



# Public Comment Proposals

Winter 2020

## TABLE OF CONTENTS

### Public Comment Proposals

<b>1. National Heart Review Board for Pediatric Candidates</b> ( <i>OPTN Thoracic Organ Transplantation Committee</i> ) .....	<b>1</b>
<b>2. Data Collection to Assess Socioeconomic Status and Access to Transplant</b> ( <i>OPTN Minority Affairs Committee</i> ) .....	<b>27</b>
<b>3. Addressing Medically Urgent Candidates in New Kidney Allocation Policy</b> ( <i>OPTN Kidney Transplantation Committee</i> ) .....	<b>43</b>
<b>4. Distribution of Kidneys and Pancreata from Alaska</b> ( <i>OPTN Kidney Transplantation and Pancreas Transplantation Committees</i> ) .....	<b>79</b>
<b>5. Modifications to Released Kidney and Pancreas Allocation</b> ( <i>OPTN Organ Procurement Organization Committee</i> ) .....	<b>88</b>
<b>6. Enhancements to the National Liver Review Board</b> ( <i>OPTN Liver and Intestinal Organ Transplantation Committee</i> ) .....	<b>122</b>



## At a glance

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**Title:** National Heart Review Board for Pediatrics

**Sponsoring Committee:** Thoracic Organ Transplantation

## What is current policy and why change it?

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Currently, when a transplant physician lists a candidate at a high urgency status (Status 1A or Status 1B) who does not meet the criteria for that status, they must submit justification for this exception to the OPTN for review by a Regional Review Board (RRB). Due to recent pediatric heart allocation changes, there has been an increase in pediatric candidates listed at higher statuses by exception, but pediatric transplant programs tend to be under-represented on RRBs.

## What's the proposal?

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- **Create a National Heart Review Board (NHRB) for Pediatric Candidates**
  - Each active pediatric heart program would be able to appoint **one primary** and **one alternate** representative to serve one year terms
  - NHRB would review exception requests for **Status 1A** and **Status 1B** pediatric heart candidates
  - Requests would be assigned to **nine randomly selected representatives**
  - Decisions based on **majority vote** within three days
  - Denials can **appeal** to same group of reviewers
    - Additional denial can be appealed to workgroup made up of members of Thoracic Committee and Pediatric Committee with relevant expertise

## What's the anticipated impact of this change?

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- **What it's expected to do**
  - Improve quality and consistency in review of pediatric heart exceptions
  - Work towards ensuring more medically appropriate status listings for pediatric heart patients
- **What it won't do**
  - It will not change the way exception requests for adult heart patients are reviewed.

## Themes to consider

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- How to ensure broad/equal representation on the NHRB
- How appeals should work
- What statuses should be reviewed
- Plan for tiebreakers

## Terms you need to know

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- **Status:** An indication of the degree of medical urgency for patients awaiting heart transplants. Status 1A is most urgent.
- **Exception:** When a physician places a candidate at a higher status even though the candidate does not meet the standard criteria in policy to automatically qualify for the status.
- **Review Boards:** Peer review panels established to review all urgent status listings for liver and heart candidates. The review boards reviews justification forms submitted by each center documenting the severity of the candidate's illness and justifies the status at which the candidate is listed. Thoracic review boards review listings for heart candidates in Status 1A and special case heart candidates in Status 1B. These boards also consider appeals of cases initially turned down for a particular medical urgency status.
- [Click here to search the OPTN glossary](#)

*Public Comment Proposal***National Heart Review Board for Pediatric Candidates***OPTN Thoracic Organ Transplantation Committee**Prepared by: Elizabeth Miller  
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Executive Summary	4
Purpose of the Proposal	5
Background	5
Pediatric Specialty	7
Rationale for a National Board	9
Operations	10
Guidance	13
Feedback Questions	13
Potential Impact on Select Patient Populations	14
Alternate Solutions Considered	15
NOTA and the OPTN Final Rule	15
Implementation and Operational Considerations	15
OPTN Actions	15
Member Actions	16
Post-implementation Monitoring	16
Member Compliance	16
Policy Evaluation	16
Conclusion	16
Policy Language	17
Operational Guidelines Language	20

# National Heart Review Board for Pediatric Candidates

<i>Affected Policies:</i>	<i>6.4: Adult and Pediatric Status Exceptions</i> <i>6.4.A: Review Board and Committee Review of Status Exceptions</i> <i>6.4.A.i: Review Board Appeals</i> <i>6.4.A.ii: Committee Appeals</i>
<i>Affected Guidelines:</i>	<i>National Heart Review Board Operational Guidelines - Pediatric</i>
<i>Sponsoring Committee:</i>	<i>Thoracic Organ Transplantation</i>
<i>Public Comment Period:</i>	<i>January 22, 2020 – March 24, 2020</i>

## Executive Summary

The number of Status 1A listings by exception has increased and the degree of increase has been mixed across OPTN regions since the implementation of changes to the criteria for Status 1A. This disparity is influenced by regionally-separated review boards, with varying levels of pediatric expertise.

This proposal would create a national heart review board (NHRB) for pediatric heart candidates. Under the NHRB, each Status 1A and Status 1B exception request would be randomly assigned to a group of specialists in pediatric heart transplant from across the country who would decide whether to approve the request. The goals are that the specialized expertise and the use of reviewers from across the country would:

1. Improve the stratification of Status 1A and Status 1B candidates by aligning the waiting list mortality rates for pediatric candidates with Status 1A and Status 1B by exceptions with those based on the standard criteria
2. Reduce the regional variance in volume of Status 1A and Status 1B exceptions.

## Purpose of the Proposal

The purpose is to improve quality and consistency in the evaluation of exceptions for heart candidates listed before their 18<sup>th</sup> birthday. Pediatric heart candidates can be listed as Status 1A, Status 1B, Status 2 or Inactive. By default, active pediatric candidates are Status 2 unless they qualify for the increased priority of Status 1A or Status 1B.<sup>1</sup> Since the pediatric heart Status 1A and Status 1B criteria were redefined in policy changes that took effect on March 22, 2016,<sup>2</sup> there has been an increase in the number of Status 1A by exception listings and the number of candidates transplanted with Status 1A exceptions. There has also been increased regional variance in the proportion of pediatric transplants for candidates listed as Status 1A by exception.<sup>3</sup>

The Organ Procurement and Transplantation Network (OPTN) Thoracic Organ Transplantation Committee (Thoracic Committee) and OPTN Pediatric Transplantation Committee (Pediatric Committee) believe that the fragmented operation of the different regional review boards (RRBs) and the fact that most of the reviewers on the RRBs are not specialists in pediatric transplantation contribute to the increase in Status 1A exceptions and the variability among the numbers of Status 1A exceptions between regions. This proposal would create a National Heart Review Board (NHRB) for pediatric candidates.<sup>4</sup>

The NHRB would be comprised of representatives from pediatric heart programs all over the country, with reviewers randomly assigned to review the exception requests. The use of reviewers who are specialists in pediatric heart transplantation would be aimed at increasing the quality of the evaluation of these exception requests. The national board would be used to minimize local differences and improve consistency.

## Background

The National Organ Transplant Act of 1984, as amended (NOTA) provides special status to pediatric transplant candidates. Under NOTA, the OPTN is required to adopt criteria, policies, and procedures that address the unique health care needs of individuals under the age of 18.<sup>5</sup> As part of its ongoing commitment to this population, the Board approved changes to pediatric heart allocation policy in 2014, with the primary goal of improving waiting list mortality rates for pediatric heart candidates. The Board sought to achieve this in part by redefining pediatric status 1A and 1B criteria to make sure that candidates of comparable levels of medical urgency are in the same statuses.<sup>6</sup>

After implementation of those changes, as part of its work to monitor their effectiveness, the Thoracic and Pediatric Committees reviewed an evaluation report in April 2018 (Report).<sup>7</sup> Findings in the Report

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<sup>1</sup> OPTN Policy 6.2 Pediatric Status Assignments and Update Requirements

<sup>2</sup> Important Policy Notice, *Changes to the OPTN Policies and Bylaws from the June Board of Directors Meeting*, July 2014, [https://optn.transplant.hrsa.gov/media/1822/optn\\_policy\\_notice\\_07-24-2014.pdf](https://optn.transplant.hrsa.gov/media/1822/optn_policy_notice_07-24-2014.pdf) (accessed November 25, 2019).

<sup>3</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018.

<sup>4</sup> For purposes of this paper, pediatric candidates refers to candidates registered for a heart transplant before their 18<sup>th</sup> birthday.

<sup>5</sup> 42 U.S.C. 274(m).

<sup>6</sup> Briefing Paper, *Proposal to Change Pediatric Heart Allocation Policy*, Thoracic Organ Transplantation Committee and Pediatric Transplantation Committee, April 2014.

<sup>7</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018.

raised concerns that the policy changes were having an inequitable effect on candidate access to organs and there were still different levels of medical urgency within each status. The Report showed an increased number of Status 1A exceptions.<sup>8</sup> The Status 1A candidates who were awarded Status 1A by exception had lower waiting list mortality than those who were placed at Status 1A by meeting the policy criteria, suggesting that some candidates who are not as medically urgent may be receiving the higher priority.<sup>9</sup> This results in a situation where the patients with the highest waiting list mortality could have decreased access to deceased donor hearts because deceased donor hearts are allocated to Status 1A exception patients who were not as medically urgent. This might be contributing to the lack of improvement in waiting list mortality rates overall following implementation of the new status criteria.

Figure 1 shows that candidates with diagnoses other than congenital heart disease (CHD) are being transplanted more often with a Status 1A exception since the implementation of the new Status 1A and 1B standards. Although the new criteria are having the intended result of decreasing the number of Status 1A and Status 1B that meet criteria, there has been an unintended result that the number of exceptions for candidates with the same diagnoses who do not meet the standard criteria for Status 1A is increasing. For example, under the old policy candidates with cardiomyopathy could qualify for status 1A. Under the new policy, there is no explicit sub-criterion in status 1A for candidates with cardiomyopathy. Therefore, post-implementation the Committee observed an increase in exception requests for status 1A based on a candidate's diagnosis of cardiomyopathy.

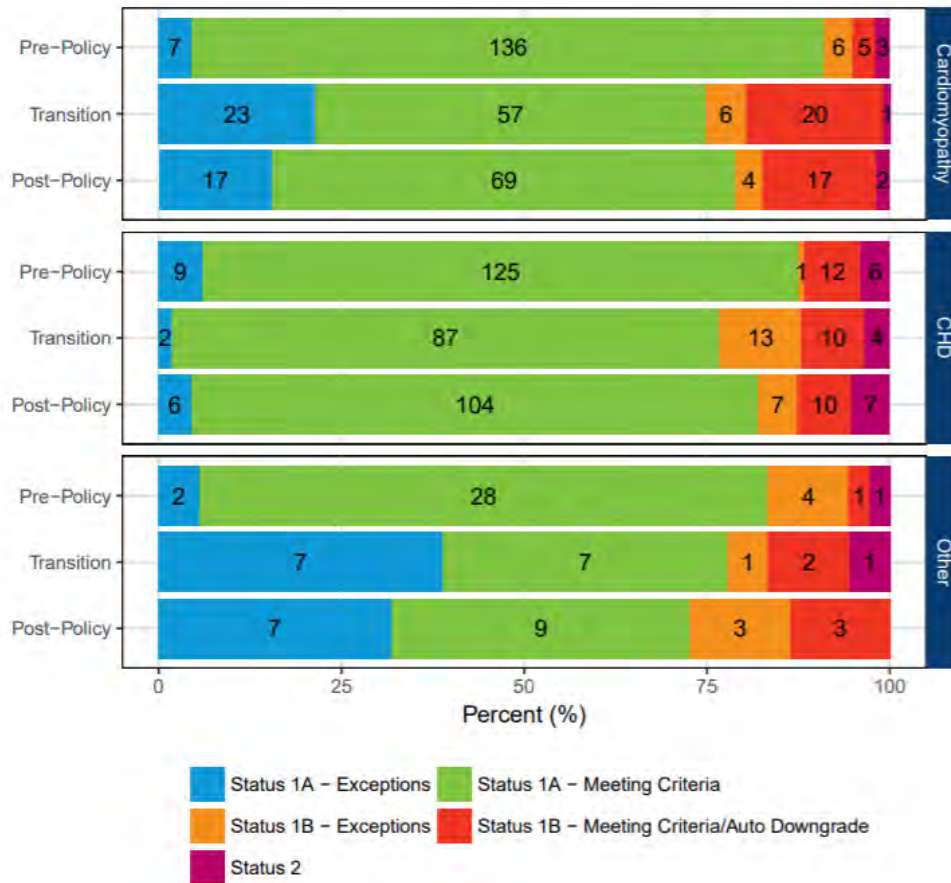
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<sup>8</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*, April 19, 2018.

<sup>9</sup> Final Report, *Changes to Pediatric Heart Allocation*, April 19, 2018, 21, Figure 17.



**Figure 1: Pediatric Heart Transplants by Exception Status, Era and Diagnosis<sup>10</sup>**



The report also identified an increase in the regional variation of the proportion of candidates transplanted while registered with a Status 1A exception. For instance, in Region 1, none of the pediatric heart transplants in the post-implementation cohort were transplanted at Status 1A by exception, while approximately 25% of the pediatric heart transplants in Region 3 were transplanted into candidates with a Status 1A exception. This suggests that some candidates may be disadvantaged in their ability to access an exception status based on their listing location.

## Proposal

The Committee proposes creating a NHRB specializing in pediatric Status 1A and Status 1B exception requests. The NHRB will be comprised of representatives of the pediatric heart programs across the nation and will decide all requests for pediatric heart Status 1A or Status 1B exceptions and exception extensions.

### Pediatric Specialty

Under *OPTN Policy 6.4, Adult and Pediatric Exceptions*, a candidate's transplant physician can register a pediatric heart candidate as Status 1A or Status 1B even though the candidate does not

<sup>10</sup> Policy eras were defined as: Pre-Policy: March 22, 2015 to March 21, 2016; Transition: March 22, 2016 to September 30, 2016; Post-Policy: October 1, 2016 to December 31, 2017.

meet the standard criteria in policy to automatically qualify for the status. When the transplant physician does this, they must submit a justification form with the requested status and the rationale for granting the status exception. Such requests are reviewed retrospectively by the appropriate Regional Review Board (RRB).

Pediatric transplantation is an accepted subspecialty within the field of transplantation,<sup>11</sup> but pediatric programs are often under-represented on a given heart RRB. For instance, in Region 4, there are 13 heart transplant programs that can each assign a representative and an alternate to participate on the RRB. As shown in *Table 1* below, of those programs, only two have listed at least one pediatric heart candidate within an 18 month span. As a result, each case decided by the Region 4 RRB is likely decided primarily by reviewers who do not typically transplant pediatric candidates.

**Table 1: Number of programs by OPTN region that listed at least one heart candidate on the waiting list between 1/1/2018 and 6/30/2019<sup>12</sup>**

OPTN Region	Heart Programs <sup>13</sup>	Heart Programs with at least one pediatric candidate listed <sup>14</sup>	% of Heart programs that have at least one pediatric candidate listed
1	6	2	33%
2	16	6	38%
3	19	11	58%
4	13	2	15%
5	20	9	45%
6	4	2	50%
7	13	8	62%
8	11	6	55%
9	7	2	29%
10	13	8	62%
11	17	8	47%

Members of the Thoracic and Pediatric Committees expressed concerns that this results in such requests receiving less scrutiny and the RRB members deferring more to the judgment of the requesting physician when granting an exception than they would when evaluating exception requests for adult candidates. For this reason, the Thoracic and Pediatric Committees favor using only pediatric specialists to review exception requests for pediatric candidates.

<sup>11</sup> Public Comment Proposal, *Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws*, OPTN/UNOS Pediatric Transplantation Committee, August 2015, [https://optn.transplant.hrsa.gov/media/1181/0815-01\\_pediatric\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/1181/0815-01_pediatric_bylaws.pdf) (accessed November 14, 2019).

<sup>12</sup> *Heart Review Board Report*, October 2019. *Heart Review Board Report*, July 2019.

<sup>13</sup> Programs in each OPTN region that listed at least one heart candidate on the waiting list between 1/1/2018 and 6/30/2019

<sup>14</sup> Programs in each OPTN region that listed at least one pediatric (age at time of listing <18) heart candidate on the waiting list between 1/1/2018 and 6/30/2019

## Rationale for a National Board

Heart programs with pediatric specialty expertise have not historically been tracked by the OPTN. However, new requirements to delineate which programs are permitted to perform pediatric transplants have been approved by the Board, and are expected to be implemented in late 2020 or early 2021.<sup>15</sup> Although the specific number of programs that will have a pediatric heart component once the membership requirements are implemented is unknown, 53 heart transplant programs have applied for that designation as of the initial deadline<sup>16</sup>. They are not evenly distributed across regions.<sup>17</sup>

If pediatric specialty boards were created within the existing RRB system, there are regions where only one or two pediatric programs would be represented. The Committee did not consider it practical to have a regional review board with only one or two representatives.

Further, there is already regional variation in the percentage of candidates being transplanted with exceptions for Status 1A, as shown in Figure 2 below.<sup>18</sup> The Final Rule requires that allocation policies “not be based on the candidate's place of residence or place of listing, except to the extent required...”.<sup>19</sup> Accordingly, the Thoracic Committee chose to remove the considerations for the place of listing in the evaluation of pediatric Status 1A and Status 1B exception requests.

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<sup>15</sup> Briefing Paper, *Revisions to Pediatric Emergency Membership Exception Pathway*, Pediatric Transplantation Committee, December 2017, available at [https://optn.transplant.hrsa.gov/media/2337/pediatric\\_boardreport\\_201712.pdf](https://optn.transplant.hrsa.gov/media/2337/pediatric_boardreport_201712.pdf).

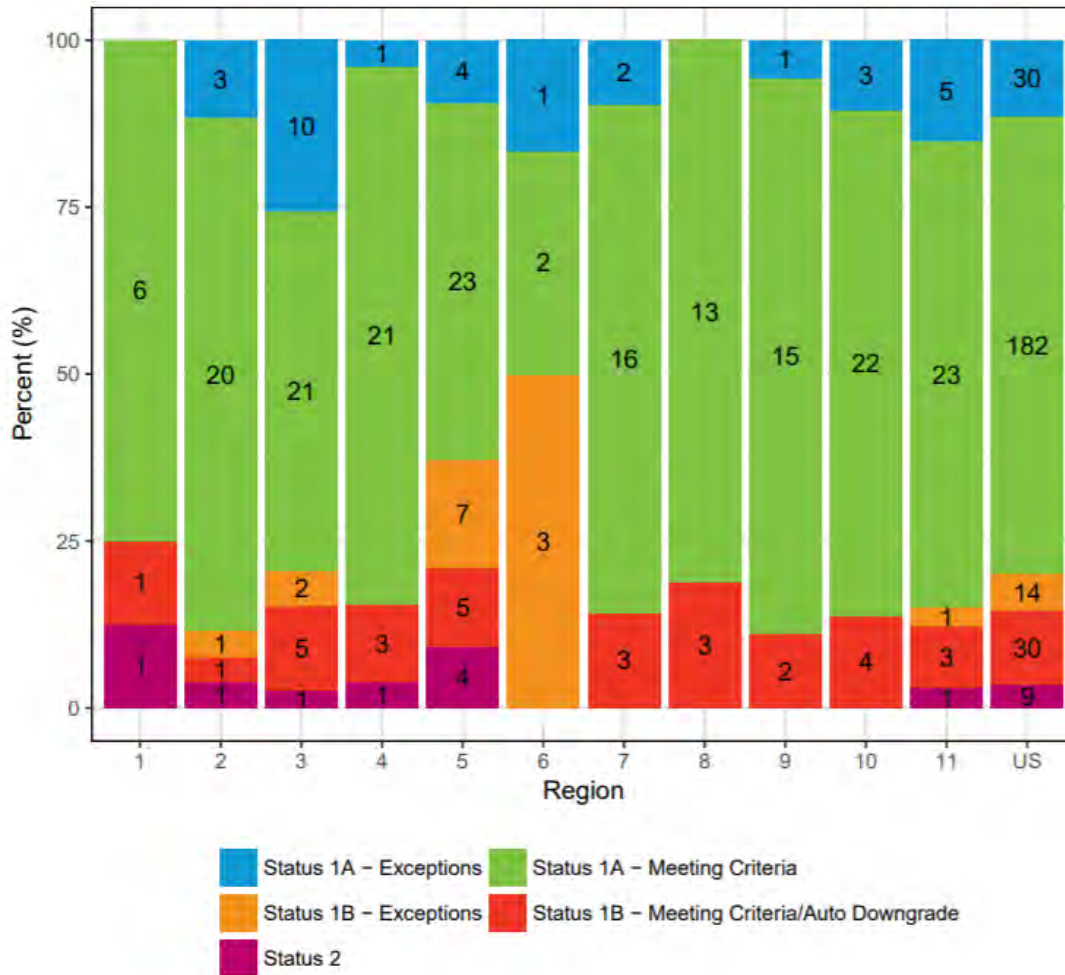
<sup>16</sup> The initial deadline to apply was December 3, 2019. On that date, 53 heart programs had applied, 20 programs had stated that they did not intend to apply, and 20 other programs were identified as likely potential applicants, but have not applied.

<sup>17</sup> See Table 1 above.

<sup>18</sup> Final report, *Changes to Pediatric Heart Allocation Policy Evaluation*.

<sup>19</sup> 42 CFR 121.8(a)(8).

**Figure 2: Pediatric Heart Transplants by Region and Exception Status, 10/01/2016-12/31/2017**



The Thoracic Committee chose to create a national review board in order to provide more equitable access to Status 1A and 1B and to facilitate efficient and practical review of these requests by pediatric heart transplant specialists.

### Operations

This proposal would create a NHRB that would review Status 1A and Status 1B exception requests for pediatric heart candidates. The Committee considered whether it was only needed for Status 1A, which is the larger proportion of the exception requests for pediatric candidates. The Committee chose to have the NHRB review both Status 1A and 1B exception requests because both would benefit from the pediatric expertise the NHRB would bring. However, the Committee seeks feedback on whether the Status 1B requests should continue to be reviewed by the RRBs instead of the proposed NHRB.

## Representation

Each heart program with an active pediatric component will be able to appoint a primary representative and an alternate to the NHRB. They will serve for a one year term and may be reappointed for additional terms.

Exception requests will be assigned to nine randomly selected reviewers from the pool of current reviewers. The Committee considered whether there is a need for additional constraints on the random assignment, such as ensuring that reviewers are assigned even amounts of exceptions, or ensuring representation from:

- Different geographic areas (north and south, different regions, etc.)
- Both small and large programs.

The Thoracic Committee did not include such restraints, but requests additional feedback on whether there should be any criteria to the random reviewer assignments.

The Thoracic Committee chose nine reviewers for each case for several reasons. The volume of cases to review is expected to be too large to have all reviewers review every case, but small enough that there was not significant concern about overburdening reviewers if nine are assigned to each case. Nine was preferred over a smaller number because the larger number might be expected to provide more consistency. Finally, it was preferred over a larger number because the Thoracic Committee expects that this will decrease the likelihood of a decision being delayed to wait for one or two slow reviewers to respond.

The exception will be approved or denied based on the vote of the majority of those nine reviewers. If a reviewer votes to deny an exception, they will be expected to provide a reason that the requesting transplant program can review. The Committee intends for reviewers to provide explanations that will help the requesting transplant center improve future exception requests or appeals.

Reviewers will be expected to report the times when they will be unavailable to vote on exception requests. A representative may be removed for failure to vote if three of the exceptions they are assigned within a year are reassigned because the representative did not vote in time. This is intended to ensure that the reviewers are responsive so that transplant programs can receive an expeditious answer to exception requests.

## Voting

Because Status 1A and Status 1B are reserved for the most medically urgent pediatric heart candidates, with the highest waiting list mortality,<sup>20</sup> and the number of exceptions each year is not large<sup>21</sup>, the Committee chose a quick timeline for review. Reviewers must vote within three calendar days. The national average number of calendar days between assigning a case and closing it with sufficient votes for the RRBs was less than 2 days between May 2019 and October

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<sup>20</sup> Colvin, M., Smith, J. M., Hadley, N., Skeans, M. A., Uccellini, K., Lehman, R., Robinson, A. M., Israni, A. K., Snyder, J.J. & Kasiske, B. L. OPTN/SRTR 2017 Annual Data Report: Heart. *Am J Transplant* 2019; 19 (Suppl 2): 323– 403. doi: [10.1111/ajt.15278](https://doi.org/10.1111/ajt.15278), Figure HR85: Pretransplant mortality rates among pediatrics waitlisted for heart transplant by medical urgency.

<sup>21</sup> In July, August and September 2019, there were 29, 19, and 25 pediatric Status 1A exception applications respectively. In the same months, there were 8, 11, and 9 pediatric Status 1B exception applications. *Heart Review Board Report*, October 2019.

2019, suggesting that three days is not an unreasonable timeline to expect reviewer responses. Further, Status 1A and 1B exceptions are reviewed retrospectively because these cases are so urgent that the candidates are awarded the status while waiting on a decision. Therefore, the longer a review board takes to reach a decision, the higher the likelihood that a candidate might be transplanted at a status that will ultimately be denied, resulting in disadvantage to other candidates in that status.

If the reviewer does not vote within one day, their alternate will be notified and either the primary reviewer or their alternate may vote on that request. If neither has voted after the third day, the exception request will be reassigned to another reviewer. If both vote before the request is closed, the primary reviewer's vote will be counted and the alternate's vote will not.

The exception will be closed when the first one of these occurs:

- There are five votes to approve
- There are five votes to deny
- Six days after the exception was requested

If the exception request is closed after six days, the exception will be decided based on the majority of the reviewers who responded within that time. If there is a tie, the exception will be granted. The Committee specifically requests feedback on whether a tie should result in approval, denial, or if the chair of the NHRB should break ties.

Currently, the voting process is manual, and managed by OPTN staff. This would change the process so that voting will occur in UNet<sup>SM</sup>. A new system to review and record exception request votes will be created in UNet that will assign reviewers and track votes. Reviewers will also be able to report the times when they will be unavailable within the system.

## Appeals

If the exception request is denied, the transplant program may appeal to the same group of nine reviewers, and provide additional information or answer any questions raised in the reviewer feedback. That request will once again be decided based on the majority vote by the reviewers. If there is no resolution within six days, the appeal will be decided based on the majority of those responding. If there is a tie, the appeal will be approved.

If the reviewers deny both the initial application and the appeal, the transplant program will have the option to submit a written appeal to a workgroup comprised of the members of the Thoracic and Pediatric Committees who have pediatric heart transplantation experience. If there are not at least five collective members with this expertise, the Thoracic Committee chair will appoint additional members to the workgroup who have pediatric heart transplantation expertise in order to have a sufficient number to decide appeal cases. The Committee considered whether the members of the workgroup need to be physicians or surgeons, since there might be transplant family or OPO representatives on either committee. Instead of making a rule on the specific qualifications, the Committee chose to allow the Thoracic Committee chair to make determinations about whether members have sufficient expertise. The Thoracic Committee specifically requests feedback on whether there should be additional requirements for participation on the workgroup, such as a requirement to be a physician or surgeon. The Thoracic Committee also seeks feedback on whether the Thoracic Committee chair is the

appropriate position to decide who may be added to the review group in order to ensure that there are enough representatives.

If the appealing transplant program or a member of the workgroup requests, the appeal will be considered during a teleconference. If there is no request, it will be considered electronically.

These appeals will be decided by the vote of the majority of the members of that workgroup. If the appeal is considered on a teleconference, it will be decided by a majority of the members of the workgroup who participate in the teleconference. If there is a tie, the exception will be granted.

The Thoracic Committee considered allowing an additional level of appeal, but decided that the workgroup would provide sufficient oversight. The Thoracic Committee requests feedback on whether there should be another level of appeal available to transplant centers whose request is denied by the workgroup. If another level of appeal is warranted, then the Committee requests feedback on the appropriate body to consider those appeals.

## Guidance

The Thoracic Committee also plans to produce a guidance document to be circulated for additional public comment later this year. It would assist transplant programs and reviewers regarding the most common diagnoses for which Status 1A is requested. The guidance document is expected to be completed and available before the implementation of the NHRB. The Thoracic Committee intends to include guidance on evaluation of candidates with cardiomyopathy. Feedback is requested on whether there are additional diagnoses that warrant guidance.

## Feedback Questions

The Committee welcomes additional feedback on the operation of the NHRB, including the following:

### Composition

1. Should there be criteria for randomization of reviewer assignment? (for instance, requirements to make sure there is a certain geographic representation, or balance of small and large centers, or ensure that numbers of cases are fairly evenly distributed).). If yes, what would need to be included?
2. Should there be other requirements for who can be on the NHRB? For instance, should the transplant program or the physician be required to have performed at least a certain number of pediatric heart transplants in the last year, or should they be required to be a physician or surgeon?
3. Is there a need for a chair of the NHRB? If so, should the chair of the NHRB be appointed by the Thoracic Committee chair and serve a two year term? Should the chair be randomly assigned cases and vote on them as a member of the NHRB? What role would the chair serve?
4. Who should determine the members of the appeal workgroup?

