

## At-a-Glance

- **Proposal to increase the safety of allocations to candidates who do not appear on the match run**
- **Policies affected: Policy 3.1 (Definitions), Policy 3.2.4 (Match System Access), and Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates)**

- **Membership and Professional Standards Committee**

- **Summary of proposal**

The revision to Policy 3.1 will incorporate the definition of a directed donation into OPTN policy. The revision to Policy 3.2.4 will require the Transplant Center to:

- determine why the candidate does not appear on the organ match run for the donor, and
- verify that the donor organ is safe and appropriate for the candidate by comparing donor information and candidate information available in UNet<sup>SM</sup> before the transplant.

The revision to Policy 3.9.3 will clarify that when multiple organs are allocated to a single recipient, the term “on a match run” means that the recipient must appear on the heart, lung, or liver match run. **This clarification does not alter the organ allocation sequence defined by organ allocation policy.**

- **Affected groups**

Transplant Candidates, Donor Families, Public, OPO Executive Directors, OPO Medical Directors, OPO PR/Public Education Staff, OPO Procurement Coordinators, Transplant Program Directors, Transplant Administrators, Transplant Coordinators, Transplant Social Workers, Transplant Physicians, Transplant Surgeons, Transplant PR/Public Education

- **Specific requests for comment**

For transplant center staff:

- How difficult will it be to incorporate the additional requirements into your current processes?
- Will the additional requirements increase the safety of transplants for candidates who do not appear on the match run?
- Will the extra effort associated with the proposed requirements balance the potential increase in safety?

For all readers: Please consider and comment on the entire proposal. Please do not feel limited to the focused questions.

## **Proposal to increase the safety of allocations to candidates who do not appear on the match run**

**Policies Affected: Policy 3.1 (Definitions), Policy 3.2.4 (Match System Access), and Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates)**

### **Membership and Professional Standards Committee (MPSC)**

#### **Summary and Goals of the Proposal:**

This proposal adds the definition of directed donation to policy; requires the transplant center to compare specific donor and candidate characteristics before transplanting a candidate who did not appear on the match run; and clarifies what “on a match run” means for a multi-organ candidate. This purpose of this proposal is to:

- increase the safety of allocations to candidates who do not appear on the match run
- prevent future policy violations by promoting a clear understanding of what a member is required to do when a candidate does not appear on a match run

The goals of this proposal are to:

- extend the same safety screening performed by the match run to candidates who cannot appear on the match run
- promote a consistent understanding of directed organ donations
- promote a consistent understanding of what “on a match run” means for a recipient of multiple organs from the same donor
- provide clear policy language to improve OPTN members’ ability to comply with policy and the MPSC’s ability to assess potential policy violations

#### **Background and Significance of the Proposal:**

The MPSC reviews potential violations of OPTN policies and OPTN/UNOS bylaws. Allocating an organ to a candidate who does not appear on the match run is a potential violation of Policy 3.2.4 and is reviewed by the MPSC. In the course of reviewing these allocations, the MPSC has identified the need to provide instruction to members about what to do when a candidate does not appear on the match run. The MPSC intends to do this by:

- including in OPTN policy the definition of a directed organ donation (Policy 3.1(Definitions));
- creating new requirements for verifying suitability of the donor organ for the candidate when an organ is allocated to a candidate who does not appear on the match run (Policy 3.2.4 (Match System Access)); and
- clarifying on which match runs a multi-organ candidate must appear for the allocation to be considered to a candidate who is “on the match run” (Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates)).

The computer match system operated by the OPTN:

- compares data entered into UNet<sup>SM1</sup> for transplant candidates and organ donors;

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<sup>1</sup>UNet<sup>SM</sup> is the web-based electronic utility used by the OPTN contractor to conduct the business of the OPTN. UNet<sup>SM</sup> comprises the Match System, all software, applications and security architecture needed for the collection, modification, validation, reporting, management and redundancy of data associated with the tasks and activities of the OPTN.

- incorporates organ acceptance criteria specific to each candidate;
- eliminates candidates who are not suitable for the donor organ;
- ranks candidates according to approved OPTN policies; and
- produces a “match” or “match run” consisting of potential recipients in sequential order according to the priority defined by OPTN allocation policy.

