

## **Public Comment Proposal**

# **Update Multi-Organ Allocation for Continuous Distribution of Lungs**

**OPTN Lung Transplantation Committee** 

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# **Update Multi-Organ Allocation for Continuous Distribution of Lungs**

Affected Policies: 5.10.F: Allocation of Lung-Kidneys

5.10.G: Allocation of Heart-Liver and Lung-Liver

6.6.F: Allocation of Heart-Lungs

Sponsoring Committee: Lung Transplantation

Public Comment Period: August 3, 2022 – September 28, 2022

## **Executive Summary**

In December 2021, the OPTN Board of Directors approved the proposal *Establish Continuous Distribution of Lungs*. <sup>12</sup> The proposal updated lung multi-organ allocation policies to reflect that lung candidates will be ranked according to a composite allocation score. Current multi-organ allocation policies use classifications, distance, and lung allocation score thresholds to indicate when an organ procurement organization must offer another organ along with a lung. The continuous distribution proposal replaced these thresholds with a composite allocation score threshold for required multi-organ offers. The score threshold was selected to preserve eligibility for required multi-organ offers for about 95% of patients who receive lung multi-organ transplants in the current allocation system. Updated analysis with more recent data suggested that the selected threshold would not maintain access for as many patients as originally expected. Accordingly, the purpose of this proposal is to update the lung composite allocation score threshold for multi-organ allocation (specifically for lung-liver, lung-kidney, and heart-lung) to ensure qualifying candidates maintain eligibility for required multi-organ shares with the implementation of continuous distribution of lungs.

<sup>&</sup>lt;sup>1</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed June 4, 2022, <a href="https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf">https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf</a>.

<sup>2</sup> Executive Summary of the OPTN Board of Directors Meeting, December 6, 2021. (Accessed May 26, 2022) <a href="https://optn.transplant.hrsa.gov/media/g23hdtxk/20211206-optn-bod-summary.pdf">https://optn.transplant.hrsa.gov/media/g23hdtxk/20211206-optn-bod-summary.pdf</a>.



### **Purpose**

The purpose of this proposal is to update the lung composite allocation score (CAS) threshold for multiorgan allocation from 28 to 25 to ensure that qualifying lung-liver, lung-kidney, and heart-lung candidates maintain eligibility for required multi-organ shares with the implementation of continuous distribution of lungs.

## **Background: Continuous Distribution of Lungs Proposal**

The OPTN released the proposal *Establish Continuous Distribution of Lungs* for public comment in August 2021.<sup>3</sup> The proposal noted that current policy uses classifications, distance, and lung allocation score (LAS) thresholds to delineate when organ procurement organizations (OPOs) must offer multiple organs from the same donor to a lung candidate. The intent of such policies is to provide access to transplant for candidates experiencing multi-organ failure, particularly those who may not be good candidates for lung-alone transplant but may have a successful outcome if they receive another organ along with a lung. The continuous distribution proposal aimed to maintain similar rules surrounding multi-organ allocation to be in effect during the transition period while lung allocation is in a continuous distribution system and other organs remain in a classification-based system. To accomplish that end, the Lung Transplantation Committee (Committee) selected a lung composite allocation score (CAS) threshold to replace the classification, distance, and LAS thresholds used in current policy.

The lung CAS is different from the current LAS in that while the LAS assigns points for waitlist survival and post-transplant survival, the lung CAS also accounts for a number of other factors, including candidate blood type, sensitization, height, pediatric status, prior living donor status, travel efficiency, and proximity efficiency. Candidates can be assigned an LAS up to 100 in the current system based on their waitlist survival and post-transplant survival scores, but in continuous distribution, a candidate will only be able to receive a maximum of 50 points in the lung CAS for their waitlist survival and posttransplant outcomes scores. Additionally, changes to how points are assigned for expected waitlist survival gives many more points to patients who very urgently need a lung transplant, and fewer points to patients who are expected to live closer to a year without transplant. Accordingly, the lung CAS is **not** comparable to LAS. Many candidates will have a lower CAS in the continuous distribution allocation system compared to their LAS in the current allocation system, but that does not necessarily mean that they have less priority for transplant in the new allocation system. The briefing paper Establish Continuous Distribution of Lungs<sup>4</sup> includes more information on the expected impact of continuous distribution on various populations. Overall, the changes are expected to reduce waitlist deaths for lung candidates while decreasing the percentage of organ recoveries that require flying, reducing geographic disparities, and increasing access for pediatric candidates.

