OPTN

Public Comment Proposal

Clarify Multi-Organ Allocation Policy

OPTN Organ Procurement Organization Committee

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Clarify Multi-Organ Allocation Policy

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Sponsoring Committee:	*Organ Procurement Organization*
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Executive Summary

Multi-organ allocation policies have been an area of concern for many years. The OPTN Ethics Committee developed a white paper to provide guidance on multi-organ transplant policy and practice.[1] The Board of Directors approved this white paper in June 2019. In 2019, the OPTN Policy Oversight Committee (POC) began developing strategic policy priorities. One of the priorities identified and approved by the OPTN Executive Committee was to improve equity for multi-organ and single organ candidates.[2] A multi-disciplinary workgroup was formed to begin addressing multi-organ allocation policies.[3]

This proposal addresses the first step of this strategic policy priority by clarifying OPTN *Policy 5.10.C: Other Multi-Organ Combinations*. The current policy addresses multi-organ combinations for candidates on the heart, lung, or liver waiting list that require a second organ. Current policy does not address which match run is used or provide specifics about the "second required organ." This leads to inconsistent application of the requirements outlined in this policy.

The OPO Committee proposes criteria for when OPOs are required to offer the liver or kidney, if available, from the same donor. For heart candidates, the criteria will include adult status 1, 2, and 3 and pediatric 1A and 1B. For lung candidates, the criteria will include candidates with a lung allocation score of greater than 35. Additionally, the proposed distance for this mandatory offer will be increased from the current 150 nautical miles (NM) for liver and 250 NM for heart and lung to a 500 nautical miles circle to better align with thoracic allocation policies.

This proposal addresses heart-liver, lung-liver, heart-kidney, and lung-kidney multi-organ combinations. This proposal establishes requirements for when OPOs must offer the liver or kidney when allocating according to the heart or lung match run.

[1] https://optn.transplant.hrsa.gov/media/2801/ethics_publiccomment_20190122.pdf
[2] https://optn.transplant.hrsa.gov/media/3615/20191008_exec_comm_summary.pdf
[3] https://optn.transplant.hrsa.gov/media/3005/201906_board_executivesummary.pdf

Background

In 2019, the OPTN Policy Oversight Committee (POC) began developing strategic policy priorities. The criteria for strategic policy priorities included the following:

- Impact to multiple organ systems
- Impact to multiple member types
- Require expertise from multiple committees and stakeholder organizations
- Require changes to multiple policies to provide consistent approach
- Results in large-scale improvement to deliver the greatest benefit to the community.

One of the priorities identified and approved by the OPTN Executive Committee was to improve equity for multi-organ and single organ candidates. The initial step in a phased approach to address multi-organ policies is to revise the general multi-organ policy prior to beginning work on any specific multi-organ policies. This will ensure that the specific multi-organ policies are consistent with the general multi-organs policy. The next phase of this effort will be to address other multi-organ combinations, with eligibility criteria for heart-kidney identified as the next step.

OPTN Policy 5.10.C: Other Multi-Organ Combinations was modified as part of several recent proposals that removed donation service area (DSA) from heart, lung, and liver allocation policies.[4,5] These changes replaced DSA with 150 nautical miles (NM) for liver and 250NM for lung and heart as the distances for when the OPO is required to offer the second required organ. The intent of these changes was to remove DSA from allocation policy, not to provide new requirements for OPOs when allocating multi-organ combinations. Current policy requires a certain level of interpretation by OPOs, which can lead to inconsistent practice across the country.

While the number of multi-organ combinations not currently addressed in policy are relatively small as illustrated in **Figure 1**, it is important for the Committee to address the combinations in this proposal as part of the phased approach to addressing multi-organ policies. Addressing heart-liver, lung-liver, heart-kidney, and lung-kidney combinations will address 84% of the combinations not currently addressed in other policies.

[4] https://optn.transplant.hrsa.gov/media/2994/thoracic_boardreport_201906.pdf - or *OPTN Thoracic Organ Transplantation Committee Report to the Board of Directors*, OPTN Thoracic Organ Transplantation Committee, June 2019.
[5] https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf or *OPTN Liver and Intestinal Organ Transplantation Committee Report to the Board of Directors*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018.

