OPTN

Briefing to the OPTN Board of Directors on

Modify Data Submission Policies

OPTN Data Advisory Committee

Prepared by: Eric Messick, MPP
UNOS Policy and Community Relations Department

Table of Contents

Executive Summary 1
Background 2
Purpose of Proposal 3
Proposal: Modifying Data Submission Policies 5
Projected Impact of the Proposal 11
Community Feedback and the Committee's Response 12
Proposal Compliance 18
Implementation and Operational Considerations 19
Monitoring and Evaluation Plan 21
Conclusion 21
Policy Language 23
Appendix A: Letter from Health Resources and Services Administration Acting Associate Administrator to UNOS Executive Director, Dated June 10, 2005 28
Appendix B: Generation Information Associated With TIEDI Data Collection Instruments and Current Submission Requirements (As of November, 2019) 30
Appendix C: Percentage of TIEDI Forms Changed After the Due Date, By the Number of Days After the Due Date 31
Appendix D: Advantages and Disadvantages Associated With Implementing a Process for Changing Officially Submitted Data 32
Appendix E: Data Standard of Review Checklist 34

OPTN

Modify Data Submission Policies

Affected Policies:	*18.1: Data Submission Requirements*
	18.4: Data Submission Standard
Sponsoring Committee:	*Data Advisory*
Public Comment Period:	*August 2, 2019 – October 2, 2019*
Board of Directors' Date:	*December 3, 2019*

Executive Summary

The National Organ Transplant Act of 1984 requires that the Organ Procurement Transplantation Network (OPTN) "collect, analyze, and publish data concerning organ donation and transplants."[1] *Policy 18: Data Submission Requirements* establishes the OPTN's data requirements. OPTN members are required to complete and submit data on transplant candidates, recipients, and donors. The data are submitted electronically through UNet℠, a secure web-based data collection system, with the exception of certain data associated with Vascularized Composite Allografts (VCA).

The OPTN Data Advisory Committee (hereafter, "Committee" or "DAC") proposes clarifying when certain data are due by eliminating policy conflicts and by extending the remaining deadlines. The Committee also proposes limiting members' ability to change data after the deadlines. Finally, the Committee will report to the Board of Directors the reasons data are changed and the frequency of such changes on a regular basis. Implementing this proposal clarifies the need for submitting accurate, high-quality data at the time of entry.

The changes will improve the widespread availability of trusted, complete, and accurate data for members seeking to use it for performance improvement, and for the OPTN's evaluation of transplant system performance. In addition, researchers, such as the Scientific Registry of Transplant Recipients (SRTR), who also study and assess transplant system performance, will benefit from the proposed efforts to improve data quality. The proposal also aligns with the Final Rule's requirement that timely and institution-specific performance data be made publicly available in order to appraise the quality of transplantation programs.[2]

[1] NOTA, 42 U.S.C. § 273 et. seq. and OPTN Briefing Paper, "Proposed Modifications to Data Elements on the following TIEDI forms: TCR, TRR, TRF, LDR, LDF, DDR, HF – BP," Policy Oversight Committee, November 11, 2011.
[2] 42 C.F.R §121.11

Background

Under the OPTN Final Rule, OPOs and transplant centers are required to submit data to the OPTN.[3] A stated reason for requiring the data is to provide OPTN and program-specific performance information to the public. Furthermore, HRSA has previously stated that failure to submit the data accurately and completely could be considered a violation of the both the Final Rule and the Social Security Act (**Appendix A**).[4]

In 2006, the OPTN established that the primary purpose of its data collection activities was to improve patient outcomes. The OPTN also created the following principles to guide data collection around the objective:

- **Allocation of organs:** Data collected on the waiting list are used to determine the medical urgency status of candidates and to develop systems by which to allocate organs to these candidates. Collecting waiting list data contributes to patient welfare by allowing the OPTN to monitor outcomes and to refine the allocation system as needed to ensure that the most appropriate patients are transplanted.