The match system is programmed to identify candidates who are not suitable for the donor in many aspects, such as ABO, serologies, HLA, and size, and then prevent these candidates from appearing on the match run. By doing this, the match system acts as both an allocation tool and a safety mechanism, ensuring *basic compatibility* between the donor and recipient. It is the transplanting surgeon’s responsibility<sup>2</sup> to ensure *medical suitability* of an organ for a recipient.

The problem is that Policy 3.2.4<sup>3</sup> currently requires all organ recipients to appear on an organ match run. However, there are other policies that prevent the member from complying with this requirement in some organ allocation scenarios. UNOS staff have identified three scenarios in which policies conflict and prevent a recipient from appearing on a match run. These scenarios include:

- directed donations;
- compatible transplants intended to prevent organ wastage; and
- multiple organ allocation to a single recipient.

**Directed donation scenario:** A donor family wishes to donate a kidney to a named candidate who does not appear on the match run because the donor is a blood type “O” and the candidate is a blood type “A.” The donor and candidate have compatible blood types, but they do not have identical blood types, and the candidate is not a zero antigen mismatch with the donor. OPTN Policy 3.5.2<sup>4</sup> requires blood type “O” kidneys to be allocated to blood type “O” recipients. According to this policy, the match system is programmed so that a kidney match run will only display a compatible, non-identical candidate if the candidate is a zero antigen mismatch with the donor. (Please note: although some candidates are not able to appear on a specific donor organ match run, transplant centers are not prevented from adding transplant candidates to the waiting list. In fact, Policy 3.2.1<sup>5</sup> requires all potential recipients of deceased donor organ transplants to be listed.)

**Organ wastage scenario:** There are instances in which the only way to prevent wasting a kidney is to perform a compatible, but non-identical transplant. An example is:

- An OPO allocates a kidney to a zero antigen mismatched candidate located out-of-state, but weather prevents the kidney from being shipped out of the recovery area in a timely manner. The transplant center that initially accepted the organ declines because the organ cannot arrive with an acceptable amount of cold ischemic time. The donor is a blood type “B” and there are a limited number of local blood type “B” candidates; many are either unavailable or have already cross-matched positive. With limited tissue typing materials

<sup>2</sup> To review this existing requirement, refer to OPTN Policy 3.1.2 (Transplant Center), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_3.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_3.pdf).

<sup>3</sup> To review this existing requirement, refer to OPTN Policy 3.2.4 (Match System Access), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_4.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_4.pdf)

<sup>4</sup> To review OPTN Policy 3.5.2 (ABO “O” Kidneys into ABO “O” Recipients and ABO “B” Kidneys into ABO “B” Recipients), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_7.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_7.pdf).

<sup>5</sup> To review this existing requirement, refer to OPTN Policy 3.2.1 (Mandatory Listing of Potential Recipients), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_4.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_4.pdf)

remaining, a local kidney transplant program has a candidate who is compatible with the donor (blood type “AB”) and is available and appropriate for transplant.

According to OPTN Policy 3.5.2<sup>6</sup>, the blood type “AB” candidate cannot appear on the kidney match run for this donor. It would be a violation of OPTN Policy 3.2.4<sup>7</sup> to allocate this kidney to a candidate who does not appear on the match run. The OPTN Final Rule<sup>8</sup> states that a transplant program shall not be prohibited from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. (Please note: Policy 3.5.2<sup>9</sup> allows for appropriate medical judgment in extreme circumstances.)

**Multiple organ allocation to a single recipient scenario:** A candidate waiting for a liver/kidney transplant is eligible to receive the liver from a local donor according to the liver match run. The donor is a blood type “O” and the recipient is a blood type “A.” The match system is programmed according to Policy 3.5.2<sup>10</sup>, and this candidate cannot appear on the match run for the kidney. If the transplant center receives the liver offer for this candidate, and the donor is local, then the kidney must also be offered for that candidate according to Policy 3.9.3<sup>11</sup>. (Please note: although some candidates are not able to appear on a specific donor organ match run, Transplant Centers are required to add candidates to the waiting list *for every organ that is required*, when one of the organs is a heart, liver or lung. Please refer to Policy 3.9.3<sup>12</sup> to review the exact language.)

**Other scenarios:** There are other scenarios in which a candidate does not appear on the match run, but the candidate could appear on the match run if the Transplant Center modified the candidate’s listing criteria and the OPO generated another organ match run. (Please note: in no way does this statement require or encourage the Transplant Center to change acceptance criteria that would make a donor organ inappropriate or unsafe for the candidate. These scenarios are only intended to illustrate examples).