Figure 1: Number of Multi-Organ Transplants (2016-2019)

Multi-Organ Transplants					
	2016	2017	2018	2019	Policy?
All deceased donor transplants	27,630	28,588	29,680	32,322	
All Multi-Organ Transplants	1801	1853	1882	1989	
Liver-Kidney	730	739	677	727	Yes
Kidney-Pancreas	798	789	835	872	Yes
Heart-Kidney	140	187	203	219	No
Liver-Intestine-Pancreas	58	55	51	35	No
Liver-Heart	18	29	39	45	No
Heart-Lung	18	29	32	45	Yes
Liver-Lung	9	8	14	12	No
Intestine-Pancreas	8	3	4	5	No
Kidney-Intestine	5	1	2	3	No
Kidney-Lung	4	7	9	13	No
Liver-Pancreas	3	1	2	1	No
Liver-Intestine	2	0	3	1	Yes
Liver-Kidney-Heart	1	0	3	6	No
Liver-Kidney-Intestine-Pancreas	7	2	7	4	No
Kidney-Heart-Lung	0	2	2	1	No
Liver-Pancreas-Lung	0	0	0	0	No
Liver-Kidney-Pancreas	0	0	0	0	No
Kidney-Intestine-Pancreas	0	0	0	0	No
Liver-Kidney-Intestine	0	0	0	0	No
Heart-Pancreas	0	0	0	0	No
Liver-Heart-Lung	0	1	0	0	No
https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/					

A multi-disciplinary workgroup (Workgroup) was formed with representation from the following OPTN committees:

- Organ Procurement Organization
- Liver and Intestinal Organ Transplantation
- Heart Transplantation
- Lung Transplantation
- Kidney Transplantation
- Pancreas Transplantation
- Pediatric Transplantation
- Transplant Coordinators
- Vascular Composite Allograft
- Ethics
- Patient Affairs

Purpose

The purpose of this proposal is to provide OPOs with clearer direction when offering multi-organ combinations by establishing criteria for when OPOs must offer the liver or kidney to heart or lung candidates listed for these organs.

The OPO Committee submits the following proposal under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing….policies for the equitable allocation of cadaveric organs"[6] and "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[7]

