



# ISHLT

A Society that Includes Basic Science, the Failing Heart, & Advanced Lung Disease

## **ISHLT Response to OPTN Proposal: Update on Lung Continuous Distribution Policy**

The International Society for Heart and Lung Transplantation (ISHLT) appreciates the opportunity to comment on the OPTN proposal, *Update on Lung Continuous Distribution Policy*.

While ISHLT supports ongoing evaluation of the lung continuous distribution framework and recognizes the importance of addressing allocation out of sequence (AOOS), the Society does not believe that sufficient evidence has been presented to justify either the policy change itself or the process through which it was adopted. Therefore, we strongly oppose this proposal and do not support continuation or permanent adoption of the policy change in its current form.

### **Insufficient Evidence to Demonstrate That Lung Allocation Change is Needed**

Although the intent of the policy change is to reduce AOOS, the number of donors affected by lung AOOS is substantially lower in terms of percentage of donors and total number of donors than kidney or liver donors. Moreover, it is clear from review of the AOOS graph presented during the provided video of the November 2025 Board meeting that AOOS tracks with policy changes that result in broader sharing rather than specifically as a result of implementation of a CAS allocation mechanism. This is seen with liver allocation where AOOS started to increase following the implementation of Acuity circles in February 2020 and kidney allocation where AOOS started to increase following the removal of DSA from the KAS in March 2021. Finally, it is also clear from the graph that AOOS rates had dropped dramatically by the November 2025 Board meeting; at that time lung AOOS rates had returned to pre-CAS levels. Thus, the AOOS lung allocation “problem” had essentially resolved at the time of the Board meeting, likely explaining why the lung committee voted unanimously to “make no change to lung placement efficiency at this time pending a monitoring period of trends in lung AOOS and identification of drivers of lung AOOS”

### **Insufficient Evidence to Support the Change**

The proposal asserts that increasing the weighting of placement efficiency from 10% to 15% will reduce logistical complexity and improve compliance with allocation policy by reducing AOOS. However, the evidence presented does not establish a clear causal relationship between the current weighting structure and AOOS, nor does it demonstrate that the proposed modification will further reduce lung AOOS or prevent it from rising again.

Major allocation policy changes should be supported by rigorous evidence demonstrating both the existence of a problem and the effectiveness of the proposed remedy. ISHLT does not believe that either aspect of that standard has been met.

### **Failure to Fully Assess Impact on Patients and Equity**

ISHLT is particularly concerned that additional modeling requested by the Lung Transplantation Committee was not completed prior to implementation.

The proposal moves allocation policy toward greater geographic prioritization by increasing the influence of donor-recipient proximity. Available analyses suggest this change may worsen geographic disparities and adversely affect candidates who already face barriers to



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transplantation, including blood type O candidates, highly sensitized candidates, candidates with size-matching challenges, and other biologically disadvantaged populations.

These concerns are not theoretical. Continuous distribution was developed, in part, to address the stipulation in the OPTN final rule that a candidate's place of residence/listing should have the minimum possible impact on access to transplantation. The current policy change may move the system in the wrong direction without sufficient evidence that the anticipated benefits justify that tradeoff.

ISHLT believes that a policy with potentially significant implications for equity and access should not be maintained without a more complete assessment of its consequences.

### **Concerns Regarding Use of the Emergency Action Pathway**

ISHLT also has significant concerns regarding use of the emergency action pathway.

The evidence presented publicly does not adequately demonstrate that circumstances warranted emergency action. The emergency pathway was designed to address urgent situations requiring immediate intervention. Based on the information available, ISHLT does not believe sufficient justification was provided to demonstrate that this threshold was met.

Moreover, comments made during the Board's deliberations suggest that broader concerns voiced by HRSA in relation to implementation of CAS for other organs may have influenced the decision-making process. Regardless of intent, the result was implementation of a significant allocation policy change without completion of requested modeling, without the level of evidence normally expected for such a change, and without the opportunity for stakeholder input prior to implementation.

ISHLT is concerned that allowing this approach to stand without challenge may establish a precedent for future allocation policy changes to be implemented through the emergency pathway despite incomplete evidence and limited stakeholder engagement.

### **Recommendations**

ISHLT recommends that OPTN:

- Reverse the policy change or at a minimum refrain from taking any further action on the lung allocation policy without providing sufficient evidence to support such changes and receipt of favorable public comment.
- Complete the additional modeling and analyses requested by the Lung Transplantation Committee.
- Conduct further evaluation of the impact on access, equity, geographic disparities, waitlist mortality, transplant rates, and biologically disadvantaged populations.
- Publicly release the results of those analyses.
- Provide an additional public comment period after those analyses are completed and before any decision regarding permanent adoption is considered.



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- Develop clearer evidentiary standards and decision criteria governing future use of the emergency action pathway for allocation policy changes.

## **Conclusion**

ISHLT supports evidence-based refinement of the lung allocation system and recognizes the importance of improving policy compliance and operational efficiency. However, the Society does not believe that sufficient evidence was presented to justify this policy change, that its potential impact on access and equity was adequately evaluated, or that use of the emergency pathway was appropriately supported.

For these reasons, ISHLT strongly opposes this proposal and urges OPTN to undertake additional analysis, stakeholder engagement, and public review before considering whether these changes should remain part of the lung allocation system.

**ISHLT Level of Support:** Strongly Oppose