- **Policy compliance:** To ensure trust in the transplant system, data are collected in order to verify that members are complying with policies and procedures of the OPTN. Collection of compliance-related data allows the OPTN to maintain a fair and transparent system, which is beneficial to all patients.

- **Institutional performance:** In collaboration with the SRTR, the OPTN is required to make information on OPO and transplant center performance publicly available. Publication and monitoring of outcomes data creates accountability, and accountability leads to better outcomes for patients.

- **Policy development:** Ongoing policy development is critical to the function and continual improvement of the OPTN. Evidence-based decision making requires the collection of a variety of data elements that are used to analyze system performance and the well-being of candidates/recipients. Enhancing the data required for these analyses is in agreement with the requirements of the Final Rule.

- **Patient Care/Safety:** Given the overall goal to improve patient outcomes and the implicit objective to operate a patient-driven system, it is incumbent on the OPTN to facilitate a better understanding of the burden of disease and to be diligent in maintaining and disseminating information in the best interest of patients. Ultimately, this will lead to improved patient care.

Current policies and practices evolved from a time when members submitted data to the OPTN using paper forms. UNOS staff would then manually enter the data on the members' behalf. Following data entry, UNOS staff would request that the members review the accuracy of the entered information. In the years since, technological changes have resulted in members submitting their data electronically and conducting their own data quality checks.

[3] 42 C.F.R. §121.11(b)(2).
[4] Letter from Joyce G. Somsak, Acting Associate Administrator, HRSA to Walter K. Graham, Executive Director, UNOS, dated June 10, 2005.

The expectation has always been that OPTN members will submit accurate, high-quality data upon entry. Nonetheless, OPTN members and other data users have since raised concerns about the integrity of the submitted data. They point to different data submission deadlines in policy as a problem. They also point out the ability of members to change data indefinitely after submission and the high volume of changed data as reasons to question the data's accuracy. Data users have raised concerns that the issues may impact program performance evaluations and ultimately patient outcomes.

The Committee proposes addressing the data quality concerns by modifying the initial submission deadlines associated with the TIEDI data and reducing members' ability to make changes following submission. Together, the resulting changes will improve OPTN data quality and products such as research analyses and program specific reports.

Purpose of Proposal

The Committee considered two of the primary issues associated with OPTN data integrity. First, clarifying policy so members know what information should be submitted and when the information is due. Second, addressing members' ability to make post-deadline changes to data. The Committee members focused their efforts on the data elements collected using the Transplant Information Electronic Data Interchange® (TIEDI), as shown in **Table 1**.[5] (See **Appendix B** for the current TIEDI data reporting requirements.) The Committee chose the data elements reported using TIEDI in part because those values are expected to be available by the associated deadlines.

Table 1: TIEDI Data Collection Instruments Addressed in This Proposal and Responsible OPTN Member

Title	Acronym	Responsible Member
Deceased Donor Registration	DDR	Organ Procurement Organization
Donor Histocompatibility	DHS	Histocompatibility Lab
Living Donor Follow-up	LDF	Transplant Program
Living Donor Registration	LDR	Transplant Program
Recipient Histocompatibility	RHS	Histocompatibility Lab
Transplant Candidate Registration	TCR	Transplant Program
Transplant Recipient Follow-up	TRF	Transplant Program
Transplant Recipient Registration	TRR	Transplant Program

Source: OPTN Policy 18: Data Submission Requirements, Table 18-1: Data Submission Requirements.

