This plan is in response to the Secretary's Directive on February 21, 2025, regarding allocation out of sequence. The OPTN was tasked with work falling into four parts:

Part A: Provide a detailed remediation plan to improve OPTN allocation policy requirements and policy definitions.

Part B: Propose a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs. The OPTN's proposed compliance plan, which will be reviewed and approved by HRSA, should specifically describe potential OPTN actions that will protect the ongoing utility and function of the organ allocation process, as well as technical enhancements and data reporting that support the implementation of the policies proposed by OPTN in response to the directions described at (A)2-5 above – updates to policy regarding refusal codes, "batch organ offers," defining "offers and requirements for modalities and content of offers.

Part C: Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants.

Part D: Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS.

For each Part, the OPTN has highlighted an estimated schedule of milestones related to the work, a proposed high-level approach, as well as highlighting relevant assumptions and anticipated challenges specific to the objective outlined, as appropriate. These estimates and approach are all subject to the following assumptions:

- The scope of this Directive does not change. If scope is expanded, by either the OPTN or HRSA, the resources, timelines, and approach will be impacted.
- Timelines within this proposal assume consistent and constant progress on the initiative; they do not account for time spent on other directives or time sensitive requests from HRSA.
- Timelines within this proposal do not include any additional time HRSA may deem necessary for HRSA to review information, provide feedback, or grant approvals. Given the importance and complexity of the topics within this directive, HRSA's active participation throughout the process is essential for the successful execution of this plan.
- The Executive Committee and the full Board will be kept abreast of the progress of the work pursuant to this Directive at regular and relevant intervals.

- This work will not begin until HRSA provides approval and requests the OPTN execute the plan, in writing, to both the OPTN and the OPTN contractors supporting this work.

This work will be completed across several different committees which represent diverse viewpoints across the transplant community, but largely led by MPSC, DAC, and OSC. Every OPTN organ-specific and stakeholder committee includes at least two patient, donor, or caregiver representatives serving as active members. This ensures continuous input from the patient community throughout the policymaking process, with their involvement increasing as more committees are engaged.

Part A: Provide a detailed remediation plan to improve OPTN allocation policy requirements and policy definitions.

Within Part A, HRSA tasked the OPTN with five objectives.

Objective 1: Audit of OPTN member usage of "other, specify" codes in cases where AOOS has occurred, including assessments of patterns of organ type, peri-procurement timing, sequence at final recipient, and centers.

Objective 2: Direct the OPTN Data Advisory Committee (DAC) to undertake an urgent review and revision of refusal codes for greater specificity and standardization.

Objective 3: Develop a policy and definition to describe and prohibit "batched organ offers" to comply with NOTA and the OPTN Final Rule.

Objective 4: Develop a policy and definition for the "offer" of an organ by an OPO to a transplant center, including improved minimum requirements for notification and information accuracy.

Objective 5: Develop a policy and definition to describe acceptable modalities and content of organ offers made by OPOs to transplant patients at transplant centers.

To create a plan that will improve OPTN allocation policy while addressing the Objectives HRSA has included, the OPTN proposes grouping the objectives in the following manner:

1. Preliminary Work
2. Audit of OPO Usage of Bypass Codes in AOOS (Objective 1)
3. Review and Revise OPTN Codes related to AOOS (Objective 2)
4. Proposed OPTN Policy Updates on Organ Offers by OPOs to Transplant Centers (Objective 3, 4, and 5)

Additionally, the OPTN proposes to combine the work of Part A and Part B, as the compliance aspects must go hand in hand with the changes to OPTN allocation policy. The following plan assumes such a structure is amenable to HRSA.

Preliminary Work: Data Analysis

A robust data analysis is necessary to support this Directive. While much data is already available and has been reviewed by different segments of the OPTN to support previous work, an assessment of current data available, as well as what additional data is needed to support this work should be the first step of the plan, after which, all lead committees can benefit from the use of a common data set to fuel the different approaches they may take to the analysis. As such, the preliminary work is outlined as follows:

Milestones and Estimated Delivery Timelines

Milestone	Estimated Timeline
AOOS Defined	2 weeks
AOOS Dataset implemented for OPTN workflows	6 weeks
Total Estimated Duration	2 months following approval of the plan by HRSA

Approach:

1. **Adopt definition of allocation out of sequence**
    a. OPTN Contractor to recommend a data definition of AOOS to the Executive Committee for review to ensure a standardized definition is used for data analysis, policy development, policy monitoring, and public reporting.
    b. Executive Committee to approve
    c. Align with SRTR on the definition and final metrics for dashboard/reporting
2. **Develop and implement AOOS Dataset for OPTN Workflows**
    a. Develop and operationalize a single AOOS dataset based on the approved definition for consistent reporting and analysis.
    b. Finalize requirements and commit to using this dataset in all OPTN workflows.

