

## ***At a Glance***

### **Proposal to Reduce the Reporting Requirements for the Deceased Donor Registration Form**

- **Affected/Proposed Policy:** Policy 18.1 (Data Submission Requirements)

- **Organ Procurement Organization Committee**

Policy 18.1 (Data Submission Requirements) requires all OPOs to complete the deceased donor registration (DDR) for all deceased donors and authorized but not recovered potential deceased donors. This must be completed within 30 days after the deceased donor feedback form is submitted. Due to inconsistent data reporting on those potential donors that do not proceed to donation, the OPO Committee is proposing that the requirement to complete the DDR for non donors be removed from policy. The goal of this proposal is to reduce the data reporting requirements for “non donors” by only requiring the completion of the DDR on actual donors.

- **Affected Groups**

Directors of Organ Procurement  
Lab Directors/Supervisors  
OPO Executive Directors  
OPO Medical Directors  
OPO Coordinators  
Transplant Administrators  
Transplant Data Coordinators  
PR/Public Education Staff  
Donor Family Members  
General Public

- **Number of Potential Candidates Affected**

This proposal does not impact potential candidates.

- **Compliance with OPTN Strategic Plan and Final Rule**

The proposal promotes the OPTN’s Strategic Plan “promoting the efficient management of the OPTN” by eliminating the collection of unnecessary data elements.

## **Proposal to Reduce the Reporting Requirements for the Deceased Donor Registration Form**

**Affected/Proposed Policy: Policy 18.1 (Data Submission Requirements)**

**Organ Procurement Organization Committee**

**Public comment response period: September 29 – December 5, 2014**

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

Policy 18.1 (Data Submission Requirements) requires all OPOs to complete the deceased donor registration (DDR) for all deceased donors and authorized but not recovered potential deceased donors. This must be completed within 30 days after the deceased donor feedback form is submitted. Due to inconsistent data reporting on those potential donors that do not proceed to donation, the OPO Committee is proposing that the requirement to complete the DDR for non-donors be removed from policy. The goal of this proposal is to reduce the data reporting requirements for “non-donors” by only requiring the completion of the DDR on actual donors.

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

Policy 18.1 requires members to report data to the OPTN using standardized electronic forms. Table 18.1 lists the member responsibilities and timeframe for each of the data forms, including the deceased donor registration and donor feedback form. Currently, the host OPO is responsible for completing the deceased donor registration form for all deceased donors and authorized but not recovered potential deceased donors. However, the DDR was never intended to be used for “non-donors.” Prior to December 2001, a cadaver donor referral form was available for members. This form was generated only for donors that were added to the UNOS database through UNet and ultimately did not become an organ donor. The data collected on this form included demographic information, cause of death, mechanism of death, circumstances of death, suitability for procurement and consent information. One reason for the elimination of this form is the inconsistencies in reporting by the OPOs on this form. However, the requirement that OPOs report on all donors and authorized but not recovered potential donors did not change. This required OPOs to complete the DDR even for those cases that did not go on to donation. Much of the DDR is only applicable to an actual donor and therefore much of the data that are submitted on non-donors is reported as unknown.

The current process for submitting donor information is outlined below:

- OPO adds a donor or potential donor into DonorNet®.
- If the OPO does not request or obtain authorization for organ donation, the OPO marks the record as “Referral Only” and has completed their data submission requirements.
- If authorization for organ donation is obtained, the OPO then fills out the Donor Organ Disposition (Feedback) for each organ (recovered or not).
- Once feedback is complete and reconciled with the transplant center, the DDR is generated. The OPO has 30 days to complete the DDR.
- There is basic information on imminent and eligible deaths that is collected on the death notification report form.

The Committee discussed the purpose of collecting data on authorized but not recovered donors or those for whom authorization was not obtained. Because there is limited information available on non-donors there is no need to collect it on a form that was designed for deceased donor

information. The Committee also discussed the purpose of collecting information on decedents from whom organs are recovered for reasons other than transplant. The Committee agreed that only information on individuals from whom at least one organ was recovered for the purpose of transplantation should be collected.