Some scenarios include:

- Minimum donor acceptance criteria – if a candidate’s minimum acceptance criteria (e.g. age, height, weight, etc.) is set too narrow for a particular donor, and the criteria are used by the match system for that organ type, then the candidate could be screened off the match run.
- Unacceptable antigens – if the candidate is listed for a multi-organ transplant, such as a liver/kidney transplant, it is possible that one match run (e.g. liver) was generated before the HLA was available. If the kidney match run was generated after the HLA was entered,

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<sup>6</sup> To review OPTN Policy 3.5.2 (ABO “O” Kidneys into ABO “O” Recipients and ABO “B” Kidneys into ABO “B” Recipients), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_7.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_7.pdf).

<sup>7</sup> To review this existing requirement, refer to OPTN Policy 3.2.4 (Match System Access), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_4.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_4.pdf)

<sup>8</sup> Refer to § 121.7 Identification of organ recipient (e) Wastage of the Final Rule to review the exact language. The Final Rule is available at [http://www.optn.org/policiesAndBylaws/final\\_rule.asp](http://www.optn.org/policiesAndBylaws/final_rule.asp).

<sup>9</sup> To review OPTN Policy 3.5.2 (ABO “O” Kidneys into ABO “O” Recipients and ABO “B” Kidneys into ABO “B” Recipients), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_7.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_7.pdf).

<sup>10</sup> To review OPTN Policy 3.5.2 (ABO “O” Kidneys into ABO “O” Recipients and ABO “B” Kidneys into ABO “B” Recipients), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_7.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_7.pdf).

<sup>11</sup> To review OPTN Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_11.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_11.pdf)

<sup>12</sup> To review OPTN Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_11.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_11.pdf)

and the donor had an antigen that was unacceptable for the candidate, then the candidate would not appear on the kidney match run but could appear on the liver match run.

- Other donor characteristics – if the candidate is listed for a multi-organ transplant, such as liver/kidney, and the donor is an expanded criteria kidney donor, then the candidate may appear on the liver match run but not on the kidney match run.

### **Collaboration:**

The MPSC collaborated with the Operations and Policy Oversight Committees to prepare this proposal for public comment distribution.

The Operations Committee reviewed the proposed changes to Policies 3.1, 3.2.4, and 3.9.3 during its April 17 meeting. The Operations Committee offered the following feedback to the MPSC:

- Policy 3.2.4 – the Committee was supportive of the proposed changes to this policy and suggested that the MPSC define when the Transplant Center is required to provide written justification to the OPTN in the policy language. The sentence that prompted this suggestion is included below:
  - “If the Transplant Center deems it necessary to transplant a candidate who does not appear on a match run for the donor, such as in the event of a directed organ donation or to prevent organ wastage, the Transplant Center must maintain all related documentation and **provide written justification to the OPTN.**”
- Policy 3.1 – the Committee was supportive of including in policy language the definition of a directed donation. The Committee offered these suggestions to the MPSC:
  - The proposed language is worded in a negative fashion and should be defined in a positive way. Instead of stating that “Nothing in OPTN Policy shall prohibit...” reword it to state “OPOs are permitted to...”
  - The Committee had questions about state Uniform Anatomical Gift Act (UAGA) laws that may be in conflict with the Final Rule because some state laws allow the directed donation of an organ to a hospital instead of limiting the donation to a specific candidate. If you keep the donor families and their wishes in mind, is it truly prohibited to honor a family’s wish to direct an organ donation to a local transplant program? The Committee requested clarification on this matter.
  - The Committee had questions about the documentation an OPO must maintain in a directed donation situation. Specifically, the Committee wanted to know what the OPO’s responsibility was to verify (and document) that the candidate was on the waiting list at a transplant center and wanted to know what documentation the MPSC would expect to see from the donor family about the directed donation. The Committee suggested that if there is specific documentation the MPSC would expect the OPO to maintain and provide about a donor family’s wishes, it would be helpful to define the documentation requirement and communicate it to the OPOs.

The Policy Oversight Committee reviewed the proposed changes to Policies 3.1, 3.2.4, and 3.9.3 during its April 17 meeting. The Policy Oversight Committee offered the following feedback to the MPSC:

- Please specify if there is additional documentation that the OPO must maintain for a directed donation that is not included in the routine documentation that the OPO must maintain for donated organs.
- Please make it clear, either through policy language or the Evaluation Plan document, how members are expected to submit documentation to the OPTN.