When selecting the CAS threshold for lung multi-organ allocation, the Committee aimed to maintain about the same level of access to transplant for lung-liver, lung-kidney, and heart-lung candidates as in the current system. Current policy for lung-liver and lung-kidney allocation was implemented on

<sup>&</sup>lt;sup>3</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed June 5, 2022, https://optn.transplant.hrsa.gov/media/4772/continuous\_distribution\_of\_lungs-public\_comment.pdf. <sup>4</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.

February 10, 2022, and requires offering livers and kidneys to lung candidates with an LAS of 35 or greater, or less than 12 years old. The LAS threshold was determined using the data shown in **Figure 1.**6

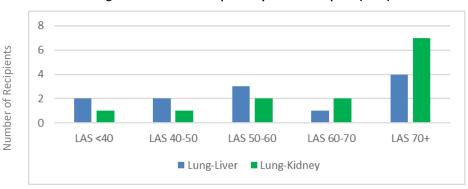


Figure 1: Number of Recipients by LAS at Transplant (2019)<sup>7</sup>

For multi-organ transplants performed in 2019, all of the lung-liver and lung-kidney transplants performed (12 and 13, respectively) would meet the criteria.<sup>8</sup>

Current policy for heart-lung allocation refers to lung classifications, which are being eliminated in continuous distribution since candidates will be assigned a CAS. The classifications order candidates on the match run based on their medical urgency, age, blood type, and distance from the donor hospital (see OPTN *Policy 10.4 Lung Allocation Classifications and Rankings*). Current heart-lung policy directs OPOs to make organ offers to medically urgent heart and heart-lung candidates on the heart match run before offering the heart along with the lungs on the lung match run to candidates in classifications 1 through 12.

To determine the lung CAS threshold that should replace the LAS threshold and lung classifications, the Committee considered the expected distribution of CAS scores for patients who received lung-liver, lung-kidney, and heart-lung transplants in the current allocation system. The Committee set a CAS threshold of 28 to include most multi-organ lung recipients while preserving access to transplantation for single-organ heart, kidney and liver candidates. As an OPO makes offers down the lung match run, the OPO would be required to offer the heart, kidney, or liver to lung candidates registered for both organs if the candidate's CAS was 28 or greater. The OPO would not be required to offer a heart, kidney, or liver to lung candidates with a CAS below 28. At that point, the OPO would proceed with allocation by following other multi-organ policies or offering the organs individually.

**Table 1** shows the data that the Committee initially reviewed when selecting the CAS threshold of 28. This table shows the cumulative percent of lung multi-organ recipients that would be captured if the multi-organ threshold were set at a specified composite allocation score. The Committee sought to capture 99% of the lung-kidney recipients and therefore chose 28 as the cutoff for the composite allocation score. Overall, this cut-off was expected to capture about 95% of the recipients who received heart-lung, lung-liver, and lung-kidney transplants.

<sup>&</sup>lt;sup>5</sup> "Clarify Multi-Organ Allocation Policy," Notice of OPTN Policy Change, accessed July 1, 2022. https://optn.transplant.hrsa.gov/media/4698/clarify multi-organ june 2021 policy notice.pdf.

<sup>&</sup>lt;sup>6</sup> OPTN Public Comment Proposal, Clarify Multi-Organ Allocation Policy, January 21, 2021 – March 23, 2021. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/media/4354/2021\_pc\_opo\_clarify\_multi\_organ\_allocation\_policy.pdf.

<sup>8</sup> Ibid.



Table 1: Percentages of Lung Multi-Organ Recipients by Estimated Composite Allocation Score 01/01/2011-05/13/20219

<b>Composite Allocation Score</b>	Heart	Kidney	Liver	Total
32	23.84%	70.59%	46.94%	39.60%
31	50.19%	91.27%	68.23%	62.93%
30	74.28%	97.21%	82.02%	80.24%
29	83.76%	98.96%	92.39%	89.44%
28	89.19%	99.62%	98.09%	94.55%
27	93.02%	99.88%	99.36%	96.79%
26	95.15%	99.88%	99.47%	97.72%
25	97.24%	99.91%	99.52%	98.61%
24	98.59%	99.91%	99.52%	99.17%
23	99.13%	99.91%	99.52%	99.40%
22	99.41%	99.91%	99.52%	99.51%