Anticipated Challenges:

- Alignment on definition will require coordination and agreement by multiple external parties

Preliminary Work: Ethical Analysis

The OPTN Ethics Committee has completed a white paper consisting of an ethical analysis of AOOS for community consideration using the principles of utility, autonomy, and equity. In January 2025, this white paper was delayed from being released for public comment due to the AOOS Directive being imminent. It is, however, still an important first step for the community to evaluate the complex interactions between utility, autonomy, and equity in AOOS in accordance

with the National Organ Transplant Act, before undertaking the substantive changes to policy and data collection.

The OPTN Ethics Committee "aims to guide the policies and practices of the OPTN related to organ donation, procurement, distribution, allocation and transplantation so they are consistent with ethical principles."[1] By accomplishing this initial step concurrent with preliminary data analysis and while evidence gathering occurs on the committee level, the OPTN will efficiently and effectively lay the groundwork for other committees to identify and complete the most appropriate solutions for the tasks identified in this plan.

As such, the preliminary work is outlined as follows:

Milestones and Estimated Delivery Timelines

Milestone	Estimated Timeline
Ethics Committee reviews content of analysis and votes on AOOS analysis for public comment*	1-2 meetings over 2 months
Public comment	1-2 months
Analysis submitted to BOD for review	2 months following conclusion of public comment, barring significant public comments requiring substantive change to proposal, and assuming approval of compliance plan
Analysis approved and disseminated for use by OPTN Committees and community at large	1 month following approval
Total Estimated Duration	6- 8 months

Approach:

1. **Confirm AOOS analysis is prepared for public comment**
    a. The OPTN Ethics Committee will review their previously completed analysis for any updates needed since the Directive has been issued.
    b. *Assumption: Updates to the analysis will be minimal; the inclusion of additional content will add to the timeline.*
    c. Vote to recommend for public comment
2. **AOOS analysis follows the policy development process**
    a. Feedback on the analysis is sought from stakeholders, the community, with pointed outreach to the Committees leading the Directive efforts (OSC, Kidney, DAC, MPSC).

[1] "Ethics Committee." OPTN: Organ Procurement and Transplantation Network - OPTN. https://optn.transplant.hrsa.gov/about/committees/ethics-committee/.

b. Feedback is incorporated and the Ethics Committee votes to recommend the adoption of the analysis to the Board of Directors

3. **Dissemination of approved white paper**
    a. Specific outreach to the Committees leading the Directive efforts (OSC, Kidney, DAC, MPSC).

Anticipated Challenges:

- The OPTN Ethics Committee will have to communicate effectively with stakeholder committees (OSC, Kidney, DAC, MPSC) to ensure stakeholder committees understand the implications of the analysis and relevant feedback is incorporated as appropriate in the paper prior to Board consideration of approval.

Audit of OPO Usage of Bypass Codes in AOOS

Lead Committee: Membership and Professional Standards Committee

Collaborating Committees: DAC

Objective 1: Audit of OPTN member usage of "other, specify" codes in cases where AOOS has occurred, including assessments of patterns of organ type, peri-procurement timing, sequence at final recipient, and centers.

Assumption: HRSA's reference to "other, specify" codes in this portion of the Directive refers to the "799 Other, specify" bypass code based on context "in cases where AOOS has occurred."

Milestones and Estimated Delivery Timelines

Milestone	Estimated Timeline
Data analysis completed that compares individual OPO bypass code 799 Other, specify usage and individual OPOs rates of AOOS to individual transplant hospitals	6-8 weeks following HRSA approval of plan and notification to OPTN Contractor, depending on final decisions regarding scope and committee needs
MPSC to establish: 1. Threshold for high rate of bypass code 799 to warrant MPSC review 2. Criteria for evaluation of potential organ diversion	3-4 meetings over 2 months following the finalization of the data analysis
Commencement of MPSC review of OPOs with high rate of bypass code 799 "Other, specify" usage and that meet criteria for potential organ diversion	2-4 months from establishment of thresholds
Total Estimated Duration	6-8 months following finalization of OPTN AOOS dataset

Approach:

1. **Audit dataset development:**
    a. **Engage Committee**: Gather feedback from MPSC on data needed to evaluate 799 Other, specify usage; MPSC requested addition of data on prevalence of provisional yes being converted to 799 bypass.
    b. **Dataset Creation**: MPSC evaluates available data, identifies any additional data needs and pulls data for review by MPSC using the AOOS dataset created in Preliminary Work.

c. **Committee Review**: MPSC will provide review and determine if dataset meets needs to develop review criteria.
d. **Anticipated Challenges**:
    - OPTN computer system does not contain reliable timestamps for peri-procurement timing since OPOs have 30 days to close out the match run (Potential Transplant Recipient (PTR)) per Policy 18. Explore other ways to access information on peri-procurement timing.
    - Use of the 799 Other specify bypass code does not always reflect an AOOS so the manual review of the free text reasons in the data pulled from the system will be required to determine which allocations were AOOS. One example of use of 799 Other, specify for non-AOOS is if a new match run is generated and the OPO enters bypass codes in the new match for candidates that refused the organ on the original match run.
    - MPSC raised concerns about focusing only on the "other, specify" bypass code rather than including other clear AOOS codes such as "863, Offer not made due to expedited placement attempt."