The MPSC appreciated this input and considered the feedback while crafting the final proposal.

**Alternatives considered:**

UNOS staff presented an alternative policy modification to the MPSC during its February 1, 2008 meeting. That alternative included requiring the Transplant Center and OPO to work together to get the candidate on the match run when possible, meaning the Transplant Center would have to modify the candidate's screening criteria (when appropriate and possible), and then the OPO would have to generate an additional match run.

The main benefit of that alternative would have been a decrease in the number of organ allocations to a candidate who did not appear on the match run. However, there were several potential negative consequences to that alternative including:

- a conflict with Policy 3.6.5.1<sup>13</sup>; and
- the potential for decreasing the efficiency of organ placement and creating an undue burden for OPO staff because refusal codes generally do not cascade from one match run to future match runs (exception for donor refusals).

After considering the alternative policy modification, the MPSC provided this feedback to staff:

- the policy changes should not undermine or create conflict with existing policies;
- the language should not empower transplant centers to transplant candidates who do not appear on the match run; and
- the legitimate reasons why a transplant center may transplant a candidate who does not appear on the match run should be included in the language.

As a separate but coordinated effort, the Operations Committee explored the possibility of a technological solution for directed kidney donations to candidates of a compatible blood type who could not appear on the match run because of Policy 3.5.2<sup>[1]</sup>. One of the options considered was to give OPOs and Transplant Centers the technical ability to create a match run that would only show one candidate (the named recipient of the directed kidney donation). This strategy would enable the candidate to receive the benefit of the screening performed by the computer match program. Because this solution would only address the directed donation scenario, and was resource intensive, the Operations Committee chose to stop working on technological solutions and assist with the policy development effort.

**Strengths and weaknesses:**

The major strength of this proposal is the enhanced safety for candidates who cannot appear on the match run. This change requires the Transplant Center to verify that the donor organ is safe and appropriate for the candidate before transplanting the organ. The language includes a requirement for these actions to be documented so that compliance with this policy can be monitored and evaluated.

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<sup>13</sup> To review Policy 3.6.5.1 (Execution of the Liver Match System), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_8.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_8.pdf)

<sup>[1]</sup> To review OPTN Policy 3.5.2 (ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients), go to [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy\\_7.pdf](http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_7.pdf).

An additional strength is that this change will give OPOs and Transplant Centers written instruction about what to do when a candidate does not appear on the match run. By clearly stating requirements in policy language, the OPTN is promoting:

- policy compliance;
- consistent organ allocation practice throughout the community; and
- a process for recipients who cannot appear on a match run to receive the same safety checks prior to transplant as recipients who do appear on the match run.

Weaknesses of this proposal include:

- an increased burden for Transplant Centers and OPOs related to the additional requirements;
- a potential delay in organ placement and transplant related to the additional requirements; and
- the lack of an objective way to measure if the changes increase safety for recipients who cannot appear on a match run.

#### **Description of intended and unintended consequences:**

The intended consequences of the proposed changes are:

- a decrease in the number of organ allocations to a recipient who did not appear on the match run; and
- an increase in safety for candidates who cannot appear on a match run.

The potential unintended consequences of the proposed changes are:

- the increase in burden for members to comply with these requirements being so great that OPOs and Transplant Centers are unable to perform other, vital, responsibilities; and
- an increase in organ placement time caused by the additional requirements that results in fewer organs being placed for transplant.

To monitor, measure, and evaluate the consequences of these changes, the MPSC plans to continue to review allocations to candidates who did not appear on a match run. This information is currently identified by UNOS staff and forwarded to the MPSC for review on a quarterly basis, or more frequently as appropriate to the occurrence. In addition to this mechanism for review, the MPSC receives and reviews the complaints and information related to potential policy violations that is reported to UNOS staff through the OPTN Member Reporting Line and the UNOS Patient Services Line.

Some of the potential unintended consequences of these changes relate to an increased burden. The MPSC requests members to submit information related to the burden of these changes to the MPSC for review. To clarify, feedback available during the public comment cycle should be submitted through the public comment process feedback mechanisms. Any feedback available after these changes are approved and implemented should be submitted to the MPSC through the Member's UNOS Regional Administrator.