The Committee agreed to the following:

- OPOs should only be required to complete the deceased donor registration (DDR) form on actual donors, defined as having at least one organ recovered for the purpose of transplantation.
- Make the following change to the deceased donor definition: An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.

#### **Supporting Evidence and/or Modeling:**

The Committee analyzed the number of Deceased Donor Registration (DDR) forms that were submitted by the OPOs to determine those that were submitted for actual donor cases and those that were submitted for non-donor cases. The Committee looked at DDRs submitted to the OPTN from 2010 through 2013. The Committee wanted to know what percentage of DDRs submitted by an OPO was for non-donors. Below is a table that groups the OPOs by the percentage of non-donor DDRs they submitted.

<b>Percentage of DDRs Submitted for Non Donors</b>	<b>Number of OPOs</b>
< 1%	16
1% to < 5%	9
5% to < 10%	7
10% to < 15%	13
15% to < 20%	9
20% 23%	4

The Committee determined that many OPOs are not filling out the DDR for their non-donors. The Committee also noted that many of the fields on the DDR cannot be filled out for these non-donors.

#### **Expected Impact on Living Donors or Living Donation:**

Not applicable

#### **Expected Impact on Specific Patient Populations:**

No known impact to specific patient candidates.

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

The proposal promotes the OPTN's Strategic Plan "promoting the efficient management of the OPTN" by eliminating the collection of unnecessary data elements.

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

This proposal will not require evaluation since it eliminates unnecessary data collection.

**Additional Data Collection:**

This proposal does not require additional data collection; instead, it will decrease the data collection burden on members.

**Expected Implementation Plan:**

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and effective upon completion of programming.

As mentioned earlier in the proposal, OPOs have the option of clicking “Referral Only” in the Donor Organ Disposition (Feedback). Referral is defined as when no consent was requested or obtained. One consideration for implementation is to change “Referral Only” to “No organs were recovered for the purpose of transplantation.” This will provide OPOs with the opportunity to suspend the DDR for those potential donors that do not proceed to donate any organs.

**Communication and Education Plan:**

Upon Board approval, communications vehicles can be used to inform transplant professionals (specifically OPOs) about the policy modifications regarding the Deceased Donor Registration (DDR) form, the associated requirement change and definition changes. OPOs already record the information in UNet<sup>SM</sup> via the DDR, so there is no substantive change in practice. This policy modification would not be significant enough to require extensive notification, UNet<sup>SM</sup> system training, or special instructional sessions. There is actually a reduction in OPO effort because reporting requirements for non-donors are being removed from policy. There are no actual system changes associated with this effort, only updates to the online help documentation are needed.

The first notification of this change will be sent to members through the policy notice 30 days after the Board meeting and a link to the policy notice will be included in the Transplant Pro e-newsletter. Additional communications will be provided, if necessary.

**Compliance Monitoring:**

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet<sup>SM</sup> may be subject to OPTN review, and members are required to provide documentation as requested.

**Policy Proposal:**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

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

<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 the following groups:</i></b>
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30 days after the OPO submits the deceased donor registration	For each 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>	For each transplant recipient typed by the laboratory
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	For 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	For 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	For each deceased donor organ that is offered to a potential recipient
Host OPO	<i>Deceased donor feedback</i>	5 business days after the procurement date	<u>For all deceased donors</u>

<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 the following groups:</i></b>
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>deceased donor feedback</i> form is submitted and disposition is reported for all organs	For all deceased donors and <del>authorized but not recovered potential deceased donors</del>
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	For each living donor organ recovered at the hospital
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	For each living donor organ recovered at the hospital
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	1. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14-days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60-days after transplant hospital submits the <i>recipient feedback</i> form	For each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60-days after transplant hospital submits the <i>recipient feedback</i> form	For each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	24-hours after the transplant	For 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 the following groups:</i></b>
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	For each 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	For each candidate on the waiting list or recipient transplanted by the hospital

## 1.2 Definitions

### **Deceased donor**

An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.