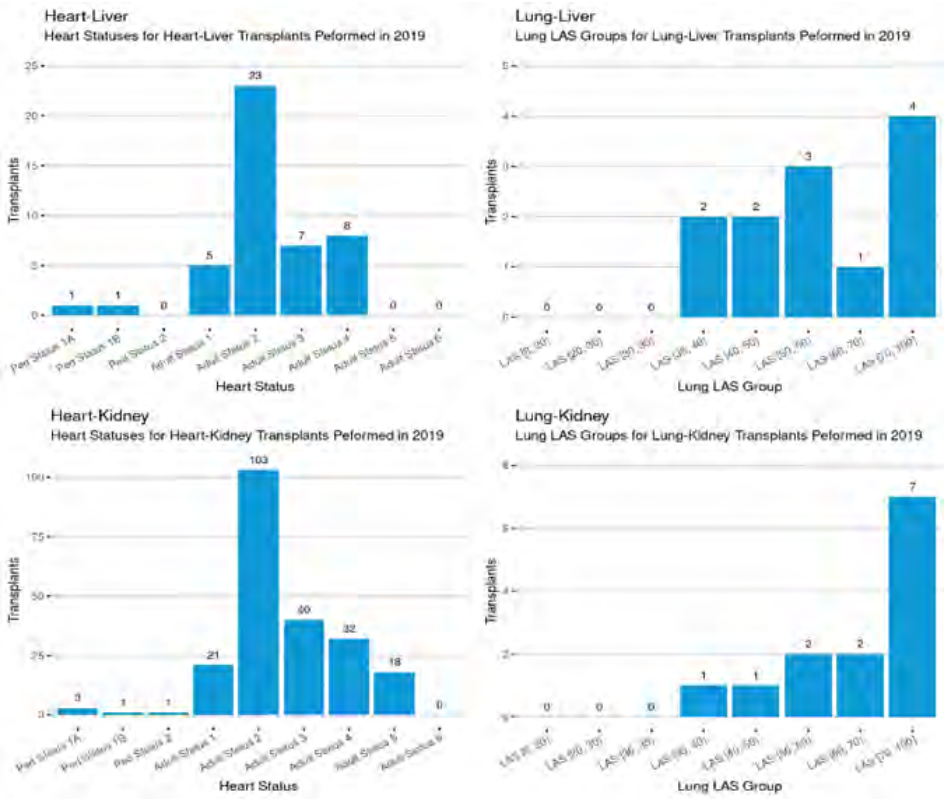
Overview of Proposal

The OPO Committee proposes adding medical criteria and increasing the distance for heart and lung candidates that require a second organ. The criteria will establish requirements for when OPOs must offer the second organ to the same candidate when allocating according to either the heart or lung match run. The Committee is also proposing clarity that the heart and lung match runs will drive the allocation of these combinations.

Heart and Lung Multi-Organ Criteria

The workgroup reviewed data on the statuses of multi-organ candidates who received heart-liver, lung-liver, heart-kidney, or lung-kidney transplants in 2019.[8] **Figure 2** shows the recipient statuses for these combinations of multi-organ transplants.

Figure 2: Recipient Statuses at Transplant (2019)



[6] 42 CFR §121.8(a)
[7] 42 CFR §121.8(a)(4)
[8] See Multi-Organ Policy Workgroup Meeting Summary, May 29, 2020. Available at https://optn.transplant.hrsa.gov/

The Committee proposes the following criteria for heart and lung candidates to receive offers for either a kidney or liver, if listed for a second organ:

- Heart Adult Status 1, 2, and 3, Pediatric Status 1A and 1B
- Lung Candidates with a lung allocation score of greater than 35

The statuses were determined based on the data shown in **Figure 2**. The higher status heart and lung candidates are admitted to the hospital, as required in *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.

For multi-organ transplants performed in 2019, the following multi-organ transplants would meet the proposed criteria:

- Heart-liver transplants - 37 of 45
- Heart-kidney – 169 of 219
- Lung-liver – 12 of 12
- Lung-kidney – 13 of 13

Several workgroup members were concerned about disadvantaging liver and kidney alone candidates if livers or kidneys are placed with heart or lung candidates listed for a second organ. It is important to note that the current policy does not prioritize multi-organ candidates over single organ candidates. Even with the proposed changes, OPOs will still be required to allocate organs according to current *Policy 2.2: OPO Responsibilities*, which states that OPOs execute the match run and use "the resulting match for each deceased donor allocation."

As referenced in the Ethics Committee white paper, Reese et al. outlined the challenges of identifying candidates who most benefit from a multi-organ transplant while also trying to avoid undermining utility (defined as optimal patient and graft survival).[9] For example, a heart status 1 candidate might receive the liver from the same donor regardless of model for end-stage liver disease (MELD) score when there is a higher status liver alone candidate in need of a liver transplant. Further complicating the issue is the difficulty in trying to evaluate such a small population of candidates. Goldberg et al. found that "although transplant is delayed, liver transplant waitlist candidates bypassed by heart-liver recipients do not have excess mortality compared to three sets of matched controls."[10]

Another consideration is the biological disadvantage of heart and lung candidates. Donor-recipient height, weight and gender matching are important factors in post-transplant outcomes. While recent publications, such as Eberlein et al., recommend changes to how thoracic organ sizes are measured, "donor-to-recipient organ size matching is a critical aspect of thoracic transplantation."[11] This can limit the number of offers that heart and lung candidates can accept and further impact those candidates needing a liver or kidney. This contributed to the decision to establish criteria for heart and lung candidates.