The Committee also made some additional changes to heart-lung policy. OPOs will continue to offer organs to high-status heart and heart-lung candidates within 500 NM first. After that, OPOs will offer lungs and heart-lungs on the lung match run to candidates with a CAS of at least 28 before a heart alone would be offered from the heart match run to candidates further than 500 NM from the donor hospital, or listed at status three or lower. These changes provided more direction to OPOs than current allocation policies, by not permitting heart-alone allocation to continue until the heart was offered to all heart-lung candidates on the lung match run with a CAS of at least 28. However, if the lungs are placed with lung-alone candidates on the lung match run, then the OPO can proceed with heart-alone allocation. Fundamentally, the Committee sought to balance the difficulty in finding an appropriate donor for a candidate who requires multiple organs with the desire to provide earlier access to transplant for heart-alone candidates who are the most medically urgent, according to their status, and with the desire to save the largest number of lives possible with the limited supply of organs for transplant. The Heart Transplantation Committee supported this approach.<sup>10</sup>

Public comment responses were generally supportive of these changes to lung multi-organ allocation. There were some concerns from OPOs who wanted to ensure there was sufficient room for discretion when allocating several organs. The Committee retained the same level of OPO discretion as current policy in relation to lung-liver and lung-kidney allocation. In relation to heart-lung, the Committee decided that their approach balanced the comments supporting the prescriptive order between the heart and lung match with the feedback requesting more flexibility.

In December 2021, the OPTN Board of Directors approved the proposal *Establish Continuous Distribution of Lungs*. <sup>11,12</sup> The OPTN subsequently began implementing the proposal. In spring 2022, further analysis indicated that the composite allocation score threshold of 28 would not preserve eligibility for required shares for as many multi-organ lung candidates as originally expected.

<sup>&</sup>lt;sup>9</sup> OPTN Data as of June 11, 2021.

<sup>&</sup>lt;sup>10</sup> Heart Transplantation Committee Meeting Summary for September 21, 2021, OPTN, accessed June 19, 2022, https://optn.transplant.hrsa.gov/media/ju1jptbx/20210921\_heart-committee-meeting-summary\_final.pdf.

<sup>11 &</sup>quot;Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022,

https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.

<sup>&</sup>lt;sup>12</sup> Executive Summary of the OPTN Board of Directors Meeting, December 6, 2021. (Accessed May 26, 2022) https://optn.transplant.hrsa.gov/media/g23hdtxk/20211206-optn-bod-summary.pdf.

Accordingly, the Committee determined that the threshold should be updated for the implementation of continuous distribution of lungs.

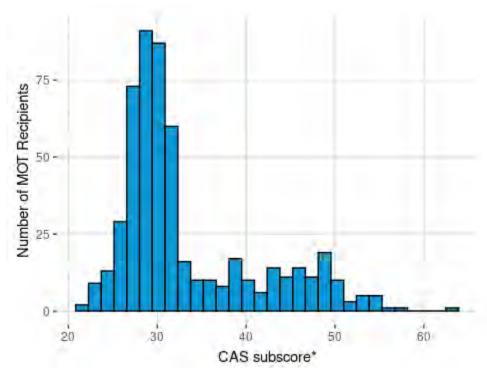
## **Overview of Proposal**

The Committee proposes changing the lung CAS threshold for lung-liver, lung-kidney, and heart-lung allocation from 28 to 25, and clarifying the policy language for heart-lung allocation.

#### Update the Lung CAS Threshold

The Committee reviewed **Figure 2**, which shows the distribution of calculated lung CAS for patients who previously received lung-liver, lung-kidney, or heart-lung transplants based on match run data from January 1, 2011, to May 24, 2022. This analysis includes an additional year of data relative to the original analysis reviewed by the Committee. These scores do not include points for sensitization or prior living donor status, since those factors are not currently considered in lung allocation, and the OPTN does not have data to estimate how many points previous recipients would have received for those parts of the CAS. However, these scores do account for the patient's expected waitlist survival, expected post-transplant outcomes, blood type, height, pediatric status, travel efficiency, and proximity efficiency. The efficiency scores were calculated based on the patient's distance from the donor hospital on the match run on which they received their lung multi-organ transplant.

Figure 2. Distribution of Calculated Lung CAS for Patients Who Received Lung Multi-Organ Transplants between January 1, 2011 and May 24, 2022<sup>13</sup>



<sup>\*</sup>Does not include points for CPRA and prior living donor

Most of the calculated CAS scores for lung multi-organ recipients fall within a range of 25 to 32. Accordingly, **Figure 3** below shows that a CAS threshold of 28 would be expected to capture only about

<sup>&</sup>lt;sup>13</sup> OPTN Data as of May 2022.