Members Indicate Data Submission Requirements Are Unclear

During the course of the project, member institutions provided feedback that the deadlines for data submission are confusing. Specifically, *Policy 18.1: Data Submission Requirements* and *Policy 18.4: Data Submission Standards* provide different requirements for when data are submitted. *Policy 18.1* identifies specific timeframes for data submission based on when other events occur. For example, information associated with the Recipient Histocompatibility collection instrument is required within 30 days of the

[5] As used here, the TIEDI data collection instruments represent the section of UNet℠ where data coordinators and program staff members receive, complete, and submit data on transplant candidates, recipients, and donors to the OPTN. See, OPTN Briefing Paper, "Proposed Modifications to Data Elements on the following TIEDI forms: TCR, TRR, TRF, LDR, LDF, DDR, HF – BP," Policy Oversight Committee, November 11, 2011.

transplant hospital removing the candidate from the waiting list because of transplant.[6] However, *Policy 18.4* mandates that members must submit 95 percent of their required forms within three months of the form due date, and 100 percent of the forms within six months of the form due date.[7] That it is permissible for a certain percentage of reported data to be late directly conflicts with *Policy 18.1's* requirement that all data must be submitted by the deadlines.

After the OPTN's adoption of the language in *Policy 18.4*, the Centers for Medicare and Medicaid Services (CMS) adopted similar language in its Conditions of Participation (CoP) among transplant hospitals, adding another layer of potential confusion.[8] Under 42 CFR §482.82, members have 90 days after the OPTN's established due date to submit at least 95 percent of their data. On September 30, 2019, CMS published notice in the Federal Register that 42 CFR §482.82 will be eliminated effective November 29, 2019.[9]

The unclear policies increase the burden on members trying to understand the data submission requirements. Additionally, the Final Rule emphasizes the importance of collecting institution-specific performance data to evaluate the quality of transplantation programs.[10] It is important for the collected data to accurately reflect transplant-related information because of its use in organ allocation, policy development and compliance, and patient safety.[11]

Data Changes Following Submission Raise Accuracy Concerns

Members' ability to change what is considered 'final' data has raised integrity concerns, particularly involving how such modifications can affect analysis of allocation policy and practices, and other uses of the information. For example, SRTR uses TIEDI data to produce risk adjusted models for use with the Program Specific Reports (PSR). The models are based on the data available at a point-in-time. SRTR has found that members make so many data changes following the creation of the models that their validity is negatively impacted.

Experiences like SRTR's generate a lack of trust in both the accuracy and completeness of the OPTN data. As previously mentioned, *Policy 18.1* states that members must enter accurate data according to the established timeframes. As such, the policy's intent was to make members verify the accuracy of their data prior to submission.

Committee Efforts Developing Proposal

The Committee is comprised of transplant and donation professionals who enter, validate, and use the data.[12] Committee members were selected, in part, based on their experience with data reporting, quality control, and analysis. When evaluating the information and issues associated with this project, Committee members relied on their experiential expertise. The members also relied on each other's understanding of the differences in practices, as well as the types of challenges different member institutions experience.

[6] OPTN *Policy 18.1: Data Submission Requirements*.
[7] OPTN *Policy 18.4: Data Submission Standards*.
[8] 42 C.F.R. §482.80 and 42 C.F.R. §482.82, 2007.
[9] "Medicare and Medicaid Programs." Federal Register 84:189 (September 30, 2019) p. 51822.
[10] 42 C.F.R §121.11
[11] OPTN, "Principles for Data Collection," Board approved language, December 13, 2006.
[12] Refer to the OPTN website for a list of current Committee members and their organizations, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/

The Committee collaborated with multiple other OPTN committees in developing this proposal. The Committee sought feedback about why members often do not submit data within the existing timeframes. The Committee also sought feedback regarding the circumstances by which data may need to be amended after it is formally submitted.

During this phase of the project, UNOS staff presented background information about the project and the proposed solutions to the following OPTN committees:[13]

- Histocompatibility
- Living Donor
- OPO
- Transplant Administrators
- Transplant Coordinators
- Vascularized Composite Allograft

The committees' comments and suggestions were shared with the DAC members, who considered it as they continued developing on policy options.

