ASTS
American Society of Transplant Surgeons

January 17, 2024

Organ Procurement & Transplantation Network
Lung Allocation Policy
Attn: Dianne LaPointe Rudow, DNP, ANP-BC, FAAN, OPTN President & Jon Snyder, PhD, MS, Director, SRTR

Dear Dr. LaPointe Rudow & Dr. Snyder,

This letter is being sent on behalf of the ASTS Leadership as a follow-up to our meeting on Monday, January 8, 2024. We would like to thank you again for meeting with us to discuss the errors made by the SRTR/OPTN in modeling the impact of the newly implemented lung continuous distribution policy. Based on an independent analysis conducted by Jesse Schold, PhD, it is our understanding that this modeling error may have adversely impacted organ offers made to an estimated 129 blood type "O" patients on the lung transplant waitlist. Several aspects of this incident remain deeply troubling to us.

The response to the ASTS Executive Committee's concerns on Monday over the lack of transparency in the proposed policy correction was distressing given the significance of the error for our patients and the pressing need for transparency in transplantation. As was discussed on the call, in the follow-up report assessing the effect of the introduction of the lung continuous distribution policy, we do not believe that the disclosure was properly framed or presented. The modeling and data entry error should have been highlighted at the beginning of the document, rather than buried in the middle. This manner of disclosure –best characterized as "hidden in plain sight"- obviously has not effectively communicated the implications of the modeling error for patients and does a disservice to the transplant community and the patients we serve. In fact, most recently, the OPTN released an assessment lauding the success of the continuous distribution system in increasing lung transplants overall without any mention of the negative patient impact of the modeling error or the lessons learned from it *("Letter to lung transplant community: Working together to increase efficiency"; January 2, 2024)*.

We are also extremely concerned about what this incident has revealed about the process used by the SRTR/OPTN to model proposed allocation policy changes. OPTN committees with subject matter expertise rely heavily on these models in formulating critical organ allocation policy. In this case, it is our understanding that the Thoracic Committee clearly flagged the potential adverse impact of continuous distribution on blood type "O" waitlisted patients, and the accuracy of the model with respect to this particular issue was specifically confirmed both by SRTR and MIT, the SRTR's outside contractor. Yet, an error in basic ABO compatibility was made

waitlisted patients in order to correct the disadvantage introduced by implementation of the policy.

We understand that, since the incident, the SRTR has adopted a completely new methodology for modeling allocation policy changes. However, it is unclear to us what changes in SRTR or OPTN processes–especially processes intended to catch programming errors and to implement effective outside third-party review—have been made to ensure that incidents of this kind do not recur.

Finally, we are concerned that, based on information provided to us, the adverse impact of this error on blood type "O" waitlisted patients was flagged by alert clinicians and not by the SRTR or the OPTN during the three-month review of the continuous distribution system. It is unclear to us what steps, if any, have been taken to improve the quality of monitoring efforts undertaken by SRTR/OPTN when allocation policy is modified.

In light of these concerns, we request that the SRTR/OPTN:

- *Supplement the recently released statement on the continuous lung distribution policy to include a comprehensive report on the modeling error that was made; an estimate of the number of "O" blood type waitlisted patients adversely impacted; the process issues contributing to the six-month delay in corrective action; and the steps taken by the SRTR/OPTN to ensure that incidents of this kind do not recur;*
- *Increase the transparency of modeling methodologies to enable experts outside of the SRTR to simulate and independently interpret the results;*
- *Clarify the process by which modeling algorithms are vetted and selected;*
- *Assess the adequacy of current SRTR contractors engaged to ensure the accuracy of SRTR/OPTN modeling.*
- *Develop a comprehensive approach for modeling, implementation, and post-implementation assessment of new policies that includes simulations and data analyses that are reviewed, monitored and serially assessed in a timely manner by clinicians and other experts in the field;*
- *Engage with ASTS and other professional organizations to codify expectations for transparent reporting of new policy outcomes; and*
- *Place any further changes in allocation and variances in allocation on hold until the issues described above are addressed.*

We look forward to your reply.

Sincerely, the Executive Committee of the American Society of Transplant Surgeons
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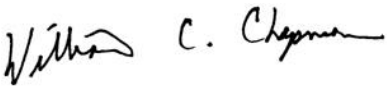

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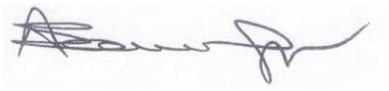

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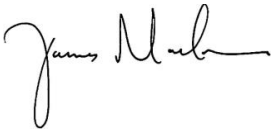

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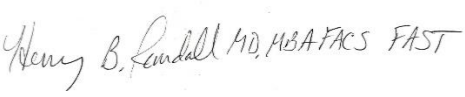

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