

Mini-Brief

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

OPTN Executive Committee

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

Affected Policies: 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency
Sponsoring Committee: Executive
Executive Committee Date: April 26, 2021

Executive Summary

The COVID-19 crisis created challenges to conducting routine outpatient activities, including clinical testing, needed to obtain information required for transplant candidates, recipients, and living donors. OPTN emergency actions were adopted in March and April 2020 with the intent to protect patient safety by reducing the need for potential exposure to COVID-19 at health care facilities.

One of the emergency actions enabled 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.

The Executive Committee has regularly reviewed use of this policy since its adoption on March 17, 2020 (effective March 13, 2020). All COVID-19 emergency policy actions went out retrospectively for public comment in summer 2020. COVID-19 emergency policies, including *OPTN Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*, were adopted by the OPTN Board of Directors at their December 7, 2020 meeting. The OPTN Board of Directors approved these actions until such a time as the COVID-19 emergency no longer requires them. The BOD supported the Executive Committee taking actions in accordance with changes observed in the transplant community and COVID-19 impacts.

As transplant programs have adopted candidate management practices to protect their patients during the COVID-19 pandemic, use of this policy has declined over time. Although when first adopted up to 17 percent of adult lung and 8 percent of adult liver candidates were using the policy allowance, only five adult liver and three adult lung candidates used this policy for maintaining waitlist status during the last week monitored (March 29-April 4, 2021). Following data review and discussion, the OPTN Heart, Liver, and Lung Committees have recommended that this policy is no longer necessary to protect patient safety. This proposed action will repeal *OPTN Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*. The proposed effective date is July 27, 2021, giving members 90 days prior to repeal to obtain current lab values required to maintain their current candidates' waiting list statuses.

Background

The purpose of this proposal is to provide the latest data and feedback supporting the repeal of OPTN *Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*. This was the first of several actions taken by the OPTN Executive Committee in response to the COVID-19 pandemic.

The OPTN Executive Committee collectively passed four actions related to the COVID-19 public health crisis on March 17 and April 3, 2020, using OPTN *Bylaw 11.7: Emergency Actions*.^{1,2} Creation and implementation of Policy 1.4.F. was the first action taken and was originally set to expire a year from its original passage date.

This action created a policy to allow candidates to reuse most recent existing lab data in order to maintain waiting list status and avoid potential COVID-19 exposure by having to go to health care facility to obtain updated labs.

COVID-19 related circumstances may prevent a transplant program from obtaining clinical data updates required by OPTN policy for a candidate maintain their current allocation priority, such as a liver candidate that must have updated lab values for their MELD or PELD score. This policy allows the transplant program to carry forward the candidate's most recently reported lab results as the candidate's current lab values. Transplant programs use the day of the updated submission as the "new" test result date. This prevents the system from lowering a candidate's allocation priority due to inability to obtain updated testing. Thus, candidates who have been appropriately prioritized within a status or score previously will maintain that prioritization until new clinical data can be obtained. This rationale reflects the original reasons for passing the action.

Other emergency actions taken were to relax OPTN data submission requirements, provide a waiting time modification request pathway for certain kidney candidates unable to obtain all required registration lab work, and create data collection deceased donor COVID-19 testing status.

Following passage of all four items through the emergency pathway, the Executive Committee conducted regular monitoring at their 2020 meetings on April 20, June 7, July 30, September 18, November 2, and December 6. The Executive Committee sent the COVID-19 actions out for retrospective for public comment, August 4 – October 1, 2020, as required by OPTN Bylaw 11.7. The Executive Committee specifically requested and received feedback on how and when the actions should expire.³ After reviewing public comment feedback, the Executive Committee referred recommendations on all four actions to the OPTN Board of Directors (BOD). On December 7, 2020, the OPTN Board of Directors approved all four actions until such time the Executive Committee determines that the actions are no longer necessary given the state of the COVID-19 pandemic.⁴

The Executive Committee has continued to monitor data related to these policies and assess the need to take action as necessary at their 2021 meetings on January 13 and March 1. See **Table 1: COVID-19 Related Policy Actions** below for a summary of emergency action history and current state of actions.

