

Briefing to the OPTN Board of Directors on

Modify Effect of Acceptance Policy

OPTN Ad Hoc Multi-Organ Transplantation Committee

*Prepared by: Sarah Roache
UNOS Policy Department*

Contents

Executive Summary	2
Purpose	2
Background	2
Proposal for Board Consideration	3
Overall Sentiment from Public Comment	4
Compliance Analysis	7
Implementation Considerations	9
Post-implementation Monitoring	10
Conclusion	11
Policy Language	12
Appendix A: Post-Public Comment Changes	13

Modify Effect of Acceptance Policy

<i>Affected Policy:</i>	<i>5.6.D Effect of Acceptance</i>
<i>Sponsoring Committee:</i>	<i>Ad Hoc Multi-Organ Transplantation</i>
<i>Public Comment Period:</i>	<i>January 23, 2024 – March 19, 2024</i>
<i>Board of Directors Meeting:</i>	<i>June 17-18, 2024</i>

Executive Summary

The proposal addresses situations in which organ offer acceptance conflicts with a multi-organ offer required by policy. Such conflicts emerge when organs have been accepted, then an accepted organ is declined, and the next candidate on the match run is a multi-organ candidate registered for the organ that has already been accepted. For example, an Organ Procurement Organization (OPO) may place a heart with a heart-alone candidate and the kidneys with other candidates and then receive notification that the heart candidate can no longer accept the organ. If the next candidate on the match is a qualifying heart-kidney candidate, policy states that the OPO must offer the kidney along with the heart, but the OPO no longer has a kidney to offer since the kidneys were accepted by other candidates. The purpose of the proposal is to clarify that organ offer acceptance takes priority over requirements to offer more than one organ to multi-organ candidates. It is important to note that OPOs are still required to place multi-organ combinations according to current OPTN policies and to offer available organ(s) to multi-organ candidates, even when one of the organs they are registered for has been accepted.

The proposal would support OPOs to move forward with placing single organs, once required multi-organ shares are completed. It is expected to promote efficiency in organ placement and equity in access to transplants between single and multi-organ candidates.

After reviewing public comments, the Committee made minor revisions to the policy language to clarify application and scope.

Purpose

The purpose of this proposal is to clarify that, if an organ has been accepted by a transplant program, acceptance takes priority over requirements to offer more than one organ to a single candidate.

Background

During the Winter 2023 OPTN public comment period, the Ad Hoc Multi-Organ Transplantation Committee (Committee) requested feedback on the concept paper *Identify Priority Shares in Kidney-Multi-Organ Allocation*.¹ The concept paper was the first step in a project that aims to improve equity in access to transplant between kidney-alone and kidney multi-organ candidates, and to improve efficiency in allocating multiple organ types from one donor. One of the topics included in the concept paper was how to handle situations in which organ offer acceptance conflicts with a multi-organ offer required by

¹ "Identify Priority Shares in Kidney Multi-Organ Allocation," OPTN, Concept Paper, accessed March 21, 2024, available at https://optn.transplant.hrsa.gov/media/mc0hfxrg/priority-shares-in-kidney-mot_concept_pc-winter-2023.pdf.

policy. OPOs provided public comment feedback expressing concern that policies requiring multi-organ shares may conflict with the requirements in *Policy 5.6.D: Effect of Acceptance*.

In developing the policy proposal, the Committee noted feedback that the conflicting policies were causing confusion and delays in organ allocation and placement. The conflicting policies also resulted in inefficient and inconsistent practices among OPOs and transplant hospitals. For example, some OPOs report that they have delayed an organ offer, so that in case of a late organ offer refusal, they could fulfill a required multi-organ share further down the match run. Other OPOs report responding to this situation by withdrawing an organ offer from a single-organ candidate and redirecting that organ to fulfill the required multi-organ share. The Committee determined that clarifying that acceptance pursuant to *Policy 5.6.D* takes priority over required multi-organ shares would improve organ placement efficiency and promote equity in access to transplant between single and multi-organ candidates. With the increase in multi-organ transplants in recent years, it is imperative that policies impacting multi-organ transplants are equitable and efficient. **Table 1** shows the increasing number of multi-organ transplants over the last 10 years.

