

## **IMPORTANT POLICY NOTICE**

**To:** Transplant Professionals

**From:** James B. Alcorn  
UNOS Policy Director

**RE:** Changes to OPTN Bylaws and Policies from actions at OPTN/UNOS Executive Committee Meetings July 2015-November 2015

**Date:** November 23, 2015

This report summarizes changes to the OPTN Policies and Bylaws approved by the OPTN/UNOS Executive Committee at meetings from July 2015 through November 2015. This policy notice provides the specific Policy and Bylaws language changes and the corresponding implementation dates.

When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the approved changes reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, as well as changes from previous Board of Directors meetings, can be found at <http://optn.transplant.hrsa.gov/governance/policy-notices/>.

The Evaluation Plan, which reviews specific details regarding how members will be assessed for compliance with OPTN policies and bylaws, has also been updated to reflect the changes resulting from the meeting. It can also be found at <http://optn.transplant.hrsa.gov/governance/compliance/optn-evaluation-plan/>.

Thank you for your careful review of this policy notice. If you have any questions about a particular Board of Directors' action, please contact your regional administrator at (804) 782-4800.

## ***Policy Clarification to KPD Histocompatibility Requirements – Test Date***

<b>Policy/Bylaws Affected:</b>	<b>Policy 13.5.B (Antibody Screening Requirements for OPTN KPD Candidates)</b>
<b>Distributed for Public Comment:</b>	<b>No</b>
<b>Effective Date:</b>	<b>Pending programming and notice to OPTN members</b>

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### **Problem Statement**

In November 2014, the OPTN/UNOS Board of Directors approved a proposal to move kidney paired donation (KPD) histocompatibility testing requirements from OPTN/UNOS KPD Pilot Program Operational Guidelines into OPTN policy. Included in these policies was a requirement for candidate transplant hospitals to test KPD candidates for antibodies “at least once every 90 days (+/- 20 days) from the date of the first antibody test.” During IT programming meetings, staff found that although the policy specifically mentions that candidates must be tested every 90 days from the date of the first antibody test, the intent of the policy was to prohibit a candidate from going longer than 90 days without being retested. However, if the candidate was more recently tested due to a potentially sensitizing event or unacceptable positive crossmatch, the candidate would need to be retested again within that 90 day timeframe. By tying the testing requirement to the date of the first antibody test, members might have to test more frequently which could be unnecessary and overly burdensome for both the member and the candidates.

### **Summary of Changes**

This change ties the 90 day requirement to the most recent antibody test date. The change also removes the window created by the +/- 20 days language and simplifies the timeframe by changing it to “within 110 days from the date of the most recent antibody test.” This change only clarifies the timeframe for the policy, but does not make the requirement more stringent as members have up to 110 days for compliance whether it is written as 90 (+ 20) days or simply “within 110 days.”

These changes will allow transplant hospitals to test KPD candidates within 110 days from the most recent test date, in order to reduce the number of potentially unnecessary tests.

### **What Members Need to Do**

This change lessens the amount of member burden by reducing the number of potentially unnecessary tests for KPD candidates. Members will still need to comply with all other testing and reporting requirements. This policy change will not require additional data collection. This policy modification does not change how members will be evaluated for compliance.

### **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

### **13.5.B Antibody Screening Requirements for OPTN KPD Candidates**

The paired candidate's transplant hospital must complete antibody screening tests and report to the OPTN Contractor as follows:

1. Use an antibody testing method that is at least as sensitive as the crossmatch method. If antibodies are detected, then identify unacceptable antigens using a solid-phase single phenotype or solid-phase single-antigen test.
2. If no HLA antibodies or unacceptable antigens are detected, then report the paired candidate as unsensitized.
3. Report donor antigens that are considered absolute contraindications to transplant with the paired candidate as unacceptable antigens.
4. Before candidates can appear on their first OPTN KPD match run, each paired candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee must review and sign a written approval of the unacceptable antigens listed for the paired candidate. The paired candidate's transplant hospital must document this review in the paired candidate's medical record.
5. Retest active candidates for antibodies according to #1 above at all of the following times:
  - ~~At least once every 90 days (+/- 20 days)~~ Within 110 days from the date of the first most recent antibody test
  - When any potentially sensitizing event occurs
  - When a paired candidate who has been inactive for more than 90 days has been reactivated
  - When an unacceptable and positive physical crossmatch occurs that precludes transplantation of the matched candidate

If any new unacceptable antigens are identified, then the paired candidate's transplant hospital must report these antigens using the process outlined in #3 and #4 above. If no new unacceptable antigens are identified, the paired candidate's transplant hospital must document the antibody screening results in the paired candidate's medical record.

# ***Clerical Changes for Implementation of Adding Serum Sodium to the MELD Score***

<b>Sponsoring Committee:</b>	<b>Liver and Intestinal Organ Transplantation Committee</b>
<b>Policy/Bylaws Affected:</b>	<b>9.1.D (MELD Score)</b>
<b>Distributed for Public Comment:</b>	<b>No</b>
<b>Effective Date:</b>	<b>January 2016 (Estimated)</b>

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## **Problem Statement**

The goal of this proposal is to make clerical changes to policy 9.1.D MELD Score (Adding Serum Sodium to the MELD Score) for the purposes of implementation. In July 2014, the OPTN/UNOS Board of Directors approved a policy to incorporate serum sodium into the MELD score for those with a MELD score greater than 11. Some candidates whose MELD scores increase as a result will be subject to recertification of their lab values on a more frequent basis, as outlined in OPTN Policy 9.2. In July 2015, the Executive Committee approved clerical changes to provide a grace period for members who need to recertify labs as a result of this policy change.

## **Summary of Changes**

Once programmed, the system will automatically calculate candidates' new MELD score. There will be a 7-day grace period during implementation for those candidates whose scores would be moved from one recertification category to another, and may as a result require immediate recertification.

## **What Members Need to Do**

To prepare for the implementation of this policy in January, we recommend that you begin to identify candidates who may be affected by this change and make advance preparations to schedule lab testing and reporting. To help you identify candidates whose scores are most likely to increase, UNOS has added currently reported serum sodium values to the Liver Candidate MELD/PELD Report available in UNet<sup>SM</sup> under Waitlist: Reports. In addition, UNOS has added all data fields used to calculate MELD and PELD scores, including serum sodium, to the "Create Custom Report" function, also available under Waitlist: Reports. You may use either report to sort candidates by their currently reported serum sodium values, then use the attached resource chart to determine those whose MELD score is likely to change significantly upon policy implementation.

If a center has not recertified these candidates on the 8<sup>th</sup> day after implementation, the candidates will be downgraded to their previous lower MELD score as is done currently when certification expires.

## **Affected Policy/Bylaw Language:**

New language is underlined and language that will be deleted is ~~struck through~~.

### **9.1.D MELD Score**

Candidates who are at least 12 years old receive an initial MELD<sub>i</sub> score equal to:  $0.957 \times \text{Loge}(\text{creatinine mg/dL}) + 0.378 \times \text{Loge}(\text{bilirubin mg/dL}) + 1.120 \times \text{Loge}(\text{INR}) + 0.643$

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.

The following candidates will receive a creatinine value of 4.0 mg/dL:

- Candidates with a creatinine value greater than 4.0 mg/dL
- Candidates who received two or more dialysis treatments within the prior 7 days
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior 7 days

The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

For candidates with an initial MELD score greater than 11, the MELD score is then re-calculated as follows:

$$\text{MELD} = \text{MELD}_{(i)} + 1.32 \cdot (137 - \text{Na}) - [0.033 \cdot \text{MELD}_{(i)} \cdot (137 - \text{Na})]$$

Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.