The presentation and discussion focused on members' data submission compliance rates and data changes. The committees provided feedback about the potential impact of eliminating *Policy 18.4* and using only the data submission timeframes found in *Policy 18.1*. Committee members were also asked to consider the impact of preventing members from changing data after officially submitting it to the OPTN. In addition to presenting to the aforementioned OPTN committees, the Data Advisory Committee Chair also discussed the project and proposed solutions with chairs of the Histocompatibility, Pancreas, and Pediatrics Committees.

The majority of these committees agreed with the concept of removing *Policy 18.4*. While several of the committees indicated general support for the idea of preventing data changes following submission, they reserved judgement until more details about how such a "lock" would be designed.

The Committee relied on multiple sources of information in developing the proposal. They considered analyses and findings reported by UNOS Research staff addressing submission compliance rates and changes to submitted data. Committee members heard from other OPTN committees whose memberships will be impacted by the changes. The Committee also considered SRTR's findings regarding the data integrity impact associated with member data changes around the Program Specific Reports (PSR). The proposed solutions address the identified data integrity concerns.

Proposal: Modifying Data Submission Policies

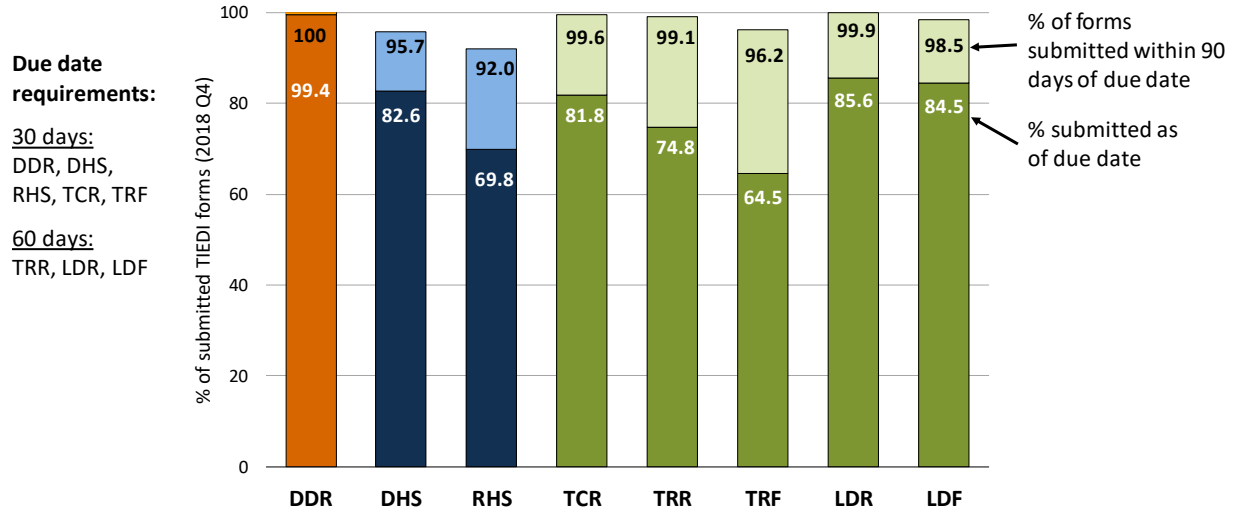
The Committee proposes addressing some of the identified gaps in current policy and practice to improve OPTN data quality. For example, to collect the highest quality data, the Committee proposes clarifying the submission deadlines for data elements collected using TIEDI data collection instruments The Committee also proposes reducing members' ability to indefinitely change data submitted through TIEDI. Finally, the proposal revises certain policy language to make it more consistent with members' data entry experiences.

[13] Dates of presentations made to other OPTN committees: Histocompatibility, March 26, 2019; Living Donor, April 1, 2019; Vascularized Allograft, April 12, 2019; OPO, April 16, 2019; Transplant Administrators, April 24, 2019; Transplant Coordinators, April 25, 2019.