Table 1: Multi-Organ Transplants (All Combinations)²

2023	2022	2021	2020	2019	2018	2017	2016	2015	2014
1,416	1,340	1,257	1,199	1,075	1,015	1,036	985	891	775

Proposal for Board Consideration

The proposal adds language to *Policy 5.6.D: Effect of Acceptance*, to clarify that, if an organ has been accepted by a transplant program, acceptance takes priority over requirements to offer more than one organ to a single candidate. Public comment responses supported the proposal on the basis that it would increase efficiency in organ allocation and help avoid last-minute redirections of organs from single to multi-organ candidates. Public comments called for clarification of the meaning of acceptance. The Committee requested public comment feedback on whether a timeframe should be included in policy language and received slightly more support for not specifying a timeframe.

Based on public comment feedback, the Committee revised the proposed policy language. To help clarify the meaning of acceptance, the Committee inserted reference to acceptance for a “primary potential transplant recipient,” which is defined in policy as “[t]he first candidate according to match run sequence for whom an organ has been accepted.”³ To ensure that OPOs can continue to make backup offers after acceptance, the Committee removed “including those according to *Policy 5.10: Allocation of Multi-Organ Combinations ...*” Finally, to allow OPOs some flexibility to proceed with multi-organ offers after acceptance, the Committee inserted “not required to be offered according to *Policy 5.10: Allocation of Multi-Organ Combinations ...*” At its meeting on April 3, 2024, the Committee voted to recommend the amended policy language to the Board of Directors.

² OPTN National Data. Accessed April 22, 2024, available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data>. Note that this data does not include heart-lung or kidney-pancreas transplants.

³ *OPTN Policy 1.2 Definitions* (see: “Primary potential transplant recipient”). Accessed April 22, 2024, available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

Overall Sentiment from Public Comment

The proposal was released for public comment from January 23, 2024 to March 19, 2024. It received 309 comments, including narrative comments and sentiment scores. The comments received represented at least at least 40 states across the country and all member types.

Sentiment is collected from participants who submit an individual public comment and from regional meeting participants. Participants are asked to provide their feedback on “What is your opinion of this proposal?” There are five Likert scale response choices with 1 representing strongly oppose up to 5 representing strongly support. Below are graphics that illustrate the sentiment received through public comment.

Figure 1 shows sentiment received from all respondents (regional meeting, online, and email) by their stated region. Overall sentiment was supportive, as indicated by a total sentiment score of 4.1.