If a candidate's recalculated MELD score requires recertification within 7 days of implementation based on *Table 9-1: Liver Status Update Schedule*, the transplant hospital will have 7 days to update laboratory values. If after 7 days the laboratory values are not updated, the candidate will be re-assigned to the previous lower MELD score.

# ***Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors***

<b>Policy/Bylaws Affected:</b>	<b>OPTN Policy 15.6</b>
<b>Distributed for Public Comment:</b>	<b>January 2016</b>
<b>Effective Date:</b>	<b>November 21, 2015</b>

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## **Problem Statement**

During the June 2015 Board of Directors meeting the Board of Directors approved policy changes to create a variance for the allocation and transplantation of HIV positive organs into HIV positive recipients. However, a Board member expressed concern that the language in *Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* addressing the allocation of HIV positive organs to HIV positive recipients not appearing on the match run did not clearly limit the practice to directed donations. During the development of the policy language, it was the OPO Committee's intent to only allow for an exception in cases where an HIV positive donor or legal next of kin wishes to directly donate organs to an HIV positive candidate, even if the candidate does not appear on the match run due to ABO incompatibility.

The HOPE Act states that "not later than 4 years after the date of enactment and annually thereafter, the Secretary shall review the results of scientific research in conjunction with the Organ Procurement and Transplant Network to determine whether the results warrant revision of the standards of quality." UNOS leadership discussed the OPTN's role in this review and how to best meet the statutory requirements. These discussions resulted in a recommended modification to the variance to require members participating in a HOPE Act research study to provide periodic reports from their data safety monitoring boards to the OPTN.

In addition, while preparing for the implementation of the HOPE Act on November 21, 2015, UNOS staff identified a proposed policy change that was not submitted to the Board of Directors in June 2015 as part of the HOPE Act proposal. This policy change was distributed for public comment during the September-December 2014 period; the policy had strong support during public comment and was approved by the OPO Committee. This policy change is necessary to remove the existing prohibition on the recovery and transplantation of organs from deceased donors known to be infected with HIV, and to allow for the conduct of research as outlined in OPTN Policy 15.6, the HOPE Act, and the OPTN Final Rule, and necessary for the successful implementation of the HOPE Act.

## **Summary of Changes**

- Policy 2.7 was modified to remove the prohibition on the recovery and transplantation of organs from HIV positive donors to allow for the conduct of research.
- Policy 15.6.A was modified to clarify that allocation of HIV positive organs to HIV positive recipients not on the match run can only occur in the event of a directed donation. Additionally, UNOS staff revised the introductory paragraph of Policy 15.6 to remove the parentheses.
- Policy 15.6 was modified to include a requirement for members participating in a HOPE Act research study to provide periodic reports from their data safety monitoring boards to the OPTN.

## What Members Need to Do

Members will be permitted to recover and transplant livers and kidneys from HIV positive donors as part of an IRB approved HOPE Act research study as outlined in OPTN Policy 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors) and the OPTN Final Rule.

The OPO must only allocate HIV positive organs to HIV positive candidates appearing on the match run, except in cases of directed donation. The OPO must verify that the potential recipient is registered as an HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*.

Transplant hospitals participating in this variance must submit a detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the requirements in the HHS research criteria. Transplant hospitals will be required to submit the IRB data safety monitoring reports at each deadline in the schedule.

### Affected Policy Language:

New language is underlined and language that will be deleted is ~~struck through~~.

## 2.7 HIV Screening of Potential Deceased Donors

~~Members may not participate in the recovery or transplantation of organs from deceased donors known to be infected with HIV. Members may only recover organs if the laboratory data, medical history, and behavioral history indicate that the donor is not HIV infected.~~

The host OPO must accurately document HIV test results for every deceased donor. All deceased donors must be tested for HIV according to *Policy 2.9: Required Deceased Donor Infectious Disease Testing*.