### Voting

5. Is three days the right length of time to vote?



6. Is there a need for an additional level of appeal, such as to the entire Thoracic Committee?
7. Is nine the correct number of reviewers to consider each application?
8. Does the alternate need to be notified and allowed to vote on cases that have been sent to the primary reviewer?
9. When both a primary and alternate representative vote on a case in the RRB system, the first vote is counted. The Thoracic Committee proposes that the primary representative's vote be the vote that counts in that situation under the NHRB. Should it be the same for both boards, and if so, which vote should count?
10. Is a simple majority the right threshold for approval?
11. Did the Committee choose the correct tiebreakers?
  - a. Should the tiebreaker be the same on appeal as it is in the initial review?
  - b. Would it be better to have a chair of the workgroup break ties when a case is appealed to that level?
  - c. Should the exception request be denied when there is a tie instead of being approved?
12. Should there be a time limit for how quickly the Thoracic committee review will take place if an application is appealed to that level?
13. If a member of the Committee-level appeal workgroup has already reviewed the application as a reviewer on the NHRB, should that reviewer participate in the review of the appeal or not? Should others be excluded from the review?

#### **Removal for failure to vote**

14. Is three the right threshold for removal for failure to vote on an application? Should it be based on a percentage instead?
15. Is two reviewers removed from the review board the right number for removing a program's ability to appoint a member for the review board? Should it be within a certain time frame (such as two within a one-year term, or two within 5 years)?

#### **Other**

16. Which diagnoses should be addressed in guidance?
17. Are the right data points for evaluating the effectiveness of the review board identified in the Post Implementation Monitoring section below?
18. Are there any other areas in which the NHRB should change to align with the way the RRBs or other organ review boards operate?
19. Should the Thoracic Committee consider using a NHRB for review of adult exception requests as well?

### **Potential Impact on Select Patient Populations**

This proposal will directly affect pediatric heart candidates. Specifically, it is expected to change approval rates for pediatric heart candidates applying for a Status 1A or Status 1B exception. If fewer exceptions are approved for these candidates, the candidates who are approved for Status 1A or 1B based on the policy criteria will likely be transplanted earlier. As shown in Figure 1 above, over a 20 month period, there were 40 transplants into recipients who were Status 1A or Status 1B by exception. During the same period, 212 recipients were transplanted while listed as Status 1A or Status 1B based on the standard policy criteria.



## Alternate Solutions Considered

The Committee considered eliminating the RRBs and having all exceptions reviewed by the NHRB, including those for adult candidates. However, the Committee chose to pursue a NHRB only for pediatric candidates at this time in order to more quickly address the difficulties experienced by this particular population.

The Committee also considered releasing guidance to assist the RRBs with evaluation of the most common diagnoses without also changing the reviewers. The Committee decided to create this guidance, and expects to release a draft for public comment later this year. The Committee chose to pursue the guidance in conjunction with a NHRB because no guidance can anticipate every situation, and pediatric expertise will be particularly important for evaluating the cases that are not directly covered by the guidance.

## NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed “in accordance with §121.4”, which in turn incorporates the requirements in §121.8. This proposal addresses the following requirements of the Final Rule.

- **Shall be based on sound medical judgment:** The Committee proposes this change based on the medical judgment that candidates within the same status should have similar medical urgency, and data that shows there are variances in Status 1A listings by region, and variances in Status 1A waiting list mortality depending on whether the candidate is listed as a Status 1A based on policy criteria or an exception, and an increase in the number of Status 1A exceptions.
- **Shall seek to achieve the best use of donated organs:** The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. This proposal seeks to make the best use of donated organs by allocating them for the most medically urgent candidates first.
- **Shall be designed to...promote patient access to transplantation:** This proposal promotes pediatric heart candidate access to transplants by assigning review of their exception requests to a single national board in order to reduce variance in their access to Status 1A and Status 1B based on which RRB reviews their request.
- **Shall not be based on the candidate’s place of residence or place of listing, except to the extent required [ other regulatory criteria]:** This proposal removes the consideration of place of listing from determining which review board will review the candidate’s Status exception request.

## Implementation and Operational Considerations

### OPTN Actions

This proposal will require programming in UNet<sup>SM</sup>. The OPTN will set up the operating structure, including case assignments and criteria, developing new forms, and onboarding reviewers.

This proposal may require instructional support. UNOS staff will continue to monitor this need throughout the discussion and development of the proposal.

## Member Actions

Pediatric heart transplant programs may appoint a representative and an alternate to both the RRB and the pediatric NHRB. This may result in reviewers from those institutions having to vote in two heart review board systems.

Pediatric heart transplant programs may also need to train staff in changes to the forms for exception requests.

Minimal or no fiscal impact is expected for members.

## Post-implementation Monitoring

### Member Compliance

The proposal will not change the current routine monitoring of OPTN members. Any data entered into UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.

### Policy Evaluation

The Final Rule requires allocation policies to be “reviewed periodically and revised as appropriate.”<sup>22</sup> The following evaluation plan will provide the Committees with information on a periodic basis about whether the policy is achieving its goals, and whether any revisions are warranted.

This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any subsequently requested by the committee, will be evaluated as data become available (Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy.

- Examine changes in the number and percent of pediatric candidates by status, exception, age group, OPTN region, and diagnosis
- Examine changes in the number and percent of pediatric transplant recipients by status, exception, age group, OPTN region, and diagnosis
- Evaluate changes in waiting list mortality rate for pediatric candidates by status and exception
- Evaluate changes in transplant rate for pediatric candidates by status and exception
- Report the percent of approvals and denials for exception requests by status
- Examine changes in post-transplant patient survival rates overall and stratified by status

## Conclusion

The Thoracic Committee proposes the creation of the NHRB for pediatrics to improve consistency in reviews, reduce variance in the volume of transplants for Status 1A candidates by region, and reduce the variance in waiting list mortality within a status.

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<sup>22</sup> 42 CFR 121.8(a)(6).

## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 **6.4 Adult and Pediatric Status Exceptions**

2 A heart candidate can receive a status by qualifying for an exception according to *Table 6-3* below.

3  
4

**Table 6-3: Exception Qualification and Periods**

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1	<ol style="list-style-type: none"> <li>Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</li> <li>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</li> </ol>	RRBs retrospectively review requests for status 1 exceptions	14 days	<ul style="list-style-type: none"> <li>Require RRB approval for each successive 14 day period</li> <li>RRB will review and decide extension requests retrospectively</li> </ul>
Adult status 2	<ol style="list-style-type: none"> <li>Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</li> <li>Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</li> </ol>	RRBs retrospectively review requests for status 2 exceptions	14 days	<ul style="list-style-type: none"> <li>Require RRB approval for each successive 14 day period</li> <li>RRB will review and decide extension requests retrospectively</li> </ul>

Adult status 3	<p>1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</p> <p>2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</p>	RRBs retrospectively review requests for status 3 exceptions	14 days	<ul style="list-style-type: none"> <li>• Require RRB approval for each successive 14 day period</li> <li>• RRB will review and decide extension requests retrospectively</li> </ul>
Adult status 4	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 4 exceptions	90 days	<ul style="list-style-type: none"> <li>• Require RRB approval for each successive 90 day period</li> <li>• RRB will review and decide extension requests retrospectively</li> </ul>
Pediatric status 1A	<ul style="list-style-type: none"> <li>• Candidate is admitted to the transplant hospital that registered the candidate on the waiting list</li> <li>• Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</li> </ul>	<p><u>The national heart review board (NHRB)</u> RRBs retrospectively reviews requests for Status 1A-exceptions</p>	14 days	<ul style="list-style-type: none"> <li>• Require <u>The NHRB</u> approval for each successive 14 day period</li> <li>• <u>The NHRB RRB</u> will review and decide extension requests retrospectively</li> <li>• If no extension request is submitted, the candidate will be assigned pediatric status 1B</li> </ul>

Pediatric status 1B	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	<u>The NHRB RRBs</u> retrospectively reviews requests for Status 1B exceptions	Indefinite	<ul style="list-style-type: none"> <li>• Not required as long as candidate’s medical condition remains the same</li> </ul>
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5  
6 The candidate’s transplant physician must submit a justification form to the OPTN Contractor with the  
7 requested status and the rationale for granting the status exception.  
8

9 **6.4.A Review Board RRB and Committee Review of Status Exceptions**

10 The heart RRB reviews applications for adult and pediatric status exceptions and extensions  
11 retrospectively. The national heart review board (NHRB) reviews applications for pediatric status  
12 exceptions and extensions retrospectively.  
13

14 If the candidate is transplanted and the relevant review board RRB does not approve the initial  
15 exception or extension request or any appeals, then the case will be referred to the Thoracic  
16 Committee. If the Thoracic Committee agrees with the review board’s RRB’s decision, then the Thoracic  
17 Committee may refer the case to Membership & Professional Standards Committee (MPSC) for review  
18 according to *Appendix L* of the OPTN Bylaws.  
19

20 **6.4.A.i. Review Board RRB Appeals**

21 If the review board RRB denies an exception or extension request, the candidate’s  
22 transplant program must either appeal to the relevant review board RRB within 1 day of  
23 receiving notification of the review board RRB denial, or assign the candidate to the status  
24 for which the candidate qualifies within 1 day of receiving notification of the review board  
25 RRB denial.  
26

27 **6.4.A.ii Committee Appeals**

28 If the review board RRB denies the appeal, the candidate’s transplant program must within  
29 1 day of receiving notification of the denied appeal either appeal to the Thoracic Organ  
30 Transplantation Committee or assign the candidate to the status for which the candidate  
31 qualifies. If the Thoracic Committee agrees with the review board’s RRB’s decision, the  
32 candidate’s transplant program must assign the candidate to the status for which the  
33 candidate qualifies within 1 day of receiving notification of the denied Committee appeal. If  
34 the transplant program does not assign the candidate to the status for which the candidate  
35 qualifies within 1 day of receiving notification of the denied Committee appeal, then the  
36 Committee will refer the case to the MPSC.  
37

## Operational Guidelines Language

# National Heart Review Board Pediatrics Operational Guidelines

### Overview

The purpose of the National Heart Review Board (NHRB) for pediatrics is to provide fair, equitable, and prompt peer review of pediatric candidate status 1A- and status 1B- justification form applications submitted by transplant programs for candidates whose medical urgency is not accurately reflected by the standard pediatric listing criteria for heart allocation. Justification form applications will be referred to throughout these guidelines as “applications” and include initial submissions, extension requests, and appeals.

### Representation

Each heart transplant program with an active pediatric component may appoint a representative and an alternate to the NHRB. Transplant programs are encouraged to appoint representatives from both cardiology and cardiac surgery who have active pediatric heart transplant experience. Heart transplant programs are not required to appoint a representative to the NHRB.

Representatives and alternates serve one-year terms. A heart transplant program may appoint the same representative or alternate to serve consecutive terms.

If a transplant hospital withdraws or inactivates its heart transplant program or the pediatric component, it may not participate in the NHRB. However, the transplant hospitals’ participation may resume once it has reactivated the transplant program and the pediatric component.

If at any time, a representative is no longer eligible to review applications, that application may be randomly reassigned to another reviewer.

### Representative and Alternate Responsibilities

Prior to each term of service, representatives and alternates are required to sign the *Confidentiality and Conflict of Interest Statement* and complete orientation training.

Representatives must vote within three days on all exception requests, exception extension requests, and appeals. A representative will receive an e-mail reminder after day 1 and day 2 if the representative has an outstanding vote that must be completed.

At the end of the first day, the alternate will be notified of the open application and either the primary or alternate will be able to vote on that application. Only one vote from any program will count. If both the primary and the alternate from the same program respond before the application is closed, only the primary representative’s vote will be counted.

42 After three days, if neither the primary nor their alternate has voted, then the request will be randomly  
 43 reassigned to a representative from another program. The primary reviewer and alternate will receive a  
 44 notification that the request has been reassigned.

45  
 46 Representatives must notify UNOS in advance of absences, during which the alternate will fulfill the  
 47 responsibilities of the representative.

48  
 49 If a representative or alternate does not vote on an open request within three days on three separate  
 50 instances within a 12 month period, the Chair may remove the individual from the NHRB. If a  
 51 representative or alternate does not vote because a case is approved and closed before the three day  
 52 timeframe expires, it is not considered a failure to vote. A representative or alternate who has been  
 53 removed for failure to perform the duties required is not eligible to serve again for three years.

54  
 55 If a transplant program exhibits a pattern of non-responsiveness, as evidenced by the removal of two  
 56 members from the NHRB, the Chair may suspend the program's participation for a period of three  
 57 months after notifying the program director. Further non-compliance with the review board process  
 58 may result in cessation of the program's representation on the NHRB until such a time as the transplant  
 59 hospital can satisfactorily assure the Chair that it has addressed the causes of non-compliance.

60

## 61 Voting Procedure

62 Each exception request is assigned to a randomly generated group of nine representatives of the NHRB.  
 63 A representative may vote to approve or deny the request, or ask that the request be reassigned.

64

65 Voting will close at the earliest of when:

- 66 • 5 reviewers have voted to approve a request;
- 67 • 5 voters have voted to deny a request; or
- 68 • 6 days after the first NHRB reviewer receives the request

69

70 When voting is closed, NHRB review of applications are decided as described in Table 1, below:

71

72

**Table 1: Effect of NHRB Votes**

<b><u>Of the votes submitted, if...</u></b>	<b><u>Then the application is...</u></b>
<u>Majority vote to approve</u>	<u>Approved</u>
<u>An equal number of voters have voted to approve as deny</u>	<u>Approved</u>
<u>Majority vote to not approve</u>	<u>Not approved</u>

73

74 Representatives no longer have the ability to vote once voting is closed.

75

## 76 Appeal Process

77 A pediatric heart transplant program may appeal the NHRB decision to deny an exception request.

78 Patients are not eligible to appeal exception requests. All reviewer comments are available in UNet<sup>SM</sup>.

79 The NHRB advises programs to respond to the comments of dissenting reviewers in the appeal.

80

81 Each appeal is assigned to the same group of nine representatives that reviewed the exception  
 82 application. A representative may vote to approve or deny the request, or ask that the request be  
 83 reassigned.

84  
 85 Voting will close at the earliest of when:

- 86 • 5 reviewers have voted to approve a request;
- 87 • 5 voters have voted to deny a request; o
- 88 • 6 days after the first NHRB reviewer receives the request

89  
 90 When voting is closed, appeals are decided as described in Table 2, below:

91  
 92 **Table 2: Effect of NHRB Appeal Votes**

<b><u>Of the votes submitted, if...</u></b>	<b><u>Then the application is...</u></b>
<u>Majority vote to approve</u>	<u>Approved</u>
<u>An equal number of voters have voted to approve as deny</u>	<u>Approved</u>
<u>Majority vote to not approve</u>	<u>Not approved</u>

93  
 94  
 95 If the appeal is denied, the pediatric heart program may initiate a final appeal to the Thoracic Organ  
 96 Transplantation Committee (Thoracic Committee)

97  
 98 **Thoracic Committee Appeals**

99 The Thoracic Committee may delegate review of appeals to a workgroup of at least five members which  
 100 may consist of members of the Thoracic Committee, Pediatric Committee, or other pediatric heart  
 101 physicians or surgeons.

102  
 103 If the appeal achieves a majority affirmative votes, it will be approved. In the event of a tie, the appeal  
 104 will be approved. The initial request will be made in writing. If either the program or a representative  
 105 requests that the appeal be considered on a conference call, then a call will be scheduled with the  
 106 workgroup.

107



# OPTN Heart Review Board (HRB) Guidelines

## 1. Overview

The purpose of the Heart Review Board (HRB) is to provide fair, equitable, and prompt peer review of adult candidate status 1-4 and ~~pediatric candidate status 1A and status 1B~~ justification form applications submitted by transplant programs. Justification form applications will be referred to throughout these guidelines as “applications” and include initial submissions, extension requests, and appeals.

## 2. Representation

- A. Every designated heart transplant program may participate on the HRB. Each HRB will consist of a minimum of representation from three programs.
- B. The Regional Councillor or the Councillor’s designee selects a heart transplant physician or surgeon affiliated with a designated heart transplant program within his or her OPTN region to serve as the HRB Chair. The HRB Chair will be called upon to decide tie votes and may not simultaneously represent his or her transplant program as an HRB member.
- C. The HRBs vary in size and rotate as determined by each OPTN region. Since larger HRBs may pose operational or administrative challenges, some HRBs rotate membership to ensure each transplant program is represented on the HRB for one term each year.
- D. Each program represented on the HRB must identify one primary and at least one alternate representative ~~to the OPTN Contractor~~. It is the responsibility of each transplant program to provide ~~the OPTN Contractor with~~ the contact information for both the HRB primary and alternate representatives. Should an HRB primary representative leave his or her transplant program, then the transplant program’s alternate representative will become the new HRB primary representative, and the program must provide ~~the OPTN Contractor with~~ the contact information for another alternate representative. The program can also choose to keep the existing alternate representative and provide ~~the OPTN Contractor with~~ the contact information for a new RB primary representative.
- E. If a transplant hospital inactivates or withdraws its heart program, it may not participate in the HRB. The term of the transplant program’s representative on the HRB ends upon program’s inactivation or withdrawal from the OPTN. However, the transplant hospital’s participation may resume once it has reactivated its heart program.

### 1. Responsibilities of HRB representatives

HRB primary and alternate representatives must:

- A. Complete the OPTN/UNOS Confidentiality Agreement and Certification Regarding Conflicts of Interest form prior to serving on the HRB.

- 44           **B.** Evaluate the eligibility criteria of other approved applications to achieve consistency in  
 45 decision-making and determine whether this candidate meets similar levels of medical  
 46 urgency and potential for benefit.
- 47           **C.** Vote to approve or not approve applications according to the timelines specified in the  
 48 guidelines below. When voting to “not approve” an application, the voter should provide  
 49 comments or questions to the program submitting the application to support the vote.  
 50

## 51 **4. Voting Procedures**

### 52

### 53 **A. Retrospective Review of Status Exceptions**

54

55 The HRB will review all applications that require HRB review retrospectively. During the entirety of  
 56 the retrospective review, extension, and/or appeal process, the candidate’s status will be equal to the  
 57 requested status and the transplant program must follow all OPTN policies applicable to the  
 58 requested status.  
 59

60 At the termination of the application or appeal process, if the requested status is not approved, then  
 61 the transplant program must change the candidate’s status to the status for which the candidate  
 62 qualifies under policy within 1 day of receiving notification of denial or initiate an appeal as described  
 63 below.  
 64

### 65 **B. Eligibility to Vote**

66

67 An HRB primary or alternate representative’s vote will not be valid and will not count towards a  
 68 quorum in any case in which the member has a conflict of interest.  
 69

### 70 **C. Regional Rotation**

71 The HRB will review applications from another OPTN region on a rotating basis. The same HRB that  
 72 reviewed an initial application will review extension requests and appeals associated with the  
 73 candidate, with the exception of applications that are extended or appealed after the regional  
 74 rotation to different regions occurs.  
 75

### 76 **D. HRB Case Review and Vote**

77

78 ~~The OPTN Contractor will first send all applications~~ All applications will first be sent to the HRB primary  
 79 representative. If the primary representative has not voted within 3 business days ~~of when the OPTN~~  
 80 ~~Contractor sends the application to the HRB~~ of the HRB receiving the application, then the OPTN  
 81 ~~Contractor will send the case~~ will be sent to the alternate representative. Thereafter, both the HRB  
 82 member and alternate representative may vote on the application within 7 days of when the OPTN  
 83 ~~Contractor originally sent the application~~ application was originally provided to the HRB. If the HRB  
 84 member and the alternate representative both submit votes for the same application, then the OPTN  
 85 Contractor will count the vote from whomever voted first will be counted.  
 86

87 In order for a decision to be rendered, a majority vote is required. A majority vote requires more than  
 88 half of the HRB representatives (or their alternates) voting on the application. If all HRB representative  
 89 have voted and the vote is tied, the HRB chair will be contacted to break the tie.  
 90

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Voting will close at the earliest of when:

- all eligible voters have voted;
- a majority of all eligible voters have voted to approve ~~or deny~~ a request
- a majority of all eligible voters have voted to deny a request; or
- 7 days after the ~~OPTN Contractor sends the request is sent~~ to the HRB

HRB review of applications (initial submissions, extensions, and appeals) are decided as described in Table 1, below:

**Table 1: Effect of HRB Votes**

If the vote is...	Then the application is...
Majority vote to approve	Approved
All voters tied and HRB chair votes to approve	Approved
Majority vote to not approve	Not approved
<del>All voters tied</del> <u>An equal number of voters have voted to approve as deny</u> and HRB chair votes to not approve	Not approved
<del>All voters tied</del> <u>An equal number of voters have voted to approve as deny</u> and HRB chair does not break tie	Approved
No majority vote reached	Approved

101  
102  
103  
104  
105  
106  
107  
108

Once voting is closed, a HRB member or alternate can no longer vote on that case.

The ~~OPTN Contractor~~ will maintain the results of the HRB’s vote. If an application is not approved, the ~~OPTN Contractor~~ will notify the program that submitted the application and will provide the transplant program with comments or questions made by the HRB members, but will not provide the votes of specific HRB members.

## 5. Appeal Process

### A. Appeal to the Review Board

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123

If the HRB does not approve an initial or extension request application, the candidate’s transplant program must either submit an appeal application to the HRB within 1 day of receiving notification of the HRB decision, or assign the candidate to the status for which the candidate qualifies within 1 day of notification of the HRB’s decision.

The transplant program may submit additional written information justifying the requested exception status, and may include responses to the comments of dissenting HRB members. This additional information will be provided to HRB members for further consideration.

If the application is not appealed to the HRB within 1 day of receiving the notification of the HRB’s decision, the appeal process is not available.

124           Appealed applications are adjudicated as described in **Table 1**, above.

125

## 126 **B. Appeals of HRB Denials to the Thoracic Committee and MPSC Review**

127

128           If the HRB denies the appeal of an initial application or extension request application, the  
129           candidate's transplant program must either appeal to the Thoracic Organ Transplantation  
130           Committee within 1 day of receiving notification of the denied appeal or assign the candidate to the  
131           status for which the candidate qualifies within 1 day of notification of the denied appeal.

132

133           The transplant program may provide the OPTN ~~Contractor~~ with additional information about the  
134           case, which the OPTN ~~Contractor~~ will send to the Committee. The Committee will approve or not  
135           approve each appeal within 7 days of submission of the case to the Committee.

136

137           Referral of cases to the Committee will include information about the number of previous case  
138           referrals from that transplant program and the outcome of those referrals.

139

140           If the application is not appealed to the Thoracic Committee within one day of receiving the  
141           notification of the HRB decision, the appeal process is not available.

## 142 **6. Extensions**

143           The HRB will retrospectively review extension request applications. If an application will expire before the  
144           deadline for the HRB or Committee to decide on the application, and the transplant program submits a  
145           request for an extension of that application, then the HRB or Committee will vote on the extension  
146           application request, and the original application will be automatically closed out.

147

## 148 **7. Administration**

149           The central office for each HRB is maintained by the OPTN ~~Contractor~~. The HRB efforts are coordinated  
150           by the OPTN ~~Contractor~~.

151

152           Data sent to the HRBs for action or review will not contain hospital, program, or candidate identifying  
153           information.

154

155           HRB member responses may be shared with the transplant program if a HRB member specifically asks  
156           that comments be shared with the program, regardless of the voting outcome.



## At a glance

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**Title:** Data Collection to Assess Socioeconomic Status and Access to Transplant

**Sponsoring Committee:** Minority Affairs

### What is current policy and why change it?

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The OPTN currently collects limited information that pertains to a transplant candidate's socioeconomic status (SES). Collecting detailed socioeconomic related data will inform the OPTN and the public. (e.g. assessment of the potential impact candidates' SES could have on access to organ transplantation).

### What's the proposal?

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- Transplant hospital staff would be responsible for asking candidates at the time of registration on the waitlist their **annual household income** and **household size**.
- These two data points would be entered on the patient's **Transplant Candidate Registration (TCR)** form.
  - At the time of listing, every transplant candidate has a TCR form entered into UNet<sup>SM</sup>, the OPTN computer system.
- This data will inform OPTN Committees and the community on the impact of a candidate's socio-economic status.

### What's the anticipated impact of this change?

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- **What it's expected to do**
  - Transplant hospitals would develop a process for collecting annual household income and household size from candidates and enter the data in the TCR form.
  - This data will inform OPTN Committees and the community on the impact of a candidate's socio-economic status.
- **What it won't do**
  - Candidates access to transplant will not be impacted by providing this information.
    - The two data points are for informational purposes in future analyses by OPTN Committees and the community.
  - Provide any data on patients who were not referred to the waiting list.

## Themes to consider

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- Best types of data to measure SES
  - Barriers to collecting data
  - Timeline to implement required collection of data
- 

## Terms you need to know

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- **Annual household income:** total income (in US dollars) for all persons living within the transplant candidate's home.
- **Household size:** the total number of people living in the same household as the transplant candidate who are dependent on the household income.
- **Transplant Candidate Registration (TCR) data collection instrument:** The data collection instrument completed and submitted by the transplant hospital when a patient is added to the waiting list or when living donor feedback is completed for patients who are not listed. The form contains information on candidate demographics, previous transplants, payment, clinical information at time of listing and organ specific medical factors.
- [Click here to search the OPTN glossary](#)

*Public Comment Proposal*

# ***Data Collection to Assess Socioeconomic Status and Access to Transplant***

*OPTN Minority Affairs Committee*

*Prepared by: Kelley Poff, MSW  
UNOS Policy and Community Relations Department*

## **Contents**

Executive Summary	4
Purpose of the Proposal	5
Background	5
Literature Review	8
Stakeholder Feedback	10
Proposal	11
Implementation and Operational Considerations	14
Post-implementation Monitoring	15
Conclusion	15

# Data Collection to Assess Socioeconomic Status and Access to Transplant

*Sponsoring Committee:* OPTN Minority Affairs Committee  
*Public Comment Period:* January 22, 2020 – April 24, 2020

## Executive Summary

Currently, the Organ Procurement and Transplantation Network (OPTN) does not collect certain data on socioeconomic status (SES) factors that could be used to explore the potential association between patient SES and patient access to organ transplantation. The collection of better patient-level data would provide the OPTN the opportunity have a more holistic understanding of how SES factors may impact transplant candidates. In this public comment document, the OPTN Minority Affairs Committee (MAC) proposes adding annual household income and household size as new fields to the OMB-approved Transplant Candidate Registration (TCR) data collection instrument<sup>1, 2</sup>. The proposed data elements would be added to the existing SES indicators collected on the TCR. The SES indicators currently collected by the OPTN are patients' primary source of payment, highest level of education, and whether they are working for income. The TCR is a data collection instrument submitted to the OPTN by transplant programs each time a patient is added to the waitlist<sup>3</sup>. These data are not intended for analysis of access to placement on the waiting list, but will be used to measure access to transplantation from the time of listing forward. The proposal aligns with the Final Rule, as it proposes gathering SES information that could inform the OPTN on methods to promote patient access to transplant.<sup>4</sup> Collection of these data could be used to inform new policy that aims to reduce inequities resulting from SES.

The MAC welcomes all feedback from individuals and organizations with vested interest, but specifically asks for input on the following:

- Are annual household income and household size the best data elements to collect to measure SES?
- What barriers might there be to collecting and reporting these data?
- Are there other data related to SES the OPTN should collect?

---

<sup>1</sup> Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here <https://unos.org/data/data-collection/>.

<sup>2</sup> September 23rd 2019, Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>3</sup> OPTN Policy 18: Data Submission Requirements, Table 18-1: Data Submission Requirements.

<sup>4</sup> 42 C.F.R. § 121.8(a).



## Purpose of the Proposal

The purpose of this proposal is to collect additional patient-level SES data. These new data will allow the OPTN to perform better analyses on the potential impact of SES on patient access to transplantation. This data collection would take place one time at the time of registration on the waiting list. This data is not intended for analysis of access to placement on the waiting list, but will be used to measure access to transplantation from the time of listing forward. This goal is consistent with the Final Rule requirement that the OPTN reform allocation policies based on their cumulative effect on socioeconomic inequalities.<sup>5</sup> Official OPTN data are defined as all data collected by the OPTN pursuant to regulatory requirements.<sup>6</sup>

SES is defined as the social standing or class of an individual or group, often measured by a combination of education, income, and occupation.<sup>7</sup> Examination of SES can show disparities in access to resources. Individuals and households are grouped based on these metrics into high, medium, or low SES. SES is known to be a key determinant of health outcomes.<sup>8</sup>

## Background

In the fall of 2018, the MAC submitted a data request aimed to investigate disparities in access to kidney transplant based on SES<sup>9</sup>. The MAC stratified candidates by SES status and examined waitlist outcomes to determine if an inequity existed. Upon the presentation of these data, the MAC observed a disparity in access to living organ donation. It was also noted that low SES patients had higher waitlist mortality when compared to higher SES patients.<sup>10</sup> The MAC expressed their need to identify data elements that better describe current challenges low SES candidates face in access to transplant, and to provide data that may assist in future OPTN policymaking including efforts to improve equity in access to transplantation as required by the Final Rule.<sup>11,12</sup>

Currently, the OPTN collects very little data on the SES of patients. Some measures of SES data are collected by the OPTN on Transplant Information Electronic Data Interchange (TIEDI) data collection instruments.<sup>13</sup> The table below displays the SES data collected by each data collection instrument.