Clarify When Data Are Due by Eliminating Policy 18.4 and Extending Deadlines in Policy 18.1

The Committee chose first to address the issues associated with the data submission deadlines. The Committee reviewed submission rates by data collection instrument and by member type to better understand member performance and behavior. **Figure 1** shows the percentage of TIEDI data collection instruments that were submitted by the timeframe established in Table 18-1 during the fourth quarter of 2018. The figure also shows the number of instruments submitted within 90 days of the Table 18-1 timeframes. As the figure shows, histocompatibility labs submitted approximately 70 to 83 percent of the Donor Histocompatibility and Recipient Histocompatibility data collection instruments within the 30 day due date. For the most part, labs submitted about 95 percent of the forms within 90 days following the due date. Likewise, transplant center submission rates were between 65 and 86 percent by the due date, and typically higher than 95 percent within 90 days of the due date. Committee members expressed concerns about the low initial submission rates for the transplant programs and histocompatibility laboratories.

Figure 1: Substantial Proportion of TIEDI Forms Not Submitted by Due Date



Source: UNOS staff analysis of form submission rate information, July 2019.

UNOS staff asked other OPTN committee members to describe the factors impacting their ability to meet the submission timelines found in *Policy 18.1*. The respondents identified the difficulty associated with obtaining certain data elements. Others reported that because data entry and validation are still largely manual processes, they require large amounts of time to complete. For instance, members of the Histocompatibility Committee expressed concerns that a large amount of staff time is needed to complete the Donor Histocompatibility and Recipient Histocompatibility collection instruments. Members also pointed to instances where individuals have had a second round of tissue typing resulting in data changes needed well after the 30 day deadline for both collection instruments.

While data submission compliance rates suggest that members do not consistently meet the due dates established in *Policy 18.1*, the compliance rates do indicate members are generally able to submit data within 90 days following the due date. The Committee considered the difference during its discussion of the timeframes in *Policy 18.1*. The Committee members acknowledged that member institutions would

be required to spend more time and resources ensuring their data entry activities are completed in enough time to then permit adequate data validation to occur prior to the submission deadlines. To help member institutions complete data entry and validation activities by the due dates, the Committee recommended extending the due dates in *Policy 18.1* for the TIEDI data collection instruments.

The Committee also considered analyses showing the number of days from the due date to the last modification made to the collection instrument. Analyzing the TIEDI data collection instruments expected during 2017, staff reported that members continued changing data on most TIEDI data collection instruments after the due date (**Table 2**). For example, 41 percent of the DDRs submitted in 2017 had at least one data element changed following the due date. The percentage of TIEDI collection instruments where the last modification occurred on or before the due date ranged from a high of 82 percent for the DHS and a low of 33 percent for the TCR. (See **Appendix C** for more details.)

Table 2: Percentage of TIEDI Forms Changed Following the Due Date

TIEDI Form	Due Date	Number of Forms	Percentage of Forms Changed Before or on Due Date	Percentage of Forms Changed After Due Date
DDR	30 days after feedback completed	10,334	59%	41%
DHS	30 days after feedback completed	16,402	82%	18%
RHS	30 days after waitlist removal	31,246	73%	27%
LDR	60 days after waitlist removal	6,084	76%	24%
TCR	30 days after registering on waitlist	59,051	33%	67%
TRR	60 days after waitlist removal	34,743	56%	44%
LDF	60 days after anniversary date	17,870	79%	21%
TRF	30 days after anniversary date	342,516	66%	34%

Note: Percentages may not sum to 100 percent due to rounding.
Source: UNOS staff analysis of submitted TIEDI date, May 1, 2019.

Based on the findings in **Table 2** and **Figure 1**, the Committee decided to extend the due dates associated with the TIEDI data collection forms. **Table 3** identifies the collection forms, the current timeframe, the proposed timeframe, and the change in the number of days. When determining the deadlines for the transplant program-specific forms, the Committee gave particular weight to the percentage of forms submitted within 90 days of the due date as shown in **Figure 1**. Additionally, the Committee knew that the availability of the data needed to complete the two follow-up forms, TRF and LDF, is impacted by the individual's willingness to stay connected with their program.