Figure 1: Sentiment by Region, Modify Effect of Acceptance Policy, 2024

Sentiment by Region

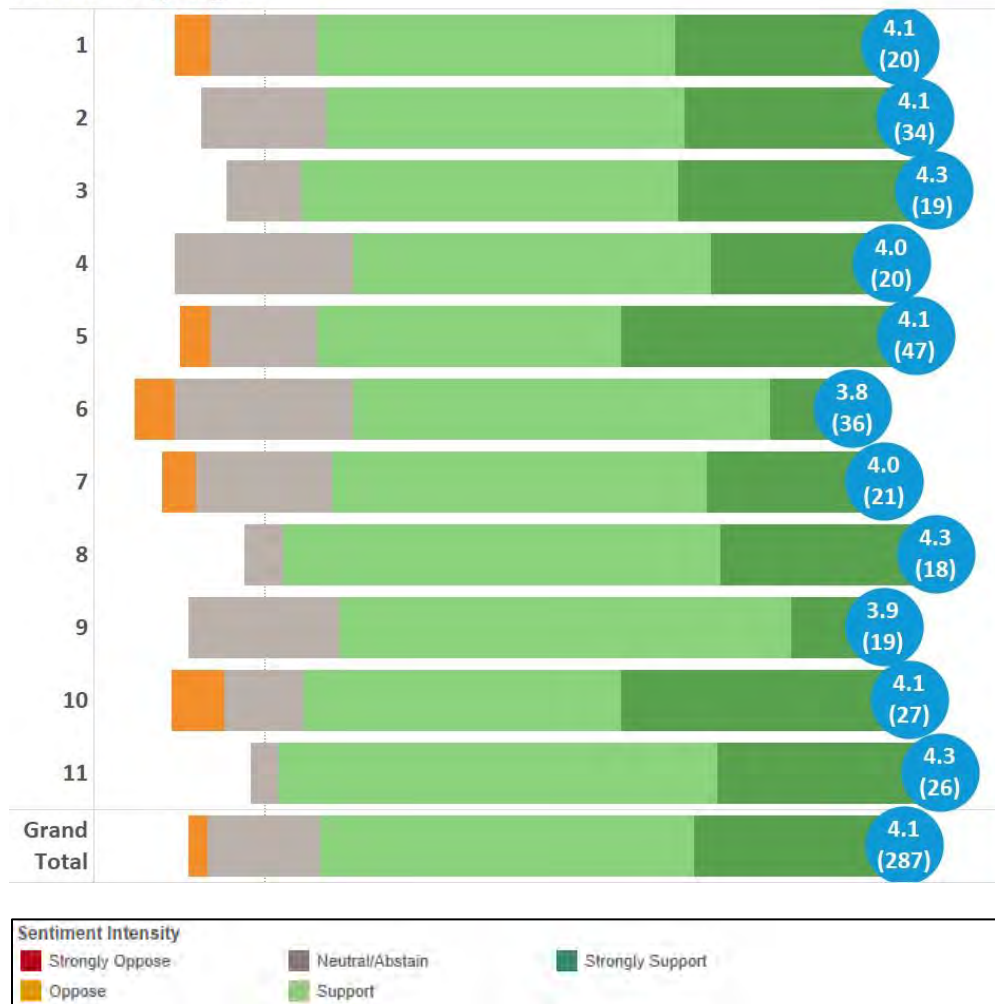
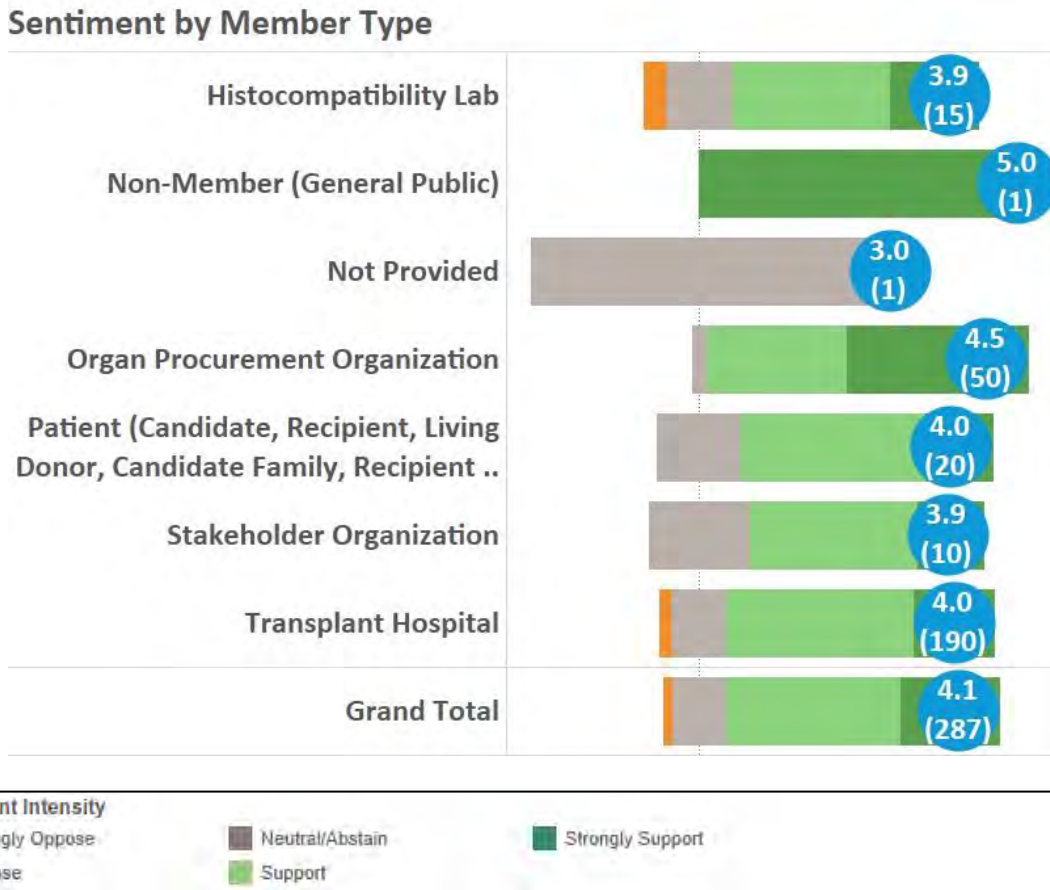