### **Supporting Evidence:**

From June, 2007 through May, 2008, there were 116 instances of allocations to a recipient not on a match run. Kidney was the most common organ, accounting for 94 (81%) of the total cases. For kidney, in more than half the cases the recipient was not on the match run because the donor ABO was O and the recipient was not. Of the 15 cases of liver transplants, 7 (47%) were due to the patient being listed after the match was run. Details on the reasons for all 116 instances are provided in Exhibit 1.

### **Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

This proposal will address the Strategic Plan Goal of improving compliance with policies in order to protect patient safety and preserve public trust in transplantation. Requiring the Transplant Center to determine why a candidate does not appear on a match run will help to prevent transplants that are not safe or appropriate for the candidate.

Incorporating the definition of a directed donation, and requirements related to candidates who do not appear on a match run into policy language, increases consistency in organ allocation practice throughout the community. By clearly communicating expectations, these policy revisions will help to reduce geographic variability in transplantation because transplant candidates who cannot appear on a match run will receive the same safety checks prior to transplant, no matter where the candidates are located.

### **Plan for Evaluating the Proposal:**

The hypotheses guiding this proposal are:

- **If** the Transplant Center is required to ensure that an organ is safe and appropriate for the candidate, when the candidate does not appear on the match run, **then** the safety of transplant for candidates who cannot appear on the match run will increase.
- **If** policy language clearly states what the Transplant Center is expected to do when the candidate does not appear on the match run, **then**:
  - compliance with these policies will improve; and
  - the MPSC's ability to assess potential violations of these policies will improve.

### **Policy Performance Measures:**

UNOS staff will continue to monitor organ allocations and refer potential policy violations to the MPSC for review. To evaluate the performance of these policy changes, the MPSC may also review the following information on a yearly basis:

- the number of allocations to a candidate who did not appear on a match run; and
- the reason the candidate did not appear on the match run.

### **Additional data collection:**

The proposed modifications will not require additional data collection. The proposed modifications will require the OPO and Transplant Center to comply with additional requirements, document compliance with the additional requirements, maintain this documentation, and provide this documentation upon request.

**Expected Implementation Plan:**

If approved, transplant centers will be expected to document why a candidate did not appear on a match run, verify that the donor organ is safe for the candidate, and provide a written justification for why it transplanted a candidate not on the match. This documentation must be maintained and submitted. The proposed policy changes do not require programming in UNet<sup>SM</sup>.

**Communication Plan:**

Information about new or modified policy language is communicated to the transplant community through the Policy Notice. The Policy Notice is distributed via e-mail and posted to the OPTN and UNOS websites approximately one month after the Board of Directors approves the changes. After the changes are implemented, the OPTN Evaluation Plan will be updated to include the policy changes. The OPTN Evaluation Plan explains how UNOS, as the OPTN contractor, assesses OPTN member compliance with Policies and Bylaws.

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice [This notice informs the community that the modifications were approved by the OPTN/UNOS Board of Directors.]	OPOs, Transplant Centers, Histocompatibility Laboratories	Email	Distributed 30 days after Board approval
OPTN Evaluation Plan [This document explains to OPTN Member transplant centers, OPOs and histocompatibility labs how UNOS, as the OPTN contractor, assesses compliance by those members with OPTN Policies and By-laws. The Plan also includes specific expectations as to how Members remain in compliance.]	OPOs, Transplant Centers, Histocompatibility Laboratories	Posted on OPTN website and notice of updated document sent via email	Distributed quarterly

**Compliance Monitoring:** The OPTN currently monitors for member compliance with organ allocation policies in different ways, including analysis of organ allocations and site surveys of member organizations. The proposed changes will potentially affect both areas, and more specific details about

OPTN/UNOS monitoring efforts will be available in the OPTN Evaluation Plan following implementation of these policy changes.

UNOS staff monitors organ allocations to ensure organs are allocated according to the match run sequence generated by the OPTN computer match system.

The computer match system operated by the OPTN:

- compares data entered into UNet<sup>SM</sup> for transplant candidates and organ donors;
- incorporates organ acceptance criteria specific to each candidate;
- eliminates candidates who are not suitable for the donor organ;
- ranks candidates according to approved OPTN policies; and
- produces a match run consisting of potential recipients in sequential order according to the priority defined by OPTN allocation policy.

