

Notice of OPTN Policy Change

Repeal Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency

Sponsoring Committee:	Executive
Policy Affected:	<i>Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency</i>
Board Approved:	April 26, 2021
Effective Date:	July 27, 2021

Summary of Changes

This policy change repeals OPTN *Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*. When implemented, transplant programs will no longer have the option to continue the use of existing clinical data when policy required updates are due for a candidate to maintain allocation status.

Purpose of Policy Change

COVID-19 pandemic impacts led to several OPTN policy actions aimed to protect patient safety and minimize negative impacts to patients and the overall transplant system. OPTN *Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency* was created to enable a candidate to maintain their current allocation priority by allowing the transplant program to carry forward the candidate's most recently reported lab results as the candidate's current lab values. This provided a safeguard to minimize risk of candidates' potential COVID-19 exposure. This policy change repeals OPTN *Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*. This action is based on transplant health care COVID-19 adaptations that have mitigated patient safety risk posed by obtaining updated laboratory values, data showing minimal current use of the policy, the need to maintain equity among all candidates with required laboratory updates, and OPTN stakeholder committee feedback.

Proposal History

- March 17, 2020: Original adoption of OPTN *Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency* (effective March 13, 2020) through emergency Executive Committee Action
- April 20, 2020; June 7, 2020; and July 30, 2020: COVID data and policy review by Executive Committee
- August 4 – October 1, 2020: Public Comment (Retrospective)
- September 18, 2020; November 2, 2020; and December 6, 2020: COVID data and policy review by Executive Committee

- December 7, 2020: Policy approval by OPTN Board of Directors with continued Executive Committee review and action as appropriate due to current COVID-19 circumstances
- January 13, 2021; March 1, 2021; and April 26, 2021: COVID data and policy review by Executive Committee
- April 26, 2021: Action to repeal policy by Executive Committee

Implementation

Transplant programs will need to assess their waiting lists and identify any candidates using this policy to maintain allocation status. Transplant programs will need to inform their candidates that they will need to obtain required clinical data or laboratory testing before the next policy required update is due.

No programming is necessary to implement this policy. Members will have 90 days to provide adequate transition time to prepare for the elimination of this policy that will go into effect on July 27, 2021.

Site surveyors will continue to verify that candidate data entered in UNetSM is consistent with documentation in the candidate's medical record.

As of July 27, 2021, Policy 1.4.F will be repealed and programs will no longer have the option of using prior obtained values for required updates required to maintain allocation status. Current organ-specific policies outline required clinical data updates and explain how candidates could be downgraded if current values are not provided.

Affected Policy Language

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

~~1.4.F~~ Updates to Candidate Data during 2020 COVID-19 Emergency

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

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

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