[9] Reese P, Veatch RM, Abt PL, and Amaral S. Revisiting Multi-Organ Transplantation in the Setting of Scarcity. *American Journal of Transplantation* 14, no. 1 (2013): 21-26. doi:10.1111/ajt.12557.
[10] Goldberg DS, Reese PP, Amaral S, Abt PL. Reframing the Impact of Combined Heart-Liver Allocation on Liver Transplant Waitlist Candidates. *Liver Transplantation*. 2014 November; 20(11): 1356–1364. doi:10.1002/lt.23957.
[11] Eberlein M, Reed RM. Donor to recipient sizing in thoracic organ transplantation. World Journal of Transplantation, 2016 March 24; 6(1): 155-164

The Committee believes that establishing criteria that provides access to the second organ for sicker heart and lung candidates aligns with current practice as the community awaits further work on eligibility criteria and safety nets for multi-organ allocation. The intent of this proposal is to provide clearer rules for OPOs when allocating a heart or lung according to the match run and a heart or lung candidate is listed for a liver or kidney. This proposal also allows OPOs the discretion to determine the best approach to placing organs according to OPTN policy, even if multi-organ candidates do not meet the criteria in this proposal.

Reference to Kidneys

Currently, *Policy 5.10.C: Other Multi-Organ Combinations* does not reference kidneys as the second required organ that must "be allocated to the multi-organ candidate from the same donor" within the geographic areas outlined in the policy. However, *Policy 9.9: Liver-Kidney Allocation* addresses the requirements for OPOs when a kidney is procured along with other organs. The OPO must first offer the kidney according to *Policies 5.10.C*, *9.9*, or *11.4.A: Kidney-Pancreas Allocation* before allocating to kidney alone candidates. This proposal does not affect an OPO's ability to decide which multi-organ policy to utilize when a kidney is procures with other organs.

The Committee agreed that it is common practice for OPOs to allocate the kidney from the same donor if a heart or lung candidate on the match run is also listed for a kidney. The absence of clear requirements in the current policy leads to inconsistent application of the rules. Therefore, the Committee proposes adding specific language addressing kidneys as part of heart-kidney and lung-kidney combinations. The Committee recognizes the impact that allocating kidneys to multi-organ candidates have on kidney alone candidates. A recent publication by Westphal et al. highlighted "the potential for multi-organ transplant prioritization to unintentionally introduce disparities in transplant access for kidney alone candidates."[12] This further underscores the importance of addressing multi-organ allocation policies in an era where the need outnumbers the supply.

The Committee acknowledges that this effort clarifies current policy but does not address medical eligibility criteria or a "safety net" as used in current simultaneous liver kidney (SLK) policy. The Committee is committed to clarifying current policy while working with stakeholders across the community during the impending effort to pursue these additional policies.

Change to Geographic Unit

The Committee is proposing changes to the distances outlined in current policy. The current distance is 250 nautical miles (NM) for heart and lung and 150 NM for liver, which are the smallest units of allocation for heart, lung, and liver. These distances were established when liver and thoracic policies changed from donation service area (DSA) to distance-based distribution.[13,14,15]

[12] Westphal, S. G., Langewisch, E. D., Robinson, A. M., Wilk, A. R., Dong, J. J., Plumb, T. J., Mullane, R., Merani, S., Hoffman, A. L., Maskin, A., & Miles, C. D. (2020). The impact of multi-organ transplant allocation priority on waitlisted kidney transplant candidates. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 10.1111/ajt.16390. Advance online publication. https://doi.org/10.1111/ajt.16390
[13] https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf
[14] https://optn.transplant.hrsa.gov/media/3003/thoracic_policynotice_201906.pdf
[15] https://optn.transplant.hrsa.gov/media/2539/thoracic_policynotice_201807_lung.pdf

The Committee proposes increasing the distance to 500 NM to better align with current heart allocation. This will allow the candidates with the proposed statuses to access a liver or kidney if needed. For example, the classifications for Status 1 and 1A heart candidates start at 500NM according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old* and *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*.

The Committee also proposes 500 NM for lung candidates in order to be consistent within the proposed policy. The allocation of lungs from donors at least 18 years old begins with 250 NM for classifications 1-6 followed by 500 NM for classifications 7-12.[16] The allocation of lungs from donors less than 18 years of age begins with 1000 NM, which presents more logistical challenges when allocating multi-organ combinations. However, the proposed distance of 500 NM does not prevent OPOs from having the discretion to place a kidney or liver with a candidate outside the 500 NM circle.