UNOS staff makes a written inquiry into allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into UNet<sup>SM</sup> for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

If these changes are approved and implemented, then UNOS staff would modify its processes to incorporate monitoring members for compliance with the additional requirements. For example, when UNOS staff does not receive a preemptive written explanation of an allocation to a recipient not on the match, UNOS staff will request additional documentation including:

- verification that the transplant center determined the reason the candidate was not on the match run;
- verification that the transplant center determined suitability of the donor organ for the recipient prior to transplant; and
- the rationale for transplanting a candidate who did not appear on the match run.

Staff would continue to refer all potential policy violations to the MPSC for review. The MPSC retains its authority to take action when it deems appropriate.

### **Policy Proposal:**

**3.1.13 Definition of Directed Donation** – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the Transplant Center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. The Transplant Center must maintain all related documentation and provide written justification to the OPTN upon request. The written justification must include:

- the rationale for transplanting the candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run; and

- documentation that the Transplant Center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
  - ABO;
  - Serologies;
  - Willingness to Accept an Expanded Criteria Donor Organ;
  - Willingness to Accept a Donation after Cardiac Death Donor Organ;
  - Donor HLA and Candidate's Unacceptable Antigens;
  - Height; and
  - Weight.

**3.2.4 Match System Access.** OPOs are required to use the Match System (UNet<sup>SM</sup>) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9 and 3.8.5) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure utilizing the ABO source documents for on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNet<sup>SM</sup>.

Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run.

If the Transplant Center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type, such as in the event of a directed donation or to prevent organ wastage, the Transplant Center must maintain all related documentation and provide written justification to the OPTN upon request. The written justification must include:

- the rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run; and
- documentation that the Transplant Center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
  - ABO;
  - Serologies;
  - Willingness to Accept an Expanded Criteria Donor Organ;
  - Willingness to Accept a Donation after Cardiac Death Donor Organ;
  - Donor HLA and Candidate's Unacceptable Antigens;
  - Height; and
  - Weight.

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

**3.9.3 Organ Allocation to Multiple Organ Transplant Candidates.** Candidates for a multiple organ transplant where one of the required organs is a heart, lung or liver shall be registered on the individual Waiting list for each organ. When the candidate is eligible to receive a heart, lung or liver pursuant to Policies 3.6 (ALLOCATION OF LIVERS) and 3.7 (ALLOCATION OF THORACIC ORGANS) or an approved variance to these policies, the second required organ shall be allocated to the multiple organ candidate from the same donor if the donor is located with the same local organ distribution unit where the multiple organ candidate is registered. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type shall be paid back to the Host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney in which case the organ shall be paid back pursuant to Policy 3.5-4-5 (Payback Requirements). This policy shall not apply to the allocation of heart-lung combinations. Heart-lung combinations shall be allocated in accordance with Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) and all other applicable provisions of Policy 3.7, or an approved variance to these policies. For candidates awaiting a combined liver-intestine transplant, please refer to Policy 3.11.4 or Policy 3.6.4.8.

Candidates who:

- have been listed for multiple organs, and
- are eligible to receive a heart, lung or liver pursuant to Policies 3.6 (ALLOCATION OF LIVERS) and 3.7 (ALLOCATION OF THORACIC ORGANS) or an approved variance to these policies, must

appear on the heart, lung, or liver match run.

Candidates who:

- have been listed for multiple organs, and
- have been named as the recipient of a directed organ(s) donation by the person(s) who authorized the donation, must

appear on at least one of the deceased donor's match runs for at least one organ type.



Reason Not on Match	Organ Received										Total	
	Heart		Kidney		Kidney-Pancreas		Liver		Lung			
	N	%	N	%	N	%	N	%	N	%	N	%
Donor's Peak Serum Creatinine level exceeds candidate's maximum acceptable value - Import Offer	0	0	2	2.1	0	0	0	0	0	0	2	1.7
Maximum miles exceeded for organ recovery	1	33.3	0	0	0	0	0	0	0	0	1	0.9
Number of HLA Mismatches exceeds the Candidate's acceptable number of mismatches for DR	0	0	1	1.1	0	0	0	0	0	0	1	0.9
Unacceptable Antigen(s) detected	0	0	2	2.1	0	0	0	0	0	0	2	1.7
<b>Total</b>	<b>3</b>	<b>100.0</b>	<b>94</b>	<b>100.0</b>	<b>3</b>	<b>100.0</b>	<b>15</b>	<b>100.0</b>	<b>1</b>	<b>100.0</b>	<b>116</b>	<b>100.0</b>