2. **Determination of review criteria:**
    a. **Usage high rate threshold**: Committee review of data to determine threshold for high rate of 799 Other, specify bypass code that warrants referral to MPSC for review and reporting to HRSA.
    b. **Define organ diversion**: Committee review of data and needed additional information to define what constitutes concerning evidence of organ diversion that warrants referral to MPSC for review and reporting to HRSA.
3. **Education:**
    a. **Member Education:** Partner with DAC to develop member education on bypass codes and appropriate usage.
    b. **Help Documentation:** MPSC to review current Help documentation to identify clarifications that will promote standardized use of bypass codes.
        - Any suggested updates will be made through the established DAC Data Definition Clarification process.
    c. **Monitoring Communications:** Add language to OPTN contractor allocation inquiries and to MPSC OPO action letters on appropriate bypass code usage to promote standardization of bypass code usage.
    d. **Anticipated Challenge**: The DAC has been charged with a similar effort related to updates to education and trainings related to refusal codes but is interested in expanding that work into review of bypass codes. If the DAC project scope expands to include the bypass work, MPSC will need to align with DAC to avoid duplication.

4. **Implementation Plan:**
    a. **Referral Process**: Determine cadence of referrals and mode of referral to HRSA.
    b. **Review Process**: Determine information to be included in MPSC review packet.

Assumptions:

- MPSC volunteers can participate in meetings, potentially up to 2 in one month, in addition to regularly scheduled monthly 3-hour MPSC meetings, case review work and higher risk informal discussions.
- When HRSA submits the 30-day federal register notice for the OPTN Process Data package, MPSC will pause AOOS Directive activities to collaborate with DAC for up to 30 days to assist the OPTN in reviewing the 30-day package and formulating the OPTN response.

Review and Revise OPTN Codes related to AOOS

Lead Committee: Data Advisory Committee

Collaborating Committees: MPSC, Organ Procurement Organization Committee (OPO), Transplant Coordinators Committee (TCC)

Objective 2: Direct DAC to undertake an urgent review and revision of refusal codes for greater specificity and standardization.

While DAC supports revising the refusal codes for greater specificity and standardization, DAC also recommends including in the review the bypass codes used by OPOs to indicate when an organ was not offered in sequence on the match run. While DAC has not analyzed the bypass codes previously, addressing their use will have a greater impact than only revising the refusal codes because OPOs use bypass codes to describe the reason(s) why they went out of sequence. The OPTN supports the DAC's approach and endorses the review including bypass codes as well.

Milestones and Estimated Delivery Timelines

Milestone	Estimated Timeline
Data request submitted	1 month following HRSA approval of the plan
Data analysis completed on refusal and bypass codes	1-2 months following submission of the data request
Revisions to refusal and bypass codes approved by DAC	2 months following completion of data analysis
Develop implementation and training plan for updated codes	2 meetings over 2 months following revision of refusal and bypass codes
Proposal developed regarding training on OPTN data collection requirements and OPTN-member accountability for reporting accurate data	3 meetings over 2 months
Public Comment	1-2 months following completion of proposal development
Compliance plan submitted to HRSA for approval	1 week following Committee vote post Public Comment
Proposal submitted to BOD for review	2 months following conclusion of public comment, barring significant public comments requiring substantive change to proposal, and assuming approval of compliance plan
Proposal implemented	3-6 months following BOD approval

Total Estimated Duration	14-19 months following approval of the plan by HRSA

Approach:

1. **Review and Revision of Updated Codes:**
    a. **Engage Committee**: Gather feedback from DAC on data needed to evaluate refusal and bypass codes.
    b. **Dataset Creation**: OPTN contractor evaluates available data, designs dataset, and pulls data for review by DAC.
    c. **Committee Review**: DAC will review and revise refusal and bypass codes, choice list values, and definitions for specificity and standardization.
        - Review to include consideration by stakeholder and relevant Committees.
    d. **Committee Approval**: DAC to approve refusal and bypass code revisions.

    Assumption: No Board or OMB approval needed to revise refusal or bypass codes.

