This letter serves as a response to the Health Resources and Services Administration (HRSA) directive issued May 13, 2025[1], which directed the Organ Procurement and Transplantation Network (OPTN) to provide to HRSA by May 27, 2025 an analytic definition of allocation out of sequence (AOOS), which can be used to quantitatively estimate AOOS practices. The HRSA directive issued May 13, 2025 is a rejoinder to the March 31, 2025 response from the OPTN to the HRSA regarding the OPTN's proposed plan for addressing the Secretary's February 21, 2025, directive on AOOS. HRSA provided an extension to the OPTN allowing additional time for discussion and requested the analytic definition be delivered by June 3, 2025.

HRSA stated that the analytic definition of AOOS should derive from an operational definition of AOOS. To address this directive, the OPTN convened a work group including members of the Board of Directors, Data Advisory Committee (DAC), Patient Affairs Committee (PAC), Ethics Committee, Pediatric Transplant Committee, Membership and Professional Standards Committee (MPSC), and the Organ Procurement Organization Committee to develop a suitable analytic definition of AOOS. This work group met three times on May 20, 27, and 30, 2025.

Operational Definition of AOOS

The OPTN, at HRSA's direction, had previously characterized AOOS as occurring when an organ is "offered, accepted, and transplanted into a transplant candidate or potential transplant recipient (PTR) that deviates from the match sequence and is not consistent with OPTN policy.[2]"

The work group proposed, voted on, and accepted a revised operational definition: "AOOS is when an organ is offered **or** accepted **or** transplanted into a transplant candidate or potential transplant recipient (PTR) that deviates from the match sequence and is not consistent with OPTN policy."

The rationale for the revised operational definition is that currently there is not a way to capture, measure, or understand all instances of AOOS. Focus has been on organ AOOS that have been transplanted. Organs AOOS can include organ offers that are never accepted, accepted organs that are never transplanted, and accepted organs that are transplanted. Without including offers and acceptances that do not make it to transplant, the OPTN does not have a complete understanding of AOOS practices and potential opportunities for improvement. If AOOS can eventually become a policy itself as a rescue pathway for organs at high risk for nonuse, it would be important to understand and compare characteristics of AOOS organs that are not transplanted versus those that are transplanted to direct future policy changes and issuance of guidelines. Therefore, the work group recommends considering AOOS as three separate tiers (offers, acceptances, transplants) for future analysis.

[1] HRSA response to 3/31/2025 OPTN letter, dated 5/13/25
[2] OPTN response to November 27, 2024 HRSA letter, dated December 13, 2024.

Analytic Definition of AOOS

The work group then worked to develop an analytic definition of AOOS which follows from this updated operational definition. Specifically, to enumerate how all instances of AOOS can be accurately identified in data using bypass codes, free text analyses, etc.

The work group contextualized the analytical definition based on a structured approach, incorporating key variables and concepts such as code flags, logic-based assessments, and data tracking within systems like UNet℠. This is meant to ensure measurement of AOOS is robust, meaningful, repeatable, and reportable. The analytical definition is informed by the following key elements:

- Metric Name: Clearly defines what is being measured.
- Formula: Specifies how the metric is calculated.
- Data Source: Identifies where the data comes from.
- Measurement Frequency: Defines how often the metric is updated.
- Benchmark or Target: Sets a standard for comparison.
- Context: Explains why the metric is important and how it impacts business objectives.

The work group reviewed all refusal and bypass codes and discussed the merits of including or excluding each individual code in an analytic definition of AOOS. Group members determined a subset of these codes were highly relevant and suitable for inclusion (see table below).

CODE	DESCRIPTION	FULL DESCRIPTION	CRITICAL ISSUE W/ CODE
799	Other, specify (Bypass)	Use only when the reason does not fit the other bypass reasons available. Provide a detailed description of the reason the potential recipient is being bypassed. This information will be shared with bypassed centers.	This is a catch-all. There is no consistent logic as to when this is used. There is a lot of free text and often that text describes a bypass situation that could be covered by another code. There is concern related to an increase in recent usage and large variation in usage across centers.
861	Operational – OPO (Bypass)	Potential recipient bypassed due to transportation logistics, including distance in relation to ischemic time or weather conditions. Requires written justification by OPO; this bypass and narrative justification will be shared with bypassed centers.	Justification for this code is required but, due to being entered as text, it is difficult to analyze and allows significant variation in how OPOs use it.
862	Donor medical urgency (Bypass)	Potential recipient bypassed due to urgent donor organ placement. Requires written justification by OPO; this bypass and narrative justification will be shared with bypassed centers.	Justification for this code is required but, due to being entered as text, it is difficult to analyze and allows significant variation in how OPOs use it.

863	Offer not made due to expedited placement attempt (Bypass)	Potential recipient bypassed as a result of offer(s) made during an expedited placement attempt. This includes OR time constraints or family time constraints. Requires written justification by OPO; this bypass and narrative justification will be shared with bypassed centers.	This code is usually related to the donor's organ suboptimal function, or to a late decline (pre- or post-clamp). However, there is ambiguity surrounding the decision to use 861/862/863 and examples have been noted where 863 was used in instances where 861/862 would have been more appropriate.
887	Not Offered - expedited placement (Bypass)	Potential recipient bypassed as a result of offer(s) made during an expedited placement attempt. This bypass is applied only when expedited placement is initiated through the expedited placement workflow.	This is not available to OPOs to enter. It is entered by workflow via the contractor.

The work group determined that AOOS is identifiable through the use of bypass codes 861 (Operational – OPO), 862 (Donor medical urgency), 863 (Offer not made due to expedited placement attempt), 887 (Not Offered - expedited placement), and 799 (Other, specify). The OPTN is proposing that the presence of one or more of these bypass codes be used to identify an instance of AOOS.

It is important to note that the work group also considered refusal code 798 (Other, specify). This is a catch-all code sometimes used as a secondary code to allow some free-text comments. While the work group did not include this refusal code in their analytic definition, the OPTN does recommend additional training on the code use and to provide alternative codes to avoid the use of catch-all codes in the future.

Members of the workgroup have stressed the importance of understanding the identification of AOOS as the first step in a multi-step process. Specifically, the workgroup has noted that within the category of AOOS, it is important to take a deeper look to determine in which situations AOOS is justifiable and beneficial and to work to refine policy to reflect these instances. The OPTN recognizes the value in measuring the totality of all organs that are AOOS, but also wants to reiterate that some proportion of AOOS is consistent with policy – specifically 42 C.F.R. §121.7(f), which states: “Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation” – and therefore additional work is needed to develop clearer policies for determining when it is or is not appropriate for a given organ to be AOOS.

OPTN Recommendations for Future Work

- Develop policies to address the practices of open and batch organ offers. Despite these sorts of offers being made, they are not explicitly addressed by current OPTN policy.

- Look into the possibility of increasing the number of bypass codes to allow increased specificity. Operational/logistical concerns are common and current codes do not provide sufficient granularity.
- Develop more precise guidelines to assist OPOs/transplant centers in making consistent determinations of when a given organ is or is not appropriate for AOOS.
- Develop more precise coding to assist OPOs/transplant centers to accurately capture the reasons for AOOS when the decisions made are based on multifactorial causes

Conclusion

The OPTN is committed to collaborating with HRSA to ensure the safety of all transplant patients, including donors, candidates, and recipients. We look forward to HRSA's feedback on this proposed analytic definition.