Clarity on Match Runs

The current policy provides little direction for OPOs regarding which match run to use when allocating multi-organ combinations. While this proposal does not establish OPO requirements for which organs must be allocated first, it does provide clarity that OPOs allocating according to the heart or lung match run must offer the liver or kidney to a candidate listed for the second organ if they meet the proposed criteria. The criteria based on proposed medical urgency and 500NM will determine when the OPO must offer the second organ. This proposal does not mandate which match run to start with – therefore allowing for OPO discretion.

Other Considerations

The multi-disciplinary workgroup discussed creating policies to require OPOs to allocate organs to higher status kidney or liver alone candidates if no higher status heart or lung candidates required a second organ. This would be required before allocating the second organ to other multi-organ candidates that do not meet the proposed criteria.

There are several challenges to creating such policy requirements. There is a lack of consistency in organs available per donor as well as the quality of organs. Additionally, there are multiple considerations for how proposed changes may affect other OPTN policies. For example, establishing a mandate that OPOs allocate to kidney alone candidates prior to other multi-organ candidates would need to align with kidney-pancreas or simultaneous liver-kidney policies.

The Committee ultimately decided not to move forward with policy requirements to address the examples shown above. The various multi-organ scenarios discussed by the Committee outlined the challenges in developing a multi-organ policy that provides clear rules for OPOs. The Committee acknowledges that this proposal is an important step forward in MOT policy, but does not address all of multi-organ combinations. The Committee is committed to working with stakeholders across the community to continue to address multi-organ allocation policies. The next phase of this effort will address other multi-organ combinations, with eligibility criteria for heart-kidney identified as the next step.

[16] OPTN Policy 10, Allocation of Lungs (April 15, 2020)

Additional Policy Changes

As the OPTN moves forward with future multi-organ policy changes, it might be beneficial to the transplant community to consolidate multi-organ policies into one location. Therefore, as a first step, the Committee proposes several non-substantive policy modifications.

Policy 5.10: Allocation of Multi-Organ Combinations currently includes the following sections:

- *Policy 5.10.A: Allocation of Heart-Lungs*
- *Policy 5.10.B: Allocation of Liver-Kidneys*
- *Policy 5.10.C: Other Multi-Organ Combinations*.

The first two sections provide references to heart-lung and liver-kidney policies and do not contain substantive policy requirements. The Committee proposes two new policy sections, *5.10.C: Allocation of Kidney-Pancreas* and *5.10.D: Allocation of Liver-Intestines* that will reference kidney-pancreas and liver-intestine policies and serve as placeholders for future consolidation of multi-organ policies. Below is the proposed structure for *Policy 5.10: Allocation of Multi-Organ Committee*:

5.10: Allocation of Multi-Organ Combinations

- *5.10.A: Allocation of Heart-Lungs*
- *5.10.B: Allocation of Liver Kidneys*
- *5.10.C: Allocation of Kidney-Pancreas*
- *5.10.D: Allocation of Liver-Intestines*
- *5.10.E: Other Multi-Organ Combinations*

Additional changes include relocating policy language from *Policy 9.9: Liver-Kidney Allocation* to kidney policy. The rationale for this change is that the policy language focuses on kidney allocation as part of multi-organ combinations. This change will not affect liver-kidney allocation policy.

Next Steps

As stated in the previous sections, this proposal by the Committee is the first step in a long-term effort and strategic policy priority by the Policy Oversight Committee (POC). The OPO Committee will collaborate with clinical and organ-specific committees in the coming efforts to further address other multi-organ OPTN policies to ensure efficient and equitable access to transplant for multi-organ and single-organ candidates.

