

## ***At-a-Glance***

### **Proposal to Clarify Data Submission and Documentation Requirements**

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

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

Policy 18.1 (Data Submission Requirements) requires members to submit data to the OPTN through the use of standardized forms. However, Policy 18.1 does not explicitly state that the data submissions must be accurate or that members must be able to provide documentation to verify the accuracy of their data submissions. The MPSC historically has agreed that the need for accurate data is implied within Policy 18.1, as is the member's obligation to provide documentation to verify the data's accuracy. This proposal's goal is to amend Policy 18.1 to explicitly state that the data must be accurate and that members must provide documentation to support their data.

- **Affected Groups**

Directors of Organ Procurement  
Lab Directors/Supervisors  
OPO Executive Directors  
OPO Medical Directors  
OPO Coordinators  
Transplant Administrators  
Transplant Data Coordinators  
Transplant Physicians/Surgeons  
Transplant Program Directors  
Transplant Social Workers

- **Number of Potential Candidates Affected**

The proposal affects all patients.

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

The proposal promotes the OPTN's Strategic Plan by promoting the efficient management of the OPTN. In particular, the proposal aims to clearly communicate with members and improve the readability of OPTN rule and requirements. The proposal clarifies member obligations under Policy 18.1. It will also reduce the amount of OPTN resources required to determine whether allegations of inaccurate or falsified data submission are valid by placing the obligation on the member to verify the data's accuracy.

## **Proposal to Clarify Data Submission and Documentation Requirements**

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

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

**Public comment response period:** March 14 – June 13, 2014

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

Policy 18.1 (Data Submission Requirements) requires members to submit data to the OPTN through the use of standardized forms. However, Policy 18.1 does not explicitly state that the data submitted must be accurate or that members must be able to provide documentation to verify the accuracy of their data submissions. The MPSC historically has agreed that the need for accurate data is implied within Policy 18.1, as is the member's obligation to provide documentation to verify the data's accuracy, if requested. This proposal's goal is to amend Policy 18.1 to explicitly state that the data must be accurate and that members must provide documentation to support their data submissions.

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

The MPSC reviews reports of inaccurate and/or falsified data submissions as part of its role to monitor member compliance and patient safety, and the MPSC cites members for noncompliance with Policy 18.1 when members submit inaccurate data. Some members who have been cited have responded that they do not understand the citation: they believed that they were complying with the policy when they submitted the information, and they noted that the policy does not state the data must be accurate. Staff often have to explain to these members that the need for accurate data is implied within the policy. In addition, staff often have to make multiple requests for documentation before members submit information.

In order to determine whether data is accurate, the MPSC has asked members to submit documentation to verify the data's accuracy. However, Policy 18.1 does not explicitly state that members must provide such documentation. More importantly, other OPTN policies do state that members are required to maintain documentation within patient records or to submit source documentation for auditing. Some members have suggested that because other policies include specific obligations to maintain or provide data, and because Policy 18.1 does not similarly specify the need to provide documentation, no such obligation exists.

The MPSC recognized the need to clarify policy language after reviewing a number of data accuracy cases and receiving the feedback from members mentioned above. By explicitly stating member obligations within Policy 18.1, the proposal aims to eliminate member confusion.

The MPSC historically has agreed that all data reported to the OPTN should be appropriately documented and considered proposing a new bylaw that would require members to provide documentation for all data rather than this policy change. However, Policy 18.1 has applied to each of the data accuracy cases reviewed by the MPSC, and the current problem is that Policy 18.1 does not explicitly state member obligations. Therefore, the MPSC felt that this policy change was a more appropriate action.

The MPSC recognizes that the proposal may be seen as a new requirement to collect and maintain documentation. However, the vast majority of information should already be contained within medical records and documented according to standard medical practice. The MPSC also recognizes that the necessary documentation for each of the many data elements may be located in different systems or records at OPOs, labs, and hospitals. Therefore, the proposal does not state that members must maintain documentation in a central location for review at any time. Instead, members must be able to obtain and provide documentation to verify data elements as needed.

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

**Not applicable.**

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

Not applicable.

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

Not applicable.

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

The proposal promotes the OPTN's Strategic Plan by promoting the efficient management of the OPTN. In particular, the proposal aims to clearly communicate with members and improve the readability of OPTN rule and requirements. The proposal clarifies member obligations under Policy 18.1. It will also reduce the amount of OPTN resources required to determine whether allegations of inaccurate or falsified data submission are valid by placing the obligation on the member to verify the data's accuracy.

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

The MPSC will evaluate whether the proposed policy is meeting its goals each time it reviews potential data submission policy violations or receives member feedback regarding violations of Policy 18.1.

### **Additional Data Collection**

This proposal does not require additional data collection.

### **Expected Implementation Plan**

The proposed change will not require members to alter their policies or procedures. Members should already be submitting accurate data to the OPTN and should be maintaining or have access to all relevant documentation according to standard medical practices. The proposal is meant only to explicitly state that the data submissions must be accurate and that the member is obligated to provide documentation to verify its data accuracy as needed. This proposal will not require programming in UNet<sup>SM</sup>.

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in November, 2014 and, if approved, will become effective on February 1, 2015.

## Communication and Education Plan

A policy notice will be distributed.

## Compliance Monitoring

The proposal is not intended to add any new requirements or to change how members are monitored for compliance with Policy 18.1. UNOS currently monitors members' data accuracy under Policy 18.1 as a part of the survey process. Members are required to provide certain documentation to UNOS site surveyors during reviews, and members will continue to be required to provide the same documentation. UNOS site surveyors will not review whether members have additional documentation to verify the accuracy of data submissions. If the OPTN is investigating reports of inaccurate or falsified data submissions, a member may be required to submit additional information.

The proposal does not specify what kind of documentation members, if asked, will be required to submit. The member will be asked to submit appropriate documentation to verify the accuracy of the data in question, including source and/or supporting documentation that includes but is not limited to medical record information, lab results, clinic notes, social work notes, etc.

## Policy or Bylaw Proposal

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

### 18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report accurate data to the OPTN using standardized forms. *Table 18-1* shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor. Members are responsible for providing documentation to verify the accuracy of all data submitted to the OPTN through the use of standardized forms.