---

<sup>5</sup> 42 C.F.R. § 121.4(a).

<sup>6</sup> 42 C.F.R. § 121.11.

<sup>7</sup> American Psychological Association. (2019) Socioeconomic Status. Available at: <https://www.apa.org/topics/socioeconomic-status/>.

<sup>8</sup> Winters- Miner, L A., Bolding, P. S., Hilbe, J. M., Goldstein, Hill. T., Nisbet, R., Walton, N., & Miner, G. D. (2015). Personalized medicine. In L. A. Winters-Miner et al. (Eds.), *Practical predictive analytics and decisioning systems for medicine* (176-204). Cambridge, Massachusetts: Academic Press.

<sup>9</sup> OPTN Descriptive Data Request. "Disparities in Access to Kidney Transplant by Socioeconomic Status." Prepared for Minority Affairs Committee In-Person Meeting, March 29, 2019.

<sup>10</sup> Id.

<sup>11</sup> May 6th 2019, Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>12</sup> 42 C.F.R. § 121.4(a).

<sup>13</sup> TIEDI Data Collection Instruments can be accessed here <https://unos.org/data/data-collection/>.

**Table 1: SES Data Collected by TIEDI Data Collection Instruments**

<b>SES Data on TIEDI Forms</b>	<b>Transplant Candidate Registration</b>	<b>Transplant Recipient Registration</b>	<b>Transplant Recipient Follow-up</b>	<b>Living Donor Registration</b>	<b>Living Donor Follow-up</b>
Primary Source of Payment	X	X	X		
Highest level of Education	X			X	
Working for Income	X	X	X		X

The Committee feels that the data currently collected by the OPTN is not adequate to fully understand factors that define the SES of transplant candidates. Collection of additional patient- level data would allow the OPTN and its committees to better assess the impact of patient SES on access to transplant.<sup>14</sup>

The MAC selected the type of proposal they would develop. The Committee compared the benefit of providing a guidance document to the community or collecting additional data. Additional data collection was assessed to be more appropriate than a guidance document.<sup>15</sup> A guidance document serves as a reference for OPTN members. It provides recommendations on best practices and protocols. Guidance documents usually have a specific audience they are aiming to reach, but do not require change from this audience. Data collection is comprehensive and captures consistent and usable information. The MAC determined that data collection was the more appropriate mechanism as the OPTN collects limited SES data. The SES data currently collected by TIEDI instruments can be seen above in **Table 1**. The Committee does not think the OPTN has enough data to fully assess equity in access to transplant based on SES factors.<sup>16</sup> With this data collection, the OPTN has the opportunity to observe the difference in access to transplant impacted by SES. This first step would establish data collection and investigate the level of disparity that exists in the current system.

The Committee collaborated with the Transplant Administrators Committee (TAC), Transplant Coordinators Committee (TCC), and the Data Advisory Committee (DAC) in developing this proposal.

MAC brainstormed the following data elements and considered which would be a better measure for patient SES:

- Annual household income & household Size
- Expanded “Working for Income” Options like Living Donor Registry (LDR)
- Access to Transportation
- Individual Patient Income

The MAC discussed each element to determine which would be the best measure of SES to include in a data collection proposal. The paragraphs below summarize their conclusions and recommendations.<sup>17</sup>

<sup>14</sup> September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>

<sup>15</sup> July 15th 2019, OPTN Minority Affairs Committee Meeting Summary, Available at <https://optn.transplant.hrsa.gov/>

<sup>16</sup> September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>

<sup>17</sup> November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>

## Annual Household Income & Household Size

When collected together annual household income and household size can be compared to the Federal Poverty Guideline (FPG), a widely used standard for measuring income.<sup>18</sup> The U.S. Federal government uses this measure to determine who is eligible for certain financial services and participation in assistance programs. The comparison of household income and size to these federal benchmarks is a common method of determining whether households have access to adequate resources or might be expected to have poor health outcomes.<sup>19</sup>

### Expanded “Working for Income”

The LDR is a data collection instrument that is submitted to the OPTN by transplant programs each time a living donor is registered.<sup>20</sup> This form requires additional data under the “working for income” field that are not included in the TCR. Yes or no responses branch out and seek more detail.<sup>21</sup> The table below displays the additional data that is required in the LDR:

<b>If No, Not Working Due To: (check one)</b>	<b>If Yes:</b>
Disability	Working Full Time
Insurance Conflict	Working Part Time due to Disability
Inability to Find Work	Working Part Time due to Insurance Conflict
Donor Choice- Homemaker	Working Part Time due to Inability to Find Full Time Work
Donor Choice- Student Full Time/Part Time	Working Part Time due to Donor Choice
Donor Choice - Retired	Working Part Time Reason Unknown
Donor Choice- Other	Working, Part Time vs. Full Time Unknown
Unknown	

After considering this potential data element the Committee decided not to recommend expanding the “Working for Income” data collection on the TCR. They concluded annual household income and household size to be more descriptive measures of SES.<sup>22</sup> Therefore, working for income data collection with simple “yes,” “no,” or “unknown” responses will continue to be collected on the TCR.<sup>23</sup>

## Access to Transportation

The Committee discussed adding transportation to the TCR to measure SES, but ultimately eliminated this potential data element from consideration because it had potential for various interpretations and no standard definition. This potential data element lacked the clarity necessary for consistent entry.<sup>24</sup>

<sup>18</sup> U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from <https://aspe.hhs.gov/poverty-guidelines>.

<sup>19</sup> Id.

<sup>20</sup> OPTN Policy 18: Data Submission Requirements.

<sup>21</sup> Living Donor Registration TIEDI Data Collection Instrument can be accessed here <https://unos.org/wp-content/uploads/unos/LDR-1.pdf>.

<sup>22</sup> September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>23</sup> Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here <https://unos.org/data/data-collection/>.

<sup>24</sup> September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

## Individual Income

MAC felt annual household income would be more informative of SES than individual income, as all people residing in one household will often share finances and be of similar SES.<sup>25</sup> The Committee also felt annual household income would be a better method of capturing economic status in the instances where a candidate is too sick to work, but is monetarily supported by another member of the household.

In summary, MAC decided to propose to adding annual household income and household size to the TCR.<sup>26</sup> The MAC determined that the TCR is the most appropriate form for these data because it captures information on every candidate registered to the waitlist and will allow the OPTN to conduct access and outcome analyses. The LDR and Living Donor Follow-up (LDF) data collection instruments were not chosen because they only collect data on living donors.<sup>27,28</sup> In order to measure inequity, the OPTN must capture data from all waitlist candidates. The TRF and TRF were also eliminated as they gather information on recipients post-transplant.<sup>29</sup> The TCR is also the only TIEDI form that collects all three SES elements currently required by the OPTN.<sup>30</sup>

## Literature Review

The Committee reviewed relevant literature, including studies that examined the association between primary healthcare payer, education level, income level, and other SES factors to transplant access and outcomes. The OPTN already collects education level and primary source of payment. The literature supports the continued collection of these SES factors that educate the OPTN on SES's relationship to transplant.

More data are needed to investigate the extent of the issue. This review of the literature confirms that gaps exist in the analysis of SES, access, and outcomes. The OPTN can collect patient-level data to explore the extent of the problem and then adequately address SES's impact on transplant.

## Education Level

The literature suggests that there is an association between education level and access to transplant. Patients who have graduated college are three times more likely to be placed on the waiting list and receive a kidney transplant than patients with less than 12 years of education.<sup>31</sup> Patients with more extensive education may have more means to seek organ transplantation as an option.<sup>32</sup> Patients with

<sup>25</sup> September 23rd 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>26</sup> August 5th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>27</sup> Living Donor Registration TIEDI Data Collection Instrument can be accessed here <https://unos.org/wp-content/uploads/unos/LDR-1.pdf>.

<sup>28</sup> Living Donor Follow-up TIEDI Data Collection Instrument can be accessed here <https://unos.org/wp-content/uploads/unos/LDR-1.pdf>.

<sup>29</sup> Transplant Recipient Registration and Transplant Recipient Follow-up TIEDI Data Collection Instrument for all organs can be accessed here <https://unos.org/data/data-collection/>.

<sup>30</sup> Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here <https://unos.org/data/data-collection/>.

<sup>31</sup> Gold-Rumyantzev et al. (2006) Role of socioeconomic status in kidney transplant outcome. *American Society of Nephrology*, 1(2), 313-322. <https://doi.org/10.2215/CJN.00630805>.

<sup>32</sup> Hod, T. & Gold-Rumyantzev, A. S. (2014). The role of disparities and socioeconomic factors in access to kidney transplantation

higher education levels have better health literacy, post-transplant compliance, and medication adherence, factors known to influence graft and patient survival. Outcomes improve incrementally as the amount of education patients receive increases.<sup>33</sup>

### Primary Source of Payment (Health Insurance)

Primary source of payment impacts a candidate's access to organs and post-transplant outcomes. Primary healthcare payer may reflect a candidate's underlying SES, as candidates with higher incomes or educational levels might be expected to have private insurance at higher rates than lower SES candidates. Liver candidates in the highest socioeconomic quartile are four times as likely to receive a transplant as those patients in the lowest quartile without private insurance.<sup>34</sup> Patients without prescription drug coverage are more likely to be of lower SES background than patients with prescription drug coverage.<sup>35</sup> These patients are more likely to forgo taking required immunosuppressant drugs due to the high cost of these medications. This impacts medication adherence and post operation outcomes for those of low SES.<sup>36</sup>

### Median Household Income by ZIP Code

Median household income by ZIP Code as used as a proxy for patient income in much of the reviewed literature. Patients living in ZIP Codes with lower median incomes are shown to have less opportunity to be waitlisted and more likely to have poor transplant outcomes.<sup>37</sup> These patients are shown to be less likely to be found medically appropriate for transplant and do not complete pre-transplant evaluations as often as those living in higher median income ZIP Codes<sup>38</sup>. Patients living in lower income ZIP Codes also have an increased risk for negative post-operation incidents such as hospitalization, rejection, and infection.<sup>39</sup> A lack of financial means can prevent patients who would otherwise be suitable transplant candidates from being placed on the national waitlist.<sup>40</sup> Those who make it onto the list, but cannot afford the required medication regimens post-transplant, have a higher risk of experiencing organ failure. Some of these patients will return to the waiting list, where the cycle will repeat itself.<sup>41</sup> This association of waitlist and transplant outcomes with ZIP Code median household income data suggests that a stronger association may be found if measured at a patient-specific level.<sup>42</sup>

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and its outcome, *Renal Failure*, 36(8), 1193-1199. <https://doi.org/10.3109/0886022X.2014.934179>.

<sup>33</sup> Hod, T. & Gold-Rumyantzev, A. S. (2014). The role of disparities and socioeconomic factors in access to kidneys transplantation and its outcome, *Renal Failure*, 36(8), 1193-1199. <https://doi.org/10.3109/0886022X.2014.934179>.

<sup>34</sup> Wong, L. L., Hernandez, B. Y., & Albright, C. L. (2012). Socioeconomic factors affect disparities in access to liver transplant for hepatocellular cancer. *Journal of Transplantation*, 2012(2012), 1-6. <https://doi.org/10.1155/2012/870659>.

<sup>35</sup> Gold-Rumyantzev et al. (2006) Role of socioeconomic status in kidney transplant outcome. *American Society of Nephrology*, 1(2), 313-322. <https://doi.org/10.2215/CJN.00630805>.

<sup>36</sup> Id.

<sup>37</sup> Hod, T. & Gold-Rumyantzev, A. S. (2014). The role of disparities and socioeconomic factors in access to kidney transplantation and its outcome, *Renal Failure*, 36(8), 1193-1199. <https://doi.org/10.3109/0886022X.2014.934179>.

<sup>38</sup> Id.

<sup>39</sup> Wayda et al. (2018). Socioeconomic disparities in adherence and outcomes after heart transplant. *Circ Heart Failure*, 11(3), 1-11. <https://doi.org/10.1161/CIRCHEARTFAILURE.117.004173>.

<sup>40</sup> Simmerling, M. (2007). Beyond scarcity; poverty as a contraindication for organ transplant. *Virtual Mentor American Medical Association Journal of Ethics*, 9(6), 441-445. <https://doi.org/10.1001/virtualmentor.2007.9.6.pfor1-0706>.

<sup>41</sup> Id.

<sup>42</sup> Schold et al. (2012). The association of community health indicators with outcomes for kidney transplant recipients in the United States. *National Institute of Health*, 147(6), 520-526. <https://doi.org/10.1001/archsurg.2011.2220>.

## Annual Household Income and Household Size

The examined literature repeatedly calls for the collection of patient-level income data that is more granular than an estimate based on summary reporting of income or poverty status for a ZIP Code, patient education level, or primary healthcare payer.<sup>43</sup> The use of ZIP Code level income data to measure an individual's poverty status or income is an incomplete measure of SES status, due to the variation of incomes within any given ZIP Code.<sup>44</sup> Therefore, the median income in a ZIP Code may not be representative of a patient's SES level.<sup>45</sup> This limitation could weaken a potential connection between SES levels and access to transplant and transplant outcomes.<sup>46</sup> The literature suggests that differences in transplant access and outcomes between low and high socioeconomic backgrounds exist even with the use of data that is not considered patient level (i.e. data at the ZIP Code level). This association may be stronger or reveal more specific patient-level findings if more granular data on patient household income were collected.<sup>47</sup> Including collection of household size when household income is collected would allow for the calculation of patient-level household poverty status, an additional measure that could be used to standardize examinations of income and associated outcomes across multiple disparate groups by accounting for differences in household size, better reflecting patients' access to financial means.<sup>48</sup>

## Stakeholder Feedback

Upon proposing these potential new data fields, MAC solicited feedback from TAC, TCC, DAC and the Society of Transplant Social Workers (STSW)<sup>49</sup>. The groups expressed some concerns.

The first concern was that the OPTN may not be able to collect this data, due to patient reluctance to provide this potentially sensitive information.<sup>50</sup> The Committee confirmed that these particular data points are already collected as routine practice when patients are evaluated for transplantation by medical social workers or finance specialists. Stakeholders agreed that these patient data likely already exists within a hospital's Electronic Health Record (EHR) because routine financial evaluations are completed before adding a patient to the waitlist. This information would need to be transferred onto the TCR form.<sup>51</sup>

These groups gave feedback that candidates may report their annual household income inaccurately and inflate their earnings for fear of not being given high quality treatment if they reveal that they are of low SES background.<sup>52</sup> However, a literature review of the public health surveys conducted by paper, telephone, and through in-person interviews by the Centers for Disease Control and Prevention and

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<sup>43</sup> Wayda et al. (2018). Socioeconomic disparities in adherence and outcomes after heart transplant. *Circ Heart Failure*, 11(3), 1-11. <https://doi.org/10.1161/CIRCHEARTFAILURE.117.004173>.

<sup>44</sup> Id.

<sup>45</sup> Id.

<sup>46</sup> Schold et al. (2012). The association of community health indicators with outcomes for kidney transplant recipients in the United States. *National Institute of Health*, 147(6), 520-526. <https://doi.org/10.1001/archsurg.2011.2220>.

<sup>47</sup> Id.

<sup>48</sup> U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from <https://aspe.hhs.gov/poverty-guidelines>.

<sup>49</sup> November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>50</sup> Id.

<sup>51</sup> Id.

<sup>52</sup> Id.

state and local health departments (including the Medical Monitoring Project, National Health Interview Survey, National Health and Nutrition Examination Survey, Behavioral Risk Factor Surveillance System, and Pregnancy Risk Assessment Monitoring System), collect self-reported income and household size for the purposes of analyzing health outcomes and health disparities in the United States.<sup>53</sup> These data are considered reliable enough that federal, state and local public health entities and public health researchers use them to study population-level health outcomes.

The STSW suggested the development of an educational training for transplant staff that will be collecting these data fields. They recommended including in the training explanations of why the OPTN is collecting these data.<sup>54</sup>

The Committee considered and responded to all stakeholder feedback. Some of this feedback, such as comments about data burden, are standard for any proposal that aims to add more fields to forms and collect more data. Other concerns, such as those about the accuracy of sensitive information, are more specific to this proposal and will need specialized consideration. The Committee welcomes all feedback during the public comment period.

Collection of additional SES data would be an effective method to examine the extent of the association between SES and access to transplant. MAC feels confident that annual household income and household size, together, were the best measure of SES to add to the TCR in order to understand potential disparities in access.<sup>55</sup> When collected together, these data elements produce estimates that can be compared to the FPG, a measure used by health researchers to determine household poverty status and access to resources.<sup>56</sup> The federal government also uses these measures to determine which households qualify for income-based assistance programs. Collection of annual household income and household size will allow the OPTN to measure a patient's information against a well-known standard to determine their SES. The presented evidence shows that annual household income and household size are valuable data that should be collected by the OPTN. MAC voted to send their data collection proposal to Spring 2020 public comment.<sup>57</sup>

## Proposal

The proposal is to add two data fields to the TCR data collection instrument: Annual Household Income and Household Size.<sup>58</sup> A table containing more details on the data proposed elements, including rationale and organ-specific TCR elements that would be added to can be found in *Appendix 1: Proposed Additions to TCR Data Collection*. This proposal does not remove any currently collected data elements from the TCR. Together, the proposed elements can produce a measure to be compared to the Federal Poverty Guideline (FPG). The FPG aims to measure the degree of poverty a household is experiencing.<sup>59</sup>

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<sup>53</sup> Center for Disease Control and Prevention. (2019) Behavioral Risk Factor Surveillance System. Retrieved from <https://www.cdc.gov/brfss/questionnaires/index.htm>.

<sup>54</sup> November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>55</sup> Id.

<sup>56</sup> U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from <https://aspe.hhs.gov/poverty-guidelines>.

<sup>57</sup> November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>58</sup> Id.

<sup>59</sup> U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. (2019). Poverty Guidelines. Retrieved from <https://aspe.hhs.gov/poverty-guidelines>.

This proposal will allow the OPTN to determine if disparities in access to transplant based on SES exist by utilizing patient-level household income and poverty data.

## Data Elements

New data collection must align with one of the OPTN Data Collection Principles as passed by the Board of Directors in 2006 collection of additional data by vetting new elements through aligning with a data collection principle and providing clear data definitions.

### OPTN Data Collection Principles

This proposal aligns with the OPTN Data Collection Principles to develop transplant, donation, and allocation policies.<sup>60</sup> If the collection of annual household income and household size data suggest that disparities in access based on SES exist, these findings could inform potential future policy changes aimed to decrease inequities.

### Proposed Data Definitions

Public health surveys such as the Behavioral Risk Factor Surveillance System (BRFSS) were used as a reference during the development of these definitions.<sup>61</sup> The Committee seeks feedback on their proposed data definitions for annual household income and household size fields.

#### Annual household income:

The purpose of this field is to monitor policy impacts on disadvantaged populations and address inequity in outcomes; annual household income impacts access to healthcare services and health outcomes.

- Explicit documentation of income from the patient is not necessary, but can be used with developing an estimate.
- The timeframe for this response is a 12-month estimate. It includes all individuals who are living in the household and financially supporting the patient.
- This field is a text box that only accepts numeric responses in whole numbers.

#### Household size:

The purpose of this field is to clarify how many individuals in the household depend on the household income reported in the previous item. Together, these fields allow for the calculation of household poverty which aims to monitor policy impacts on disadvantaged populations and better address inequity outcomes.

- A household is defined as all persons who live with the patient in a household unit.
- The timeframe for this response is the current time period, when the patient is assessed and the TCR is completed.
- This field is a text box that only accepts positive, numeric responses in whole numbers.

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<sup>60</sup> OPTN, "Principles for Data Collection," Board approved language, December 13, 2006.

<sup>61</sup> Center for Disease Control and Prevention. (2019) Behavioral Risk Factor Surveillance System. Retrieved from <https://www.cdc.gov/brfss/questionnaires/index.htm>.



## Alignment with the Final Rule

This proposal's purpose aligns with the Final Rule. The collection of these data aims to better understand and assess the potential relationship between SES and access to transplant. Section 121.11 (b) (2) of the Final Rule gives the OPTN authority to collect data from OPTN members on transplant candidates.<sup>62</sup>

The Final Rule requires the OPTN, to develop organ allocation policies that, among other factors, promote patient access to transplantation.<sup>63</sup> The Final Rule states that the OPTN is required to develop policies that reduce inequities that result from SES.<sup>64</sup> In order to reduce any existing disparities that have resulted due to SES, the OPTN must understand the extent of the impact SES has on transplant access and outcomes. The collection of additional SES data will allow the OPTN to examine this potential problem more efficiently than it can currently and determine if policies that aim to decrease disparities based on SES are necessary, as required in the Final Rule.<sup>65</sup>

## Potential Impact on Select Patient Populations

This proposal would impact all transplant candidates. Each transplant candidate would be asked to provide these new data as a requirement by transplant program staff for the completion of the TCR.<sup>66</sup> This proposal has the potential to impact low SES candidates in the long term. If access and outcome inequities based on SES are found through analysis of these new data, policy could be developed or reformed in an effort to reduce disparities and promote access more equitably across all SES levels in the patient population.

## Alternate Proposals Considered

The Committee considered several alternatives. A suggestion MAC heard repeatedly was to use ZIP Code level median income data from the United States Census.<sup>67</sup> The benefit to this alternative is that these data are easily accessible online from the United States Census Bureau. The Committee would be able to omit the field "annual household income" as a proposed data element. This alternative also relieves transplant centers from extra data burden that comes with any additional data collection. However, ZIP Code level median income data is far less patient- specific than annual household income data. ZIP Codes can cover large geographic areas with a wide range of household incomes. For this reason, the median ZIP Code income statistic could misrepresent a candidates financial standing, to the extent that those candidates have lower or higher household incomes than the ZIP Code median. ZIP Code data also becomes inaccurate as patients move and due to this factor is likely to become useless over time. The Committee believes the weaknesses of this considered alternative outweigh the strengths, as the risk for misrepresentation of patient income challenges the accuracy of the data.

<sup>62</sup> 42 C.F.R. § 121.11(b) (2) [https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5#se42.1.121\\_111](https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5#se42.1.121_111). Accessed January 19, 2020.

<sup>63</sup> 42 C.F.R. § 121.8(a).

<sup>64</sup> 42 C.F.R. § 121.4(a).

<sup>65</sup> Id.

<sup>66</sup> Transplant Candidate Registration TIEDI Data Collection Instrument for all organs can be accessed here <https://unos.org/data/data-collection/>

<sup>67</sup> November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>

ZIP Code median income data were used for MAC’s initial SES data request in October of 2018. Results from this request were detailed in the OPTN report “Disparities in Access to Kidney Transplant by Socioeconomic Status.”<sup>68</sup> The MAC does not see value in duplication of this potentially misrepresentative method when the Committee could collect and use patient-level data that more accurately represents transplant candidates.

Stakeholders suggested the Committee consider using a patient’s address to better estimate their annual household income by allowing linkage with Census tract level data on median income and poverty status.<sup>69</sup> The benefit to this alternative is that census tracts cover smaller geographic areas and are not as vast as ZIP Codes, yielding less potential misclassification of patient income or poverty status. Patients’ street addresses along with their social security numbers may require the OPTN to assume a higher level of risk. Together, these two pieces of information meet the definition of “Sensitive Personally Identifiable Information” from the Department Homeland Security.<sup>70</sup> When this definition is met, additional justifications for the collection of the data along with additional safeguards are required. Much like the ZIP Code median income alternative, the OPTN would have to assume that the patient’s income or poverty status was the same as the summary measure for that Census tract. This alternative was not selected due to its high risk and low accuracy.

## Implementation and Operational Considerations

### OPTN Actions

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. The collection of official OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval from the federal Office of Management and Budget (OMB).<sup>71</sup> The OMB approval process may impact the implementation timeline. If finalized, the data collected would be protected consistent with the Privacy Act of 1974, as amended<sup>72</sup>.

Once approved by the OMB, UNOS Information Technology (IT) would program the new data fields onto the TCR in TIEDI.

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<sup>68</sup> OPTN Descriptive Data Request. “Disparities in Access to Kidney Transplant by Socioeconomic Status.” Prepared for Minority Affairs Committee In-Person Meeting, March 29, 2019.

<sup>69</sup> November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>70</sup> U.S Department of Homeland Security. DHS Privacy Office. (2017) Handbook for Safeguarding Sensitive PII retrieved from <https://www.dhs.gov/sites/default/files/publications/dhs%20policy%20directive%20047-01-007%20handbook%20for%20safeguarding%20sensitive%20PII%2012-4-2017.pdf>

<sup>71</sup> Office of Management and Budget (1995). Paperwork Reduction Act. Retrieved from <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/index>.

<sup>72</sup> Privacy Act of 1974, as amended, 5 USC § 522a. <https://www.govinfo.gov/content/pkg/USCODE-2018-title5/pdf/USCODE-2018-title5-partI-chap5-subchapII-sec552a.pdf>.

Professional Education will monitor the proposal and determine educational needs as it approaches approval and implementation. If it is found necessary, the OPTN will prepare the community for new data submission requirements.

## Member Actions

### Transplant Programs

This proposal would impact all transplant programs who register candidates to the waiting list. The proposal adds data fields to each organ-specific TCR, meaning this proposal would impact data collection across all organ systems. Transplant centers are required to complete and submit the TCR each time they refer a patient to the transplant waiting list.<sup>73</sup> Transplant programs would be required to collect each transplant candidate's annual household income and household size as part of the TCR submission and completion process. This proposal may increase data burden for transplant programs, but stakeholders reported that these data have often already been collected during the routine financial analysis every potential transplant candidate must complete.<sup>74</sup>

## Post-implementation Monitoring

### Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.<sup>75</sup>

### Policy Evaluation

The OPTN will monitor responses entered in the new fields and produce summary reports of the number and percent of missing/refused responses out of the total number of forms, as well as summary statistics of complete responses to the two fields (household income and household size). The OPTN will examine if non-responses are disproportionately represented in specific demographic groups, waitlist organ types, or geographic areas. Additionally, the OPTN will stratify summaries of responses and non-responses by the two other available fields on the Transplant Candidate Registration Form that ask about other socioeconomic factors: 1) educational attainment, and 2) primary payer.

## Conclusion

Collecting annual household income and household size will inform OPTN policymaking and will allow the OPTN to develop a greater understanding of the impact candidate SES has on inequities in the national transplant system. With these new data, the OPTN will be able to investigate the potential relationship between patient SES and access to transplant. These data will eventually inform the development of policy aimed to reduce disparities and monitor policies for equity in access. The proposal aligns with the Final Rule requiring the development and reform of policies that reduce

<sup>73</sup> OPTN Policy 18: Data Submission Requirements, Table 18-1: Data Submission Requirements.

<sup>74</sup> November 18th 2019, OPTN Minority Affairs Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

<sup>75</sup> OPTN. About Data. Retrieved from <https://optn.transplant.hrsa.gov/data/about-data/>.

inequalities resulting from SES and the OPTN Principles of Data Collection in that the purpose is to develop transplant, donation, and allocation policies.<sup>76,77</sup>

The MAC welcomes all feedback from individuals and organizations with vested interest, but specifically asks for input on the following:

- Are annual household income and household size the best data elements to collect to measure SES?
- What barriers might there be to collecting and reporting these data?
- Are there other data related to SES the OPTN should collect?

### **Appendix 1: Proposed Additions to TCR Data Collection**

<b>Add Following Data Elements:</b>	<b>Add Listed Data Elements to Following Organ-Specific TCRs:</b>	<b>Rationale:</b>
<b>Annual Household Income</b>	Adult and Pediatric: Kidney, Pancreas, Kidney/Pancreas, Intestine, Liver, Heart, Lung, and Heart/Lung.	<i>This data element would inform the Committee about policy impacts on disadvantaged populations and assess inequity in outcomes; annual household income impacts access to healthcare services and health outcomes.</i>
<b>Household Size</b>	Adult and Pediatric: Kidney, Pancreas, Kidney/Pancreas, Intestine, Liver, Heart, Lung, and Heart/Lung.	<i>This data element would inform the Committee about how many individuals in the household depend on the household income reported in the previous item. Together, these fields allow for the calculation of household poverty which aims to monitor policy impacts on disadvantaged populations and better address inequity.</i>

<sup>76</sup> 42 C.F.R. § 121.4(a)

<sup>77</sup> OPTN, “Principles for Data Collection,” Board approved language, December 13, 2006.