¹ <https://optn.transplant.hrsa.gov/media/3722/candidatedata2020covid19emergency.pdf>.

² https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf.

³ Commenters proposed that the emergency actions not have a set expiration date, but that the Executive Committee should repeal the actions when needed based on the changing environment. <https://optn.transplant.hrsa.gov/media/4200/covid-19-emergency-policies-and-data-collection.pdf>

⁴ <https://optn.transplant.hrsa.gov/media/3687/covid-19-policy-notice-and-supporting-mini-brief.pdf>.

Table 1: COVID-19 Related Policy Actions

Emergency Action	Original Adoption Date	Most Recent Policy Action	Current State
1. Updates to Candidate Data During 2020 COVID-19 Emergency	3/17/2020	BOD approved on 12/7/2020	Review monitoring data and feedback. Consider proposed repeal.
2. Relax Data Submission Requirements for Follow-Up Forms	4/3/2020	Executive Committee repealed COVID-19 data submission exceptions on 3/1/2021	Regular data submission requirements resumed 4/1/2021. Retrospective missing data required by 7/1/2021.
3. Modify Wait Time Initiation for Non-Dialysis Kidney Candidates	4/3/2020	BOD approved on 12/7/2020	Review monitoring data and feedback
4. Incorporate COVID-19 Infectious Disease Testing into DonorNet®	4/3/2020	BOD approved on 12/7/2020	Review monitoring data

Proposal

This proposal would repeal OPTN *Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*. The most recent data and feedback from stakeholder OPTN Committees supports the Executive Committee taking this action. It is important not to maintain the policy if the circumstances do not support its continuance as it could provide an unfair advantage for a candidate not updating their laboratory values as required by policy. This policy exception was created due to an emergency situation to protect patient safety. The policy has been reviewed regularly with the intent of not perpetuating the exception when no longer needed.

Peak use of policy occurred at the beginning of the pandemic in April 2020 when 8% of adult liver candidates (week of April 6, 2020) and 17% of adult lung candidates (week of April 27, 2020) used this policy to use existing lab values to maintain status. In December 2020, low usage of the policy was noted when the BOD was asked to approve the policy. At that time, it was noted that although policy usage was low, the policy might still be necessary for some patients. Since that time, the moving 7-day average of COVID cases has decreased 72.2% from the highest peak on January 11, 2021 (249,861) to down to 69,577 as of April 19, 2021.⁵

The U.S. COVID-19 Vaccination Program began December 14, 2020. As of April 15, 2021, 198.3 million vaccine doses have been administered. Overall, about 125.8 million people, or 37.9% of the U.S. population, have received at least one dose of vaccine. Nearly one half (48.3%) of people ages 18 or older have received at least one dose of vaccine and 30.3% are fully vaccinated. As of April 15, the 7-day average number of administered vaccine doses reported to CDC per day was 3.3 million, a 10.3% increase from the previous week⁶.

Policy usage has continued to wane as transplant hospitals have found ways to adapt and obtain required candidate data despite the ongoing COVID-19 pandemic. No adult heart candidates have used this policy in 2021 and only five adult heart candidates have used this policy since its inception. **Figure 1: Potential Update to Adult Liver Candidate Data via COVID-19 Policy** and **Figure 2: Potential Update to**

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>.

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>.

Adult Lung Candidate Data via COVID-19 Policy below demonstrate the pattern of reduced and overall low use by adult liver and lung candidates.