76% of those patients who previously received lung multi-organ transplants. **Table 2** shows that a CAS threshold of 25 would be expected to capture 95% of those patients who previously received lung multi-organ transplants.

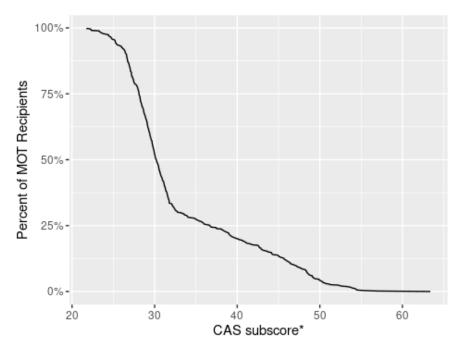


Figure 3. Percent of Lung Multi-Organ Recipients by Calculated Lung CAS<sup>14</sup>

Table 2. Percentages of Lung Multi-Organ Recipients by Estimated Composite Allocation Score 01/01/2011 to 05/24/2022<sup>15</sup>

	Composi	te Allocatio	n Score Tl	nreshold
Percentage of Recipients	Heart	Kidney	Liver	Total
90%	26.6	26.2	28.0	26.6
95%	25.2	24.0	27.7	25.2

Based on this more recent data, the Committee proposes changing the CAS threshold for required lung-liver, lung-kidney, and heart-lung organ offers from 28 to 25. This change will preserve eligibility for multi-organ allocation for about 95% of patients who receive those offers currently, consistent with the Committee's original intent as presented previously in public comment and to the OPTN Board of Directors.

#### Clarify Heart-Lung Policy

The Committee proposes clarifications to heart-lung policy to reinforce that OPOs must always follow the match run when allocating both the heart and lungs from the same donor. These clarifications do not substantively change the heart-lung policy changes approved as part of the proposal *Establish Continuous Distribution of Lungs*. <sup>16</sup> The clarifications indicate that once the OPO shifts to the lung match run after making required offers to heart and heart-lung candidates, then the OPO must offer organs to

<sup>&</sup>lt;sup>14</sup>OPTN Data as of May 2022.

<sup>15</sup> Ihid

<sup>&</sup>lt;sup>16</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed June 18, 2022, https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.

lung-alone and heart-lung candidates on the lung match run until offers have been made to all heart-lung candidates meeting the CAS threshold. At that point, the OPO must continue offering to heart and heart-lung candidates. If the lungs are placed with lung-alone candidates on the lung match run, then the OPO can proceed with heart-alone allocation.

## **NOTA and Final Rule Analysis**

The Committee submits the following proposal for the Board consideration under the authority of NOTA, which requires the OPTN to "establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria," and the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs." The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- Is based on sound medical judgment<sup>19</sup>: The proposed composite allocation score threshold for lung multi-organ allocation is an evidence-based change intended to preserve access to organ offers for candidates previously deemed by the OPTN to warrant this priority based on OPTN data analysis of previous lung multi-organ transplants.
- Seeks to achieve the best use of donated organs<sup>20</sup> by ensuring organs are allocated and transplanted according to medical urgency. Multi-organ allocation is necessary for some candidates to achieve a successful transplant outcome, in terms of patient and graft survival, whereas reasonable limits on multi-organ allocation allows organs to be offered to single-organ candidates. This proposal is consistent with recommendations from the OPTN white paper Ethical Implications of Multi-Organ Transplants to "establish allocation policies that prioritize [multi-organ] candidates who have medical urgency in both organs, but generally do not prioritize [multi-organ] candidates who do not have medical urgency in one organ."<sup>21</sup>
- Is specific for each organ or combination of organs<sup>22</sup>, in this case, lung-liver, lung-kidney, and heart-lung combinations.
- Is designed to avoid wasting organs<sup>23</sup>: The Committee does not expect impacts on organs recovered but not transplanted. Although the modeling results for the continuous distribution of lungs proposal showed a lower transplant rate, they did not show a decrease in the number

<sup>&</sup>lt;sup>17</sup> 42 U.S.C. §274(b)(2)(B).

<sup>18 42</sup> CFR §121.4(a).

<sup>19 42</sup> CFR §121.8(a)(1)s

<sup>&</sup>lt;sup>20</sup> 42 CFR §121.8(a)(2)

<sup>&</sup>lt;sup>21</sup> "Ethical Implications of Multi-Organ Transplants," OPTN, Briefing Paper, accessed June 19, 2022, https://optn.transplant.hrsa.gov/media/2989/ethics\_boardreport\_201906.pdf.