## At a glance

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**Title:** Addressing Medically Urgent Candidates in New Kidney Allocation Policy

**Sponsoring Committee:** Kidney Transplantation

### What is current policy and why change it?

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Currently, if a physician determines that a kidney candidate's condition is serious enough that they need a transplant immediately, they have the option to request approval from all other transplant hospitals in the same Donation Service Area (DSA) to give the candidate priority over others when a kidney is available. In December 2019, the OPTN Board of Directors approved a new kidney allocation policy that will replace DSAs with a 250 nautical mile circle around each donor hospital. This means that there will no longer be a standing set of transplant hospitals to approve requests for priority due to medical urgency. To make sure that this priority is used consistently, a defined practice to award this priority is necessary.

### What's the proposal?

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- Defines a **medically urgent** candidate
  - **Unable to receive dialysis** or at high risk for not being able to receive dialysis
- The candidate **receives priority** when a kidney is available within a 250 nautical mile circle

### What's the anticipated impact of this change?

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- **What it's expected to do**
  - Replace the existing medical urgency exception policy to align with the recently approved changes to kidney allocation policy
  - Help medically urgent kidney candidates get transplanted quickly
  - Ensure candidates receiving this priority meet a consistent definition of what is considered medically urgent
- **What it won't do**
  - Apply to every kidney candidate on the wait list

### Themes to consider

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- Qualifying medical urgency criteria
- Supporting evidence of criteria
- Appropriate priority over other candidates

## Terms you need to know

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- **Donation Service Area**: The geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals
- **Donor hospital**: The hospital where the deceased or living donor is admitted
- **Nautical mile**: Equal to 1.15 miles and is directly related to latitude and longitude; used in aviation
- [Click here to search the OPTN glossary](#)

*Public Comment Proposal*

# Addressing Medically Urgent Candidates in New Kidney Allocation Policy

*OPTN Kidney Transplantation Committee*

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Executive Summary	4
Purpose of the Proposal	6
Background	6
Proposal	8
Subcommittee Deliberation	10
Implementation and Operational Considerations	16
Post-implementation Monitoring	16
Compliance Analysis with NOTA and the OPTN Final Rule	17
Conclusion	18
Policy Language	20

# Addressing Medically Urgent Candidates in New Kidney Allocation Policy

<i>Affected Policies:</i>	<p>8.2.A: Exceptions Due to Medical Urgency</p> <p>8.5.C: Sorting Within Each Classification</p> <p>8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%</p> <p>8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores greater than 20% but less than 35%</p> <p>8.5.J: Allocation of Kidneys from Deceased Donors with KDPI Scores greater than or equal to 35% but less than or equal to 85%</p> <p>8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</p>
<i>Sponsoring Committee:</i>	Kidney Transplantation
<i>Public Comment Period:</i>	January 22, 2020 – March 24, 2020

## Executive Summary

Currently, prior to the OPTN Board of Directors' recent adoption of new kidney policies that remove DSA as a unit of allocation,<sup>1</sup> patients that are considered "medically urgent" are administered as exceptions to allocation policy. Specifically, policy allowed for exceptions for a candidate's transplant physician to use medical judgment to transplant a candidate out of sequence due to medical urgency."<sup>2</sup> Further, if there was more than one kidney transplant program in the same DSA, then the candidate's physician could seek agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence. These current policies will be obsolete when the newly-adopted allocation policy is implemented and DSAs cease to be a unit of allocation.

The OPTN Kidney Transplantation Committee (the Committee) is proposing the creation of a "Medically Urgent" classification within all kidney allocation tables. The purpose of this classification is to create priority for candidates who are at imminent risk of death due to an inability, or anticipated inability, to accept dialysis treatment for renal failure. The location of the proposed classification varies in priority across each of the four KDPI sequences in allocation. The classification grants medically urgent candidates increased priority within the 250 NM distribution circle only. Medical urgency would be defined as a candidate's inability to receive dialysis due to failure of dialysis access in both peritoneal and vascular methods. Additionally, leg graft access would have to be attempted, failed, or contraindicated for a specific reason. Finally, candidates would have to have lost or are imminently losing their last form of access, including transhepatic and translumbar inferior vena cava (IVC) catheters. These criteria were developed in order that the definition of medical urgency would include candidates with imminent loss of dialysis access and not exclusively candidates that have completely lost dialysis access.

<sup>1</sup> Meeting Summary for December 3, 2019 meeting, OPTN Board of Directors. Available at <https://optn.transplant.hrsa.gov/>

<sup>2</sup> OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at <https://optn.transplant.hrsa.gov/>



A candidate's medical urgency would initially be indicated on their waitlist form under a new "Medically Urgent" status in the Waitlist data collection instrument. A candidate's status as "Medically Urgent" as defined in new policy would require members to submit supporting documentation to the OPTN. The OPTN Kidney Transplantation Committee would perform periodic retrospective review of the use of the new medical urgency classification via evaluation of supporting documentation. This evaluation serves to ensure member compliance with the proposed medical urgency policy.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding the following:

1. Do you believe any additional criteria should be added to or removed from the definition of "medical urgency" as proposed by the Committee?
2. Do you believe that the new medical urgency classification should receive priority outside of the 250 NM circle? Should medically urgent candidates outside of the circle receive priority before non-medically urgent candidates inside of the circle?
3. A new medical urgency classification has been included in each KDPI category for kidney allocation. The Committee requests feedback on the proposed prioritization within each sequence.
4. What types of supporting documentation do you believe are appropriate to ensure the medically urgent classification is being utilized as intended?

## Purpose of the Proposal

When the Committee developed a proposal to remove DSA as a unit of allocation within kidney policies, its members recognized that a solution was necessary to ensure that medically urgent candidates received increased priority in allocation.<sup>3</sup> Because medically urgency exceptions were previously granted at the DSA level of allocation, the Committee set forth to propose a way to address these critical candidates in a consistent fashion across the country.<sup>4</sup>

The Committee's proposal seeks to provide a rationally determined and consistently applied definition for medical urgency in order for candidates with imminent failure of access to dialysis can receive the appropriate priority in an expedient manner while still allowing for retrospective oversight.

## Background

Prior to the OPTN Board of Directors' adoption of new kidney allocation policies,<sup>5</sup> which removed DSA and region as units of distribution and implemented a 250 nautical mile (NM) fixed-distance circle; patients that were considered "medically urgent" were administered as exceptions to allocation policy. Specifically, Policy 8.2.A "Exceptions Due to Medical Urgency" stated that, "Prior to receiving an organ offer from a deceased donor in the same DSA, a candidate's transplant physician may use medical judgment to transplant a candidate out of sequence due to medical urgency."<sup>6</sup> This language highlights the fact that there is currently no standard definition for what defines "Medical urgency" in current policy. Further, if there was more than one kidney transplant program in the same DSA, then "the candidate's physician must receive agreement from the other kidney transplant programs in the DSA to allocate the kidney out of sequence and must maintain documentation of this agreement in the candidate's medical record."

During the development of their proposal titled, "Eliminate the Use of DSAs and Regions in Kidney Allocation Policy,"<sup>7</sup> the Committee recognized that it would need to address these medically critical candidates following the dissolution of DSA as a unit of distribution. The Committee developed an initial proposal and included that proposal within the Committee's greater geography proposal released for the OPTN Fall 2019 Public Comment Period.<sup>8</sup>

Following public comment, the Committee considered the feedback received concerning the medical urgency proposal and determined that further examination was necessary.

The Committee formed the Medical Urgency Subcommittee, which met several times to further develop an appropriate proposal and consider questions previously unaddressed in the initial proposal.

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<sup>3</sup> Meeting Summary for July 8, 2019 meeting, OPTN Kidney Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

<sup>4</sup> Meeting Summary for August 19, 2019 meeting, OPTN Kidney Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

<sup>5</sup> Meeting Summary for December 3, 2019 meeting, OPTN Board of Directors. Available at <https://optn.transplant.hrsa.gov/>

<sup>6</sup> OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at <https://optn.transplant.hrsa.gov/>

<sup>7</sup> *Elimination of DSA and Region from Kidney Allocation Policy*, OPTN Kidney Transplantation Committee, August 2019, Available at <https://optn.transplant.hrsa.gov/>

<sup>8</sup> Ibid.

## Fall 2019 Proposal

At the time that the Committee developed their initial proposal for medical urgency, its members were proposing a 500 NM circle as the first unit in kidney allocation. The Committee decided that a proposal was necessary to ensure that medically urgent candidates retained priority in the new allocation system.<sup>9</sup> The Committee briefly considered utilizing the 500 NM fixed-distance circle as the geographic boundary for medical urgency approval; however, the number of centers within a 500 NM circle could far outnumber the centers that exist within the current boundary (DSA), around which current policy was originally adopted.<sup>10</sup> Furthermore, the center of that fixed boundary would change depending on the donor hospital, creating a system wherein a transplant hospital might have to receive consensus from a different set of programs than that of another transplant hospital only 50 NM away, for example.<sup>11</sup> The Committee also noted that these cases are seemingly rare, and the clinical criteria of what defines a medically urgent candidate may vary DSA-to-DSA in current policy.

The committee recognized the need for a consistently applied and rationally determined proposal and elected to treat these cases in a uniform manner across the country. The initially proposed kidney medical urgency policy would create a new “medically urgent” classification within kidney allocation tables. Transplant hospitals seeking to obtain the classification for one of their medically urgent patients would be prompted to apply for the status when certain clinical criteria are selected while initiating or updating the candidate’s waitlist record. This form would have then received an expedited, prospective review by the Medically Urgent Status subcommittee. Subcommittee review was proposed to occur within four (4) calendar days. If the subcommittee approved the candidate for medically urgent status, the candidate would receive the classification. Future match runs would have reflected that classification for the candidate.

The Committee elected to vary the placement of the medically urgent classification based on the donor KDPI of the kidney being allocated.

The Committee considered the limited community feedback regarding the medical urgency component during its monthly meetings in August and September 2019.<sup>12,13</sup> In addition to considering this feedback, The Committee proactively contacted some OPOs and OPTN regional leadership in some regions that have their own processes and clinical definitions for medically urgent candidates under current policy.

Based on the limited feedback and the procedures received from voluntarily from transplant programs, the Committee concluded:

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<sup>9</sup> Meeting Summary for July 8, 2019 meeting, OPTN Kidney Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

<sup>10</sup> OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at <https://optn.transplant.hrsa.gov/>

<sup>11</sup> Ibid.

<sup>12</sup> Meeting Summary for August 19, 2019 meeting, OPTN Kidney Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

<sup>13</sup> Meeting Summary for September 16, 2019 meeting, OPTN Kidney Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

1. Medical urgency should be clinically defined and that definition should include the inability to receive dialysis as a result of failure of vascular access
2. The medically urgency classification priority should vary depending on the KDPI of the donor kidney
3. Candidates' total allocation scores should be considered when prioritizing medically urgent candidates in the event that two appear on the same match run
4. The Committee should consider if multiple authorizations should be required in order to list a candidate as "medically urgent."

As a result of the limited feedback received as well as the desire to further consider the proposal before putting it forth for OPTN Board consideration, the Committee elected to remove the medical urgency component and its associated policy language from proposal titled, "Eliminate the Use of DSAs and Region from Kidney Allocation Policy." Instead, the Committee would convene a medical urgency subcommittee to continue developing the proposal as a separate policy project. This project received approval from the OPTN Policy Oversight Committee.<sup>14</sup> This proposal represents the work of that medical urgency subcommittee and was approved by the greater Committee at their December 2019 meeting.<sup>15</sup>

## Proposal

The Committee proposes the following to address medically urgent candidates in newly-adopted kidney allocation policies without DSA as a unit of allocation:

## Definition

Currently, there is no standard definition in kidney allocation policy as to the characteristics of a "medically urgent" candidate. DSAs currently write their own definitions and define their own procedures for granting priority for these candidates outside of the match run. The Committee believes that by developing a standard, national definition based on current practice in the community, candidates across the country, regardless of whether their DSA had procedures for medical urgency priority before, will now have access via the proposed policy.

Medical urgency would only apply to registered candidates in active status on the kidney waiting list and would be defined by the following candidate characteristics:

- First, the candidate has exhausted (and/or has a contraindication to) all dialysis access via each of the following methods:
  - Vascular access in the upper left extremity
  - Vascular access in the upper right extremity
  - Vascular access in the lower left extremity
  - Vascular access in the lower right extremity
  - Peritoneal access in the abdomen
- Also, the candidate has exhausted dialysis access, is currently being dialyzed, or has a

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<sup>14</sup> Meeting Summary for November 14, 2019 meeting, OPTN Policy Oversight Committee. Available at <https://optn.transplant.hrsa.gov/>

<sup>15</sup> Meeting Summary for December 16, 2019 meeting, OPTN Kidney Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

contraindication to dialysis via one the following methods

- Transhepatic IVC Catheter
- Translumbar IVC Catheter
- Other (must specify method)

## Medical Urgency Classification

The Committee proposes the creation of a new “Medically Urgent” classification to be placed in the kidney allocation tables within policy. The classification will receive different priority depending on the KDPI of the donor from which the kidney is being allocated. The priority of the new classification would be placed in allocation tables accordingly:

- For Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%, medically urgent candidates would be placed at Classification 7 after 100% cPRA 0-ABDR mismatch, 100% cPRA, local prior living donors, and local pediatrics
- For Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%, medically urgent candidates would be placed at Classification 7 after 100% cPRA 0-ABDR mismatch, 100% cPRA, local prior living donors, and local pediatrics.
- For Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%, medically urgent candidates would be placed at Classification 6 after 100% cPRA 0-ABDR mismatch, 100% cPRA, and prior living donors.
- For Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%, medically urgent candidates would be placed at Classification 5 after 100% cPRA 0-ABDR mismatch, and 100% cPRA.

The Committee proposes that, similar to current policy, priority for medically urgent candidates would only be awarded to medically urgent candidates inside the 250 NM initial allocation circle from the transplant program where the donor kidney is offered.

In the rare occurrence that two candidates with the medical urgency classification appear on the same match run, the Committee proposes prioritizing these candidates based on the number of consecutive days each candidate has been classified as medically urgent, with the tiebreaker going to the candidate with more days at status. Should both candidates have been classified as medically urgent on the same day, the candidates’ total allocation scores will serve to prioritize the two candidates amongst one another, with the highest score receiving higher priority.

The Committee proposes that the medical urgency classification could be applied to Kidney-Pancreas (KP) candidates seeking an isolated kidney. However, the priority would apply only to the isolated kidney. The candidate could be classified as medically urgent to receive the isolated kidney, should that candidate meet the definition of medical urgency. Furthermore, the Committee proposes that if a medically urgent kidney-alone candidate transitions to a KP candidate that wishes to seek an isolated kidney, the medical urgency classification received for the initial kidney listing should automatically transition to the isolated kidney registration associated with the KP listing. No additional approval should be required.

The Committee also proposes that the medical urgency policy could apply to en bloc kidney offers if the candidate’s program has opted-in to accepting these offers and the transplanting surgeon seeks to pursue this option for transplant.

Finally, the Committee proposes that if a medically urgent candidate has a classification with a greater priority than the new medically urgent classification, such as the classification for a candidate with “O-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible,” then that candidate will maintain the priority for the classification with the highest priority in allocation. No additional points or prioritization within that classification would be necessary.

## Documentation and Oversight

The Committee proposes that the medical urgency classification should be applied to a candidate’s listing only after new data fields on the waitlist data collection instrument are completed. These fields ensure that the candidate meets the clinical definition of medical urgency as proposed by the Committee. These fields would appear when a new “Medically Urgent” patient status on the waitlist form is selected. The fields require indication that the patient has exhausted or otherwise contraindicated all forms of access listed in the medical urgency definition. The candidate’s transplant surgeon and transplant nephrologist must review and sign a written approval of the candidate’s exhausted vascular and peritoneal dialysis access and the imminent loss of dialysis access via additional methods listed in policy. The transplant hospital must document this approval in the candidate’s medical record and submit both documents to the OPTN within seven (7) business days of indicating status.

The Committee proposes that these data are retrospectively reviewed periodically by the OPTN Kidney Transplantation Committee. If during that review, the Committee believes that the medical urgency classification has been applied inappropriately and that further review is necessary, the Committee proposals referring oversight to the OPTN Membership and Professional Standards Committee (MPSC).

The following section outlines the subcommittee’s deliberation and how the proposed policy was developed.

## Subcommittee Deliberation

The Medical Urgency Subcommittee met 5 times throughout November and December 2019 to reconsider the original proposal, gather evidence, and develop a revised proposal for public comment feedback during the OPTN Spring 2020 Public Comment period. One of the guiding principles of the subcommittee’s evidence-gathering process and deliberations was to try to mirror the current policy and practices of transplant programs within the new allocation environment. This would serve to reduce additional administrative burden or fiscal impact of the proposal and maintain the efficient placement of organs in accordance with the OPTN Final Rule while still maintaining a mechanism for medically urgent candidates to receive appropriate priority in allocation.<sup>16</sup>

## Evidence Gathering

The subcommittee’s primary focus concerning evidence gathering was to provide some context around the following questions:

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<sup>16</sup> 42 C.F.R. § 121.8.

- How often is the current medical urgency policy utilized?
- What are the current procedures utilized within DSAs to grant medical urgency?
- What patient outcomes can be expected for candidates that receive a transplant via medical urgency policy?

The subcommittee reviewed data between 2010 and 2014 regarding potentially medically urgent candidates and recipients. These candidates were defined as waiting in medically urgent or critical status at time of listing or transplant, or had indicated on their transplant candidate registration (TCR) form that they had exhausted peritoneal or vascular dialysis access. The number of donors that were potentially allocated to medically urgent candidates was determined by examining the usage of bypass codes (refusal code 860) on kidney match runs due to medical urgency of another candidate.

The data showed that OPOs bypassed candidates due to the medical urgency of another for 57 kidney donors (approximately 10 donors per year, 0.2% of all deceased kidney donors). Looking at kidney registrations, there were 478 kidney registrations on the waiting list on December 31, 2014 that had some indication of medical urgency. Medical urgency was not concentrated to a specific geographic area. Post-transplant patient and graft survival were examined for kidney transplants potentially medically urgent as defined above. Potential medically urgent recipients received significantly lower KDPI kidneys and were more likely to be pediatric, be on dialysis at transplant, have HLA sensitization, and be a repeat kidney transplant. Recipients having some indication of medical urgency had significantly lower graft and patient survival within four years post-transplant, and were more likely to experience delayed graft function (defined as the need for dialysis within the first week post-transplant). The Committee also reviewed literature examining medical urgency practices around the globe. Among countries such as Australia, New Zealand, the United Kingdom, Canada, and the Eurotransplant system, most included some element of medical urgency in allocation, though exact criteria were not well defined.<sup>17,18</sup> Generally, it included patients who had failed dialysis, is usually utilized through a consensus process, and impacts a small number of patients for organs available at a local level.

Similar to Committee deliberation of the original medical urgency proposal, The Committee proactively contacted each of the 58 OPOs to ascertain if there were any similarities in definitions and procedures concerning medical urgency under current policy. Several OPOs voluntarily shared their definitions and processes for consideration.

The subcommittee reviewed each of the voluntarily submitted process descriptions and definitions.<sup>19</sup> Subcommittee members saw similar consistencies in terms of medical urgency definitions that were observed during evidence gathering during the OPTN Fall 2019 Public Comment period, specifically, that candidates qualify for medical urgency when they are unable to receive dialysis treatment due to the lack of vascular access.<sup>20</sup> Some differences were noted in the number of signatures were required at the candidate's transplant program before intra-DSA review was initiated.<sup>21</sup>

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<sup>17</sup> Sever and Goral. Kidney transplantation due to medical urgency: time for reconsideration? *Nephrol Dial Transplant* (2016) 31: 1376-77. Available at <https://optn.transplant.hrsa.gov/>

<sup>18</sup> *Prioritization for Kidney Transplantation due to Medical Urgency*, Canadian Council for Donation and Transplantation, October 2006, Available at <https://optn.transplant.hrsa.gov/>

<sup>19</sup> Meeting Summary for November 15, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>20</sup> Ibid.

<sup>21</sup> Ibid.

## Definition Development

The subcommittee sought to develop a definition of medical urgency that would include candidates that were at “imminent risk” of losing access to dialysis as well as candidates whose dialysis access had been completely exhausted or otherwise contraindicated.<sup>22</sup> In achieving this balance, the subcommittee believes that medical urgency can be addressed before it becomes the direst emergency and thereby increase the likelihood that medically urgent candidates can receive a life-saving transplant. The subcommittee members felt, based on their medical judgment and clinical experience, candidates that had completely exhausted dialysis access would only have between 7-14 days to receive a transplant in order to survive, whereas candidates with “imminent risk” of losing dialysis could possibly extend that window for several weeks.<sup>23</sup>

The subcommittee began their deliberation with the definition borne out of public comment feedback from the first cycle, which indicated that candidates should have lost vascular access to dialysis. Subcommittee members felt strongly that peritoneal access via the abdomen should also be attempted and failed or else otherwise contraindicated in order to qualify as medically urgent.<sup>24</sup> They expanded the definition of vascular access to ensure that attempts had failed or are imminently failing in both upper extremities as well as both lower extremities.

The subcommittee believes that, in addition to the exhaustion of vascular and peritoneal access, candidates must also have pursued dialysis via one additional method.<sup>25</sup> These methods define “imminent loss” within the definition of medical urgency and allow for candidates that still have some dialysis access (though not through vascular methods in the upper and lower extremities of peritoneal access through the abdomen) to receive the priority classification.<sup>26</sup> It is also possible that this additional method has been pursued and also exhausted, in which case the candidate’s condition represents complete loss of dialysis and also qualifies for medical urgency priority.

## Classification and Priority Considerations

By creating a new classification within kidney allocation tables, the subcommittee recognized that it would have to consider medical urgency priority in relation to other high-priority classifications. Additionally, subcommittee members would have to determine if medically urgent priority should extend outside of the 250 NM allocation circle, to national offers. Other questions that required discussion included whether the classification could apply to KP candidates seeking isolated kidneys, how multiple medically urgent candidates would be prioritized if they appeared on the same match run, and how the medically urgent classification would be applied to candidates with higher priority classifications.

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<sup>22</sup> Meeting Summary for November 25, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>23</sup> Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>24</sup> Ibid.

<sup>25</sup> Meeting Summary for December 9, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>26</sup> Ibid.



Having established the definition of medical urgency to apply to candidates with “imminent” loss of dialysis access in addition to those that have completely exhausted all vascular and peritoneal access, the subcommittee agreed that the medical urgency classification should not be placed at the top of each allocation table by sequence. Specifically, subcommittee members wanted to ensure that for Sequence A and Sequence B allocation tables, the medically urgent classification did not receive a higher priority than local pediatric candidates.<sup>27</sup> Upon review of the originally proposed classification priority placement, present in the first round of public comment, the subcommittee believed that the initially proposed placement was appropriate and should continue to differ by KDPI sequence.<sup>28</sup>

Because the subcommittee is proposing that the medical urgency priority should not appear as the first sequence in each allocation table, members sought to clarify how a candidate with a priority higher than medical urgency would appear on a match run should they also be classified as medically urgent. For example, if a Sequence A donor kidney became available, how would a local pediatric candidate (Classification 6) that is also medically urgent (Classification 7) appear on a match run? Subcommittee members agreed that said candidate should appear on the match run according to the highest priority classification that they possess, so the local pediatric medically urgent candidate would appear on the match run based on their Classification 6 priority.<sup>29</sup>

The subcommittee also considered whether separate medical urgency classifications should be created in order to also give medically urgent candidates registered outside of the 250 NM circle around the donor hospital any priority.<sup>30</sup> Under current medical urgency policy, medically urgent candidates only receive priority within the DSA, assuming that all programs within that DSA have agreed to that candidate’s priority.<sup>31</sup> The subcommittee sought to mirror current policy as much as possible and maintain the efficient placement of organs seen in current policy, and so they believed that medical urgency priority should not be extended beyond the initial allocation unit of 250 NM.

The subcommittee considered the question of whether proposed medical urgency policy should apply to en bloc kidney offers. Members noted that new en bloc policy allows transplant programs to opt-in to accepting offers for these kidneys and that one of the goals of the en bloc project, in addition to better utilization, was to increase utilization of pediatric en bloc donor kidneys for pediatric candidates.<sup>32</sup> The limited available data reviewed by the subcommittee concerning candidates with characteristics similar to those defined by the subcommittee as “medically urgent” indicated that medically urgent candidates are more likely to be pediatric than non-medically urgent candidates. However, nephrologists and surgeons on the subcommittee expressed doubts that a surgeon or nephrologist of a medically urgent candidate would accept an en bloc offer, given their patient’s difficult vascular access.<sup>33</sup> The subcommittee ultimately agreed that though it is unlikely that a transplant surgeon or transplant

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<sup>27</sup> Ibid.

<sup>28</sup> Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>29</sup> Meeting Summary for November 18, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>30</sup> Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>31</sup> OPTN Policy 8.2.A Exceptions Due to Medical Urgency. Available at <https://optn.transplant.hrsa.gov/>

<sup>32</sup> *Improving Allocation of En Bloc Kidneys*, OPTN Kidney Transplantation Committee, June 2017. Available at <https://optn.transplant.hrsa.gov/>

<sup>33</sup> Meeting Summary for December 9, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

nephrologist of a medically urgent candidate would accept an en bloc offer, they did not want to limit offers to these critical candidate and therefore concluded that medically urgent candidates could receive en bloc kidney offers.

Finally, the subcommittee felt it was appropriate to consider whether different allocation options should be considered for medically urgent candidates in Hawaii and Puerto Rico.<sup>34</sup>

This consideration primarily stems from a policy proposal from the OPTN Liver and Intestines Transplantation Committee which treats medically urgent candidates within Hawaii and Puerto Rico differently, with their own larger allocation circle that ensures that they have access to donor liver offers on the mainland. The subcommittee noted that their medical urgency policy is fundamentally different from the proposed liver policy in one significant way. In DSA-based liver allocation policy, candidates that were medically urgent in Hawaii and Puerto Rico had access to offers within their region, which allowed them to get offers from the mainland. When DSA and region were removed from liver policy in favor of acuity circles, these candidates lost that regional access and thus no longer had priority for offers outside of their respective island territories.<sup>35</sup> The OPTN Liver and Intestines Transplantation Committee proposed larger circles for Hawaii and Puerto Rico in order that they would not significantly lose access to mainland offers as a result of moving from a DSA and region-based allocation system to a system utilizing acuity circles.<sup>36</sup>

Under current kidney policy, candidates in Hawaii and Puerto Rico only receive priority within their respective DSAs, which do not extend to the mainland. This priority would remain unchanged in a kidney allocation system based on an original allocation unit of 250 NM fixed-distance circle with the donor hospital at its center. Therefore, the subcommittee decided that medical urgency priority would apply only to candidates within the initial 250 NM circle across all 50 states and Puerto Rico.<sup>37</sup>

## Evaluation and Oversight Considerations

In developing a consistently applied definition of medical urgency and a method by which candidates can obtain allocation priority by meeting the outlines clinical criteria, the subcommittee sought to impose as little additional administrative data burden as feasible. Members recognized that some oversight is appropriate to ensure that the new classification is being used for its intended purposes, however, they did not want to create a system that was too burdensome for a candidate in the event that they meet the definition for medical urgency, as their time to receive a lifesaving transplant is limited.

The subcommittee explored a few options for evaluation in oversight, but ultimately worked backwards from the Committee's original proposal, which considered a 4-day prospective subcommittee review before the classification would be awarded.

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<sup>34</sup> Ibid.

<sup>35</sup> *OPTN Policy Notice Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

<sup>36</sup> *Access for Urgent Liver Candidates in Hawaii and Puerto Rico*, OPTN Liver and Intestinal Transplantation Committee. Available at <https://optn.transplant.hrsa.gov/>

<sup>37</sup> Ibid.

In discussions with UNOS IT and Organ Center concerning the time and resources necessary to conduct a prospective review, the subcommittee determined that it didn't want to pursue an option that would cause a medically urgent candidate any delay in receiving their priority classification, assuming they met the definition.<sup>38</sup>

Instead, the subcommittee worked with staff from the UNOS Organ Center representatives, to develop a retrospective system that would assure center compliance with the definition, allow for adequate post-implementation evaluation, and grant the Committee oversight over the utilization of the classification.

### **Data Collection**

New data collection would only be necessary for members seeking to grant medically urgent priority that has exhausted or will imminently exhaust all dialysis access. Transplant programs will no longer be required to seek permission from other transplant programs within their DSA in order to obtain medical urgency priority for candidates meeting the definition of medical urgency.

The subcommittee was conscious to ensure that any additional data elements aligned with the vision statement and Principles of Data Collection of the OPTN Data Advisory Committee in order to ensure that all elements are necessary and justified.<sup>39,40,41</sup>

The Committee proposes that the medical urgency classification should be applied to a candidate's listing only after new data fields on waitlist data collection instrument are completed. These fields ensure that the candidate meets the clinical definition of medical urgency as proposed by the Committee. These fields would appear when a new "Medically Urgent" patient status on the waitlist form is selected. The fields require indication that the patient has exhausted or otherwise contraindicated all forms of access listed in the medical urgency definition. The candidate's transplant surgeon and transplant nephrologist must review and sign a written approval of the candidate's exhausted vascular and peritoneal dialysis access and the imminent loss of dialysis access via additional methods listed in policy. The transplant hospital must document this approval in the candidate's medical record and submit both documents to the OPTN within seven (7) business days.