2. **Training and Implementation of Code Updates:** A proposed timeline to implement and train OPTN members on the use of updated organ refusal codes.
    a. **Training Development:** Review current training and propose revisions based on updates to refusal and bypass codes.
        - Training plan to include identifying who is assigned training, developing member communications, establishing timeframes, and reporting training activity.
        - Review training with impacted committees (i.e. MPSC, OPO, TCC).
    b. **Implementation Plan:** Contractor to develop system implementation plan for refusal and bypass code changes.
        - Code updates to deploy in system after training to members has been completed.
3. **Training and Accountability on OPTN Data Collection:** A proposed OPTN policy requirement for OPOs and transplant centers to attest that staff have been trained on OPTN data collection requirements, including updated refusal codes, and describe OPTN member-level accountability for inaccurate or insufficient coding.
    a. **Committee Review:** Review Policy 18 and existing policies for compliance options for ensuring accuracy of OPTN member entered data. Options to include data quality auditing process and/or attestation requirement.

b. **Plan development:** Draft any potential policy language changes to support compliance plan, as well as proposed metrics to monitor post implementation and cadence of reporting metrics to DAC.
    - Policy language to follow policy development process.
    - Compliance plan submitted to HRSA for approval following public comment, prior to BOD approval
c. **Anticipated Challenge**:
    - MPSC has expressed interest in a similar effort related to updates to education and trainings related to bypass codes. If the DAC project scope expands to include the bypass code work, DAC will need to align with MPSC to avoid duplication.
    - Identifying the optimal time for submission of compliance plan to HRSA for approval, recognizing changes to the compliance plan could require changes to resources, but also recognizing the need for a complete plan for appropriate review, could require multiple revisions between HRSA and the OPTN**.** Collaboration and feedback from HRSA throughout the process to limit the back-and-forth will help avoid a prolonged timeline at this step of the process.

Assumptions:

- When HRSA submits the 30-day federal register notice for the OPTN Process Data package, DAC will pause AOOS Directive activities to collaborate with MPSC for up to 30 days to assist the OPTN in reviewing the 30-day package and formulating the OPTN response.

Proposed OPTN Policy Updates on Organ Offers by OPOs to Transplant Centers

Lead Committee: Operations and Safety Committee (OSC)

Collaborating Committees: MPSC, DAC, OPO, Kidney, Ethics

Objective 3: Develop a policy and definition to describe and prohibit "batched organ offers" to comply with NOTA and the OPTN Final Rule.

Objective 4: Develop a policy and definition for the "offer" of an organ by an OPO to a transplant center, including improved minimum requirements for notification and information accuracy.

Objective 5: Develop a policy and definition to describe acceptable modalities and content of organ offers made by OPOs to transplant patients at transplant centers.

Preamble from Operations and Safety Leadership

We would like to thank HRSA for the opportunity to provide feedback on the critical comment for allocation out of sequence (AOOS). The Committee welcomes this opportunity but wants to ensure that this topic is addressed appropriately. There are several factors that need to be considered in planning this project.

The Committee wants to outline the current practices as it relates to allocation out of sequence (AOOS) and further define the scope of the problem. The topic of allocation out of sequence (AOOS) is complex in nature and it was discussed that the tasks listed, although can be addressed, will not solve the entire scope of the problem.

In order to develop a project plan, the scope of the problem must first be defined. The primary problem is that the current allocation system has competing factors that results in the current structure being imperfect. A recent study showed that since the implementation of the updated kidney allocation system (KAS), AOOS has increased, accounting for over 20% of deceased donor kidney transplants.[2] The study found variation in AOOS utilization across organ procurement organizations (OPOs); the highest quartile of OPOs use AOOS in 20.9% of transplanted kidneys.[3] The OPOs with higher AOOS usage were found to be correlated with more biopsies and lower-quality kidneys, as reflected by a high proportion of high kidney donor profile index (KDPI) and donation after circulatory death (DCD) donors.[4]

It is acknowledged that the problem is more systemic in nature as the current allocation system is not equipped to handle this increasing complexity of donors. These occurrences of AOOS

[2] Adler JT, Cron DC, Kuk AE, Yu M, Mohan S, Husain SA, Parast L, Association between out of sequence allocation and deceased donor kidney non-utilization across Organ Procurement Organizations, *American Journal of Transplantation*, https://doi.org/10.1016/j.ajt.2025.02.005.
[3] Ibid.
[4] Ibid.

are an attempt to decrease the non-use of organs, while also honoring the best interest of the patient in response to the current systemic challenges.

Additionally, there have been competing priorities of the Centers for Medicare and Medicaid Services (CMS) regulations for OPOs. The sentiment from CMS is to encourage the pursuit of marginal and complex donors to increase donations and work with programs who transplant them. In addition, the federal register document states that it is the OPO's responsibility to ensure that placement and transport of organs happens in a fast and effective manner.

Several commenters provided feedback, stating that OPOs are obligated to the allocation system and that sometimes they run out of time trying to place certain organs. Therefore, the commenters stated that the OPOs should not be punished if they cannot place a transplantable organ.

In the response, CMS stated: We respectfully disagree with the commenters' assertion. The OPTN final rule has a section on wastage that explicitly allows transplant programs to transplant an organ into any medically suitable candidate to do otherwise would result in the organ not being used for transplantation (42 CFR 121.7(f)). Therefore, we do not believe the constraints of the allocation system justify not successfully placing a transplantable organ. We believe that this final rule will allow OPOs the opportunity to improve the placement of organs and drive the transplant community to adopt the technologies necessary to optimize placement.