Figure 2 shows sentiment received from all respondents (regional meeting, online, and email) by their stated member type. There was overall support for the proposal, demonstrated by a sentiment score of 4.1. There was strong support among OPOs, the member group primarily responsible for implementing *Policy 5.6.D: Modify Effect of Acceptance*. Fifty OPOs responded with a total sentiment score of 4.5. Patients also supported the proposal, with 20 patient respondents and a total sentiment score of 4.0.

There was a total of eight “oppose” sentiments out of a total of 287 sentiment scores submitted. Most concerns focused on the potential to disadvantage multi-organ patients, the lack of timeframe in the policy language, and need for clarity on the meaning of acceptance.

Figure 2: Sentiment by Member Type, Modify Effect of Acceptance Policy, 2024



Public comment feedback themes

Efficiency

Many community members commented that the proposed policy clarification would increase efficiency in organ allocation and placement. Several commenters stated that *OPTN Policy 5.6.D: Effect of Acceptance* is confusing and causes delays, and that the proposed change would provide clarity for OPOs. Commenters also noted that the proposed change will support OPOs in the timely allocation of kidneys, once required multi-organ shares are completed.

Meaning of acceptance

“Organ offer acceptance” is defined in policy as “[w]hen the transplant hospital notifies the host OPO that it accepts the organ offer for an intended recipient, pending review of organ anatomy. For kidney, acceptance is also pending final crossmatch.”⁴ Several community members requested that policy clearly define the meaning of acceptance, suggesting that a clear definition is necessary to effectively implement the proposed policy change. Community members cited confusion about when acceptances become binding on OPOs and transplant hospitals. They provided examples of inconsistent interpretation and practices depending on the organizations involved and the types of organs. Several commenters stated that a “provisional yes” should not constitute acceptance. Two commenters noted that it is unclear how the policy impacts backup offers and called for the policy language to address backup offers.

Noting reports of confusion and inconsistent interpretations of “[o]rgan offer acceptance,” the Committee sought to clarify the meaning of acceptance by inserting reference to acceptance for a “primary potential transplant recipient,” which is defined in policy as “[t]he first candidate according to match run sequence for whom an organ has been accepted.”⁵ In addition, should the Board of Directors approve the policy proposal, the Committee will facilitate development of educational resources to promote awareness of and compliance with relevant policies and definitions.

Timeframe

The public comment proposal asked the community for input on whether a specific timeframe should be included in the policy language. Feedback on this question was mixed, with slightly more support for omitting a timeframe.

Community members in favor of a timeframe suggested that it would increase efficiency and promote consistency in OPO practices. Commenters tended to support a cut-off event or process, rather than a specific amount of time. Suggestions included that the policy take effect once an offer is accepted and the operating room is scheduled, or at time of cross clamp.

Arguments against inclusion of a timeframe included:

- Potential to increase confusion and inefficiencies for OPOs and transplant hospitals
- Potential to increase administrative burdens
- Potential to disadvantage patient groups with higher waitlist mortality
- Difficulty determining a timeframe given geographic nuances

Impacts on patient groups

Community members expressed a range of viewpoints on the proposal’s potential impacts on specific patient groups. Several commenters supported the proposal because it will help avoid last-minute

⁴ *OPTN Policy 1.2 Definitions* (see: “Organ offer acceptance”). Accessed April 22, 2024, available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

⁵ *OPTN Policy 1.2 Definitions* (see: “Primary potential transplant recipient”). Accessed April 22, 2024, available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

redirection of organs from single-organ to multi-organ candidates. Commenters raised specific concerns about the impacts on pediatric candidates and highly-sensitized kidney candidates, who are compatible with fewer donors and yet have had organ offers withdrawn and redirected to multi-organ candidates. Commenters shared experiences of having patients checked-in and prepared for transplant surgery, only to have a primary offer withdrawn for allocation to a multi-organ candidate pursuant to *Policy 5.10: Allocation of Multi-Organ Combinations*. These situations can be traumatic for patients and their families, challenging for providers, and logistically complex for OPOs.