The host OPO must report the results of all HIV tests it performs directly to all receiving OPOs and transplant programs.

## 15.6 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

This variance applies to members participating in an institutional review board (IRB) approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV positive recipients, (including Health and Human Services (HHS) research criteria pertaining to the transplantation of organs from HIV positive donors, as applicable.) ~~regarding the recovery of organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV positive recipients.~~

Transplant hospitals participating in this variance must submit all of the following to the OPTN Contractor:

1. A detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the requirements in the HHS research criteria.
2. IRB data safety monitoring reports at each deadline in the schedule.

### 15.6.A Requirements for Allocating HIV Positive Deceased Donor Organs

In addition to the requirements of the OPTN Final Rule, the OPO may allocate HIV positive organs only after determining the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol. The OPO must only allocate HIV positive organs to HIV positive candidates appearing on the match run, except in cases of directed donation. ~~In the case of a directed donation and prior to transplant, the~~ The OPO must verify that the potential recipient is registered as an HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*.

### **15.6.B Requirements for Allocating HIV Positive Living Donor Organs**

In addition to the requirements of the OPTN Final Rule, the recovery hospital must confirm that the potential living donor is HIV positive and the potential recipient is willing to accept an HIV positive organ as part of a research protocol.

### **15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs**

In addition to the requirements of the OPTN Final Rule, transplant hospitals may transplant HIV positive organs only if *all* of the following conditions are true:

1. The transplant hospital notifies and provides documentation to the OPTN Contractor that it is participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.
2. The transplant hospital obtains informed consent from the potential transplant recipient to participate in the institutional review board protocol that meets requirements in the OPTN Final Rule.
3. The transplant hospital meets the informed consent requirements according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*.

In order for an HIV positive candidate to appear on a match run for HIV positive donor kidneys or livers, the transplant hospital must complete a two-person reporting and verification process. This process must include two different individuals who each make an independent report to the OPTN Contractor that the candidate is willing to accept an HIV positive organ as part of a research protocol.

Transplant hospitals must notify the OPTN Contractor if they will no longer participating in an IRB approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.

The OPTN Contractor may release to the public the names of members participating in this variance.



## ***Clarification of Policy 18.1 Changes from June 2015 Board Meeting***

**Policy/Bylaws Affected:** OPTN Policies 18.1  
**Distributed for Public Comment:** Yes; January 2015  
**Effective Date:** Pending programming and notice to OPTN members

### **Problem Statement**

In June 2015, the Board approved numerous proposals that affected OPTN Policy 18.1: Data Submission Requirements. All five resolutions made changes to the language in this policy:

- Resolution 18 (VCA)
- Resolution 23 (Living Donation)
- Resolution 27 (VCA)
- Resolution 33 (OPO), as amended
- Resolution 35 (POC)

Upon updating the policy language for the September 1 implementation date, staff discovered that there was one line in Policy 18.1, Table 18.1 where the Board-approved language was in conflict. This conflict resulted in slight differences in phrasing in Resolution #27 and Resolution #33 as presented and approved at the June 2015 Board meeting. The Executive Committee reviewed and approved the resolved language, which corrects differences in language approved by the Board but does not make substantive changes to either proposal’s language, nor does it change member data submission requirements from what was approved by the Board in June.

### **Summary of Changes**

This change represents policy language that was approved by the Board but required resolution with another proposal that affected the same policy; both proposals were approved by the Board in June 2015. This conflict was created by slight differences in phrasing of the same language as shown in Resolution #27 and Resolution #33 below, as presented at the June 2015 Board meeting:

### **RESOLUTION 27**

**Table 18-1: Data Submission Requirements**

<i><b>This e-following member:</b></i>	<i><b>Must submit the following materials to the OPTN Contractor:</b></i>	<i><b>Within:</b></i>	<i><b>For the following groups:</b></i>
Host OPO	Deceased donor feedback	5 business days after the procurement date	<u>All deceased donors</u>

## RESOLUTION 33

### Amendment 1

**Table 18-1: Data Submission Requirements**

Host OPO	<del>Deceased donor feedback</del>  <u>Donor organ disposition (feedback)</u>	5 business days after the procurement date	<u>Individuals, except living donors, from whom at least one organ is recovered</u>
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### What Members Need to Do

Members who print out copies of their Policies or Bylaws as reference should print the updated versions when policy proposals are implemented.

### Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

## 18.1 Data Submission Requirements

Members must report accurate data to the OPTN Contractor using standardized forms according to *Table 18-1* below.

**Table 18-1: Data Submission Requirements**

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> <li>• 30 days after the transplant hospital removes the candidate from the waiting list because of transplant</li> <li>• 30 days after the transplant hospital submits the <i>recipient feedback</i></li> </ul>	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory

<b><i>The following member:</i></b>	<b><i>Must submit the following materials to the OPTN Contractor:</i></b>	<b><i>Within:</i></b>	<b><i>For:</i></b>
OPOs, all	<i>Death notification records (DNR)</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	<i>Donor organ disposition (feedback)</i>	5 business days after the procurement date	<u>Individuals, except living donors, from whom at least one organ is recovered</u>
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>donor organ disposition (feedback)</i> form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital  This does not apply to VCA donor organs

<b><i>The following member:</i></b>	<b><i>Must submit the following materials to the OPTN Contractor:</i></b>	<b><i>Within:</i></b>	<b><i>For:</i></b>
Recovery Hospitals	<i>Living Donor Feedback</i>  Members must amend the form or contact the OPTN Contractor to amend this form according to <i>Policy 18.6: Reporting of Liver Donor Adverse Events</i>	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital  This does not apply to VCA donor organs
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital  This does not apply to VCA donor organs
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	<i>Either of the following:</i>  <ul style="list-style-type: none"> <li>• 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure</li> <li>• 14 days from notification of the recipient's death or graft failure</li> </ul>	Each recipient followed by the hospital
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital

<b><i>The following member:</i></b>	<b><i>Must submit the following materials to the OPTN Contractor:</i></b>	<b><i>Within:</i></b>	<b><i>For:</i></b>
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital submits the <i>recipient feedback</i> form	Each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	24 hours after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	24 hours after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

## ***Clarification of Policy 18.1 Changes from June 2015 Board Meeting***

<b>Policy/Bylaws Affected:</b>	<b>OPTN Policies 18.1</b>
<b>Distributed for Public Comment:</b>	<b>Yes; January 2015</b>
<b>Effective Date:</b>	<b>Pending programming and notice to OPTN members</b>

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### **Problem Statement**

In June 2015, the Board approved numerous proposals that affected OPTN Policy 18.1: Data Submission Requirements. All five resolutions made changes to the language in this policy:

- Resolution 18 (VCA)

- Resolution 23 (Living Donation)
- Resolution 27 (VCA)
- Resolution 33 (OPO), as amended
- Resolution 35 (POC)

Upon updating the policy language for the September 1 implementation date, staff discovered that there was one line in Policy 18.1, Table 18.1 where the Board-approved language was in conflict. This conflict resulted in slight differences in phrasing in Resolution #27 and Resolution #33 as presented and approved at the June 2015 Board meeting. The Executive Committee reviewed and approved the resolved language, which corrects differences in language approved by the Board but does not make substantive changes to either proposal’s language, nor does it change member data submission requirements from what was approved by the Board in June.

