<sup>SM</sup> will prevent an automatic downgrade or unintended change to the candidate's status and effectively extend or preserve waiting time, status, or score.

When using this emergency policy, transplant hospitals must document these actions in the candidate's medical record. The documentation must include the circumstances that support using this emergency policy. Members have discretion in the way they document their use of this policy, provided their documentation addresses the policy requirements. An example of acceptable documentation would be a note in the candidate's medical record such as "3/20/2020 – updated candidate record in Waitlist. Due to COVID-19 emergency actions, candidate's previously reported clinical data was reported with today's date."

Members can find more detailed instructions in UNet<sup>SM</sup>.

This emergency policy will go into effect immediately on March 17, 2020. This emergency policy will be reviewed by the OPTN Executive Committee at least every three months for the duration of the 2020 COVID-19 emergency. The emergency policy will expire on March 17, 2021 if the Executive Committee or Board of Directors has not acted before that date.

As required by OPTN Bylaw 11.7: *Emergency Actions*, this policy will be distributed for public comment before September 17, 2020 for at least a 30 day period. The OPTN is notifying the community through this policy notice, a system notice in UNet<sup>SM</sup>, and other appropriate communication channels. This action will not require programming in UNet<sup>SM</sup>.

## Affected Policy Language

### 1 **Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency**

2 This emergency policy is in effect due to the public health emergency declared by the President of the  
3 United States on March 13, 2020. This emergency policy only applies to transplant programs that have  
4 candidates who require clinical data updates per OPTN policy in order to maintain prioritization or  
5 eligibility.

6 During the 2020 COVID-19 emergency:

- 7 1. Transplant programs should continue to make all reasonable efforts to collect and report clinical  
8 data as required by OPTN Policy.
  - 9 2. Any transplant program that is required by OPTN Policy to report clinical data in order to  
10 maintain a candidate's prioritization or eligibility, and: a) is prevented from collecting such data  
11 due to the COVID-19 emergency, or: b) in their medical judgment chooses not to collect such  
12 data due to the COVID-19 emergency, may use the candidate's clinical data values that were  
13 most recently reported to the OPTN. When reporting previous clinical data pursuant to this  
14 emergency policy, the transplant program must report the date the program is entering the data  
15 as the collection date.
  - 16 3. While using this policy, transplant programs must document in the candidate's medical record  
17 the circumstances that support use of this emergency policy.
- 18