Figure 1: Potential Update to Adult Liver Candidate Data via COVID-19 Policy

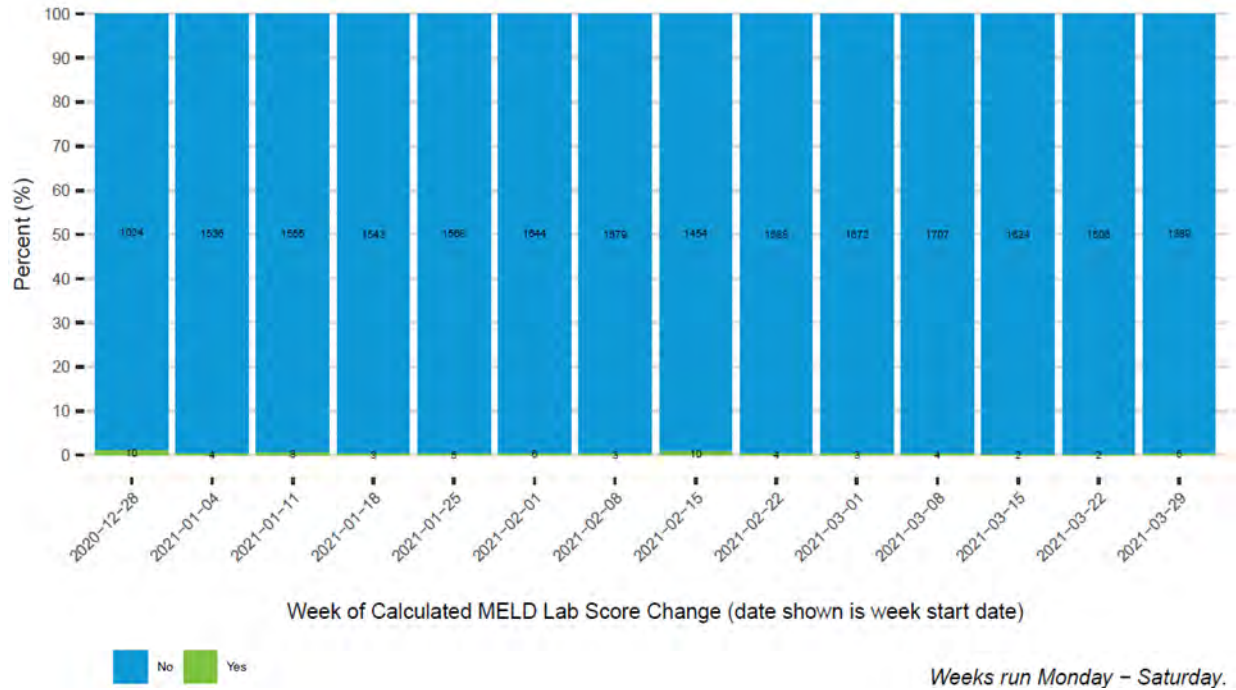
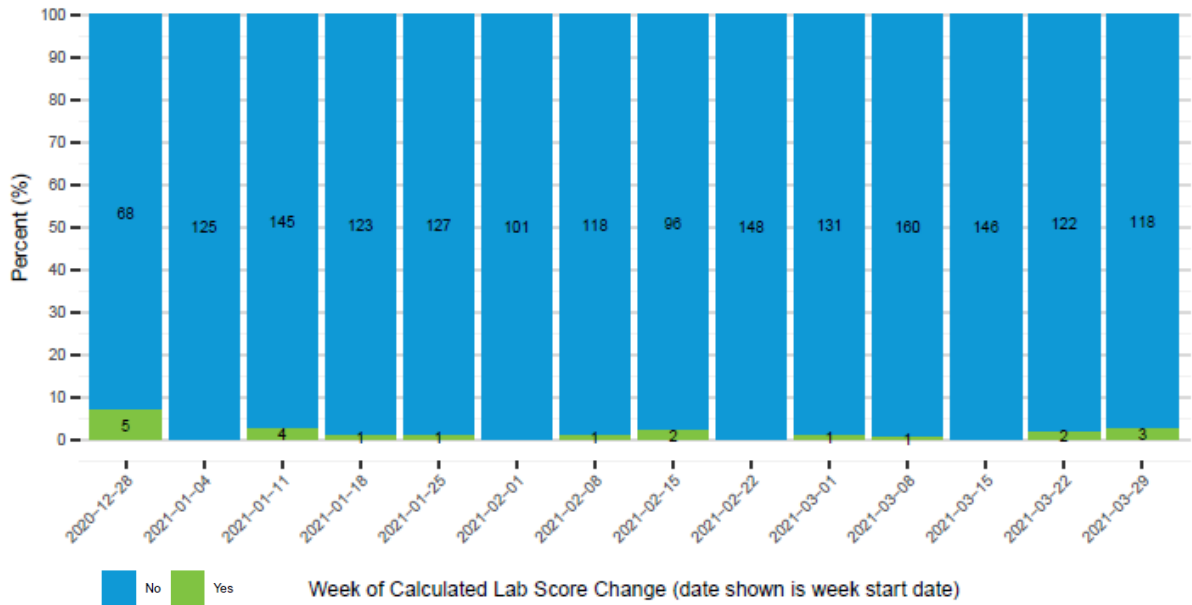