The OPTN has done extensive work to further evaluate and promote efficiencies within the allocation system and develop policies, such as various studies conducted by the OPTN Expeditious Task Force, the development of Continuous Distribution allocation, and increasing the utilization of offer filters as summarized below:

There have been previous/continued efforts made by the OPTN that should be mentioned and considered that include the following:

- OPTN Expeditious Task Force (Task Force): The Task Force has had numerous projects outlined over the past two years with the aim of addressing this problem. The Task Force shared these plans across regional meetings and received strong support. These efforts were paused and it is recommended that these studies are reconvened.
- Continuous Distribution: This project has been in development since 2019 (starting with lung transplantation, and then later expanding across all other organ types) and continues to be a working effort among the organ-specific Committees. The goal of this project is to develop an allocation system that is:
    - Flexible – applying to all organ types
    - Equitable – no one factor will determine a candidate's placement on the waiting list
    - Agile – the framework will be more responsive and adaptable to future changes
- Offer Filters: This project has been in development since 2019 as a pilot project and later progressed to a voluntary rollout in 2022. The offer filters tool allows transplant programs

to apply program-specific, custom-designed, multi-factorial filters to bypass donor offers that they do not want to receive.[5] Since then, there has been work to increase the use of (kidney) offer filters through the development of a default offer filter model that would be generated based on a transplant program's previous kidney offer acceptance behavior.[6] This project has since expanded across all organs.

The Committee developed a Workgroup that comprised of the following OPTN Committees: Kidney Transplantation, Liver and Intestinal Organ Transplantation, Lung Transplantation, Heart Transplantation, Pancreas Transplantation, Organ Procurement Organization (OPO), Transplant Coordinators, Transplant Administrators, Pediatrics, and Patient Affairs. The Workgroup also includes members who have had expertise and experience in previous projects that addressed organ allocation. This Workgroup will be maintained to help in the development of this project (pending the approval of the project). The Workgroup met on March 19th and March 21st where they reviewed the tasked critical comment items (A.3-5). Those discussions helped in the development of the proposed plan of action outlined below.

Milestones and Estimated Delivery Timelines

Assumption: This plan assumes Objective 3, 4, and 5, as well as the OSC's proposed additional task of development of criteria for permitting AOOS in limited circumstances, will be joined as one proposal for policy development and public comment. However, depending on the solution developed, the proposal could have a split implementation of the approved policies.

Milestone	Estimated Timeline
Workgroup creation	Complete
Data analysis completed	1-4 months, depending on any additional data requests needed
Problem analysis and proposal development on defining and clarifying current terminology (i.e. Objective 3, 4, and 5)	5-7 meetings, over 6-8 months, following approval of the plan by HRSA, and assuming the data analysis is available by the middle of this timeline to account for updates the data may support
Problem analysis and proposal development of criteria for permitted instances of AOOS	5-7 meetings, over 6-8 months, following completion of data analysis
Public Comment	1-2 months following completion of proposal development
Compliance plan submitted to HRSA for approval	1 week following Committee vote post Public Comment
Proposal submitted to BOD for review	2 months following conclusion of public comment, barring significant public

[5] Finnie, J. & Moriarty, S. "Better organ offer screening", https://unos.org/news/innovation/reducing-unwanted-organ-offers/.
[6] *Optimizing Usage of Offer Filters,* OPTN Operations and Safety Committee, January 2023.

	comments requiring substantive change to proposal, and assuming approval of compliance plan
Implementation of updated policy terminology and criteria for permitted instances of AOOS	3-12 months following BOD approval, contingent upon implementation needs of solution developed
Total Estimated Duration	19-36months following approval of the plan by HRSA

Approach:

1. **Workgroup Creation:** Create a workgroup that involves all required stakeholders (all organ specific committees, OPO, TCC, Transplant Administrators Committee (TAC), Pediatric Transplantation Committee, Expeditious Task Force (ETF) leadership and patients, include business member volunteers)
2. **Analyzing the Problem:**
    a. **Engage diverse workgroup:** Include representatives of all organ-specific committees and other stakeholders, including OPOs, transplant centers, and patients, to ensure a comprehensive definition that can be applied consistently across all uses in OPTN policy.
    b. **Orientation to Current State:** Overview of the match and organ offer process and current OPTN policy and programming functionality.
    c. **Data Analysis:** Assess data currently available and determine if any additional data requests are needed.
3. **Proposal Development:**
    a. **Defining/clarifying terminology:**
        - Clearly state that organ offers must be made to individual transplant patients, not to transplant programs or centers. (Objective 3)

          Assumption: The Workgroup noted that in the current system, offers are typically sent in a series of sequential electronic notifications to potential transplant recipients at different transplant programs, and members of the community sometimes refer to these notifications as batches of organ offers. The Workgroup assumes that the practice to be prohibited that HRSA describes as "batched organ offers" " refers to the practice of

making organ offers to transplant programs, rather than to individual transplant patients.