Some community members expressed concern that the proposed policy change would disadvantage multi-organ candidates. In particular, commenters suggested there might be longer wait times for multi-organ candidates if the proposal is implemented. One commenter called for policy language allowing opportunity for offers according to *Policy 5.10: Allocation of Multi-Organ Combinations* after a single organ has been accepted, if agreed by the OPO and transplant hospital. The Committee agreed that OPOs would benefit from flexibility to proceed with multi-organ offers after acceptance in some circumstances, and revised the policy language so that it does not prohibit multi-organ offers after acceptance.

Education to support implementation

The Committee noted that public comments highlighted the need for education to support implementation of the policy proposal and related policies and definitions. Should the Board of Directors approve the policy proposal, the Committee will facilitate development of educational resources to promote awareness of and compliance with *Policy 5.6.D: Effect of Acceptance*, relevant definitions such as “organ offer acceptance,” and the requirement to report acceptances immediately pursuant to *Policy 5.6.C: Organ Offer Acceptance Limit*.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to “establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria.”⁶ The OPTN Final Rule states the OPTN “shall be responsible for developing ...policies for the equitable allocation for cadaveric organs.”⁷ This proposal would clarify the effect of acceptance and how it applies to the allocation of organs with multi-organ candidates and single organ candidates.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed

⁶ 42 USC §274(b)(2)(B).

⁷ 42 CFR §121.4(a)(1).

to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.”⁸

This proposal:

- **Is based on sound medical judgment**⁹ because it addresses unclear policies contributing to inconsistent and inefficient allocation practices. The policy proposal will allow transplant programs to proceed with coordinating transplants for organs accepted for candidates without concern that a previously accepted organ may be reallocated. The proposal balances the need to place organs and avoid delays while prioritizing allocation of organs for multi-organ candidates and single organ candidates.
- **Is designed to avoid wasting organs**¹⁰ by decreasing the number of organs recovered but not transplanted which maximizes the gift of organ donation by using each donated organ to its full potential. This proposal allows OPOs to move forward with allocation more expediently and reduce the cold ischemic time on organs, which may help prevent non-use of organs.
- **Is designed to...promote patient access to transplantation**¹¹ by giving similarly situated candidates equitable opportunities to receive an organ offer. This proposal allows organ placement with single organ candidates that may otherwise be placed with multi-organ candidates.
- **Promotes the efficient management of organ placement**¹² by taking into account the costs and logistics of procuring and transplanting organs. This proposal allows OPOs to move forward with placing all organs without holding organs in case of an organ offer refusal to streamline the logistics of coordinating organ recovery and transplantation.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient.¹³ The proposal is not specific to an organ type¹⁴ because it is intended to provide more direction to OPOs on how to manage allocation of multiple organs across several different match runs.

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- **Seeks to achieve the best use of donated organs**¹⁵ by ensuring organs are allocated and transplanted according to medical urgency. This proposal does not change how candidates are ranked on each organ match run and therefore preserves the considerations for medical urgency that are incorporated into the organ-specific allocation policies.

⁸ 42 CFR §121.8(a).

⁹ 42 CFR §121.8(a)(1).

¹⁰ 42 CFR §121.8(a)(5).

¹¹ Id.

¹² Id.

¹³ 42 CFR §121.8(a)(3).

¹⁴ 42 CFR §121.8(a)(4).

¹⁵ 42 CFR §121.8(a)(2).

- **Is designed to avoid futile transplants:**¹⁶ This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes as it does not impact patient selection for transplant.
- **Is not based on the candidate’s place of residence or place of listing.**¹⁷

Transition Plan

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies” whenever organ allocation policies are revised.¹⁸ This proposal clarifies that acceptance pursuant to *Policy 5.6.D* takes priority over required multi-organ shares. As this policy clarifies rather than changes policy, the Committee did not identify any populations that may be treated “less favorably than they would have been treated under the previous policies.”