The subcommittee continually updated the OPTN Data Advisory Committee (DAC) of their progress in developing necessary new data collection, the DAC endorsed the proposal at their meeting on December 9, 2019.

### **Potential Impact on Select Patient Populations**

This proposal is projected to affect very few kidney and kidney-pancreas candidates in total; however, those candidates that are affected will see a significant impact in terms of priority in allocation. Available data suggest that this policy could be applied as many as 100 times annually, which reflects less than one percent of total kidney transplants. Candidates that meet the definition for medical urgency will see increased priority in allocation. Furthermore, candidates from small DSAs may see the range of their

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<sup>38</sup> Meeting Summary for November 18, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>39</sup> Meeting Summary for November 26, 2019 meeting, OPTN Kidney Transplantation Committee Medical Urgency Subcommittee. Available at <https://optn.transplant.hrsa.gov/>

<sup>40</sup> Data Advisory Committee Charge. Available at <https://optn.transplant.hrsa.gov/>

<sup>41</sup> Data Advisory Committee Principles for Data Collection. Available at <https://optn.transplant.hrsa.gov/>

priority expanded, as it now extends to 250 NM from the donor hospital in all directions. Conversely, candidates from very large DSAs with policies for medical urgency may see the range of their priority diminished, as their DSAs may have been larger than 250 NM. Finally, because of the placement of the classification below classifications for inside-the-circle pediatric candidates, living donor candidates and the most highly-sensitized candidates, this policy proposal is not expected to significantly affect these candidate populations.

## Implementation and Operational Considerations

### Overview

Overall, implementation and operational considerations are minimal for this policy proposal. Some IT programming is required, as well as some additional document maintenance to maintain records of supporting documentation received by the OPTN.

### OPTN Actions

Programming changes will be required to implement a new Medically Urgent classification. Changes will be made to the Kidney allocation systems and to candidate's waitlist record in order to add the medically urgent classifications. UNOS will follow established protocols to inform members and provide educational materials regarding any policy changes.

The OPTN will maintain and secure all submitted supporting documentation for retrospective review of the OPTN Kidney Transplantation Committee.

### Member Actions

Member actions are anticipated to be very minimal, as the new policy affects a very low-volume candidate population. New data collection requirements are nominal and merely represent a codification in OPTN policy of practices that many transplant programs are conducting for this candidate population within their respective DSAs.

## Post-implementation Monitoring

### Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. The OPTN Contractor may review any data entered in UNet<sup>SM</sup>, and members are required to submit documentation as requested.

### Policy Evaluation

This policy will be formally evaluated approximately 3 months, 6 months, 1 year, and 2 years post-implementation.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

- How many registrations receive medical urgency allocation priority?
- What were the characteristics of medically urgent candidates and donor kidneys received by them?
- What were the waiting list outcomes of registrations receiving medically urgent allocation priority?
- What were the post-transplant outcomes of medically urgent transplant recipients?
- How long do candidates wait in medically urgent status before receiving a transplant?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to pre- and post-policy implementation:

Overall and by OPTN Region:

- #/% of candidates on the WL that received medically urgent allocation priority (also by candidate characteristics such as CPRA (%), EPTS (%), age group, primary vs. repeat transplant, dialysis vintage)
- Distribution of time in medical urgency classification before WL removal (min, q25, mean, sd, median, q75, max)
- #/% by WL removal reason for registrations in medical urgency status
  - o Competing risk median time to transplant
  - o #/% of medically urgent deceased donor kidney transplant recipients by KDPI sequence (0-20%, 21-34%, 35-85%, 86-100%)
- National unadjusted post-transplant graft and patient survival for medically urgent transplant recipients (compared to non-medically urgent transplants)
- National DGF rates for medically urgent transplant recipients (compared to non-medically urgent transplants)

## Compliance Analysis with NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed “in accordance with §121.4”, which in turn incorporates the requirements in §121.8 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.” This proposal addressing the following requirements of the Final Rule:

- **Shall be based on sound medical judgment:** The Committee proposes this change based on the medical judgment that candidates with complete loss or imminent loss to dialysis access should receive allocation priority to address their medical urgency.
- **Shall seek to achieve the best use of donated organs:** The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. This proposal seeks to make the best use of donated organs by using them for the most medically urgent candidates when they have exhausted dialysis access.

- **Shall be designed to... promote patient access to transplantation:** This proposal seeks to promote access to transplant for the most medically urgent candidates on the kidney transplant waiting list.
- **Shall not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** This proposal presents a uniform, consistent policy that is standardized across the country. Whereas, under previous policy, the definition of a medically urgent candidate could vary DSA-by-DSA, there is now one proposed national definition, which removes variability based on a candidates place of listing.
- **Shall 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:** This proposal includes mechanisms for retrospective review and oversight to ensure the new medical urgency classification is utilized appropriately.
- **Shall be reviewed periodically and revised as appropriate:** The Committee has outlined post-implementation evaluation strategies to allow for necessary changes to be made based on the execution of the proposed policy in the new kidney allocation framework.

Although the proposal outlined in this policy proposal addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- 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);
- Shall be designed to avoid wasting organs, to avoid futile transplants, ... and to promote the efficient management of organ placement;

## Conclusion

The Committee's proposal seeks to provide a rationally determined and consistently applied definition for medical urgency in order that candidates with imminent failure of access to dialysis can receive the appropriate priority in an expedient manner while still allowing for retrospective oversight. One of the guiding principles of the subcommittee's evidence-gathering process and deliberations was to try to mirror the current policy and practices of transplant programs within the new allocation environment. This would serve to reduce additional administrative burden or fiscal impact of the proposal and maintain the efficient placement of organs in accordance with the OPTN Final Rule while still maintaining a mechanism for medically urgent candidates to receive appropriate priority in allocation.<sup>42</sup> Committee members believe that their definition for medical urgency and proposal for implementation is appropriate based on these goals and principles and is a product of sound medical judgement, evidence-gathering, and community feedback.

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback regarding the following:

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<sup>42</sup> 42 C.F.R. § 121.8.

1. Do you believe any additional criteria should be added to or removed from the definition of “medical urgency” as proposed by the Committee?
2. Do you believe that the new medical urgency classification should receive priority outside of the 250 NM circle? Should medically urgent candidates outside of the circle receive priority before non-medically urgent candidates inside of the circle?
3. A new medical urgency classification has been included in each KDPI category for kidney allocation. The Committee requests feedback on the proposed prioritization within each sequence.
4. What types of supporting documentation do you believe are appropriate to ensure the medically urgent classification is being utilized as intended?

## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

# 1 Policy 8: Allocation of Kidneys

## 2 8.2 Exceptions

### 3 8.2.A Exceptions Due to Medical Urgency

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5 To qualify for medically urgent priority in allocation, both the candidate's transplant nephrologist and  
6 transplant surgeon must confirm medical urgency based on meeting the following criteria:

7  
8 First, the candidate must have exhausted, or has a contraindication to, all dialysis access via all of the  
9 following methods:

- 10 • Vascular access in the upper left extremity
- 11 • Vascular access in the upper right extremity
- 12 • Vascular access in the lower left extremity
- 13 • Vascular access in the lower right extremity
- 14 • Peritoneal access in the abdomen

15  
16 After exhaustion or contraindication to all dialysis via the methods listed above, the candidate must also  
17 either have exhausted dialysis, be currently dialyzed, or have a contraindication to dialysis via one of the  
18 following methods:

- 19 • Transhepatic IVC Catheter
- 20 • Translumbar IVC Catheter
- 21 • Other method of dialysis (must specify)

22  
23 The candidate's transplant surgeon and transplant nephrologist must review and sign a written approval  
24 of the candidate's qualification for medical urgency, based on the criteria above. The transplant hospital  
25 must document this medical urgency qualification in the candidate's medical record and submit  
26 supporting documentation to the OPTN within seven business days of indicating medical urgency status.  
27 Candidates classified as medically urgent may be retrospectively reviewed by the Kidney Transplantation  
28 Committee. Cases may be referred to Membership & Professional Standards Committee (MPSC) for  
29 review according to Appendix L of the OPTN Bylaws.

## 31 8.5 Kidney Allocation Classifications and Rankings

### 32 8.5.C Sorting Within Each Classification

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34 Within each classification that is not a medically urgent classification, candidates are sorted in  
35 the following order:

- 36 1. Total points (highest to lowest)
- 37



38 2. Date and time of the candidate's registration (oldest to most recent)

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Within each medically urgent classification, candidates are sorted in the following order:

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1. Total waiting time at medically urgent status (highest to lowest)

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2. Total points (highest to lowest)

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3. Date and time of the candidate's registration (oldest to most recent)

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#### 8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

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Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates according to *Table 8-6* below.

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**Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%**

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
7	<u>Medically Urgent</u>	<u>250NM</u>	<u>Any</u>

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>8</u></b>	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
<b><u>9</u></b>	CPRA equal to 99%, blood type identical or permissible	250NM	Any
<b><u>10</u></b>	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any
<b><u>11</u></b>	CPRA equal to 98%, blood type identical or permissible	250NM	Any
<b><u>12</u></b>	0-ABDR mismatch, top 20% EPTS, and blood type identical	250NM	Any
<b><u>13</u></b>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<b><u>14</u></b>	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<b><u>15</u></b>	0-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Nation	Any
<b><u>16</u></b>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>17</u></b>	0-ABDR mismatch, top 20% EPTS, and blood type B	250NM	O
<b><u>18</u></b>	0-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	Nation	O
<b><u>19</u></b>	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
<b><u>20</u></b>	0-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	Nation	O
<b><u>21</u></b>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
<b><u>22</u></b>	0-ABDR mismatch, top 20% EPTS, and blood type permissible	250NM	Any
<b><u>23</u></b>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<b><u>24</u></b>	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>25</u></b>	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Nation	Any
<b><u>26</u></b>	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<b><u>27</u></b>	Top 20% EPTS, blood type B	250NM	A2 or A2B
<b><u>28</u></b>	Top 20% EPTS, blood type permissible or identical	250NM	Any
<b><u>29</u></b>	0-ABDR mismatch, EPTS greater than 20%, blood type identical	250NM	Any
<b><u>30</u></b>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<b><u>31</u></b>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<b><u>32</u></b>	0-ABDR mismatch, EPTS greater than 20%, and blood type B	250NM	O
<b><u>33</u></b>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	O

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>34</u></b>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
<b><u>35</u></b>	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	250NM	Any
<b><u>36</u></b>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<b><u>37</u></b>	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<b><u>38</u></b>	EPTS greater than 20%, blood type B	250NM	A2 or A2B
<b><u>39</u></b>	All remaining candidates, blood type permissible or identical	250NM	Any
<b><u>40</u></b>	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
<b><u>41</u></b>	Top 20% EPTS, blood type B	Nation	A2 or A2B
<b><u>42</u></b>	Top 20% EPTS, blood type permissible or identical	Nation	Any
<b><u>43</u></b>	All remaining candidates, blood type permissible or identical	Nation	Any

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### 8.5.1 Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-7* below.

**Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%**

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b>1</b>	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
<b>2</b>	CPRA equal to 100%, blood type permissible or identical	250NM	Any
<b>3</b>	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
<b>4</b>	CPRA equal to 100%, blood type permissible or identical	Nation	Any
<b>5</b>	Prior living donor, blood type permissible or identical	250NM	Any
<b>6</b>	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
<b>7</b>	<u>Medically Urgent</u>	<u>250NM</u>	<u>Any</u>
<b>8</b>	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
<b>9</b>	CPRA equal to 99%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>10</u></b>	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
<b><u>11</u></b>	CPRA equal to 98%, blood type permissible or identical	250NM	Any
<b><u>12</u></b>	0-ABDR mismatch, blood type identical	250NM	Any
<b><u>13</u></b>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<b><u>14</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
<b><u>15</u></b>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
<b><u>16</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<b><u>17</u></b>	0-ABDR mismatch, blood type B	250NM	O
<b><u>18</u></b>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>19</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
<b><u>20</u></b>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
<b><u>21</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
<b><u>22</u></b>	0-ABDR mismatch, blood type permissible	250NM	Any
<b><u>23</u></b>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<b><u>24</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Nation	Any
<b><u>25</u></b>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Nation	Any
<b><u>26</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any



Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>27</u>	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any
<u>28</u>	Blood type B	250NM	A2 or A2B
<u>29</u>	All remaining candidates, blood type permissible or identical	250NM	Any
<u>30</u>	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
<u>31</u>	Blood type B	Nation	A2 or A2B
<u>32</u>	All remaining candidates, blood type permissible or identical	Nation	Any

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**8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%**

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Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-8* below and the following:

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- Classifications 1 through 30 for one deceased donor kidney
- Classifications 31 and 32 for both kidneys from a single deceased donor

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**Table 8-8: Allocation of Kidneys from Deceased Donors  
with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%**

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b>1</b>	O-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
<b>2</b>	CPRA equal to 100%, blood type permissible or identical	250NM	Any
<b>3</b>	O-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
<b>4</b>	CPRA equal to 100%, blood type permissible or identical	Nation	Any
<b>5</b>	Prior living donor, blood type permissible or identical	250NM	Any
<b>6</b>	<u>Medically Urgent</u>	<u>250NM</u>	<u>Any</u>
<b>7</b>	O-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
<b>8</b>	CPRA equal to 99%, blood type permissible or identical	250NM	Any
<b>9</b>	O-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
<b>10</b>	CPRA equal to 98%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>11</u></b>	0-ABDR mismatch, blood type identical	250NM	Any
<b><u>12</u></b>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<b><u>13</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
<b><u>14</u></b>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
<b><u>15</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<b><u>16</u></b>	0-ABDR mismatch, and blood type B	250NM	O
<b><u>17</u></b>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
<b><u>18</u></b>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
<b><u>19</u></b>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>20</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
<u>21</u>	0-ABDR mismatch, blood type permissible	250NM	Any
<u>22</u>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
<u>23</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Nation	Any
<u>24</u>	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Nation	Any
<u>25</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<u>26</u>	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any
<u>27</u>	Blood type B	250NM	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>28</u></b>	All remaining candidates, blood type permissible or identical	250NM	Any
<b><u>29</u></b>	Blood type B	Nation	A2 or A2B
<b><u>30</u></b>	All remaining candidates, blood type permissible or identical	Nation	Any
<b><u>31</u></b>	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
<b><u>32</u></b>	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

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### 8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

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With the exception of O-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% are allocated to adult candidates according to *Table 8-9* below and the following:

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- Classifications 1 through 21, 23 and 24 for one deceased donor kidney
- Classifications 22 and 25 for both kidneys from a single deceased donor

**Table 8-9: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%**

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b>1</b>	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
<b>2</b>	CPRA equal to 100%, blood type permissible or identical	250NM	Any
<b>3</b>	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
<b>4</b>	CPRA equal to 100%, blood type permissible or identical	Nation	Any
<b><u>5</u></b>	<u>Medically Urgent</u>	<u>250NM</u>	<u>Any</u>
<b><u>6</u></b>	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
<b><u>7</u></b>	CPRA equal to 99%, blood type permissible or identical	250NM	Any
<b><u>8</u></b>	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
<b><u>9</u></b>	CPRA equal to 98%, blood type permissible or identical	250NM	Any
<b><u>10</u></b>	0-ABDR mismatch, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<u>11</u>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
<u>12</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
<u>13</u>	0-ABDR mismatch, blood type B	250NM	O
<u>14</u>	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
<u>15</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
<u>16</u>	0-ABDR mismatch, blood type permissible	250NM	Any
<u>17</u>	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Nation	Any
<u>18</u>	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
<u>19</u>	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any
<u>20</u>	Blood type B	250NM	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital	With this donor blood type:
<b><u>21</u></b>	All remaining candidates, blood type permissible or identical	250NM	Any
<b><u>22</u></b>	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
<b><u>23</u></b>	Blood type B	Nation	A2 or A2B
<b><u>24</u></b>	All remaining candidates, blood type permissible or identical	Nation	Any
<b><u>25</u></b>	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

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## At a glance

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**Title:** Distribution of Kidneys and Pancreata from Alaska

**Sponsoring Committees:** Kidney Transplantation and Pancreas Transplantation

## What is current policy and why change it?

Deceased donor kidneys and pancreata from donors in Alaska are first offered to candidates in a designated Donation Service Area (DSA), which helps prevent the organ traveling further to go to a patient in similar need. A new policy will replace DSA with a 250 nautical mile circle around the donor hospital. When this changes, because there are no transplant hospitals in Alaska, there will not be any transplant hospitals located within 250 nautical miles of donor hospitals in Alaska. Without a policy change, all organs procured in Alaska would be offered nationally, which could create inefficiencies in organ placement. This means that these organs could be offered to a patient in Florida before a very similar patient in California if not addressed by a modification of policy.

## What's the proposal?

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- The **Seattle-Tacoma International Airport (Sea-Tac)** would be a substitute for the donor hospitals in Alaska as the center of the 250 nautical mile circle

## What's the anticipated impact of this change?

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- **What it's expected to do**
  - Promote the efficient placement of kidneys and pancreata from donors in Alaska
- **What it won't do**
  - Affect the placement of organs donated anywhere other than Alaska

## Themes to consider

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- How this would impact efficient placement of organs

## Terms you need to know

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- **Donation Service Area:** The geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals
- **Donor hospital:** The hospital where the deceased or living donor is admitted
- **Nautical mile:** Equal to 1.15 miles and is directly related to latitude and longitude; used in aviation

- [Click here to search the OPTN glossary](#)

*Public Comment Proposal*

# Distribution of Kidneys and Pancreata from Alaska

*OPTN Kidney Transplantation and Pancreas Transplantation Committees*

*Prepared by: Abby Fox and Scott Castro M.P.P.  
UNOS Policy and Community Relations Department*

## Contents

Executive Summary	4
Purpose of the Proposal	5
Background	5
Proposal	6
Implementation and Operational Considerations	7
Post-implementation Monitoring	8
Conclusion	8
Policy Language	9

# Distribution of Kidneys and Pancreata from Alaska

<i>Affected Policies:</i>	<i>Policy 8.7.C: Location of Donor Hospitals</i> <i>Policy 11.8.A: Location of Donor Hospitals</i>
<i>Sponsoring Committee:</i>	<i>Kidney Transplantation and Pancreas Transplantation</i>
<i>Public Comment Period:</i>	<i>January 22, 2020 – March 24, 2020</i>

## Executive Summary

In December 2019, the OPTN Board of Directors approved policy changes to remove DSA and region from kidney and pancreas allocation. Currently, donors from Alaska are allocated in a DSA that includes areas of the Pacific Northwest. The local unit is changing from DSA (which currently includes most of Washington, parts of Idaho, and all of Montana) to a 250 nautical mile (NM) circle. Alaska does not have any transplant programs. Therefore, in the absence of any transplant programs within a 250NM radius, all kidney and pancreas offers from Alaska will be first offered nationally if this change isn't made.

If allocation is not modified to reflect priority for candidates of closer proximity to Alaska, utilization could be impacted. The organs already accrue significant ischemic time because the total straight flight distance from Anchorage to Seattle is 1,250 nautical miles. Therefore, the OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committees (the Committees) propose modifying policy to administratively allocate kidneys and pancreata from Alaska as though they were recovered from Seattle-Tacoma Airport (SeaTac), where most kidneys and pancreata are flown currently.

This proposed solution promotes efficient placement of organs and avoiding unnecessary organ loss, in accordance with the OPTN Final Rule.

## Purpose of the Proposal

DSA and region are being removed from kidney and pancreas allocation policy, and Alaska donors will no longer be allocated in a DSA or region closer to Alaska than other parts of the continental U.S. Without modification to policy, kidneys and pancreata from Alaska donors could accrue additional ischemic time because there are no transplant programs in Alaska and organs could be shipped a significantly further distance to candidates with similar medical priority. Specifically, Alaska organs could be allocated at a national scale before offers go to candidates closer to the geographically-isolated region.

The proposed solution seeks to avoid a negative impact on utilization and efficient placement of organs recovered in Alaska by administratively allocating kidney and pancreata from Alaska as though they were recovered in Seattle, which is where most of the Alaska organs are flown now.

## Background

The Kidney-Pancreas Workgroup (KP Workgroup) identified addressing Alaska donors in new allocation policies at the outset of deliberations about removing DSA and Region from allocation policy.<sup>1</sup> A KP Workgroup member expressed concern that Alaska would no longer provide local offers to Seattle under a concentric circle model with a small local circle. At the time, the Ad Hoc Geography was considering options to address geographically isolated hospitals uniformly across all organ types, and the KP Workgroup elected to wait for a recommendation from that committee.<sup>2</sup>

During the OPTN Spring 2019 Public Comment period, three OPTN regions, including Region 6, expressed the need for the Committee to further pursue an option to address donors in Alaska.<sup>3</sup> The Committees did not specifically address Alaskan donors in their proposal for the OPTN Fall 2019 Public Comment Period; however, feedback from the community, requesting that the Committee develop a solution for these organs, continued to be received. Specifically, several commenters on the OPTN Public Comment website expressed concern that these donors were not explicitly addressed in the proposal.<sup>4</sup> Region 6 noted the absence of a solution as well, suggesting that the Sea-Tac airport be used as the center of any allocation circle developed by the Committee.<sup>5</sup> Additionally, the OPTN Minority Affairs Committee stated concerns that Alaska donors would go straight to national allocation, and that this could potentially be an inefficient allocation method.<sup>6</sup>

The Committees considered this feedback at their in-person meetings in October 2019.<sup>7,8</sup> Kidney Committee members from Region 6 expressed the necessity of addressing this problem in order to maximize the utilization of kidneys from Alaska. In 2018 there were 30 kidney deceased donors from

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<sup>1</sup> August 7, 2018, KP Workgroup Meeting Summary. Available at <https://optn.transplant.hrsa.gov/> (accessed December 19, 2019).

<sup>2</sup> August 28, 2018, OPTN Ad Hoc Geography Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/> (accessed November 14, 2019)

<sup>3</sup> OPTN Public Comment, Available at <https://optn.transplant.hrsa.gov/> (accessed November 14, 2019).

<sup>4</sup> OPTN Public Comment, Available at <https://optn.transplant.hrsa.gov/> (accessed November 14, 2019).

<sup>5</sup> *Ibid.*

<sup>6</sup> *Ibid.*

<sup>7</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>. (Accessed December 19, 2019).

<sup>8</sup> October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/> (Accessed December 19, 2019).

Alaska. There were 31 such donors in 2017, 22 in 2016 and 20 in 2015.<sup>9</sup> The Kidney Committee deliberated the option of using Sea-Tac airport as the center of the allocation circle for these donors as well as whether proximity points should be utilized for this type of allocation. The Kidney Committee agreed that, given the long travel time these kidneys may have already accrued, it would be prudent to include proximity points in order to mitigate any further cold ischemic time.<sup>10</sup> This is in accordance with the use of proximity points in the Board-approved policy removing DSA and region. Based on the Committee's discussion, language was included adding an administrative rule to the proposal treating Alaska donors as from Sea-Tac. The Kidney Committee approved the proposed changes removing DSA and region from policy and including the administrative rule for Alaska donors with 13 votes in support and 4 votes in dissent.<sup>11</sup>

The Pancreas Committee also elected to include in their proposal a new administrative rule, similar to Board-approved liver policy, which would allow organs recovered in Alaska to be allocated as if they were located at Sea-Tac Airport in Seattle, Washington, with the circle (which has a radius of 250 NM) surrounding that location.<sup>12,13</sup> There were 2 pancreas deceased donors in 2018, 3 in 2017, 6 in 2016 and 5 in 2015.<sup>14</sup> Region 6 expressed that this practice should be adopted in order to maintain utilization of these pancreata in an allocation system without DSA and region. This change will bring consistency to distribution of abdominal organs recovered from Alaska.

Subsequent to their October meetings, the Committees received and considered feedback suggesting public consideration and comment would be prudent for the Sea-Tac change. The Committees agreed that the change to how Alaska donors are allocated should be put forward for public comment. Both Committees voted on amended language that omitted the Alaska change at November 18 and 20 teleconferences (for kidney and pancreas, respectively).

## Proposal

The Committees propose policy language specifying that organs recovered in Alaska be allocated as if they were located at Sea-Tac Airport in Seattle, Washington.

The proposed solution is consistent with the solution to remove DSA and region from policy and allocate instead using a 250 NM circle with up to two points inside the circle and up to four points outside the circle. For purposes of kidneys and pancreata recovered from Alaska, Sea-Tac will serve as center of the 250 NM circle. Proximity points will decrease linearly based on proximity of the candidate's hospital to that location. This approach for Alaska donors aligns with the Board-approved allocation policy.

### Compliance Analysis with NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed "in accordance with §121.4", which in turn incorporates the requirements in §121.8 that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs;

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<sup>9</sup> Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>10</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/> (accessed December 20, 2019).

<sup>11</sup> *Ibid.*

<sup>12</sup> October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/> (accessed December 20, 2019).

<sup>13</sup> December 3-4, 2018, OPTN Board of Directors Meeting Summary. Available at <https://optn.transplant.hrsa.gov/> (accessed October 31, 2019).

<sup>14</sup> Wilk, Amber. UNOS Research, 2019 OPTN data.

(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.” This proposal addresses the requirements of the Final Rule by promoting the efficient management and avoiding unnecessary organ loss. By allocating organs as if they were procured from Sea-Tac airport instead of a transplant hospital in Alaska, these kidney and pancreata could be allocated to local candidates in closer proximity to the place of procurement before being offered nationally. Recognizing that there is currently no transplant programs in Alaska such organs will have several hours of cold ischemic time by the time they reach Sea-Tac airport and be allocated, it promotes more efficient management to propose policy that would prevent adding further ischemic time to promote the utilization of these organs.

### **Potential Impact on Select Patient Populations**

This proposal impacts all kidney and pancreas candidates who could have received an offer from an organ recovered in Alaska. However, the Committees agrees that considerations of ischemic time could prevent utilization of Alaska-recovered organs for candidates in, for example, Florida, because of cold ischemic time and concerns about organ loss. Candidates in the Pacific Northwest would continue to have additional access to organs recovered in Alaska, which would be modified so candidates closer to Sea-Tac would receive additional priority. The Committees consider that this proposal will lead to fewer non-utilized kidneys and pancreata that are donated in Alaska.

## **Implementation and Operational Considerations**

### **OPTN Actions**

Programming changes will be required for this proposal. This would be a “small” size effort in terms of IT implementation. UNOS will follow established protocols to inform members and educate them on any policy changes through Policy Notices. UNOS Professional Education will monitor for additional educational needs throughout the development of this proposal.

### **Member Actions**

Transplant programs and OPO staff may require training and communication about the new policies, with most of the impact being on OPOs and transplant programs within 250 NM or the initial distribution unit of Sea-Tac. However, all programs and OPOs should be aware and informed that the

distance between the program or OPO and the organs recovered from Alaska is determined based on the location of the Sea-Tac airport, and the affect that could have on ischemic time.

## Post-implementation Monitoring

### Member Compliance

No new policy compliance requirements will arise as a result of this policy change.

### Policy Evaluation

This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post implementation. The following metrics, and any subsequently requested by the Committee, will be evaluated as data become available (Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet (e.g., TIEDI forms may take 60+ days to be submitted)) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy:

- # and % of kidney and pancreas donors recovered in Alaska
- # and % of kidneys and pancreata recovered in Alaska
- # and % of kidney and pancreas transplants performed from donors recovered in Alaska
- # and % of kidneys and pancreata transplanted inside/outside fixed circle of Sea-Tac.
- Distribution of kidney and pancreas travel distance (NM) for transplants performed from donors recovered in Alaska

## Conclusion

Kidneys and pancreata recovered from Alaska accrue significant ischemic time due to the distance from Alaska to the continental U.S. There are no transplant programs in Alaska. To avoid these organs accruing ischemic time that leads to unnecessary organ loss, the Committees propose administratively allocating kidneys and pancreata recovered from Alaskan donors as from the Sea-Tac airport in Seattle, Washington. This solution prevents organs being transported a significant distance to a candidate with a similar waiting time, promoting efficiency of organ placement in accordance with the Final Rule.



## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 **8.7 Administrative Rules**

#### 2 **8.7.C Location of Donor Hospitals**

3 For the purpose of determining the location of the donor hospital, kidneys procured in Alaska  
4 will be considered procured from the Sea-Tac Airport, Seattle, Washington.

5

### 6 **11.8 Administrative Rules**

#### 7 **11.8.A Location of Donor Hospitals**

8 For the purpose of determining the location of the donor hospital for allocation of pancreas,  
9 kidney-pancreas, or islets, kidneys and pancreata procured in Alaska will be considered procured  
10 from the Sea-Tac Airport, Seattle, Washington.



