HRSA
Health Resources & Services Administration

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To: Organ Procurement and Transplantation Network Board of Directors, AOOS Workgroup Leads

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Subject: HRSA Feedback Regarding Potential Implications of Analytic Choices for OPTN AOOS Datasets and Considerations for Continuous Distribution

Background

The Health Resources and Services Administration (HRSA) asks the Organ Procurement and Transplantation Network (OPTN) and Allocation Out of OPTN Sequence (AOOS) Workgroup to consider two emerging issues outlined below.

HRSA looks forward to reviewing the OPTN's response to this memo. Please note that HRSA will hold separate meetings with OPTN contractors regarding any necessary changes, adjustments, or support the OPTN requires to remediate policy noncompliance in organ allocation.

Issues for the OPTN's Attention

(A) Potential Implications of Analytic Choices for OPTN AOOS Datasets

On July 11, 2025, HRSA directed the OPTN operations contractor to develop queries that can be run against raw OPTN data to produce a consensus, living dataset for the analysis of AOOS. This dataset will be updated regularly with new records and made available, under appropriate data use agreements, to any transplant community member interested in the issue of allocation policy noncompliance. The contractor has delivered draft queries for five organ types.

Upon reviewing these draft queries, HRSA identified a number of implicit analytic decisions that will impact the construction of the resulting dataset and should be made by the OPTN. These decisions include:

(1) The analytic definition of AOOS refers to organs offered, accepted, and/or transplanted out of sequence. While acceptances and transplants are well characterized in OPTN data, there is no administrative definition of a primary offer, and the data may fail to reflect some offers that were made. The OPTN should consider the following decisions:
    i) How should match runs that led to some offer responses but not to any acceptances or transplants be characterized in this dataset?
    ii) How should match runs that can be used to place multiple different organ types or segments (for example, heart/lung, right/left kidney, or multiple liver segments) be characterized? The exact organ(s) associated with a given offer response may be ambiguous if the same organs were offered, accepted, and/or transplanted via other match runs.
(2) Which information about an allocation event should be captured in this dataset? For example: the allocating organ procurement organization (OPO), the accepting transplant center (if there is one), the number and codes of bypasses, etc.
(3) Which allocation events should this dataset include? Should this dataset include all allocations, with an indication of whether they were in or out of sequence, or only out-of-sequence allocations?
(4) When the same organ is allocated on multiple match runs, which of these runs should be included in the final dataset? If only one match run is counted per organ, how should that run be selected?
(5) How should allocations be counted for multi-organ transplants?

HRSA would like to bring these analytic decisions to the attention of the Board of Directors, Data Advisory Committee, and AOOS Workgroup because we believe these foundational characteristics of the consensus dataset for use by the broader community should be determined transparently and in alignment with the full breadth of OPTN community expertise.

HRSA stands ready to support the OPTN in identifying preferred solutions. The OPTN should provide HRSA with detailed responses to (A) (1) – (5) above, and, once reviewed by HRSA, we will direct the operations contractor to update the draft queries accordingly.

(B) Considerations for Continuous Distribution in Light of AOOS

HRSA recognizes concern among some members of the community regarding the pause in creation of new policies under the continuous distribution (CD) framework. HRSA also recognizes that a large amount of committee volunteer effort has already gone into setting

groundwork for these policies, along with a considerable expenditure of OPTN resources in the form of contractor effort over multiple years. For these reasons, HRSA wishes to clarify the reasons underlying the pause and expectations for moving forward with these policies.

The primary reason for the pause is practical; the OPTN has limited financial resources and multiple critical and time sensitive priorities. A number of these, including AOOS, normothermic regional perfusion (NRP), and organ donation safety are critical to the OPTN's ability to ensure high quality care and fairness in access to care for large numbers of patients. The ability to assure the American public of the OPTN's commitment to reliable and safe care is fundamental to trust in the system and must take precedence over other efforts. HRSA anticipates that changes to planning and resource allocation should improve the OPTN program's financial situation going forward, while the surge in effort required to address AOOS, NRP, and organ donation safety are likely to be time-limited, if OPTN interventions are effective.

HRSA anticipates that as resource constraints ease, the OPTN will be able to resume work on allocation policies and the continuous distribution framework. A benefit of this staged approach is that deliverables from the resolution of the AOOS remediation process will be invaluable in defining, reviewing, and revising future allocation policies. Through the OPTN's analytic definition of AOOS and forthcoming consensus datasets, insights into the correlation between policy implementation and changes in compliance patterns will be attainable, informing OPTN policy discussions in ways that were not previously considered.

Should the OPTN wish to resume work on CD policy development, HRSA requests that the OPTN develop and submit the detailed plans for the following items, with involvement from the AOOS Workgroup and all relevant organ committees:

(1) Proposed remediation actions to address existing AOOS in lung transplantation.
(2) Proposed monitoring and mitigation steps for the next potential organ system for which CD may be deployed (e.g., heart).

Once submitted, HRSA will review these plans considering the availability of OPTN resources, and the requirements of National Organ Transplant Act (NOTA) and the OPTN Final Rule.