- Review use of term "offer" across all OPTN policy for possible updates to the term and its related policies (Objective 4) and develop policy for acceptable modalities/content of an organ offer (Objective 5), including the following:
    1. Specification of the required clinical information (Objective 4) and associated content (Objective 5) that must be included in an organ offer.
    2. Requirements related to updates to the clinical status of the organ and its provision to the transplant center (Objective 4).
    3. Requirements regarding acceptable methods for communication of organ offers, to enhance transparency and audit capabilities (Objective 5).
- Policy language will follow policy development process outlined in Step 5.

b. **Development of policy criteria**: Develop policy criteria to standardize allocation behaviors in certain situations that are likely to currently result in AOOS.

- Per Board leadership feedback on March 25, 2025, consider developing criteria based on standards such as sequence number, amount of cold time, etc.
- Collaboration with MPSC for review in conjunction with AOOS case reviews.
- Policy language will follow policy development process outlined in Step 5.

4. **Implementation Plan:**

a. **Monitoring and Compliance:** Establish a monitoring system that aligns with Directive in Part B by ensuring compliance with the policy and addresses any violations.

- Compliance plan submitted to HRSA for approval following public comment, prior to BOD approval

- Anticipated Challenge: Identifying the optimal time for submission of compliance plan to HRSA for approval, recognizing changes to the compliance plan could require changes to resources, but also recognizing the need for a complete plan for appropriate review, could require multiple revisions between HRSA and the OPTN**.** Collaboration and feedback from HRSA throughout the process to limit the back-and-forth will help avoid a prolonged timeline at this step of the process.

b. **Education and Training:** Develop educational materials and training sessions to inform stakeholders about the new policy.

5. **Review and Feedback:**

a. **Public Comment:** Solicit feedback from the community, relevant committees, and other stakeholders through public comment period.

b. **Revisions:** Revise the policy based on feedback and finalize it for approval by the OPTN Board of Directors.

Anticipated Challenges:

- **Implications for Other Policy Projects:** As described in the preamble, there are other ongoing OPTN policy projects to address systemic allocation challenges. As policy development continues for projects like continuous distribution, expedited placement, and multi-organ allocation, OPTN committees will need to ensure proposed policies are aligned with this directive and the work of this workgroup.

Part B: Propose a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs. The OPTN's proposed compliance plan, which will be reviewed and approved by HRSA, should specifically describe potential OPTN actions that will protect the ongoing utility and function of the organ allocation process, as well as technical enhancements and data reporting that support the implementation of the policies proposed by OPTN in response to the directions described at (A)2-5 above – updates to policy regarding refusal codes, "batch organ offers," defining "offers and requirements for modalities, and content of offers.

Assumption: The compliance plans proposed pursuant to this Directive are distinct from the OPTN's current evaluation plan. While the development of the components of the plan will mirror the process for other compliance aspects of policy, these compliance plans will have an additional step of the process in that they are required to be submitted to HRSA for approval as part of the policy development process, which will extend the policy development process timeline.

Note: The ability to monitor a policy for compliance is dependent upon the solution created; programming and other implementation decisions by the policy development committees and ultimately the OPTN will impact the shape of the compliance plan.

The OPTN fully supports the role and importance of compliance in protecting the organ allocation process. Compliance monitoring is an integrated aspect of any policy development process and is central to the design of solutions proposed by the OPTN. With the priority work described above in reforming allocation policies, the OPTN proposes addressing compliance aspects of allocation work alongside updates to the policies. Therefore, the OPTN proposes folding the work of Part B into Part A for efficiency and comprehensiveness of the solution, as well as recognizing the resources available in terms of volunteer time.

As the committees evaluate the allocation issues tasked to them, the MPSC will review proposed compliance methods along the way, to ensure that compliance with statutory and regulatory provisions is maintained, and enhancements and improvements supporting compliance work is considered. The general approach for compliance review is included here, and the specific sequencing of the compliance work is highlighted in the relevant sections above in Part A(2-5).

Schedule of Delivery and Milestones: Provided in Part A(2-5) above.

Approach:

The OPTN drafts policy to ensure it is done in a manner conducive to monitoring upon implementation. All policy proposals are accompanied by a compliance monitoring plan, with the following factors considered:

- Specific policy requirements
- Potential impact of noncompliance on patient safety and the integrity of the system
- Expected frequency of the potential noncompliance, and
- The tools and data available and required to assess member compliance.

The compliance plans are shared with the community during public comment periods and are adapted as the proposals are refined, with review from stakeholder committees, including the MPSC with a focus on compliance measures. The final recommendation for type, frequency and outcome of compliance activities will be based on specific requirements of newly developed policies, as well as how policies may be programmed into the applicable OPTN computer systems.