## At a glance

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**Title:** Modifications to Released Kidney and Pancreas Allocation

**Sponsoring Committee:** Organ Procurement Organization

## What is current policy and why change it?

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If a transplant hospital is unable to transplant a kidney or pancreas into the patient they accepted the organ for, they must contact the Organ Procurement Organization (OPO) that offered them the organ so that a new recipient can be found. That “host” OPO has the option to continue offering the organ or they can delegate that responsibility to the “importing” OPO that serves the transplant center that declined the organ. The importing OPO then runs a list of eligible candidates within their Donation Service Area (DSA) to hopefully find another recipient that is close-by.

The OPTN Board of Directors approved policy in December 2019 that removes DSA and region from OPTN kidney and pancreas allocation policy and instead uses a 250 nautical mile (NM) circle with the donor hospital at the center. Having policies for **reallocation** of a kidney or pancreas that are consistent with the Board-approved changes promotes efficiency and organ utilization.

## What’s the proposal?

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- Host OPO would have 2 options when an original recipient can’t receive intended kidney or pancreas:
  - **Continue** to find a new recipient
  - Delegate responsibility to the **UNOS Organ Center**
- If host OPO decides to continue to find new recipient, they can:
  - Use the **original match run**; or
  - Create a **new match run** based on the transplant hospital that originally accepted the organ
    - Offers organ to patients within a **250NM circle** of the donor hospital first
    - Candidates inside the circle receive up to 2 **proximity points** based on how close their transplant hospital is to the center of the circle
    - If no candidate within the circle accepts the organ it would then be offered to **patients outside of the circle**
- These candidates could receive up to 4 **proximity points**

## What's the anticipated impact of this change?

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- **What it's expected to do**
  - Create a process for reallocation of organs from candidates who cannot be transplanted that aligns with the new kidney and pancreas allocation policies

## Themes to consider

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- The circle size for reallocation
- Should the process be the same for kidney and pancreas
- Who should be responsible for reallocating the organ(s)

## Terms you need to know

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- **Match run:** A computerized ranking of transplant candidates for an organ being offered based upon donor and candidate medical compatibility and criteria defined in OPTN policies.
- **Nautical Mile:** Equal to 1.15 miles and is directly related to latitude and longitude; used in aviation.
- **Proximity Points:** additional points given to transplant candidates on a match run based off of the location of their transplant hospital in relation to the center of the allocation circle. The closer to the center of the circle, the more points a candidate receives.
- **Reallocation:** The process of finding the next suitable transplant candidate for an organ after it has been accepted and then declined for the original intended recipient.
- [Click here to search the OPTN glossary](#)

*Public Comment Proposal*

# Modifications to Released Kidney and Pancreas Allocation

*OPTN Organ Procurement Organization Committee*

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## Contents

Executive Summary	4
Purpose of the Proposal	6
Background	6
Proposal	9
Implementation and Operational Considerations	12
Potential Fiscal Impact of Proposal	13
Post-implementation Monitoring	13
Conclusion	14
Policy Language	16

# Modifications to Released Kidney and Pancreas Allocation

<i>Affected Policies:</i>	<p>5.9: Released Organs</p> <p>8.3: Kidney Allocation Score</p> <p>8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%</p> <p>8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% But Less Than 35%</p> <p>8.5.J: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%</p> <p>8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</p> <p>11.2: Pancreas Allocation Score</p> <p>11.4.F: Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m<sup>2</sup></p> <p>11.4.G: Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m<sup>2</sup></p>
<i>Sponsoring Committee:</i>	Organ Procurement Organization
<i>Public Comment Period:</i>	January 22, 2020 – March 24, 2020

## Executive Summary

Reallocation refers to situations in which an organ allocated to an original intended recipient is unable to be transplanted in that recipient. In current policy, the host OPO that allocated the organ to the intended recipient's transplant hospital may continue allocating according to the original match run, or allow the organ to be allocated by the OPO in the DSA of the transplant program that originally accepted and then released the organ. Because DSA is being removed from both kidney and pancreas policy, policy needs to be updated to reflect a circle-based approach to reallocate organs not transplanted in their intended recipients. This is particularly a problem in kidney allocation because of the volume of reallocated kidneys compared to other organs.<sup>1</sup> Utilization is a concern in the pancreas community. While pancreata are less likely to be reallocated because of ischemic time, utilization concerns imply that even a small decrease in utilization would be unacceptable to the community.<sup>2</sup> Furthermore, kidney and pancreas allocation are intertwined, in that a majority of pancreas transplants are performed as simultaneous pancreas-kidneys (SPKs). Therefore, both kidney and pancreas would benefit from a solution that improves efficiency and avoids unnecessary organ loss by addressing situations of reallocation.

The proposed solution retains the responsibility to reallocate a previously accepted organ with the host OPO that originally allocated the organ to the intended recipient's transplant hospital. The Committee considers that the host OPO retaining responsibility for reallocation avoids inefficiencies and added

<sup>1</sup>2018 OPTN data

<sup>2</sup> Stratta, Robert J., Jonathan A. Fridell, Angelika C. Gruessner, Jon S. Odorico, and Rainer W.g. Gruessner. Pancreas transplantation: A Decade of Decline. *Current Opinion in Organ Transplantation* 21, no. 4 (August 2016): 386-92.

doi:10.1097/mot.000000000000319.

complexity. The host OPO may continue allocation using the original match run, use a match run based around the transplant program that released the organ, or delegate to the OPTN (the UNOS Organ Center). The new released organ match run would utilize a straight line distance of 250 nautical mile (NM) around the transplant program, with up to two proximity points inside the 250 NM circle and up to four points outside the circle, depending on the proximity of the candidate's hospital to the transplant program.

The OPO Committee appreciates all feedback related to this proposal, but in particular asks for feedback on the following:

- Do you agree with the host OPO retaining responsibility for reallocation instead of delegating to the OPO in the DSA of the transplant program that originally accepted the organ? If not, please state why.
- Do you agree with a reallocation circle of 250 NM around the transplant program with proximity points inside and outside the circle? If not please state your alternative.
- What operational challenges would the new system incur for you? Specifically, what are the operational challenges related to having new "backup" match runs generated that include offers already screened off?
- In addition to the host OPO being able to continue down the original match run or run a new match run around the transplant program that released the organ, does a third option need to be identified in policy for situations in which it would be appropriate to allow center backup? For example, a high kidney donor profile index (KDPI) kidney placed beyond 250 NM.
- Do you have concerns about cross matching under the proposed solution, or anticipate more use of virtual cross matching?
- Do you agree it is appropriate having the same solution for kidney and pancreas reallocation?

## Purpose of the Proposal

The OPTN Board of Directors approved policy in December 2019 that removes DSA and region from OPTN kidney and pancreas allocation policy. Having policies for reallocation of a kidney or pancreas that are consistent with the Board-approved changes promotes efficiency and organ utilization. Therefore, modifications to pancreas and kidney allocation policy to remove DSA and region as distribution units require the modification of policy related to the reallocation of released kidneys and pancreata, including *Policy 5.9: Released Organs*.

Released organs refer to organs released by the transplant program back to the host OPO or the OPTN (UNOS Organ Center) for reallocation. Without modification to policy on reallocation of released kidneys and pancreas, the changes to distribution in pancreas and kidney allocation imply that OPOs would have to follow the original match run to reallocate kidneys and pancreata, even when the organ(s) have accrued significant ischemic time and are far from the donor hospital around which the original match run is based. This could negatively impact patient outcomes and system efficiency with the reallocated organ traveling further and accruing more ischemic time. This could also increase the chance of organs not being used for transplantation.

## Background

### Kidney and Pancreas Proposals

The Kidney and Pancreas Transplantation Committees worked together in 2018 and 2019 to identify a solution to remove DSA and region from kidney and pancreas allocation. In discussions regarding the implications of removing DSA and region, the Committees identified that reallocation policy would be impacted by replacing DSA and region with a fixed-distance circle around a donor hospital.

OPTN *Policy 5.9: Released Organs* specifies that transplant programs must let the host OPO know when an organ is not transplanted in the intended recipient. The host OPO that originally allocated the organ to the intended recipient's transplant hospital has the opportunity to continue allocating according to the original match run or delegate that responsibility to the OPO in the DSA of the transplant program that received the organ. The latter practice is known as "import backup" or "local backup" and is utilized to prevent ischemic time and inefficiencies in organ allocation by providing OPOs with options regarding what to do with organs that are not transplanted into the original, intended recipient.

To make reallocation options for kidney and pancreas consistent with the changes removing DSA and region, both the Kidney Transplantation Committee and the Pancreas Transplantation Committee included solutions in their fall 2019 public comment proposals to allow host OPOs to delegate placement of the organ to the import OPO (which is currently permissible according to *Policy 5.9: Released Organs*). The import OPO could utilize a new match run based around the transplant hospital, which would be a smaller circle than the initial distribution unit. In the fall 2019 proposals, the original allocation unit was 500 NM and the reallocation circle was 150 NM.<sup>3</sup> Both Committees agreed that with

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<sup>3</sup> August 2019, Proposal to Eliminate the Use of DSA and Region in Kidney Allocation Policy, OPTN Kidney Transplantation Committee and Proposal to Eliminate the Use of DSA and Region in Pancreas Allocation Policy, OPTN Pancreas Transplantation Committee. Available at <https://optn.transplant.hrsa.gov>.

a 500 NM circle of distribution, the reallocation circle should be smaller to account for concerns regarding ischemic time, organ loss and efficient organ placement.

In fall 2019 public comment, feedback was mixed on the proposed solution of a 150 NM circle around the transplant program as the reallocation circle and the ability of the host OPO to delegate responsibility to the import OPO.<sup>4</sup> In particular, public comment feedback indicated some concern with the ability of the host OPO to delegate responsibility to the import OPO. The concerns related to efficiency and the fact that the import OPO would not have context related to donor characteristics and donor management that could impact efficiency and complexity of placing the organ. The Committees received mixed feedback regarding the size of the circle itself, with some support for a 150 NM circle and some concerns, particularly with pancreas, that the circle may be too big and a smaller circle (or center backup) may be more appropriate.<sup>5</sup> Center backup refers to the idea that the OPO allows the transplant program to go outside the strict sequence of the match run and use the organ in another candidate at their hospital who may be lower down the match run.

The initial kidney and pancreas public comment documents proposed replacing DSA and region with a 500 NM circle. In response to community feedback, post-public comment changes included modifying the original allocation circle from 500 NM to 250 NM with fewer proximity points inside and outside the circle (two and four, respectively). These changes reflected Final Rule considerations related to efficiency of organ placement, best use of organs, and unnecessary organ loss.

Given the Committees' post-public comment change from utilizing an initial distribution unit of 500 NM to an initial distribution unit of 250 NM, both Committees recognized that the import backup solution would need modification as well. The ischemic time accrued with a 500 NM circle differs from a 250 NM circle, which impacts how far the organ can be reallocated. Thus, an initial distribution unit of 250 NM changes the necessity of having a 150 NM reallocation circle, which was identified as a solution in tandem with an initial distribution unit of 500 NM. The Committees also recognized that public comment feedback was not uniform in support of the 150 NM solution, and additional conversations were needed to discuss some of the public comment received (specifically, feedback related to whether the host OPO should retain responsibility to reallocate the organ and feedback on center backup for pancreas reallocation).

## Import Backup Workgroup

Based on these discussions, both the Kidney and Pancreas Committees agreed to remove reallocation policy language from the proposals removing DSA and region from kidney and pancreas allocation, respectively, before these proposals were presented to the OPTN Board of Directors.<sup>6</sup> A new Workgroup was formed with members from the Kidney, Pancreas, OPO, Operations and Safety, and Histocompatibility Committees to address reallocation policy for pancreas and kidney. The Workgroup members included perspectives from transplant surgeons of different organs, histocompatibility lab directors and OPOs from different regions of the country. Given their collectively varied background and experience, these stakeholders were uniquely positioned to collaborate and identify an appropriate solution to send out for public comment. Because OPOs are directly involved in the challenges and

<sup>4</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov>.

<sup>5</sup> October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov>.

<sup>6</sup> October 21, 2019, OPTN Kidney Transplantation Committee Meeting Summary and October 23, 2019, OPTN Pancreas Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov>.



processes related to reallocation, the OPO Committee was identified as an appropriate sponsor for the proposed changes.

The Workgroup reviewed several options for making current reallocation policy consistent with the changes removing DSA and region from kidney and pancreas policy, as well as relevant data.

### *Supporting Data*

Relevant reallocation data from 2018 included the number of kidney, kidney- pancreas, and pancreas acceptances outside the donor recovery DSA and from released organ match runs.<sup>7</sup> The number of acceptances outside a DSA give a bigger picture of the landscape of kidney and pancreas acceptance patterns:

- 6,458 (40%) kidney acceptances were from centers outside the donor recovery DSA (“non-local”)
  - These acceptances encompassed 4,888 kidney matches (50%) for 3,451 kidney donors\* (41%)
- 370 (34%) KP/pancreas acceptances were from centers outside the donor recovery DSA (“non-local”)
  - These acceptances encompassed 335 donors (32%)

The Workgroup also considered the specific number of acceptances that came from released organ or import match run, as these data directly relate to the impact of modifying reallocation policy:<sup>8</sup>

- 1,683 (10%) kidney acceptances came from an released organ or import (versus host) match run
  - These acceptances encompassed 1,451 kidney matches (15%) for 1,351 kidney donors (16%)
- 35 (3%) KP/pancreas acceptances came from a released organ or import (versus host) match run
  - These acceptances encompassed 35 donors (3%)

Kidney reallocation accounts for the majority of organ reallocation overall, and therefore should be modified to avoid inefficiencies in a circle-based system. Although pancreata account for much smaller proportion of reallocated organs, pancreas utilization has been a concern and a priority for the community, given the overall decline in pancreas transplantation.<sup>9</sup> Therefore, any efforts to promote efficiency and avoid organ loss are to be pursued.

### *Workgroup Discussions*

The Workgroup reviewed and considered the scope of this project, which is not to address every challenge related to reallocation, but to identify a solution that brings consistency to the kidney and pancreas allocation policies that utilize fixed distance circles and not a DSA and region based system,

<sup>7</sup> Urban, Read. Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>8</sup> Urban, Read. Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>9</sup> Stratta, Robert J., Jonathan A. Fridell, Angelika C. Gruessner, Jon S. Odorico, and Rainer W.g. Gruessner. Pancreas transplantation: A Decade of Decline. *Current Opinion in Organ Transplantation* 21, no. 4 (August 2016): 386-92. doi:10.1097/mot.0000000000000319.

and to propose a reasonable solution that will avoid unnecessary organ loss.<sup>10</sup> The Workgroup also carefully considered kidney and pancreas reallocation differences. Pancreata can handle less ischemic time than kidneys, and kidneys account for a greater percent and number of reallocated organs.<sup>11</sup>

Some Workgroup members and the Pancreas Committee expressed concern that a 250 NM reallocation circle would be too large for efficient placement.<sup>12</sup> A majority of Workgroup members agreed, however, that equity concerns trumped the concerns over efficiency and utility.<sup>13</sup> The Workgroup overall agreed that community input should be solicited, especially since the proposed solution is explicit in its requirement that OPOs follow the match sequence. The proposal would only allow allocation according to the original match run or the released organ match run in cases that the organ would be reallocated. Any transplants out of sequence would be in non-compliance of policy, and potentially reviewed. However, any review of policy violations by its nature takes into account the context in which the match sequence is not followed. Since “rescue” placement during kidney allocation does happen, the Workgroup discussed whether it would be appropriate to allow a third option outside of the strict sequential order of the match run. This would allow those placements to be compliant with policy (such as allowing for center backup for high KDPI kidneys when necessary to avoid unnecessary organ loss) and agreed to ask for feedback during public comment. A question regarding a potential third option is included at the end of the Executive Summary and the Conclusion of this paper for community feedback.

Workgroup members also expressed concerns about reallocation circles overlapping with original match run circles, and including offers to candidates with refusals on the original match run.<sup>14</sup> Workgroup members indicated reviewing the same offers unnecessarily would be inefficient and could contribute to increased organ ischemic time. The challenge of implementing a system that removes refusal codes would significantly push back the proposed implementation timeline, however. The Workgroup agreed to ask the community in public comment about the impact of operational concerns related to inputting refusal codes multiple times and other operational concerns.

## Proposal

The proposed solution for reallocating kidneys and pancreata provides that the host OPO retain responsibility in managing reallocation of the kidney, pancreas or combined kidney-pancreas. The host OPO would retain the option to continue down the original match run, have the option to use a new released organ match run based around the transplant program that originally accepted the organ for one of their patients, or delegate to the OPTN (the UNOS Organ Center). The reallocation distribution units and proximity points would be consistent with those distribution units and proximity points used in the original match run: a straight line initial distribution unit of 250 NM with up two proximity points within 250 NM, and up to four proximity points outside 250 NM. Proximity points would decrease linearly based on the proximity of the candidate's hospital to the transplant program that originally accepted and then released the organ, and these points would only apply within allocation classifications.

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<sup>10</sup> November 7, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at <https://optn.transplant.hrsa.gov>

<sup>11</sup> Urban, Read, Wilk, Amber. UNOS Research, 2019 OPTN data.

<sup>12</sup> November 20, 2019, OPTN Pancreas Transplantation Committee Meeting Summary and December 12, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at <https://optn.transplant.hrsa.gov>

<sup>13</sup> November 21, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at <https://optn.transplant.hrsa.gov>

<sup>14</sup> December 12, 2019, OPTN Import Backup Workgroup Meeting Summary. Available at <https://optn.transplant.hrsa.gov>

This is the same distribution schema that will be used in kidney and pancreas allocation once DSA and region are removed from allocation policy and a circle-based system is utilized. The proposed solution serves to avoid inefficiencies and additional ischemic time that could lead to organ loss. A reallocation circle would be particularly helpful for situations in which the organ has already traveled significantly and accumulated ischemic time, and is far away from the donor hospital which is used to create the original match run. The proposed solution also avoids inefficiencies through disallowing host OPOs that originally allocated the organ to the intended recipient's transplant hospital to delegate to other OPOs that do not have context or know the history of the organ.

## Compliance with NOTA and the Final Rule

The Final Rule 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.”<sup>15</sup> This proposal addresses the requirements of the Final Rule.

- **Shall be based on sound medical judgment:** The Committee proposes this change based on the medical judgment of OPO professionals, transplant surgeons, and members of four stakeholder committees in deriving the proposed changes.
- **Shall be designed to avoid wasting organs:** The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. This proposal seeks to avoid organ loss by ensuring alternative allocation is available for organs that may otherwise not be utilized when ischemic time and organ quality impact availability and utilization opportunities.
- **Shall be designed to...to promote the efficient management of organ placement:** This proposal avoids sending organs cross-country unnecessarily by allowing the host OPO to run a match around the transplant program that accepted but can no longer use the organ.

Additionally, this proposal is consistent with other changes removing DSA and region, units of distribution that were determined to not be compliant with the Final Rule.

## Potential Impact on Select Patient Populations

All kidney, kidney-pancreas and pancreas candidates have the potential to be impacted by this proposal in terms of offers received and how those organs are distributed. In particular, candidates within 250 NM of a transplant program that was unable to use a kidney, kidney-pancreas or pancreas may receive an offer based on their proximity to the transplant program and other donor and candidate characteristics.

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<sup>15</sup> 42 C.F.R. § 121.8(a)(8).

## Alternate Solutions Considered

The Workgroup reviewed several alternative solutions for situations in which the kidney or pancreas is unable to be transplanted into the original intended recipient:

1. Host OPO continues distribution down the original match run; no reallocation alternative match run is available (make no modifications to policy)
2. Host OPO may continue distribution down the original match run OR delegate to the OPO in the DSA of the transplant program that originally received the organ for one of their candidates. This other OPO runs a new match run using a distribution circle around the transplant program that originally received the organ instead of the donor hospital. The distribution circle remains the same (250 NM).
3. Host OPO may continue distribution down the original match run OR runs a new match run using a distribution circle around the transplant program that originally received the organ instead of the donor hospital. The distribution circle remains the same (250 NM). In this scenario, the host OPO retains responsibility for placement of the reallocated organ instead of delegating to another OPO.

The Workgroup considered that option 1 would have negative consequences regarding efficiency of placement and potential impact on ischemic time and organ loss. This option would imply that an organ recovered in New York and sent to a candidate in California could only be reallocated according to the New York match run, with its associated proximity points around the donor hospital in New York. Thus, candidates would be receiving priority based on proximity to a donor hospital in New York, even when the organ was in California. Given the additional ischemic time that an organ may accrue during the original allocation, it seemed unacceptable to the Workgroup to disallow reallocation from a new match as an option.

The Workgroup considered option 2, but had concerns similar to those raised in public comment related to the impact of the host OPO delegating responsibility to an import OPO. Specifically, the Workgroup considered that it is important to retain responsibility with the host OPO because the host OPO is vested in the placement of that organ, having worked with the donor from the beginning, in a way that the other OPO is not. The efficiency of the reallocation may be greatly enhanced by the host OPO handling the reallocation compared to the OPO that has no background or history on the organ or the match. These concerns were raised with the public comment proposal that proposed allowing delegation of the reallocation to another OPO.

Currently, the host OPO is able to delegate to an OPO in the DSA of the transplant program that originally accepted the organ; however, the other OPO would be allocating based on its DSA, which contains programs the OPO has worked with and in a certain defined area. With a 250 NM circle, the new import match run may contain many more programs than the importing OPO's DSA. The potential for increased efficiency and the vested interest of the host OPO indicates the appropriate reallocation distribution responsibility should be kept with the host OPO.

Given the Workgroup concerns regarding delegation to the importing OPO, the Workgroup supported option 3, in which the host OPO retains responsibility and has the option of using a released organ match run based on a 250 NM circle around the transplant program that originally accepted the organ. The Workgroup agreed that 250 NM was an appropriate distance given the proximity points in place that give additional priority based on candidate proximity to the transplant program. The Workgroup

also considered it important to have the option of distribution units based around the transplant program and not around the original donor hospital because of concerns about efficiency and organ loss. Within the context of efficiency, it is also important to note that relatively few organs are expected to leave the 250 NM circle for the first allocation.<sup>16</sup>

## Implementation and Operational Considerations

### OPTN Actions

Programming changes will be required for this proposal. This will be a “large” size effort in terms of IT implementation. Changes will be made to kidney allocation and combined kidney-pancreas & pancreas match allocation to allow host OPOs to run matches based around the transplant program that originally accepted the organ instead of around the donor hospital from which the organ was procured. UNOS will follow established protocols to inform members and educate them on any policy changes through Policy Notices. UNOS Professional Education will monitor for additional educational needs throughout the development of this proposal.

### Member Actions

Both Transplant Center and OPO staff would require training and communication about new policies.

### Transplant Hospitals

Transplant programs may be impacted because of limited blood or tissue samples, which may inhibit some programs from performing testing for their potential candidates. A 250 NM circle from the transplant program could encompass a longer list of potential candidates than most DSAs, which are currently utilized for reallocation purposes. Transplant programs would be impacted if they requested blood or tissue samples but the OPO did not have enough to distribute. In practice, transplant programs may need to adjust their behavior based on limited tissue availability and the potential sensitization of their candidates, as well as the donor organ characteristics and other factors, such as where the candidates for which the testing would be performed are located on the reallocation list. Specifically, transplant programs may also increase utilization of virtual cross-matching to mitigate the effect of the policy change.

### OPOs

OPOs will continue allocating donor organs through the match runs, and will retain responsibility to place organs even if the organ travels far from the OPO. This in practice could mean building new relationships with transplant programs outside the OPO’s DSA. Additional staff or staff hours may be necessary, dependent on change in volume of reallocation under the new allocation system using a 250 NM circle around the donor hospital instead of DSA or region. In addition, OPOs placing an organ for reallocation may be challenged to distribute sufficient tissue samples for cross-matching. If tissue samples are in limited supply, the OPO would need to decide which transplant programs receive those tissue samples (programs with candidates high on the list). OPOs may need to reassess protocols regarding when to delegate to the Organ Center.

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<sup>16</sup> Scientific Registry of Transplant Recipients, SRTR KI2019\_01, June 21, 2019, [https://optn.transplant.hrsa.gov/media/2985/ki2019\\_01\\_analysisreport.pdf](https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf) (accessed December 17, 2019).

## Histocompatibility Laboratories

A 250 NM circle from the transplant program could encompass a longer list of potential candidates than most DSAs, which are currently utilized for reallocation purposes. Histocompatibility laboratories may need to perform additional HLA tests using blood or tissue samples before the organ is reallocated. This may be challenging if the organ has limited samples available for distribution to transplant programs. Histocompatibility laboratories may need to reevaluate practices and thresholds for virtual cross-matching.

## Potential Fiscal Impact of Proposal

Implementation of changes to kidney and pancreas reallocation policy may require programming at OPOs, if all elements programmed by the OPTN are not fully supported by local software systems.

Ongoing additional OPO or Transplant center staff time may be significant, depending on change in transplant volume and potential reallocation work. If an organ allocation-sequencing list is re-run, this may result in staff time reviewing the same organ multiple times to determine placement.

Overall transportation costs may also increase for centers, due to potential lost costs in staff time and transport, if organs are not allocated despite attempt. Total average annual cost of transplants determines the annual invoice cost for a regulatory payer, so program and payer costs may change due to any change in organ utility due to reallocation process changes. It may also be challenging for programs to amend existing contracts with non-regulatory (commercial) payers to recover additional costs due to transportation.

However, any staff training at OPOs or Transplant Centers on process changes to implement this proposal can be included in reimbursement requested from payers.

Program size may make cost impact difficult to assess. Large, high volume centers may experience increased volume and staff burden. Small centers can also be affected. While smaller center volume burden may be less, the time burden could be significant with less staff to handle any increased time spent on offers and allocation.

Despite possible impact on OPO and transplant center cost, the potential to place more organs through an efficient process warrant the proposed changes.

## Post-implementation Monitoring

### Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. In addition to the monitoring described below, all policy requirements and data entered in UNet<sup>SM</sup> may be subject to OPTN review, and members are required to provide documentation as requested.

OPTN staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure allocation was carried out according to OPTN organ specific policies and will continue to examine any allocation deviations. When allocation of an organ does not follow the sequence of the match run, such as bypassing potential transplant recipients (PTR) or accepting for one PTR but transplanting the

organ into another PTR, the OPTN will inquire with the OPO and transplant program, as applicable, for additional information. The MPSC will review all relevant information to determine if a policy noncompliance has occurred and what type of action, if any, is warranted.

## Policy Evaluation

This policy will be formally evaluated approximately 3 months, 6 months, 1 year, and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to pre- and post-policy implementation:

- Overall and by OPTN Region:
  - #/% of donors in which an acceptance came from an import match overall and by KDPI
  - #/% of acceptances that came from an import match overall and by KDPI
  - #/% of matches with a bypass code prior to the actual recipient
- For import matches specifically:
  - #/% of kidneys recovered but not utilized (discarded), overall by KDPI
  - #/% and percent kidneys with a final acceptance
  - #/% of matches with a bypass code prior to the actual recipient
  - Distribution of the number of bypass codes applied for import matches

## Conclusion

Modifications to pancreas and kidney allocation policy to remove DSA and region as distribution units require the modification of reallocation policy as well. The proposed solution provides that the host OPO retain responsibility in managing reallocation of the kidney, pancreas or combined kidney-pancreas. The host OPO would retain the option to continue down the original match run, use a new match run based on a 250 NM circle around the transplant program that originally accepted the organ for one of their patients, or delegate to the OPTN (the Organ Center). This solution keeps responsibility with the OPO most vested in placing the organ and is consistent with the proposed change to removing DSA and region from kidney and pancreas policy, which will promote efficiency in the new allocation system.

The OPO Committee appreciates all feedback related to this proposal, but in particular asks for feedback on the following:

- Do you agree with the host OPO retaining responsibility for reallocation instead of delegating to the OPO in the DSA of the transplant program that originally accepted the organ? If not, please state why.
- Do you agree with a reallocation circle of 250 NM around the transplant program with proximity points inside and outside the circle? If not please state your alternative.
- What operational challenges would the new system incur for you? Specifically, what are the operational challenges related to having new “backup” match runs generated that include offers already screened off?
- In addition to the host OPO being able to continue down the original match run or run a new match run around the transplant program that released the organ, does a third option need to be identified in policy for situations in which it would be appropriate to allow center backup? For example, a high KDPI kidney placed beyond 250 NM.
- Do you have concerns about cross-matching under the proposed solution, or anticipate more use of virtual cross-matching?

- Do you agree it is appropriate having the same solution for kidney and pancreas reallocation?



## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 5.9 Released Organs

2 The transplant surgeon or physician responsible for the care of a candidate will make the final decision  
3 whether to transplant the organ.  
4

5 The transplant program must transplant all accepted, deceased donor organs into the original intended  
6 recipient or release the deceased donor organs back to and notify the host OPO or the OPTN Contractor  
7 for further distribution. If a transplant program released an organ, it must explain to the OPTN  
8 Contractor the reason for refusing the organ for that candidate. The host OPO must then allocate the  
9 organ to other candidates according to the organ-specific policies. For kidneys, pancreata, and islets, the  
10 host OPO may delegate this responsibility to the OPTN Contractor. For all other organs, the host OPO  
11 may delegate this responsibility to the OPTN Contractor or to the OPO serving the candidate transplant  
12 program’s DSA.  
13

### 14 8.3 Kidney Allocation Score

15 **Table 8-4: Points for Released Kidneys**  
16 **based on Proximity to Transplant Hospital that Originally Accepted the Organ**

17 For purposes of this section, distance is calculated in nautical miles between the candidate’s hospital of  
18 registration and the transplant hospital that released the kidney.  
19

If the candidate is:	Then the candidate receives this many points:
<u>Registered at a transplant program that is 250 nautical miles or less away from the transplant hospital that originally accepted the kidney</u>	$2 - \left[ \left( \frac{2}{250 - 0} \right) \times distance \right]$
<u>Registered at a transplant program that is more than 250 nautical miles but 2,500 nautical miles or less away from the transplant hospital that originally accepted the kidney</u>	$4 - \left[ \left( \left( \frac{4}{2500 - 250} \right) \times distance \right) - \left( 4 \times \frac{250}{2500 - 250} \right) \right]$
<u>Registered at a transplant program that is more than 2,500 nautical miles away from the transplant hospital that originally accepted the kidney</u>	0

### 20 8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or 21 equal to 20% 22

23 Kidneys from deceased donors with a kidney donor profile index (KDPI) score of less than or equal to  
24 20% are allocated to candidates according to Table 8-6 below. For the purposes of Table 8-6,

25 distribution will be based on the distance from the candidate's transplant program to the donor  
 26 hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For  
 27 kidneys that are released and the host OPO or the OPTN Contractor executes a released kidney match  
 28 run, distribution will be based on the distance from the candidate's transplant program to the transplant  
 29 program that released the organ.  
 30  
 31

**Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal To 20%**

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type identical or permissible	250NM	Any
2	CPRA equal to 100%, blood type identical or permissible	250NM	Any
3	0-ABDR mismatch, CPRA equal 100%, blood type identical or permissible	Nation	Any
4	CPRA equal to 100%, blood type identical or permissible	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 99%, blood type identical or permissible	250NM	Any
8	CPRA equal to 99%, blood type identical or permissible	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type identical or permissible	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
10	CPRA equal to 98%, blood type identical or permissible	250NM	Any
11	O-ABDR mismatch, top 20% EPTS, and blood type identical	250NM	Any
12	O-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	O-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
14	O-ABDR mismatch, less than 18 years old at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type identical	Nation	Any
15	O-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	O-ABDR mismatch, top 20% EPTS, and blood type B	250NM	O
17	O-ABDR mismatch, top 20% EPTS or less than 18 years at time of match run, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	O-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
19	O-ABDR mismatch, less than 18 at time of match, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type B	Nation	O

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
20	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
21	0-ABDR mismatch, top 20% EPTS, and blood type permissible	250NM	Any
22	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
23	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
24	0-ABDR mismatch, less than 18 years old at time of match run, CPRA greater than or equal to 0% but less than or equal to 20%, and blood type permissible	Nation	Any
25	0-ABDR mismatch, top 20% EPTS, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	Top 20% EPTS, blood type B	250NM	A2 or A2B
27	Top 20% EPTS, blood type permissible or identical	250NM	Any
28	0-ABDR mismatch, EPTS greater than 20%, blood type identical	250NM	Any
29	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
30	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
31	0-ABDR mismatch, EPTS greater than 20%, and blood type B	250NM	O
32	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type B	Nation	O
33	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
34	0-ABDR mismatch, EPTS greater than 20%, and blood type permissible	250NM	Any
35	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
36	0-ABDR mismatch, EPTS greater than 20%, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
37	EPTS greater than 20%, blood type B	250NM	A2 or A2B
38	All remaining candidates, blood type permissible or identical	250NM	Any
39	Registered prior to 18 years old, blood type permissible or identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
40	Top 20% EPTS, blood type B	Nation	A2 or A2B
41	Top 20% EPTS, blood type permissible or identical	Nation	Any
42	All remaining candidates, blood type permissible or identical	Nation	Any

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**8.5.I Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%**

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Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-7* below. For the purposes of *Table 8-7*, distribution will be based on the distance from the candidate's transplant program to the donor hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN Contractor executes a released kidney match run, distribution will be based on the distance from the candidate's transplant program to the transplant program that released the organ.

42  
43**Table 8-7: Allocation of Kidneys from Deceased Donors  
with KDPI Scores Greater Than 20% but Less Than 35%**

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	CPRA equal to 99%, blood type permissible or identical	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	CPRA equal to 98%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
11	0-ABDR mismatch, blood type identical	250NM	Any
12	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
14	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, blood type B	250NM	O
17	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
20	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O



Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
21	0-ABDR mismatch, blood type permissible	250NM	Any
22	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
23	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Nation	Any
24	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Nation	Any
25	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
26	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any
27	Blood type B	250NM	A2 or A2B
28	All remaining candidates, blood type permissible or identical	250NM	Any
29	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
30	Blood type B	Nation	A2 or A2B

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
31	All remaining candidates, blood type permissible or identical	Nation	Any

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**8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%**

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Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-8* below and the following:

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- Classifications 1 through 29 for one deceased donor kidney
- Classifications 30 and 31 for both kidneys from a single deceased donor

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For the purposes of *Table 8-8*, distribution will be based on the distance from the candidate's transplant program to the donor hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN Contractor executes a released kidney match run, distribution will be based on the distance from the candidate's transplant program to the transplant program that released the organ.

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**Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%**

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Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> <u>the hospital that distribution will be based upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> the hospital that distribution will be based upon	With this donor blood type:
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
7	CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
9	CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, blood type identical	250NM	Any
11	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
12	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> the hospital that distribution will be based upon	With this donor blood type:
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
15	0-ABDR mismatch, and blood type B	250NM	O
16	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
17	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
18	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
20	0-ABDR mismatch, blood type permissible	250NM	Any
21	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
22	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Nation	Any
23	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> the hospital that distribution will be based upon	With this donor blood type:
24	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
25	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any
26	Blood type B	250NM	A2 or A2B
27	All remaining candidates, blood type permissible or identical	250NM	Any
28	Blood type B	Nation	A2 or A2B
29	All remaining candidates, blood type permissible or identical	Nation	Any
30	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
31	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

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### 8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% are allocated to adult candidates according to *Table 8-9* below and the following:

- Classifications 1 through 20, 22 and 23 for one deceased donor kidney
- Classifications 21 and 24 for both kidneys from a single deceased donor

For the purposes of Table 8-9, distribution will be based on the distance from the candidate's transplant program to the donor hospital, unless the kidney is allocated according to Policy 8.8: Allocation of Released Kidneys. For kidneys that are released and the host OPO or the OPTN Contractor executes a released kidney match run, distribution will be based on the distance from the candidate's transplant program to the transplant program that released the organ.

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**Table 8-9: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%**

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> the hospital that <u>distribution will be based upon</u>	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
6	CPRA equal to 99%, blood type permissible or identical	250NM	Any
7	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
8	CPRA equal to 98%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> the hospital that distribution will be based upon	With this donor blood type:
9	0-ABDR mismatch, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
11	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
12	0-ABDR mismatch, blood type B	250NM	O
13	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
15	0-ABDR mismatch, blood type permissible	250NM	Any
16	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Nation	Any
17	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
18	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from a <del>donor</del> the hospital that distribution will be based upon	With this donor blood type:
19	Blood type B	250NM	A2 or A2B
20	All remaining candidates, blood type permissible or identical	250NM	Any
21	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
22	Blood type B	Nation	A2 or A2B
23	All remaining candidates, blood type permissible or identical	Nation	Any
24	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

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66 **8.8 Allocation of Released Kidneys**

67 For kidneys allocated according to *Policy 5.9: Released Organs*, the host OPO may

- 68 1. Continue allocation according to the original match run  
 69 2. Execute a released kidney match run and allocate the kidney using the released kidney match  
 70 run in accordance with Tables 8-6, 8-7, 8-8, and 8-9.  
 71 3. Delegate allocation of the kidney to the OPTN Contractor.

72 **11.2 Pancreas Allocation Score**

73 **Table 11-3: Points for Reallocation of Pancreas, Kidney-Pancreas, and Islets**  
 74 **based on Proximity to Transplant Hospital that Originally Accepted the Organ(s)**

75 For purposes of this section, distance is calculated in nautical miles between candidate’s hospital of  
 76 registration and the transplant hospital that originally accepted the organ(s).



77

<b>If the candidate is:</b>	<b>Then the candidate receives this many points:</b>
<u>Registered at a transplant program that is 250 nautical miles or less away from the transplant hospital that originally accepted the organ(s)</u>	$2 - \left[ \left( \frac{2}{250 - 0} \right) \times distance \right]$
<u>Registered at a transplant program that is more than 250 nautical miles but 2,500 nautical miles or less away from the transplant hospital that originally accepted the organ(s)</u>	$4 - \left[ \left( \left( \frac{4}{2500 - 250} \right) \times distance \right) - \left( 4 \times \frac{250}{2500 - 250} \right) \right]$
<u>Registered at a transplant program that is more than 2,500 nautical miles away from the transplant hospital that originally accepted the organ(s)</u>	<u>0</u>

78

79 **11.4.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To**  
80 **30 kg/m<sup>2</sup>**

81 Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than or  
82 equal to 30 kg/m<sup>2</sup> will be allocated to candidates according to *Table 11-5*. For the purposes of *Table 11-*  
83 *5*, distribution will be based on the distance from the candidate's transplant program to the donor  
84 hospital, unless the kidney-pancreas, pancreas or islets are allocated according to *Policy 11.7: Allocation*  
85 *of Released Kidney-Pancreas, Pancreas or Islets*. For kidney-pancreas, pancreas or islets that are released  
86 and the host OPO or the OPTN Contractor executes a released kidney-pancreas match run, distribution  
87 will be based on the distance from the candidate's transplant program to the transplant program that  
88 released the organ(s).

89 **Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less**  
90 **with a BMI Less Than or Equal To 30 kg/m<sup>2</sup>**

<b>Classification</b>	<b>Candidates that are</b>	<b>And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be based upon</u></b>
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation

Classification	Candidates that are	And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be based upon</u>
4	Pancreas or kidney-pancreas candidates	250NM
5	Either pancreas or kidney-pancreas candidates, and CPRA greater than or equal to 80%	Nation
6	Pancreas or kidney-pancreas candidates	Nation
7	Islet candidates	250NM
8	Islet candidates	Nation

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#### 11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m<sup>2</sup>

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94 Pancreas, kidney-pancreas, and islets from deceased donors more than 50 years old or from deceased  
 95 donors who have a BMI greater than 30 kg/m<sup>2</sup> are allocated to candidates according to *Table 11-6*  
 96 below. For the purposes of Table 11-6, distribution will be based on the distance from the candidate's  
 97 transplant program to the donor hospital, unless the kidney-pancreas, pancreas or islets are allocated  
 98 according to Policy 11.7: Allocation of Released Kidney-Pancreas, Pancreas or Islets. For kidney-pancreas,  
 99 pancreas or islets that are released and the host OPO or the OPTN Contractor executes a released  
 100 kidney-pancreas match run, distribution will be based on the distance from the candidate's transplant  
 101 program to the transplant program that released the organ(s).

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**Table 11-6: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m<sup>2</sup>**

Classification	Candidates that are:	And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be based upon</u>
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation
4	Pancreas or kidney-pancreas candidates	250NM
5	Islet candidates	250NM
6	Islet candidates	Nation

Classification	Candidates that are:	And registered at a transplant hospital that is within this distance from <del>a donor</del> <u>the hospital that distribution will be based upon</u>
7	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	Nation
8	Pancreas or kidney-pancreas candidates	Nation

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### 106 **11.7 Allocation of Released Kidney-Pancreas, Pancreas or Islets**

107 For kidney-pancreas, pancreas or islets released according to *Policy 5.9: Released Organs*, the host OPO  
 108 may

- 109 1. Continue allocation according to the original match run
- 110 2. Execute a released kidney-pancreas match run and allocate the kidney-pancreas, pancreas or  
 111 islets using the released kidney-pancreas match run.
- 112 3. Delegate allocation to the OPTN Contractor.

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## At a glance

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**Title:** Enhancements to the National Liver Review Board

**Sponsoring Committee:** Liver and Intestinal Organ Transplantation

## What is current policy and why change it

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When a transplant program believes that a liver candidate's model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score does not accurately reflect the candidate's medical urgency, they may request a MELD or PELD score exception. The National Liver Review Board (NLRB) is responsible for reviewing exception requests and either approving or denying the requested score. Since implementation, the transplant community and the OPTN Liver and Intestinal Organ Transplantation Committee (Liver Committee) have noted numerous ways to improve the NLRB in its goal to provide more efficient and equitable access to transplant.

## What's the proposal?

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- To improve the NLRB by:
  - **Automatically granting extension requests for Hepatocellular Carcinoma (HCC) candidates**, as long as they meet the standard extension criteria and are requesting a policy-assigned score.
  - **Clarifying the update schedule** for median MELD at transplant and median PELD at transplant.
  - Updating **operational guidelines** to include
    - Language instructing review board members on how to evaluate **candidates with unique situations**
    - Adjusted threshold for **removing inactive reviewers**
    - Clarification that the Liver Committee may delegate authority for final **appeal review** to a subcommittee.
  - Updates to **guidance documents** to include
    - **Recommendations** for secondary sclerosing cholangitis (SSC) and adults with metabolic disease
    - **Removing unnecessary language** for portopulmonary hypertension (PH)
    - **Clearer guidance** for handling candidates with history of hepatocellular carcinoma (HCC)

## What's the anticipated impact of this change?

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- **What it's expected to do**
  - Make the NLRB more transparent, efficient, and equitable
  - Increase transparency in the update schedule of score changes
  - Increase the likelihood that candidates with similar clinical characteristics are treated in a similar fashion

- **What it won't do**
  - Will not impact any specific patient group such as pediatric candidates, minority candidates, sensitized candidates, or living donors
  - There is no anticipated negative impact for any group

## Themes to consider

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- NLRB scope of review
- NLRB voting thresholds for removing inactive reviewers
- Changes to NLRB Guidance Documents
- Other ways to improve the NLRB

## Terms you need to know

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- **MMaT**: Median Model for End-Stage Liver Disease (MELD) at Transplant. The NLRB awards exception points for candidates 18 years or older relative to the MMaT for the area where the candidate is listed. This ensures that exception candidates are assigned scores that reflect the candidate pool in the area that they are listed.
- **MPaT**: Median Pediatric End-Stage Liver Disease (PELD) at Transplant. The NLRB awards exception points for candidates less than 18 years old relative to the MPaT for the nation. This ensures that pediatric exception candidates are assigned scores that reflect the pediatric candidate population across the nation.
- **Exception Points**: Additional points added to a MELD or PELD score for a candidate by the NLRB to more accurately reflect the candidate's medical urgency
- [Click here to search the OPTN glossary](#)

*Public Comment Proposal*

# Enhancements to the National Liver Review Board

*OPTN Liver and Intestinal Organ Transplantation Committee*

*Prepared by: Matt Cafarella  
UNOS Policy and Community Relations Department*

## Contents

Executive Summary	4
Purpose of the Proposal	5
Background	5
Enhancements	6
Implementation and Operational Considerations	13
Post-implementation Monitoring	13
Conclusion	14
Policy Language	17

# Enhancements to the National Liver Review Board

<i>Affected Policies:</i>	<i>Policy 9.4.C: MELD or PELD Score Exception Extensions</i> <i>Policy 9.4.D: Calculation of Median MELD or PELD at Transplant</i> <i>Policy 9.5.I.vii: Extensions of HCC Exceptions</i>
<i>Affected Guidelines:</i>	<i>National Liver Review Board Operational Guidelines</i> <i>Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review</i> <i>Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exceptions for Hepatocellular Carcinoma</i>
<i>Sponsoring Committee:</i>	<i>Liver and Intestinal Organ Transplantation</i>
<i>Public Comment Period:</i>	<i>January 22, 2020 – March 24, 2020</i>

## Executive Summary

The National Liver Review Board (NLRB) was implemented on May 14, 2019. The purpose of the NLRB is to provide equitable access to transplant for liver candidates whose calculated model for end-stage liver disease (MELD) score or pediatric end-stage liver disease (PELD) score does not accurately reflect the candidate's medical urgency.<sup>1</sup> As of September 30, 2019, there have been 5,300 exception request forms submitted to the NLRB.<sup>2</sup> Since implementation, the transplant community and the OPTN Liver and Intestinal Organ Transplantation Committee (Liver Committee) have noted numerous ways to improve the NLRB in its goal to provide more efficient and equitable access to transplant.

This proposal seeks to make enhancements to the NLRB policy, operational guidelines, and guidance documents in order to make the system more efficient and equitable.

- **Policy:** The proposed changes to policy will allow any candidate with hepatocellular carcinoma (HCC) meeting standard extension criteria to be automatically approved and increase transparency in the update schedule for median MELD at transplant (MMaT) and median PELD at transplant (MPaT).
- **Operational Guidelines:** The improvements to the operational guidelines include adding direction to reviewers on how to evaluate requests for candidates with unique situations, adjusting the threshold for removing inactive reviewers to be more in line with reviewer practice, and clarifying that the Liver Committee may delegate authority for final appeal review to a subcommittee.
- **Guidance:** The proposed updates to the guidance documents, which are intended to assist NLRB reviewers in evaluating exception requests, include the addition of recommendations for secondary sclerosing cholangitis (SSC) and adults with metabolic disease, the removal of unnecessary language for portopulmonary hypertension (PH), and clarification for how to handle cases where the candidate has a prior history of HCC.

The Liver Committee is seeking public feedback on the proposed changes to the NLRB policy, operational guidelines, and guidance documents, as well as other ideas on improving the NLRB system.

<sup>1</sup> *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

<sup>2</sup> OPTN Descriptive Data Request. "National Liver Review Board Out-of-the-Gate Report, Four Months of Data Report" Prepared for Liver and Intestinal Organ Transplantation Committee Meeting, October 22, 2019, Available at <https://optn.transplant.hrsa.gov/>

## Purpose of the Proposal

Since the implementation of the NLRB, the Liver Committee has carefully evaluated the effectiveness of the system. The Liver Committee has identified a number of ways in which the NLRB could be improved through updates to the NLRB policy, operational guidelines, and guidance documents. The purpose of this proposal is to incorporate feedback from the transplant community on the function of the NLRB. The proposed changes are anticipated to create a more efficient and equitable system for the review of exception requests.

## Background

When being listed for a liver transplant, candidates receive a calculated MELD or PELD score, which are based on a combination of the candidate's clinical lab values. These scores are designed to reflect the probability of death within a 3-month period, with higher scores indicating a higher probability of mortality and increased urgency for transplant. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. Candidates that are particularly urgent are assigned a priority 1A or 1B status.

When a transplant program believes that a candidate's calculated MELD or PELD score does not accurately reflect a candidate's medical urgency, they may request a score exception. The NLRB is responsible for reviewing exception requests and either approving or denying the requested score.

Prior to the implementation of the NLRB, exception requests were reviewed by regional review boards that evaluated all exception requests for candidates listed in that particular region. Most regions had their own criteria for exception review, contributing to differences in exception review practices between regions.<sup>3</sup>

To address this issue, the OPTN Board of Directors (Board) approved a proposal to establish the NLRB at their June 2017 meeting.<sup>4</sup> The NLRB was designed to create a more efficient and equitable system for reviewing exception requests for candidates across the country.

Under the NLRB, if an exception request or an extension of a granted exception score meets the criteria outlined in OPTN policy for one of the standard diagnoses, then the request is automatically approved by the system. In the first four months of the NLRB, 1,559 (29.4%) of the 5,300 exception request forms were auto-approved by the system.<sup>5</sup> Allowing requests that meet standard criteria to be automatically approved ensures that similar candidates are treated consistently and reduces the workload for NLRB reviewers and transplant programs.

Exception requests that are automatically approved are granted a policy-assigned exception score that is relative to the MMaT in the area of the transplant program where the candidate is listed or the MPaT for the nation. The assigning of exception points relative to the MMaT for the area around the transplant program at which the candidate is listed ensures that similar diagnoses are treated consistently across the country but also reflects local differences in the candidate pool.<sup>6</sup> The cohort and update schedule for the MMaT and MPaT calculations are included in NLRB policy.

<sup>3</sup>Proposal to Establish a National Liver Review Board, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

<sup>4</sup> Ibid.

<sup>5</sup> OPTN Descriptive Data Request. "National Liver Review Board Out-of-the-Gate Report, Four Months of Data Report" Prepared for Liver and Intestinal Organ Transplantation Committee Meeting, October 22, 2019, Available at <https://optn.transplant.hrsa.gov/>

<sup>6</sup> The area used in the calculation of MMaT aligns with the units of distribution used in the allocation of deceased donor livers in place. At the time of the writing of this proposal, the MMaT is calculated using the transplant program's DSA. Upon implementation of the Acuity Circles policy, it will be calculated using a 250 nautical mile (NM) circle around the transplant program.



Most standard diagnoses are granted a score of MMaT-3. Adolescent candidates who meet the criteria for a standard diagnoses are typically given a score of MMaT and pediatric candidates are given a score of MPaT. Some diagnoses are given additional priority due to their increased urgency.

If an exception request or extension does not meet the criteria for a standard diagnosis, the candidate has a diagnosis not included in the list of standard diagnoses, or the transplant program is requesting a score different than the policy-assigned score, then the request is reviewed by one of three specialty review boards that make up the NLRB. The three specialty boards are: Adult HCC, Adult Other Diagnosis, and Pediatric. All active liver transplant programs can appoint a representative and alternate to the Adult HCC and Adult Other Diagnosis specialty boards. Live programs with an active pediatric component may appoint a representative and alternate to the pediatric specialty review board.

Each request reviewed by a specialty board is assigned five random reviewers from across the country. The request is approved if four of the five reviewers submit their approval. If the case is denied, the submitting program has the opportunity to appeal the decision, first to the same group of reviewers, then to the Appeals Review Team (ART), and finally to the Liver Committee.

When reviewing requests, NLRB members are required to use the NLRB guidance documents that were approved by the Board and are posted to the OPTN website.<sup>7</sup> Each specialty board has its own guidance document summarizing the available evidence to guide reviewers in approving exception requests.

During the time that the NLRB has been in place, the Liver Committee has continuously assessed the system for ways in which it can be improved. Much of the work described herein was led by the NLRB Subcommittee, a subgroup of the Liver Committee specifically focused on the NLRB. Committee members drew upon their own experiences with the NLRB and solicited feedback from members of the transplant community, including NLRB reviewers and transplant programs submitting exception requests, to identify ways in which the NLRB can be improved. The identified enhancements involve changes to OPTN policy language, the operational guidelines, and the guidance documents.

The following section provides more detailed information on the proposed enhancements to OPTN policy language, the operational guidelines, and the guidance documents.

## Enhancements

### OPTN Policy Language

*OPTN Policies 9.4: MELD or PELD Score Exceptions* and *9.5: Specific Standardized MELD or PELD Score Exceptions* outline the processes through which exception cases are reviewed, how the MMaT and MPaT calculation cohorts are defined, and the standard diagnoses and related clinical criteria that must be met in order for an exception request or extension of an exception request to be automatically approved by the system.

The Liver Committee is proposing changes to OPTN Policy related to automatic approval of HCC extensions and the recalculation of MMaT and MPaT.

### Automatic Approval of HCC Extensions

Under the current system, candidates who have an automatically-approved exception request for a standardized MELD or PELD diagnosis are able to have subsequent extensions automatically approved as long as they continue to meet the extension criteria included in *OPTN Policy 9.5*. However, candidates

<sup>7</sup> The guidance documents for each of the NLRB specialty boards are available at <https://optn.transplant.hrsa.gov/>

who have their initial exception form reviewed by the NLRB are unable to have future extensions forms automatically approved, even if they meet the extension criteria listed in policy. This has created unnecessary work for the NLRB reviewers, increased the burden of managing exception requests for these patients on transplant programs, and delayed the assignment of exception scores caused by NLRB review.

Candidates with HCC are eligible to have their initial exception and subsequent extension requests automatically approved, as long as they meet the criteria described in *OPTN Policy 9.5*. However, many HCC candidates do not meet the standard criteria and must have their requests reviewed by the Adult HCC Specialty Board. HCC candidates that do not initially meet standard criteria may eventually meet the standard extension criteria listed in OPTN Policy. Because these candidates did not initially meet standard criteria, there is no way for them to have subsequent extension requests automatically approved, even when they do subsequently meet standard extension criteria. Therefore, the Committee is proposing updating OPTN policy so that any HCC candidate can have an extension form automatically approved as long as they meet the standard extension criteria and are requesting a policy-assigned score.

The proposed changes to OPTN policy would reduce the workload on the Adult HCC Specialty Board and increase the overall efficiency of the system. The majority (50.7%) of forms reviewed by the Adult HCC Specialty Board over the first four months of the NLRB were extension requests.<sup>8</sup> Additionally, members of the Liver Committee have noted that many of the extension requests submitted to the HCC review board appeared to meet the criteria for automatic approval. Allowing candidates who meet the standard extension criteria to be automatically approved in the system will enable reviewers to devote more attention to those cases where their discretion is needed and increase the overall efficiency of the system.

The proposed changes will also reduce the administrative burden on transplant programs. Currently, transplant programs submitting extension requests for candidates that meet standard extension criteria but who were not initially approved must explain in the candidate's narrative that they meet standard extension criteria. There is also the possibility that the transplant program will need to appeal the decision of the NLRB if the extension request is not granted. Allowing any HCC candidate who meets standard extension criteria to be automatically approved will reduce the need for transplant programs to write extensive narratives and eliminate the need for appeals for these candidates.

Finally, the proposed enhancements will ensure that candidates with similar clinical characteristics are treated in the same manner and eliminate any delay in the assigning of exception scores for HCC candidates meeting standard extension criteria who would have otherwise had their extension request reviewed by the NLRB.

The Committee is seeking public feedback on the proposed approach and if the policy language is sufficiently clear that any HCC candidate is eligible for automatic approval of an extension request as long as they meet standard extension criteria.

### **Recalculation of MMaT and MPaT**

*OPTN Policy 9.4.D: Calculation of Median MELD or PELD at Transplant* outlines when the OPTN will recalculate the MMaT and MPaT scores upon which exception scores are based. The current policy states that scores will be updated every 180 days using a cohort from the previous 365 days. However,

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<sup>8</sup>OPTN Descriptive Data Request. "National Liver Review Board Out-of-the-Gate Report, Four Months of Data Report APPENDIX" Prepared for Liver and Intestinal Organ Transplantation Committee Meeting, October 22, 2019, Available at <https://optn.transplant.hrsa.gov/>

after recalculating the scores once, it became evident that such restrictive language regarding when the scores must be updated was unreasonable. For example, when updating the scores it is impossible to base the scores on a cohort from the immediately previous 365 days, as there needs to be time to complete programming and data validation. Additionally, the new scores are published and communicated to the community at least two weeks in advance of their implementation. The current language does not take into account that the 180-day update could occur on a holiday or weekend. As a result, the proposed language allows for more discretion regarding the precise timing of the updates, giving the OPTN sufficient time to properly calculate, publish, and communicate the updated scores in advance of their implementation. The proposed language still requires that the OPTN update the MMaT and MPaT scores on a semi-annual basis.

## Operational Guidelines

The operational guidelines<sup>9</sup> outline the function and operation of the NLRB. Specifically, the operational guidelines describe who may participate as an NLRB reviewer and their responsibilities, the voting procedure, and the appeal process. Since the implementation of the NLRB, the Liver Committee has identified a number of ways in which the operational guidelines can be improved. The Liver Committee is proposing changes to the operational guidelines related to the scope of NLRB review, the removal of inactive reviewers, and the Liver Committee appeal process.

### Scope of NLRB Review

NLRB reviewers are expected to leave comments on each exception request they are assigned. These comments are particularly important when a reviewer votes to deny an exception request, as the feedback provided can be used by the transplant program to update the form for resubmission or appeal. Liver Committee members noted that some comments submitted by reviewers included statements regarding surgical practice, listing decisions, suitability of the candidate for transplant and a host of other comments outside of the NLRB's purview.<sup>10</sup> The diversity of comments submitted on exception requests shows the wide range of factors that reviewers are considering when voting on requests and the lack of clear instructions on what NLRB reviewers should base their decisions, particularly when there is no guidance or policy. As a result, the Liver Committee is proposing the addition of language to the operational guidelines outlining what information should be taken into account when NLRB reviewers are assigned a case when there is no clear policy or guidance.

The proposed language instructs review board members to use guidance and policy when applicable and to base their decisions on the medical urgency of the candidate, anticipated transplant efficacy, waitlist dropout rates, and waitlist mortality risk of the candidate when there is no relevant policy or guidance.