<sup>22 42</sup> CFR §121.8(a)(4)

<sup>23 42</sup> CFR §121.8(a)(5)

- of transplants. The change in transplant rate is a result of an increase in waiting time for candidates who can wait longer for a transplant.<sup>24</sup>
- Is designed to...promote patient access to transplantation<sup>25</sup>: Setting a composite allocation threshold for multi-organ allocation balances access to transplantation for multi-organ and single-organ candidates by ensuring that more medically urgent lung candidates who need a second organ will receive those offers, and allowing the OPO to offer the second organ to single-organ candidates when the lung multi-organ candidates do not have as much medical urgency for transplantation.
- Is designed to...promote the efficient management of organ placement<sup>26</sup>: Reasonable, evidence-based, and clear limits in multi-organ allocation policy allow OPOs to move through the organ allocation process without excessively delaying allocation, ensuring that organs get to the right candidate expeditiously.
- Is not based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]<sup>27</sup>: This proposal is not based on a candidate's place of registration or place of listing, except to the extent required to achieve efficient management of organ placement, as captured by the placement efficiency component of the CAS.<sup>28</sup>

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient.<sup>29</sup>

#### Transition Plan

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised. 30 This change is not expected to treat any patients less favorably than current policy. In fact, this change is intended to preserve access to transplant for lung multi-organ candidates by updating the threshold for required multi-organ shares so that these candidates are not treated less favorably in the continuous distribution allocation system.

As this change would be incorporated into implementation of continuous distribution of lungs, the Committee determined that no additional transition procedures were necessary for this change. Prior to implementation, information will be provided to members to assist them in determining the impact of the new allocation system on their candidate, and such information would include the updated threshold for lung multi-organ allocation.

<sup>&</sup>lt;sup>24</sup> SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021 01 cont distn report final.pdf

<sup>&</sup>lt;sup>25</sup> 42 CFR §121.8(a)(5)

<sup>&</sup>lt;sup>26</sup> Id.

<sup>&</sup>lt;sup>27</sup> 42 CFR §121.8(a)(8)

<sup>&</sup>lt;sup>28</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf. <sup>29</sup> 42 CFR §121.8(a)(3).

<sup>30 42</sup> CFR § 121.8(d)



## **Implementation Considerations**

#### **Member and OPTN Operations**

This proposal is not expected to have any impact on transplant hospitals, organ procurement organizations, or histocompatibility laboratories, but would have a small impact on the OPTN.

#### Operations affecting the OPTN

The OPTN would distribute educational materials related to the new lung allocation system, which would include the updated CAS threshold for lung multi-organ allocation.

#### Potential Impact on Select Patient Populations

This proposal is intended to preserve access to transplantation for lung multi-organ candidates (specifically lung-liver, lung-kidney, and heart-lung) in the continuous distribution allocation system, while balancing access to transplantation for single organ candidates. This proposal is not expected to disadvantage any patient population. However, if this proposal is not approved, then lung multi-organ candidates may have less access to transplantation in the continuous distribution allocation system compared to the current allocation system.

#### **Projected Fiscal Impact**

This proposal is not anticipated to have any fiscal impact on transplant hospitals, organ procurement organizations, or histocompatibility laboratories, but had a small fiscal impact on the OPTN.

#### Projected Impact on the OPTN

The OPTN conducted analysis and facilitated conversations with the Committee to determine the appropriate threshold for lung multi-organ allocation. No additional resources are required for implementation as the hours required to update lung multi-organ allocation were accounted for in the proposal *Establish Continuous Distribution of Lungs*.<sup>31</sup>

## **Post-implementation Monitoring**

#### **Member Compliance**

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."<sup>32</sup> As indicated in the proposal *Establish Continuous Distribution of Lungs,* <sup>33</sup> the OPTN will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and the OPTN will investigate potential policy violations that are identified.

<sup>&</sup>lt;sup>31</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, <a href="https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf">https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf</a>.

<sup>32</sup> 42 CFR §121.8(a)(7)

<sup>&</sup>lt;sup>33</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.



#### **Policy Evaluation**

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate." <sup>34</sup> As indicated in the proposal to *Establish Continuous Distribution of Lungs*, <sup>35</sup> monitoring reports using pre vs. post comparisons will be presented to the Committee after approximately 3 months, 6 months and then annually for 3 years following the allocation change, and will include metrics such as the number of multi-organ candidates on the waiting list, and the number of multi-organ transplant recipients.