NOTA and Final Rule Analysis

The OPO Committee submits this proposal under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing….policies for the equitable allocation of cadaveric organs"[17] and "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[18]

[17] 42 CFR §121.8(a)
[18] 42 CFR §121.8(a)(4)

The Final Rule 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 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." This proposal:

- **Is based on sound medical judgment:**[19] The Committee proposes this change based on the medical judgment of OPO professionals, transplant surgeons, and members of eleven stakeholder committees in deriving the proposed changes. The Committee's recommendations were informed by reviews of OPTN data and peer review literature.
- **Is designed to avoid wasting organs:**[20] The Committee believes this proposal will decrease 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 seeks to avoid organ loss by ensuring clear rules for allocating multi-organ combinations while also allowing OPOs the flexibility to make discussions related to organ placement.
- **Shall be designed to…to promote the efficient management of organ placement:**[21] This proposal provides clear rules for when to offer the second organ with the heart or lung. This reduces inconsistent application created by the current policy language.

This proposal also preserves the ability of a transplant program to decline and offer or not use the organ for a potential recipient,[22] and it is specific to various combinations of organ types.[23]

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:

- This proposal is not based on a candidate's place of residence or place of listing

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[24] The Committee did not identify any populations may be treated "less favorably than they would have been treated under the previous policies" if these proposed policies are approved by the Board of Directors, and does not recommend any particular transition procedures.

[19] 42 CFR §121.8(a)(1)
[20] 42 CFR §121.8(a)(5)
[21] 42 CFR §121.8(a)(5)
[22] 42 CFR §121.8(a)(3)
[23] 42 CFR §121.8(a)(4)
[24] 42 CFR §121.8(d)

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

OPOs will continue allocating donor organs according to the heart and lung match runs. OPO staff will need to be aware of the new requirements for when the liver or kidney is offered to a heart or lung potential transplant recipient.

Operations affecting Transplant Hospitals

Transplant programs may be impacted by the change to 500NM for heart and lung candidates who need either a liver or kidney. In practice, transplant programs receiving offers for both organs should evaluate the logistics and work with the host OPO to facilitate placement.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories

Operations affecting the OPTN

This proposal will require programming in UNet^{SM} to include a visual indicator on the organ match runs to display candidates who meet the requirements for multi-organ allocation. This is meant to aid the OPO in determining if multi-organ allocation requirements have been met prior to offering the second required organ. Proposed programming does not require approval from the federal Office of Management and Budget (OMB).

Potential Fiscal Impact of Proposal

OPOs

Policy and programming changes associated with this proposal adds efficiency and consistency across systems because it creates a better organ matching system. Current workflow varies at each OPO for multi-organ allocation, but minimal effort is needed to adjust and create these efficiencies.

Transplant Hospitals

There is no or minimal expected fiscal impact for transplant hospitals.

Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on the OPTN

Preliminary estimates indicate that this will be a medium effort, as over 700 hours may be needed for IT programming, communication, educational efforts, and post-implementation monitoring.

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."[25]

The proposed language will not change the routine allocation monitoring of OPTN members. The OPTN will continue to review all deceased donor match runs that result in a transplanted organ and will continue to investigate potential policy violations.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[26] This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available (appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data to UNet℠) and compared to an appropriate pre-implementation cohort.

For heart-liver, heart-kidney, lung-liver, and lung-kidney:

- Number of multi-organ transplants
    - Stratify by required vs permissible share
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - Stratify by distance from donor hospital to transplant center
    - By OPTN Region
- Number of deaths on the waiting list for multi-organ candidates
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - By OPTN Region
- Waitlist volumes for multi-organ candidates
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - By OPTN Region

Conclusion

This proposal addresses the initial phase of the POC strategic policy priority to address multi-organ policies by clarifying OPTN *Policy 5.10.C: Other Multi-Organ Combinations*. The OPO Committee proposes criteria for when OPOs are required to offer the liver or kidney, if available, from the same donor. For heart candidates, the criteria will include adult status 1, 2, and 3 and pediatric 1A and 1B. For lung candidates, the criteria will include candidates with a lung allocation score of greater than 35.

[25] 42 CFR §121.8(a)(7)
[26] 42 CFR §121.8(a)(6)

Additionally, the proposed distance for this mandatory offer will be increased from the current 150 nautical miles (NM) for liver and 250 NM for heart and lung to a 500 nautical miles circle to better align with thoracic allocation policies.

The Committee is also proposing additional policy changes as the initial step towards consolidating multi-organ allocation policies.