Potential OPTN Actions in Response to Non-Compliance

Reports of non-compliance with any OPTN obligation are subject to review by the MPSC. The MPSC is authorized to take action against an OPTN member in accordance with OPTN Management and Membership Policies Appendix L: Reviews and Actions.

Part C: Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants.

To ensure patient awareness of variances and to ensure effective oversight of these expedited placement protocols, including the potential to sunset any variances that meet stopping criteria, all proposed variances, approved protocols, associated effective dates, and monitoring metrics should be published on the OPTN website prior to implementation.

The OPTN Final Rule at 42 CFR 121.8c states "Each organ-specific allocation policy shall include performance indicators. These indicators must measure how well each policy is…[g]iving patients… accurate information to assess the performance of transplant programs." Publicly accessible information on the OPTN website describing all variances proposed, approved and in progress will ensure patient access to information about variances that may increase their access to transplants.

The OPTN should also publish data and analysis describing the performance of each variance and the aggregate effects of all variances implemented under OPTN policy 5.4.G to inform patients and the public of the results of all activities under the open variance.

In conjunction with this letter, HRSA is permitting the OPTN to restart exploring expedited placement protocols based on the parameters above.

In 2024, the OPTN Kidney Transplantation Committee began developing a protocol to propose for testing under OPTN *Policy 5.4.G Open Variance for Expedited Placement*. Subsequent to direction from HRSA to delay implementation of such protocols, the Kidney Committee shifted its focus to developing a national kidney expedited placement policy. On March 6, 2025, the Executive Committee asked the Kidney Committee to continue developing a national kidney expedited placement policy for the summer 2025 public comment period, in alignment with this Directive. Given the amount of work completed to date on the policy, and the upcoming expiration of *Policy 5.4.G* on December 31, 2025, the OPTN recommends proceeding with a national kidney expedited placement policy through the policy development process.

The OPTN's policy development process will ensure transparency and awareness of the policy, which will lead to an increase in patient access to transplants. The policy is being developed by a cross-committee workgroup including transplant program, organ procurement, ethics, and patient representatives, and the Kidney Committee plans to request early feedback from various stakeholders, including the Patient Affairs Committee and the MPSC. The process includes sending a policy proposal, including proposed policy monitoring metrics (performance indicators), through the OPTN Policy Oversight Committee and OPTN Executive Committee for

public comment approval and releasing the proposal on the OPTN website for public comment. During public comment, the OPTN will conduct outreach to patient, donor, and caregiver organizations and encourage participation in public comment. This outreach ensures patients who are not directly involved in the OPTN policy making process can participate in public comment and provide feedback. Following public comment review, Board approval, and implementation, data and analysis describing the performance of the policy may be posted on the OPTN website.

After implementation of the policy, the OPTN can then evaluate what the role for variances to test other protocols related to expedited placement may be.

Part D: Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS.

Milestones and Estimated Delivery Timelines

Milestone	Estimated Timeline
Development and Implementation of AOOS Public Tool	12-16 weeks
Total Estimated Duration	12-16 weeks

Approach:

1. **Preliminary Work:** OPTN to assign Sponsoring Committee or Workgroup to lead this effort.
2. **Phase 1: Planning and Design**:
    a. Define the scope and requirements with key stakeholders.
    b. Develop a detailed project plan with timelines, milestones, and resource allocation.
    c. Create a communication strategy for wide engagement and adoption.
    d. Develop educational and support materials.
3. **Phase 2: Development and Testing:**
    a. The design of the tool will be determined based on scope and requirements collected from key stakeholders.
    b. Development and testing requirements will be determined based on the design of the tool.
4. **Phase 3: Launch and Training:**
    a. Launch the tool with a comprehensive communication and outreach plan.
    b. Provide educational and support materials.
    c. Determine ongoing support plan, including contractor support.
5. **Phase 4: Monitoring and Evaluation:**

a. Seek feedback on the tool from key stakeholders and the community, including patients.

b. Make iterative improvements based on data analysis and community input/feedback.

Anticipated Challenges

- Depending on scope of outreach, and if outreach to the community is sought at other steps of the process, the timeline could be significantly impacted.

Anticipated Challenges Overall

In addition to the challenges mentioned on the discrete components of the plan above, the OPTN anticipates the following challenges to the plan proposed as a whole:

- **Volunteer Capacity:** The availability and capacity of volunteers assigned to committees can impact the timeline and progress of policy development.
- **Prioritization of OPTN Work**: At the drafting of this plan, the OPTN is currently subject to several HRSA directives, as well as OPTN operational work and other policy development work. The OPTN will need to prioritize the work accordingly to ensure progress continues, but timelines will be impacted. See below for Initial Assessment of Prioritization of OPTN Work.
- **HRSA Capacity**: HRSA feedback and input throughout the development process is crucial to avoiding rework and compromised timelines. HRSA representatives, like OPTN colleagues, also have other OPTN work to prioritize, and may find it difficult to provide the engagement needed to ensure an efficient project.