#### **Conclusion**

The Committee proposes changing the lung composite allocation score threshold for required lung-liver, lung-kidney, and heart-lung offers from 28 to 25.

## **Considerations for the Community**

The Committee requests feedback on the following questions:

- Does the score threshold of 25 appropriately balance access to transplant between lung multiorgan candidates and kidney, liver, and heart single-organ candidates?
- Once all organs are in continuous distribution, how might the Committee update lung multiorgan allocation across a continuous spectrum?

<sup>34 42</sup> CFR §121.8(a)(6).

<sup>&</sup>lt;sup>35</sup> "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.



## **Policy Language**

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

#### 5.10.F: Allocation of Lung-Kidneys

When an OPO is offering a lung, and a kidney is also available from the same deceased donor, then the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a lung and a kidney at the same transplant hospital, and who meets either of the following criteria:

- PTR was less than 18 years old when registered on the lung waiting list, or
- PTR has a Lung Composite Allocation Score of <u>2825</u> or greater, and meets eligibility according to *Table 5-5*: *Medical Eligibility Criteria for Lung-Kidney Allocation*

If a host OPO is offering a kidney and a lung from the same deceased donor, then before allocating the kidney to kidney-alone candidates, the host OPO must offer the kidney with the lung to candidates who meet either of the eligibility criteria described in Policy 5.10.F. [...]

#### 5.10.G Allocation of Heart-Liver and Lung-Liver

When an OPO is offering a heart or lung, and a liver is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver* must be offered the liver. When an OPO is offering a heart or lung and two PTRs meet the criteria in *Table 5-6*, the OPO has the discretion to offer the liver to either PTR.

Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver

If an OPO is offering a heart or lung, and a PTR is also registered for a liver:	The OPO must offer the liver if the PTR meets the following criteria:
Heart	<ul> <li>Registered at a transplant hospital at or within 500 NM of the donor hospital</li> <li>Heart Adult Status 1, 2, 3 or any active pediatric status</li> </ul>
Lung	Has a Lung Composite Allocation Score of 2825 or greater

It is permissible for the OPO to offer the liver to other PTRs who do not meet the criteria in Policy 5.10.G.

#### 6.6.F. Allocation of Heart-Lungs

#### 6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old

If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must offer the heart and lung in the following order:

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candidates.

33	1.	To all heart and heart-lung PTRs in allocation classifications 1 through 4 according to <i>Policy</i>
34		6.6.D: Allocation of Hearts from Donors at Least 18 Years Old
35	2.	To all <u>lung and</u> heart-lung PTRs with a lung composite allocation score of 28 or higher
36		according to Policy 10.1 Allocation of Lungs until offers have been made to all heart-lung
37		PTRs with a lung composite allocation score of 25 or higher
38	3.	To heart and heart-lung PTRs in classifications 5 or later according to Policy 6.6.D: Allocation
39		of Hearts from Donors at Least 18 Years Old.
40	The hos	st OPO must follow the order on each match run, including heart-lung, heart, and lung
41	candida	ates.
42		
43	6.6.F.ii	Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old
44	If a hos	t OPO is offering a heart and lung from the same deceased donor, then the host OPO must
44 45	If a hos offer:	t OPO is offering a heart and lung from the same deceased donor, then the host OPO must
	offer:	t OPO is offering a heart and lung from the same deceased donor, then the host OPO must  To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to <i>Policy</i>
45	offer:	
45 46	offer: 1.	To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to <i>Policy</i>
45 46 47	offer: 1.	To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to <i>Policy</i> 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old
45 46 47 48	offer: 1.	To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to <i>Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old</i> To all <u>lung and</u> heart-lung PTRs with a lung composite allocation score of 28 or higher
45 46 47 48 49	offer: 1. 2.	To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to <i>Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old</i> To all <u>lung and</u> heart-lung PTRs-with a lung composite allocation score of 28 or higher according to Policy 10.1 Allocation of Lungs <u>until offers have been made to all heart-lung</u>
45 46 47 48 49 50	offer: 1. 2.	To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to <i>Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old</i> To all <u>lung and</u> heart-lung PTRs with a lung composite allocation score of 28 or higher according to Policy 10.1 Allocation of Lungs <u>until offers have been made to all heart-lung PTRs with a lung composite allocation score of 25 or higher</u>