### Summary of Changes

This change represents policy language that was approved by the Board but required resolution with another proposal that affected the same policy; both proposals were approved by the Board in June 2015. This conflict was created by slight differences in phrasing of the same language as shown in Resolution #27 and Resolution #33 below, as presented at the June 2015 Board meeting:

### RESOLUTION 27

**Table 18-1: Data Submission Requirements**

<i>This e-following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
Host OPO	Deceased donor feedback	5 business days after the procurement date	<u>All deceased donors</u>

## RESOLUTION 33

### Amendment 1

**Table 18-1: Data Submission Requirements**

Host OPO	<del>Deceased donor feedback</del>  <u>Donor organ disposition (feedback)</u>	5 business days after the procurement date	<u>Individuals, except living donors, from whom at least one organ is recovered</u>
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## 18.1 Data Submission Requirements

Members must report accurate data to the OPTN Contractor using standardized forms according to *Table 18-1* below.

**Table 18-1: Data Submission Requirements**

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> <li>• 30 days after the transplant hospital removes the candidate from the waiting list because of transplant</li> <li>• 30 days after the transplant hospital submits the <i>recipient feedback</i></li> </ul>	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory

<b><i>The following member:</i></b>	<b><i>Must submit the following materials to the OPTN Contractor:</i></b>	<b><i>Within:</i></b>	<b><i>For:</i></b>
OPOs, all	<i>Death notification records (DNR)</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	<i>Donor organ disposition (feedback)</i>	5 business days after the procurement date	<u>Individuals, except living donors, from whom at least one organ is recovered</u>
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>donor organ disposition (feedback)</i> form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital  This does not apply to VCA donor organs



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Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital  This does not apply to VCA donor organs
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital  This does not apply to VCA donor organs
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Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital

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Transplant hospitals	<i>Recipient feedback</i>	24 hours after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	24 hours after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

## Clerical Changes to OPTN Bylaws and Policies

**Policy/Bylaws Affected:** OPTN Bylaws D.5 and Appendix K  
OPTN Policies 14.4.B and 14.4.C

**Distributed for Public Comment:** No

**Effective Date:** August 11, 2015

### Problem Statement

In November 2014, the Board approved changes to the OPTN Bylaws that enable staff to make clerical, or non-substantive, changes to the Bylaws and Policies as they're identified, without prospective approval from the Executive Committee or Board of Directors as was previously required. This enables staff to make simple, clerical corrections that are then reviewed and approved by the Executive Committee at a subsequent meeting.

### Summary of Changes

These clerical changes will increase the accuracy and clarity of our Policies and Bylaws. The table below summarizes the changes and the reason for each change.

Clerical Change	Reason
<b>Bylaws D.5 Transplant Program Key Personnel</b>	Deleted obsolete reference to <i>Appendix J: Membership and Personnel Requirements for Joint Heart and Lung Programs</i> , which no longer exists as of June 2014.
<b>Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination</b>	Corrected typo that said "The following provisions of Appendix D do not apply to VCA transplant programs," with the correct reference to <b>Appendix K</b> .
<b>Policy 14.4.B: Living Donor Medical Evaluation Requirements, Table 14-6: Requirements for Living Donor Medical Evaluations</b>	Removed unnecessary period.
<b>Policy 14.4.B: Living Donor Medical Evaluation Requirements, Table 14-6: Requirements for Living Donor Medical Evaluations</b>	Corrected typo from <i>preventative</i> to <i>preventive</i> in "U.S. Preventive Services Task Force"
<b>Policy 14.4.C, Table 14-7: Additional Requirements for Medical Evaluation of Living Kidney Donors</b>	Deleted repeated language that introduces list of items required for the kidney-specific person history. Removed the first colon to combine the two lead clauses to only one, using a comma between. This also required making the letter "A" before <i>kidney-specific</i> a small "a."

### What Members Need to Do

Members who print out copies of their Policies or Bylaws as reference should print the updated versions.

### Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

## D.5 Transplant Program Key Personnel

Designated transplant programs must have certain key personnel on site. These key personnel include a qualified primary surgeon and primary physician that meet the requirements set forth in these Bylaws. For the detailed primary surgeon and primary physician requirements for specific organs, see the following appendices of these Bylaws:

- *Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs*
- *Appendix F: Membership and Personnel Requirements for Liver Transplant Programs*
- *Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs*
- *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*
- *Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*
- ~~*Appendix J: Membership and Personnel Requirements for Joint Heart and Lung Transplant Programs*~~

### **Appendix K: Transplant Program Inactivity, Withdrawal, and Termination**

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

The following provisions of Appendix ~~D~~K do *not* apply to VCA transplant programs:

- *K.1: Transplant Program Inactivity*
- *K.2: Short-term Inactive Transplant Program Status*
- *K.3: Long-term Inactive Transplant Program Status*

## **OPTN Policies**

### **14.4.B Living Kidney Donor Medical Evaluation Requirements**

**Table 14-6: Requirements for Living Kidney Donor Medical Evaluations**

<b>Transmissible disease screening</b>	<p>Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> <li>1. CMV (Cytomegalovirus) antibody</li> <li>2. EBV (Epstein Barr Virus) antibody</li> <li>3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery</li> <li>4. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery</li> <li>5. Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery</li> <li>6. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery</li> <li>7. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery</li> <li>8. Syphilis testing</li> </ol> <p>If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to <i>the U.S. Public Health Services (PHS) Guideline</i>, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the <i>U.S. Public Health Services (PHS) Guideline</i>.</p> <p>For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using <i>either</i>:</p> <ul style="list-style-type: none"> <li>• Intradermal PPD</li> <li>• Interferon Gamma Release Assay (IGRA)-</li> </ul>
<b>Cancer screening</b>	<p>Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventative Services Task Force to screen for:</p> <ul style="list-style-type: none"> <li>• Cervical cancer</li> <li>• Breast cancer</li> <li>• Prostate cancer</li> <li>• Colon cancer</li> <li>• Lung cancer</li> </ul>

### 14.4.C Additional Requirements for the Medical Evaluation of Living Kidney Donors

Table 14-7: Additional Requirements for the Medical Evaluation of Living Kidney Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Kidney - specific donor history	<p>A personal history of significant medical conditions which include, but are not limited to:</p> <ul style="list-style-type: none"> <li>a. A kidney-specific personal history including:               <ul style="list-style-type: none"> <li>a. Genetic renal diseases</li> <li>b. Kidney disease, proteinuria, hematuria</li> <li>c. Kidney injury</li> <li>d. Diabetes including gestational diabetes</li> <li>e. Nephrolithiasis</li> <li>f. Recurrent urinary tract infections</li> </ul> </li> </ul>
Kidney-specific family history	<ul style="list-style-type: none"> <li>• Kidney disease</li> <li>• Diabetes</li> <li>• Hypertension</li> <li>• Kidney Cancer</li> </ul>
Physical Exam	<ul style="list-style-type: none"> <li>• Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring</li> </ul>
Other metabolic testing	<ul style="list-style-type: none"> <li>• Fasting blood glucose</li> <li>• Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol)</li> <li>• Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals</li> </ul>
Kidney-specific tests	<ul style="list-style-type: none"> <li>• Urinalysis or urine microscopy</li> <li>• Urine culture if clinically indicated</li> <li>• Measurement of urinary protein and albumin excretion</li> <li>• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection</li> <li>• Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history</li> <li>• Patients with a history of nephrolithiasis or nephrolithiasis (&gt;3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:           <ul style="list-style-type: none"> <li>○ Calcium</li> <li>○ Oxalate</li> <li>○ Uric acid</li> <li>○ Citric acid</li> <li>○ Creatinine</li> <li>○ Sodium</li> </ul> </li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Anatomic assessment</b>	Determine: <ul style="list-style-type: none"><li>• Whether the kidneys are of equal size</li><li>• If the kidneys have masses, cysts, or stones</li><li>• If the kidneys have other anatomical defects</li><li>• Which kidney is more anatomically suited for transplant</li></ul>