EXAMPLE

Initial Assessment of Prioritization of OPTN Work

OPTN contractor staff have completed an initial assessment of OPTN activities that could be deprioritized to support the activities described in this plan. Final prioritization decisions will need to be made at the time the plan is approved and in conjunction with OPTN and HRSA. Additional contractor resources may be required to conduct a more detailed assessment and support additional prioritization activities.

This initial assessment was based on factors such as risk to patient safety, percentage completion of project, overlap of volunteer assignments, and contractor resources required to support current activities versus activities described in this plan.

OPTN committee projects and other committee work to be paused due to AOOS Directive:

Committee	Type of Work	Item to be Impacted
AHIRC	Monthly Meetings	Monthly meetings to be paused after June Board meeting
DAC	Research Report	Annual Data Quality report; Revisions due in September/October to present to BOD in November
DAC	Board Document	June Board Report would not be prioritized
DAC	Project Development	Two of the following: - Improving data quality by enhancing API functionality - Expedite implementation of OPTN data changes - Creation of public facing data dictionary - Modifying Policy 18 to address accountability and data quality - Establishing and defining critical OPTN data fields
Ethics	Project Development	Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation
Ethics	Monthly Meetings	Monthly meetings to be paused
Liver	Public Comment Update	Update Community on Continuous Distribution; Summer 2025
Lung	Project Development	Modify Lung Allocation by Candidate Biology; contingent on new project approval
Heart	Public Comment Update	Update Community on Continuous Distribution; Summer 2025
MAC	Project Implementation	Monitor Ongoing eGFR Modification Policy Requirements
MAC	Monthly Meetings	Monthly meetings to be paused after June Board meeting
MOT	Research Report	Potential Data Request (DR) on minimum acceptance criteria for priority shares policy

EXAMPLE

Committee	Type of Work	Item to be Impacted
MOT	Research Report	6 Month Modify Effect Acceptance monitoring report (MR); Work planned to begin in April
MOT	Research Report	Any new MOT DRs (they are about to receive/already received 3 large DRs)
MPSC	Research Report	3 Year Performance Monitoring Enhancement MR; October due date
MPSC	Project Development	Establish Multi-Organ Post-Transplant Graft Survival Review
MPSC	Post-Implementation Evaluation	Transplant Program Performance Monitoring Enhancement project post-implementation evaluation of effectiveness of review process for each metric
MPSC	Project Development	OPO Performance Monitoring Enhancement project consideration of SRTR metrics
MPSC	Project Development	Guidance for members contracting with third party vendors
NOOC	Project Development	Revisit of Reasons for Permissible Use of OPTN Computer System for Research
NOOC	Policy Work	While NOOC could continue to meet in an operations oversight role, would not have support to create or modify OPTN policy
Ops and Safety	Project Development	Re-evaluation of Deceased Donor Testing Requirements
Ops and Safety	Project Development	Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement
Ops and Safety	Research Report	1 Year Data to Evaluate Organ Logistics and Allocation MR; Current April/May due date
Ops and Safety	Research Report	2 Year Data to Evaluate Organ Logistics and Allocation MR; Early 2026 due date
Ops and Safety	Research Report	6 Month Required Kidney Offer Filters MR; Current July due date
Ops and Safety	Research Report	1 Year Required Kidney Offer Filters MR; Early 2026 due date
Ops and Safety	Research Report	6 Month Deceased Donor Support Therapy MR; Early 2026 due date
Pancreas	Project Development	KP Offer Filters
PAC	Monthly Meetings	Monthly meetings to be paused
Pediatric	Project Development	Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care
Pediatric	Monthly Meetings	Monthly meetings to be paused
TAC	Monthly Meetings	Monthly meetings to be paused

EXAMPLE

Committee	Type of Work	Item to be Impacted
TCC	Project Development	Inactive Candidate Status Notifications (pending project approval)
TCC	Monthly Meetings	Monthly meetings to be paused
VCA	Research Report	1 Year Update Transplant Outcomes Data Collection MR; dependent on IT data conversion; potential May due date
VCA	Research Report	1 Year VCA into UNet MR; dependent on IT data conversion; potential May due date
VCA	Research Report	1 Year Graft Failure Definition MR; dependent on IT data conversion; potential May due date
VCA	Research Report	1 Year Uterus Program Membership Requirements MR; Current May due date
VCA	Monthly Meetings	Monthly meetings to be paused
VCA	Dataset Analysis	Updates to Analysis VCA transplant datasets

Other OPTN tasks/projects that could be paused due to prioritization of AOOS work:

- CMS Quarterly ESRD data update
- Equity dataset updates
- Ongoing Analysis dataset documentation
- NTIS data addition to death verification process
- Initiation of new OPTN committee project work not previously identified in the plan