The addition of this language is intended to put parameters on the scope of NLRB review and to best approximate the purpose of MELD and PELD exception scores. The goal is to reduce the variety of factors that NLRB reviewers consider when evaluating unique exception requests to increase the consistency with which these reviews are conducted.

The Committee is seeking public input on whether the proposed considerations are the appropriate factors upon which NLRB reviewers should base their decisions when there is no policy or guidance available. If factors beyond medical urgency are to be considered by NLRB reviewers, the Committee will

<sup>9</sup> Current operational guidelines are available at <https://optn.transplant.hrsa.gov/>

<sup>10</sup> November 19, 2019, OPTN Liver and Intestinal Organ Transplantation Committee Meeting Summary, Available at <https://optn.transplant.hrsa.gov/>

review OPTN policy to ensure that the scope of NLRB review is consistent with the proposed changes to the operational guidelines.

### Removal of Inactive Reviewers

The operational guidelines include language requiring the removal of reviewers who do not vote in a timely manner on open cases on three separate instances within a 12 month period. This requirement is intended to ensure prompt review of exception cases and remove reviewers who are consistently unable to meet the requirements of their position. However, in the first four months of the NLRB, 83 reviewers were reassigned due to inactivity at least three times.<sup>11</sup> This represents approximately 25% of unique participants that have voted on any of the specialty review boards.<sup>12</sup>

Based on the data from the first four months of the NLRB, the Committee is proposing that the threshold for removal due to inactivity be less restrictive. The proposed language includes two changes. First, the threshold for removal would change from three missed cases to missing 5% of all cases assigned to the reviewer within a 12 month period.<sup>13</sup> The change from a set number to a percentage of cases reviewed accounts for the fact that the different specialty review boards are assigned a different number of cases and individual reviewers are assigned a different caseload depending on their availability. Second, the proposed language gives discretion for removal to the NLRB Chair. The Committee recognizes that there may be extenuating circumstances that disallow a reviewer from responding to cases and the proposed language provides for discretion when such situations occur. For example, NLRB reviewers have cited instances where they travelled outside of the country and did not enable the out of office functionality causing them to miss three cases. These reviewers were otherwise responsive. The proposed language would allow the NLRB Chair to consider such circumstances when deciding to remove an inactive reviewer.

The Committee is seeking public input on whether 5% of assigned cases is the appropriate threshold and if additional clarification on what constitutes a failure to vote is needed.

### Liver Committee Appeal Process

The operational guidelines state that transplant programs can submit a final appeal to the Liver Committee if a case is denied by the ART. However, the operational guidelines do not include information on the format of the final appeal or who must participate. Historically, the Liver Committee has delegated this responsibility to the NLRB Subcommittee, which is made up of a subset of Liver Committee members.

The proposed changes to the operational guidelines make it clear that the Liver Committee can delegate responsibility for the final appeal to a subcommittee and provide more detail on the format of the appeal review. Specifically, the Committee is proposing the addition of language stating that the appeal must achieve a majority of affirmative votes to be approved and that a majority is based on the size of the subcommittee. The proposed changes also make it clear that final appeals will be reviewed

<sup>11</sup> OPTN Descriptive Data Request. "National Liver Review Board Out-of-the-Gate Report, Four Months of Data Report" Prepared for Liver and Intestinal Organ Transplantation Committee Meeting, October 22, 2019, Available at <https://optn.transplant.hrsa.gov/>

<sup>12</sup> The OPTN surveyed reviewers who had a case reassigned due to inactivity and found that the major reasons they noted for missing cases were lack of education on the system, voting process and out of office functionality; technology issues related to Mac or Safari; and high case load.

<sup>13</sup> In the first four months of the NLRB, 145 unique reviewers on the Adult HCC Specialty Board were assigned 2039 total exception requests, 133 unique reviewers on the Adult Other Diagnosis Specialty Board were assigned 1188 total exception requests, and 62 unique reviewers on the Pediatric Specialty Review board were assigned 355 total exception requests. Some individuals may be participants on more than one specialty board and this includes both primary and alternate representatives.

electronically unless one of the subcommittee members requests a conference call at which point a quorum is a majority of the subcommittee.

These proposed changes to the operational guidelines increase transparency and efficiency in the appeal process by making it clear that the Liver Committee can delegate the final review to a subcommittee. Delegation of final appeal review to a subcommittee will increase the efficiency of the system because the subcommittee is made up of a subset of the Liver Committee that is specifically focused on the NLRB, allowing appeals to be reviewed more quickly than if they went to the full Liver Committee.

The Committee is seeking public input on if the process outlined for the final appeal is sufficiently clear in the operational guidelines. The Committee is also seeking feedback on if the language in the “Voting Procedure” section that instructs reviewers on how to access exception requests is necessary.

## Guidance Documents

Each of the three specialty review boards has specific, clinical guidance to assist reviewers in evaluating exception requests for the corresponding candidate pool. The guidance documents are not OPTN policy and are intended to provide guidance to review board members and transplant programs to help ensure consistent and equitable review of exception cases. The Committee is proposing changes to the guidance documents for the Adult Other Diagnosis and Adult HCC Specialty Boards.

### Adult Other Diagnosis

Portopulmonary Hypertension (PH) is a standard diagnosis in policy that is granted an automatic exception when certain clinical criteria are met. It is also included in the Adult Other Diagnosis guidance document. The guidance document for PH includes a statement noting that candidates with PH who meet the criteria in policy are eligible for an automatic exception. However, it also includes language allowing for transplant programs to submit a request for a specific score as long as they provide a written narrative supporting the score. In addition, the guidance document includes a recommendation for transplant programs to report three specific clinical elements for the purposes of policy research and a reference to outdated policy language. Because candidates with PH are eligible for an automatic exception when they meet the criteria listed in policy, the Committee recommends striking all subsequent language from the PH section of the Adult Other Diagnosis guidance document.

The proposed changes would remove all language in the guidance related to PH, except for the language stating that candidates with PH are eligible for a standard exception as long as they meet the criteria listed in OPTN policy. The subsequent language serves no substantive purpose, the recommended clinical elements are not being used for policy research, and the reference to policy is outdated.

The Adult Other Diagnosis guidance document includes a section for primary sclerosing cholangitis (PSC) but no corresponding guidance for secondary sclerosing cholangitis (SSC). SSC and PSC have similar clinical features with the primary difference being that PSC is of unknown etiology, while SSC has a known cause.<sup>14</sup> Literature suggests that individuals with SSC may have a shortened life expectancy as compared to individuals with PSC and that individuals with SSC could benefit from liver transplantation.<sup>15</sup> Given the similarity of PSC and SSC and the potential benefit from transplant, the

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<sup>14</sup> Gossard, Andrea A., Paul Angulo, and Keith D. Lindor. “Secondary Sclerosing Cholangitis: A Comparison to Primary Sclerosing Cholangitis.” *The American Journal of Gastroenterology* 100, no. 6 (2005): 1330–33. <https://doi.org/10.1111/j.1572-0241.2005.41526.x>.

<sup>15</sup> Ibid.

Committee is proposing adding SSC to the section in guidance for PSC. This would allow candidates with SSC to receive the same consideration as candidates with PSC.

The Committee is also proposing the addition of guidance for adult candidates with metabolic disorders. Individuals with metabolic disease are typically transplanted during infancy or childhood. However, in rare cases, adults can develop metabolic symptoms secondary to an inherited organic acidemia or urea cycle defect.<sup>16</sup> Pediatric candidates with a metabolic disorder are eligible for a standard MELD or PELD exception, and if they have an exception for more than 30 days, they are eligible to be listed as Status 1B. However, there is no corresponding consideration for adults.

In the rare case that an adult develops metabolic symptoms, the Committee agreed that guidance on how to handle such a case would be beneficial. The Committee proposes recommending a score of MMaT-3 for adults with a metabolic disorder, but allowing for consideration of a higher score if life-threatening complications are present. The Committee is seeking public feedback on if MMaT-3 is the proper score to recommend for these patients.

### Adult HCC

The Adult HCC guidance document includes ambiguous language regarding how candidates with a history of HCC more than two years prior should be treated. The guidance states that candidates who had HCC more than two years ago that was treated but then recurs should be considered the same as those with no prior HCC when applying for an exception. The intent of this guidance was to only apply to candidates on their initial MELD exception, not if they have been listed with an exception previously. The proposed language clarifies this distinction and aligns the guidance with OPTN policy for HCC exception candidates.

### Potential Impact on Select Patient Populations

The proposal will impact candidates with certain diagnosis who are applying for a MELD or PELD exception. Candidates with SSC will now be considered by review board members in a similar way to candidates with PSC. There was previously no guidance for SSC, so the proposal should increase the standardization of exception review for these candidates. Adults with metabolic disorders will now be treated in a consistent manner, as the updated guidance recommends how these cases should be handled. The inclusion of SSC and metabolic disease for adults in the guidance will standardize how these cases are reviewed by the NLRB. This will both increase equity, by treating similar patients in a similar way, and increase efficiency in the system, by providing clear recommendations for NLRB reviewers.

The proposal also impacts candidates with HCC. HCC candidates who meet standard extension criteria will be able to be automatically approved by the system, even if they were not automatically approved previously. This will make the approval of HCC extensions more efficient and equitable, by treating similar candidates alike and by having more forms automatically approved by the system. Also, the proposal could impact candidates with a previous history of HCC, as the proposed guidance is clearer regarding how these cases should be handled.

The overall purpose of the proposed changes is to make the NLRB more transparent, efficient, and equitable, and therefore, all exception candidates could see an indirect, positive impact.

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<sup>16</sup> Saudubray, J.-M., F. Sedel, and J. H. Walter. "Clinical Approach to Treatable Inborn Metabolic Diseases: An Introduction." *Journal of Inherited Metabolic Disease* 29, no. 2-3 (2006): 261–74. <https://doi.org/10.1007/s10545-006-0358-0>.



The proposal will not impact any specific patient group such as pediatric candidates, minority candidates, sensitized candidates, or living donors. There is no anticipated negative impact for any group.

## Alternate Proposals Considered

Since the implementation of the NLRB, the Liver Committee has carefully monitored for ways to improve the system. This proposal represents the first round of enhancements. The Liver Committee has discussed a multitude of other potential improvements and anticipates submitting another proposal for public comment in the future.

## Compliance Analysis with NOTA and the OPTN Final Rule

The Final Rule requires that policies with the goal of improving allocation must be developed “in accordance with §121.4, which in turn incorporates the requirements in §121.8 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.” This proposal addresses the following requirements of the Final Rule.

- **Shall be based on sound medical judgment:** The changes proposed by the Committee are based on their medical judgment as transplant professionals and the published literature, when applicable.
- **Shall seek to achieve the best use of donated organs:** The proposal seeks to achieve the best use of donated organs by increasing the likelihood that similarly urgent candidates will be treated in a similar manner, and increasing the likelihood that candidates with increased medical urgency receive organ offers before those candidates that are not as urgent.
- **Shall be designed to...promote patient access to transplantation:** The proposal promotes patient access to transplantation by more efficiently granting HCC exception extension requests and by adding guidance for candidates with SSC and adults with metabolic disease to make sure candidates that are similarly situated are granted access to the same scores and extensions.
- **Shall not be based on the candidate’s place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** This proposal is not based on the candidates’ place of residence or place of listing.

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- 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);
- Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
- Shall be designed to avoid wasting organs, to avoid futile transplants, ... and to promote the efficient management of organ placement;

## Implementation and Operational Considerations

### Overview

The proposed changes will require additional communication and training from the OPTN to both transplant programs and NLRB reviewers.

Programming will be required in UNet<sup>SM</sup> to allow all HCC extension requests that meet standard extension criteria to be automatically approved.

### Fiscal Impact

Minimal or no member impact.

### OPTN Actions

The OPTN will need to implement programming changes in UNet<sup>SM</sup> to allow all HCC extension requests that meet standard extension criteria to be automatically approved. No additional programming will be required for the proposed changes to the MMA/T/MPaT update schedule, the operational guidelines, or the guidance documents.

The OPTN will need to communicate the proposed changes to all liver transplant programs and NLRB reviewers. Updates to existing education for NLRB reviewers and transplant programs will be made to reflect the changes in policy, operational guidelines and guidance documents. Additional supplemental materials may also be created to highlight these changes.

### Member Actions

Liver transplant programs will need to ensure that staff responsible for submitting exception requests are familiar with the updated operational guidelines and guidance documents. They will also need to be aware that any HCC candidate meeting standard extension criteria is eligible for automatic approval, even if they were not previously automatically approved.

## Post-implementation Monitoring

### Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet<sup>SM</sup> may be reviewed by the OPTN, and members are required to provide documentation as requested.

### Policy Evaluation

The changes to NLRB policy, operational guidelines, and guidance documents will continue to be analyzed and reviewed during the 6-month intervals up to 36 months post-implementation (or longer if requested by the Committee) of the initial NLRB policy. Results will be provided nationally, by region, and specialty board type as appropriate. To monitor specific changes to HCC extension automatic approval, the metrics below, in addition to those identified for evaluation of the NLRB, will be considered:

- Number and percent of initial and extension HCC exception requests, overall and by HCC specialty board vs automatic approval



- Number and percent of extension HCC exception requests automatically approved after an NLRB-reviewed request (initial or extension)
- Other measures as deemed appropriate by the Committee

## Conclusion

The NLRB has been in place for over six months. As with any major implementation, the users of the system have noted a multitude of ways to improve the NLRB. The proposed changes to policy will allow any HCC candidate meeting standard extension criteria to be automatically approved and increases transparency in the update schedule for MMaT and MPaT. The improvements to the operational guidelines include adding language to instruct review board members on what criteria to base decisions when no guidance is available, adjusting the threshold for removing inactive reviewers to be more in line with reviewer practice, and clarifying that the Liver Committee has the right to delegate authority for final appeal review to a subcommittee. The proposed updates to the guidance documents include the addition of recommendations for SSC and adults with metabolic disease, the removal of unnecessary language for portopulmonary hypertension (PH), and clarification for how to handle cases where the candidate has a prior history of hepatocellular carcinoma (HCC).

These changes will increase equity, transparency, and efficiency in the NLRB system.

## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 **9.4 MELD or PELD Score Exceptions**

#### 2 **9.4.C MELD or PELD Score Exception Extensions**

##### 3 **9.4.C.i Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception Extensions**

4 A candidate with an approved exception for HCC is eligible for automatic approval of an  
 5 extension according to *Policy 9.5.I.vii Extensions of HCC Exceptions*, even if the initial exception  
 6 was not a standardized MELD or PELD score exception.

##### 8 **9.4.C.ii Other MELD or PELD Score Exception Extensions**

9 A candidate's approved exception will be maintained if the transplant hospital enters a MELD or  
 10 PELD Exception Score Extension Request before the due date, even if the NLRB does not act  
 11 before the due date. If the extension request is denied or if no MELD or PELD Exception Score  
 12 Extension Request is submitted before the due date, then the candidate will be assigned the  
 13 calculated MELD or PELD score based on the most recent reported laboratory values.

14  
 15 Each approved MELD or PELD exception extension is valid for an additional 90 days beginning  
 16 from the day that the previous exception or extension expired.

#### 18 **9.4.D Calculation of Median MELD or PELD at Transplant**

19 Median MELD at transplant (MMaT) is calculated by using the median of the MELD scores at the time of  
 20 transplant of all recipients at least 12 years old who were transplanted at hospitals within 250 nautical  
 21 miles of the candidate's listing hospital in the last 365 days.

22  
 23 Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of  
 24 transplant of all recipients less than 12 years old in the nation.

25  
 26 The MMaT and MPaT calculations exclude recipients who are either of the following:

- 27 1. Transplanted with livers from living donors, DCD donors, and donors from donor hospitals more
- 28 than 500 nautical miles away from the transplant hospital
- 29 2. Status 1A or 1B at the time of transplant.

30  
 31 ~~The OPTN Contractor will recalculate the MMaT and MPaT every 180 days using the previous 365-day~~  
 32 ~~cohort. If there have been fewer than 10 qualifying transplants within 250 nautical miles of a transplant~~  
 33 ~~hospital in the previous 365 days, the MMaT will be calculated based on the previous 730 days.~~ The  
 34 OPTN will recalculate the MMaT and MPaT twice a year based an updated cohort. The updated cohort  
 35 will include transplants over a prior 365 day period. If there have been fewer than 10 qualifying  
 36 transplants within 250 nautical miles of a transplant hospital in the cohort, the MMaT will be calculated  
 37 based on a total of a 730 day period.

38  
39 Exceptions scores will be updated to reflect changes in MMaT or MPaT each time the MMaT or MPaT is  
40 recalculated. The following exception scores are not awarded relative to MMaT or MPaT and will not be  
41 updated:

- 42 1. Exception scores of 40 or higher awarded by the NLRB according to *Policy 9.4.A: MELD or PELD Score*  
43 *Exception Requests*
- 44 2. Any exception awarded according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT)*  
45 *MELD Score Exceptions*
- 46 3. Exceptions awarded to candidates less than 18 years old at time of registration according to *Policy*  
47 *9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*
- 48 4. Initial exceptions and first extensions awarded to candidates at least 18 at time of registration  
49 according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score*  
50 *Exceptions*

51  
52 **9.5.I.vii Extensions of HCC Exceptions**

53 ~~In order for a candidate to maintain an approved exception for HCC, the transplant program~~  
54 ~~must submit an updated MELD or PELD Exception Score Request Form that contains the~~  
55 ~~following: A candidate with an approved exception for HCC is eligible for automatic approval~~  
56 ~~of an extension if the transplant program enters a MELD or PELD Exception Score Extension~~  
57 ~~Request that contains the following:~~

- 58
- 59 1. Documentation of the tumor using a CT or MRI
- 60 2. The type of treatment if the number of tumors decreased since the last request
- 61 3. The candidate's alpha-fetoprotein (AFP) level
- 62 ~~The candidate will then receive the additional priority. The candidate's exception extension~~  
63 ~~will then be automatically approved unless any of the following occurs:~~

- 64
- 65 • The candidate's lesions progress beyond T2 criteria, according to *9.5.I.ii: Eligible*  
66 *Candidates Definition of T2 Lesions*
- 67 • The candidate's alpha-fetoprotein (AFP) level was less than or equal to 1,000 ng/mL on  
68 the initial request but subsequently rises above 1,000 ng/mL
- 69 • The candidate's AFP level was greater than 1,000 ng/mL, the AFP level falls below 500  
70 ng/mL after treatment but before the initial request, then the AFP level subsequently  
71 rises to greater than or equal to 500 ng/mL
- 72 • The candidate's tumors have been resected since the previous request
- 73 • The program requests a score different from the scores assigned in Table 9-10.

74  
75 When a liver candidate at least 18 years old at the time of registration submits an initial  
76 request or the first extension request that meets the requirements for a standardized MELD  
77 score exception, the candidate will receive a MELD score of 6, and appear on the match  
78 according to that exception score or the calculated MELD score, whichever is higher.

79  
80 A candidate who meets these requirements for a ~~standardized~~ MELD or PELD score  
81 exception for HCC will be assigned a score according to *Table 9-10* below.  
82

83

**Table 9-10: HCC Exception Scores**

Age	Age at registration	Exception Request	Score
At least 18 years old	At least 18 years old	Initial and first extension	6
At least 18 years old	At least 18 years old	Any extension after the first extension	3 points below MMaT
At least 12 years old	Less than 18 years old	Any	40
Less than 12 years old	Less than 12 years old	Any	40

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# National Liver Review Board Operational Guidelines

## 1. Overview

The purpose of the National Liver Review Board (NLRB) is to provide fair, equitable, and prompt peer review of exceptional candidates whose medical urgency is not accurately reflected by the calculated MELD/PELD score. The NLRB will base decisions on policy, the guidance documents, and in cases which lack specific guidance, the medical urgency, anticipated transplant efficacy, waitlist dropout rates, and waitlist mortality risk of the candidate.

The NLRB is comprised of specialty boards, including:

- Adult Hepatocellular Carcinoma (HCC)
- Adult Other Diagnosis
- Pediatrics, which reviews requests made on behalf of any candidate registered prior to turning 18 years old and adults with certain pediatric diagnoses

The immediate past-Chair of the Liver and Intestinal Organ Transplantation Committee serves as the Chair of the NLRB for a two year term.

## 2. Representation

Every active liver transplant program may appoint a representative and alternate to each of the adult specialty boards. A liver transplant program with an active pediatric component may appoint a representative and alternate to the pediatric specialty board. Individuals may serve on more than one specialty board at the same time. Transplant programs are encouraged to appoint representatives from both hepatology and surgery who have active transplant experience. Liver transplant programs are not required to provide a representative to the NLRB.

Representatives and alternates serve a one year term. A liver transplant program may appoint the same representative or alternate to serve consecutive terms.

If a transplant hospital withdraws or inactivates its liver program, it may not participate in the NLRB. However, the transplant hospital's participation may resume once it has reactivated its liver program.

## 3. Representative and Alternate Responsibilities

Prior to each term of service, representatives and alternates are required to sign the *UNOS Confidentiality and Conflict of Interest Statement* and complete orientation training.

Representatives must vote within 7 days on all exception requests, exception extension requests, and appeals. A representative will receive an e-mail reminder after day 3 and day 5 if the representative has an outstanding vote that must be completed. On the eighth day, if the vote has not been completed, then the request will be randomly reassigned to another representative. The original reviewer will receive a notification that the request has been reassigned.

The representative must notify UNOS in UNet<sup>SM</sup> of an absence, during which the alternate will fulfill the responsibilities of the representative.

If a representative or alternate does not vote on an open request within 7 days on ~~three separate instances~~ more than 5% of the cases assigned to that reviewer within a 12 month period, the Chair may ~~will~~ remove the individual from the NLRB. If a representative or alternate does not vote because a case is approved and closed before the 7 day timeframe expires, it is not considered a failure to vote. A representative or alternate who has been removed for failure to perform the duties required is not eligible to serve again for 3 years.

If a transplant program exhibits a pattern of non-responsiveness, as evidenced by the removal of two members from the NLRB, the Chair may suspend the program's participation for a period of three months after notifying the program director. Further non-compliance with the review board process may result in cessation of the program's representation on the NLRB until such a time as the transplant hospital can satisfactorily assure the Chair that it has addressed the causes of non-compliance.

#### **4. Voting Procedure**

An exception request is randomly assigned to five representatives of the appropriate specialty board. A representative may vote to approve or deny the request, or ask that the request be reassigned. The request must achieve four out of five affirmative votes in order to be approved. If the request does not achieve the necessary four affirmative votes, it is denied.

As part of the MELD/PELD Exception program in UNet<sup>SM</sup>, NLRB members are notified of new cases by email. To access the exception request, click on the emailed link or go to <https://www.unet.unos.org/>. Log-in using your UNet<sup>SM</sup> username and password and click on "Waitlist," then "NLRB."

Voting on an exception request is closed either at the end of the appeal period or when no additional votes will change the outcome of the vote, whichever occurs earlier. Members no longer have the ability to vote once a request is closed.

#### **5. Appeal Process**

A liver program may appeal the NLRB's decision to deny an exception request. Patients are not eligible to appeal exception requests. All reviewer comments are available in UNet<sup>SM</sup>. The NLRB advises programs to respond to the comments of dissenting reviewers in the appeal.

The same five members that reviewed the original request will review the appeal. The appeal must achieve four out of five affirmative votes in order to be approved. If the appeal does not achieve the necessary four affirmative votes, it is denied. If the appeal is denied, the liver program may request a conference call with the Appeals Review Team (ART).

If the ART denies the request, the liver program may initiate a final appeal to the Liver and Intestinal Organ Transplantation Committee (Liver Committee). Referral of cases to the Liver ~~and Intestinal Organ Transplantation~~ Committee will include information about the number of previous referrals from that program and the outcome of those referrals.

## **6. Appeals Review Team (ART)**

At the beginning of each new service term, nine NLRB members are randomly assigned to serve each month of the year on the ART. There may be multiple ARTs, depending on the volume of cases. An NLRB member will be selected to serve for no more than one month each year on the ART. The ART meets via conference call at the same day and time each week; however calls may be rescheduled in advance to accommodate federal holidays.

In the event of a planned absence, the ART member may designate their alternate to serve. The representative must notify UNOS of this in UNet<sup>SM</sup>.

Five members of the ART must participate in the call. If at least five members do not attend the call, the appeal will be rescheduled for the following regularly scheduled conference call. If at least five members do not attend the second attempt to review the appeal, the candidate's exception request is automatically approved.

The appeal must achieve a majority plus one affirmative votes in order to be approved.

A representative at the petitioning program may serve as the candidate's advocate. If a representative is unable to attend the conference call, the program may ask for the appeal to be scheduled for the following regularly scheduled conference call. If after two attempts a representative is unable to attend the call, the ART will review the appeal without the program's participation. In the absence of a representative on the conference call, the program may submit written information for the ART's consideration.

The ART will work with UNOS staff to document the content of the discussion and final decision in UNet<sup>SM</sup>.

## **7. Liver Committee Review**

The Liver Committee may delegate review to a subcommittee. If the review is delegated, majority is based on the size of the subcommittee.

Appeals to the Liver Committee will be considered electronically unless at least one member of the Liver Committee requests a conference call. If the case is discussed on a conference call, quorum is a majority of the Liver Committee (or the subcommittee, if delegated).

The appeal must achieve a majority affirmative votes in order to be approved.

## National Liver Review Board for Adult MELD Exception Review

### Portopulmonary Hypertension

Candidates meeting the criteria in *Policy 9.5: Specific Standardized MELD or PELD Score Exceptions* are eligible for MELD or PELD score exceptions that do not require evaluation by the full Review Board. The transplant program must submit a request for a specific MELD or PELD score exception with a written narrative that supports the requested score. Templates were developed for these exceptions to aid the transplant programs in the process of submitting the required information to justify the exception. The Committee recommends that the following three elements be considered in reviewing the exception application in addition to the requirements listed in policy for the purposes of policy research:

1. Although policy only requires reporting of the MPAP and PVR, complete Hemodynamics should be reported, including MPAP, PVR, PWAP and CO.
2. To be considered abnormal, the initial mean pulmonary artery pressure (MPAP) should be >35 mmHg and pulmonary vascular resistance (PVR) levels should be > 240 dynes.s.cm<sup>-5</sup>.
3. The initial transpulmonary gradient (MPAP-PVR) to correct for volume overload should be > 12 mmHg

As noted in policy, these candidates will receive a MELD score of 22/ PELD score of 28. In order to qualify for MELD/PELD extensions and a 10% mortality equivalent increase in points, the required documentation must be resubmit every three months and the mean pulmonary arterial pressure (MPAP) must remain below 35 mmHg, confirmed by repeat heart catheterization.

### Primary Sclerosing Cholangitis or Secondary Sclerosing Cholangitis

Candidates with Primary Sclerosing Cholangitis (PSC) or Secondary Sclerosing Cholangitis (SSC) historically have low mortality rates, and therefore do not need exception scores. Based on clinical experience and a review of the available literature, the Committee recommends that four specific elements be considered.

**Transplant programs should provide the following criteria when submitting exceptions for PSC or SSC. The Review Board should consider the following criteria when reviewing exception applications for candidates with PSC or SSC.**

The candidate must meet both of the following two criteria:

1. The candidate has been admitted to the intensive care unit (ICU) two or more times over a three month period for hemodynamic instability requiring vasopressors
2. The candidate has cirrhosis

In addition the candidate must have one of the following criteria:

- The candidate has biliary tract stricture which are not responsive to treatment by interventional radiology (PTC) or therapeutic endoscopy (ERCP) or
- The candidate has been diagnosed with a highly-resistant infectious organism (e.g. Vancomycin Resistant Enterococcus (VRE), Extended Spectrum Beta-Lactamase (ESBL) producing gram negative organisms, Carbapenem-resistant Enterobacteriaceae (CRE), and Multidrug-resistant Acinetobacter.)



## Metabolic Disease

Adults who develop metabolic symptoms secondary to an inherited organic acidemia or urea cycle defect which are typically transplanted during infancy or childhood may be suitable for MELD exception. Given later onset, anticipate a reduced urgency compared to early-onset disease, thus priority for transplant may be similar to other exceptions and would recommend MMaT-3, though if a patient has more urgent medical condition, as reflected by life-threatening complications, a higher priority score can be considered.

## Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exceptions for Hepatocellular Carcinoma (HCC)

### Recommendation

1. Patients with the following are contraindications for HCC exception score:

- Macro-vascular invasion of main portal vein or hepatic vein
- Extra-hepatic metastatic disease
- Ruptured HCC
- T1 stage HCC

While in most cases, ruptured HCC and primary portal vein branch invasion of HCC would be contraindications, some patients who remain stable for a prolonged (minimum of 12 months) interval after treatment for primary portal vein branch invasion or after ruptured HCC may be suitable for consideration.

2. Patients who have a history of prior HCC more than→2 years ago which was completely treated with no evidence of recurrence, who develop new or recurrent lesions after 2 years should generally be considered the same as those with no prior HCC, in order to determine the current stage suitability for an initial MELD exception, and initial MELD exception score assignment.