Figure 2: Potential Update to Adult Lung Candidate Data via COVID-19 Policy



Weeks run Monday–Sunday.

No pediatric lung candidates have used this policy. In 2021, so far only three pediatric liver candidates used this policy, with all three reporting use in January 2021.

During the last week of available monitoring data (March 29–April 4, 2021), only eight candidates used this policy to keep required data current which represented than 0.4% of candidates with data needed to maintain waiting list status. See **Table 2: Use of Policy 1.4.F during Week of March 29–April 4, 2021** below for details.

Table 2: Use of Policy 1.4.F during Week of March 29–April 4, 2021

Candidate Type	Use of Policy		
	Yes	No	% Use
Adult liver	5	1389	0.4%
Pediatric liver	0	17	0.0%
Adult lung	3	118	2.5%
Pediatric lung	0	0	0.0%
Adult heart	0	297	0.0%
Total	8	1821	0.4%

The OPTN Heart, Liver, and Lung Committees support repeal of this policy following discussion and review of current data at their latest meetings. The Heart Committee reviewed data and discussed the policy on April 20, 2021. They unanimously agreed that it was time to repeal the policy as transplant

programs and candidate have adjusted to the current circumstances. They did support a 90-day implementation timeframe to account for varying circumstances across the country and to allow for adequate assessment and planning time to obtain labs for candidates as required by regular allocation policies. The Liver Committee reviewed current data on April 15, 2021. They unanimously expressed that they did not think the policy was still needed, given that the policy is rarely being utilized and there were no concerns or obstacles for getting liver patients in for updated laboratory tests, and no patient safety risk for doing so. The Lung Committee reviewed current data and discussed the policy on April 15, 2021. Committee members expressed that transplant programs have generally been able to see their patients on a regular basis, although there are some instances where patients may be reluctant to come in for updated labs. Transplant programs have adjusted their practices to incorporate telehealth versus in-person appointments and have alternated as needed. Overall, the Committee supported repeal of the policy. They supported a 90-day timeline to sunset this policy to allow transplant programs to make any necessary adjustments to update candidate lab results.

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, repeal of the policy is logical and timely.

NOTA and Final Rule Analysis

The OPTN Board of Directors is “responsible for developing...policies for the equitable allocation for cadaveric organs.”⁷ Requirements regarding the recency of candidates’ lab values may impact candidates’ priority on the match run. The Final Rule requires that policies for the equitable allocation of organs must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.”⁸

The proposed repeal of Policy 1.4.F:

- **Is based on sound medical judgment**⁹ because it is an evidenced-based change relying on the following:
 - Monitoring of COVID-19 trends and policy usage have shown continued lowered use or absence of use of this particular policy, indicating that medical professionals do not believe this policy is necessary
 - Improvements in the pandemic conditions overall as evidenced by lowered new case rates and the availability and use of vaccinations
 - Feedback from OPTN stakeholder committees indicating that transplant hospitals and their candidates have adapted and are able to obtain the medical lab values needed to assess medical urgency and status, as defined by organ specific policies.

⁷ 42 CFR §121.4(a)(1).

⁸ 42 CFR §121.8(a).

⁹ 42 CFR §121.8(a)(1).