OPTN Strategic Plan

The proposal supports achievement of the 2021-2024 OPTN Strategic Plan goal of increasing equity in access to transplants. Specifically, it promotes equity in access to transplants between single and multi-organ candidates by supporting OPOs to move forward with placing single organs, once required multi-organ shares are completed, and by helping avoid last-minute redirections of organs from single to multi-organ candidates.

Implementation Considerations

Histocompatibility Laboratories

Operational Considerations

There are no anticipated operation considerations for histocompatibility laboratories.

Fiscal Impact

There are no anticipated fiscal impacts on histocompatibility laboratories.

¹⁶ 42 CFR §121.8(a)(5).

¹⁷ 42 CFR §121.8(a)(8).

¹⁸ 42 CFR § 121.8(d)(1).

Organ Procurement Organizations

Operational Considerations

OPOs may need to evaluate their internal policies and procedures and educate staff to account for this policy change.

Fiscal Impact

There are no anticipated fiscal impacts on OPOs.

Transplant Programs

Operational Considerations

Transplant programs may need to evaluate their internal policies and procedures and educate staff to account for this policy change.

Fiscal Impact

There are no anticipated fiscal impacts on transplant programs.

OPTN

Operational Considerations

There are no anticipated impacts on OPTN operations.

Resource Estimates

It is estimated that 200 hours would be needed to implement this proposal. Implementation would involve updates and educational resources for OPOs and transplant hospitals. These entities may need to evaluate and adjust their internal policies and procedures to comply with the proposed policy changes. It is estimated that 105 hours would be needed for ongoing support, including allocations team support, research post-implementation monitoring, and answering member questions, as necessary.

Potential Impact on Select Patient Populations

There is potential for fewer offers for MOT candidates, if OPOs no longer hold back on final placement of second organs in case of late turndowns. However, this change is expected to improve access for single organ candidates and improve efficiency in organ placement.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”¹⁹ The OPTN will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and staff will investigate potential policy violations that are identified.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”²⁰ Monitoring reports using pre vs. post comparisons would be presented to the Committee after approximately 6 months, 1 year and 2 years. This policy will monitor MOT, kidney, pancreas, liver, heart, and lung alone as data permits and after a sufficient sample size has accumulated. Metrics include:

- Number of MOT transplants and single organ transplants
 - MOT transplants will be stratified by organ combinations
- Waiting list deaths for MOT candidates and single organ candidates
 - Counts will be stratified by medical urgency and age (Pediatric vs. Adult), when appropriate
- Distribution of sequence number of MOT and single organ recipients by match run
- Non-use rate by organ type

Conclusion

The policy proposal would clarify that organ offer acceptance takes priority over requirements to offer more than one organ to multi-organ candidates. During the Winter 2024 public comment period, there was overall support for the proposal, demonstrated by sentiment scores of 4.1 by both member type and by region. In response to public comment feedback, the Committee revised the proposed policy language to 1) clarify the meaning of acceptance; 2) ensure that OPOs can continue to make backup offers after acceptance; and 3) allow OPOs some flexibility to proceed with multi-organ offers after acceptance.

The policy proposal would support OPOs to move forward with timely placement of single organs, once required multi-organ shares are complete. It would also help avoid last-minute redirections of organs from single to multi-organ candidates. It is expected to promote efficient and consistent organ placement and equity in access to transplants between single and multi-organ candidates.

¹⁹ 42 CFR §121.8(a)(7).

²⁰ 42 CFR §121.8(a)(6).

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, cross-references, and footnotes affected by the numbering will be updated as necessary.

1 **5.6.D Effect of Acceptance**

2 When a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the
3 transplant hospital and OPO unless they mutually agree on alternative allocation of the organ.

4 If an organ has been accepted by a transplant program for a primary potential transplant recipient, the
5 organ is not required to be offered according to *Policy 5.10: Allocation of Multi-Organ Combinations*.

#

Appendix A: Post-Public Comment Changes

New language that was proposed following public comment is underlined and highlighted (example); language that is proposed for removal following public comment is struck through and highlighted (~~example~~).

5.6.D Effect of Acceptance

When a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ.

If an organ has been accepted by a transplant program for a primary potential transplant recipient, ~~that organ is no longer available for subsequent offers, including those not required to be offered~~ according to *Policy 5.10: Allocation of Multi-Organ Combinations*.