The Committee proposes these policy changes to promote efficient and equitable allocation for these multi-organ combinations. This proposal is a continuation of previous efforts and builds a foundation for the continued work within the strategic policy priority to address multi-organ allocation policies.

The Committee encourages all interested individuals to comment on this proposal in its entirety, but specifically asks for feedback on the following:

1. Is Heart Adult Status 1, 2, 3 and Pediatric Status 1A and 1B appropriate thresholds for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?
2. Is a lung allocation score of greater than 35 an appropriate threshold for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?
3. Is 500 NM an appropriate distance for when OPOs must offer a liver or kidney to a multi-organ candidate meeting the proposed criteria?
4. Do you believe all multi-organ policies should be located in the same section of policy?

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, and cross-references affected by the numbering of these policies will be updated as necessary.

5.10 Allocation of Multi-Organ Combinations

5.10.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to *Policy 6.6.F: Allocation of Heart-Lungs*.

5.10.B Allocation of Liver-Kidneys

Liver-kidney combinations are allocated according to *Policy 9.9: Liver-Kidney Allocation*.

5.10.C Allocation of Kidney-Pancreas

Kidney-pancreas combinations are allocated according to *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets.*

5.10.D Allocation of Liver-Intestines

Liver-intestine combinations are allocated according to *Policy 9: Allocation of Livers and Liver-Intestines*

5.10.E Other Multi-Organ Combinations

~~When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor according to *Table 5-4.*~~

~~**Table 5-4**~~

~~**Organ**~~	~~**Candidate is registered at a transplant hospital that is at or within the following this distance of the donor hospital**~~
~~Heart~~	~~250NM~~
~~Liver~~	~~150NM~~
~~Lung~~	~~250NM~~

~~If the multi-organ candidate is on a waiting list outside the geographical areas listed above, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.~~

When an OPO is offering a heart or lung, and a liver or kidney is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-4* must be offered the second organ.

Table 5-4 Second Organ for Heart or Lung PTRs

If the OPO is offering to PTRs appearing on the following match run:	And a PTR is also registered for one of the following organs:	The OPO must offer the second organ if the PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and meets the following criteria:
Heart	Liver or Kidney	Heart Adult Status 1, 2, 3 or pediatric 1A or 1B
Lung	Liver or Kidney	Lung allocation score of greater than 35

It is permissible for the OPO to offer the second organ to other multi-organ PTRs that do not meet the criteria above.

If the OPO is offering to PTRs appearing on either the heart or lung match runs, and two PTRs appear that both meet the criteria in *Table 5-4*, it is permissible for the OPO to offer the second organ to the PTR on the heart match run or the PTR on the lung match run, at the OPO's discretion.

8.7.C. Kidney Allocation in Multi-Organ Combinations

If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to one of the following policies before allocating the kidney to kidney alone candidates according to Policy 8: Allocation of Kidneys:

- *Policy 5.10.E: Other Multi-Organ Combinations*
- *Policy 9.9: Liver-Kidney Allocation*
- *Policy 11.4.A: Kidney-Pancreas Allocation Order*

8.7.~~C~~.D Multi-Organ Combinations Allocated but Not Transplanted

8.7.~~D~~.E Location of Donor Hospitals

9.9 Liver-Kidney Allocation

~~If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to one of the following policies before allocating the kidney to kidney alone candidates according to Policy 8: Allocation of Kidneys:~~

- ~~*Policy 5.10.C: Other Multi-Organ Combinations*~~
- ~~*Policy 9.9: Liver-Kidney Allocation*~~
- ~~*Policy 11.4.A: Kidney-Pancreas Allocation Order*~~

If a host OPO is offering a kidney and a liver from the same deceased donor, then before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to candidates who meet eligibility according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation* and are one of the following:

1. Within 150 nautical miles of the donor hospital and have a MELD or PELD of 15 or higher
2. Within 250 nautical miles of the donor hospital and have a MELD or PELD of at least 29
3. Within 250 nautical miles of the donor hospital and status 1A or 1B.

The host OPO may then do either of the following:

1. Offer the kidney and liver to any candidates who meet eligibility in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*.
2. Offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-Intestines* and offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.