- **Seeks to achieve the best use of donated organs¹⁰ by** ensuring organs are allocated and transplanted according to medical urgency. This proposal:
 - Ensures that the medically urgent status assigned to candidates are based on organ specific policy required lab values and therefore prioritize those with laboratory values reflecting the most urgent need
 - Prioritizes the most medically urgent candidates by restoring requirements to update lab values, which will confirm the continued medical urgency of the candidate
- **Is designed to...promote patient access to transplantation¹¹ by** giving similarly situated candidates equitable opportunities to receive an organ offer. This proposal promotes equitable access for all candidates by restoring requirements for updated lab testing as specified by organ specific policy. By removing the ability to carry forward existing lab values that existed due to emergency conditions, the policies will resume promoting access as originally designed.

The policy action is not expected to impact the following aspects of the Final Rule:

- **Is designed to avoid wasting organs¹²** by decreasing the number of organs recovered but not transplanted
- **Is designed to avoid futile transplants¹³:** This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes.
- **Promote the efficient management of organ placement¹⁴** by taking into account factors including the costs and logistics of procuring and transplanting organs
- **Is not based on the candidate's place of residence or place of listing.¹⁵**

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation...no less favorably than they would have been treated under the previous policies.”¹⁶ The Committee recommends a 90-day period between approval and implementation of the repeal to provide adequate transition time for any candidates who may have used Policy 1.4.F to obtain updated labs as defined by the organ specific policies.

Post-Repeal Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”¹⁷ For retrospective site survey reviews of candidate data that are used to maintain a candidate's prioritization or eligibility reported through UNetSM:

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

¹⁰ 42 CFR §121.8(a)(2).

¹¹ 42 CFR §121.8(a)(5).

¹² Id.

¹³ Id.

¹⁴ Id.

¹⁵ 42 CFR §121.8(a)(8).

¹⁶ 42 CFR § 121.8(d).

¹⁷ 42 CFR §121.8(a)(7).

- If a surveyor is unable to locate documentation in the medical record that corroborates the collection date entered in UNet, and the collection date is during the effective period of Policy 1.4.F: *Updates to Candidate Data during 2020 COVID-19 Emergency* (March 13, 2020 to July 27, 2021, presumably), the surveyor will look for documentation that the transplant program exercised authority under Policy 1.4.F to re-report the candidate's most recently reported data on that date as the "collection date."

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate." Usage of *Policy 1.4.F: Updates to Candidate Data During 2020 COVID-19 Emergency* will no longer be monitored once the policy is repealed. Updates to candidate data will be monitored according to organ specific monitoring plans and upon the request of the Executive Committee.

Conclusion

This proposal would repeal *OPTN Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*. Based on recommendations from the OPTN Lung Committee, the repeal would go into effect 90 days after the Executive Committee acts. This will allow transplant programs adequate transition time to review and identify candidates who are due for lab updates and to arrange for these updates to occur.

No programming changes will be required in UNetSM. Existing instructions related to this policy will be updated to reflect the changes associated with the repeal. Communications of this upcoming change will be provided through the standard OPTN Policy Notice as well as targeted COVID-19 communications regularly provided to the community.

Policy Language

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

RESOLVED, that *Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency*, is hereby repealed, effective July 27, 2021.

- 1 ~~1.4.F~~ — ~~Updates to Candidate Data during 2020 COVID-19 Emergency~~
- 2 This policy is in effect due to the public health emergency declared by the President of the
- 3 United States on March 13, 2020. ~~This policy only applies to transplant programs that have~~
- 4 ~~candidates who require clinical data updates per OPTN policy in order to maintain prioritization~~
- 5 ~~or eligibility.~~
- 6
- 7 1. ~~Transplant programs should continue to make all reasonable efforts to collect and report~~
- 8 ~~clinical 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~~
- 11 ~~data due to the COVID-19 emergency, or: b) in their medical judgment chooses not to~~
- 12 ~~collect such data due to the COVID-19 emergency, may use the candidate's clinical data~~
- 13 ~~values that were most recently reported to the OPTN. When reporting previous clinical data~~
- 14 ~~pursuant to this policy, the transplant program must report the date the program is entering~~
- 15 ~~the data as the collection date.~~
- 16 3. ~~While using this policy, transplant programs must document in the candidate's medical~~
- 17 ~~record the circumstances that support use of this policy.~~
- 18
- 19 #