Table 3: Current and Proposed Due Dates for TIEDI Forms

TIEDI Form	Current	Proposed	Change
DDR	30 days	60 days	+30 days
DHS	30 days	60 days	+30 days
RHS	30 days	60 days	+30 days
LDR	60 days	90 days	+30 days
TCR	30 days	90 days	+60 days
TRR	60 days	90 days	+30 days
LDF	60 days	90 days	+30 days
TRF	30 days	90 days	+60 days

Source: Data Advisory Committee, Meeting Summary May 1, 2019, available at https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/

Improve Data Quality by Implementing Data Change Process and Reporting Requirements

Committee members began discussing the implications of members making changes to data after the data were submitted and reports had been produced as early as April 2018.[14] The members agreed that this was a problem and discussed possible ways to remedy the issue. The Committee discussed the possibility of locking the data in the system after it had been submitted so that changes could not be made. Concerns that there may be valid reasons for revising data after submission led the Committee members to consider a process for when the data could be unlocked and a way to determine the circumstances under which unlocking the data would be permissible.

As part of its deliberations, the Committee received a presentation from SRTR staff describing one of the data integrity problems it had encountered after releasing the new kidney PSR model. In December 2015, SRTR performed a detailed analysis of OPTN members' data changes around the time the new kidney PSR models were released during October 2014.

Based on their findings, SRTR reported concerns that the data changes SRTR found were making members' patients medical status appear riskier than the patients actually were. SRTR staff compared the data elements used for the deceased donor graft survival and living donor graft survival models to determine which data elements were changed after programs became aware of the new models.[15] According to SRTR staff, the analysis found examples of more than 3,500 records where at least one variable had been changed (**Table 4**).

Table 4: Changes to Deceased and Living Donor Adult Graft Survival Kidney Model Variables

	Deceased Donors		Living Donors	
Description of Change	**Number**	**Percent**	**Number**	**Percent**
Candidate total serum albumin	1,099	4%	411	3%
Recipient pre-transplant blood transfusions	816	3%	365	3%
Recipient Body Mass Index (BMI)	607	2%	275	2%
Candidate Peripheral Vascular Disease (PVD)	565	2%	188	1%
Recipient primary insurance	268	1%	103	1%
Candidate Chronic Obstructive Pulmonary Disease (COPD)	254	1%	115	1%
Recipient primary diagnoses at transplant	243	1%	109	1%
Recipient cold ischemia time	772	3%	NA	NA
Donor clinical infection	399	1%	NA	NA
Candidate previous malignancy	194	1%	NA	NA
Donor Body Mass Index (BMI)	NA	NA	202	1%
Epstein-Barr Virus (EBV) (Donor/Recipient)	NA	NA	193	1%
Recipient medical condition at transplant	NA	NA	145	1%
Total Number of Changed Records	**3,542**	**NA**	**1,338**	**NA**

Source: SRTR staff presentation to OPTN Data Advisory Committee, Meeting minutes from April 29, 2019.

[14] OPTN Data Advisory Committee, Meeting Summary April 4, 2018, available at https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/

[15] Scientific Registry of Transplant Recipients (SRTR), "OPTN/SRTR Data Quality" presentation made to the OPTN Data Advisory Committee on April 29, 2019.

The SRTR provided transplant programs with a 30 day preview of the new risk adjustment models. The preview was intended to provide transplant programs with the opportunity to review the data elements incorporated in the new risk adjustment models. Because transplant programs are permitted to edit data after it has been reported to the OPTN, some programs took the opportunity to revise existing data values as well as enter data that had been previously missing.

Such data changes impacted the stability of the entire OPTN dataset. As SRTR described at the time, accurate data are not only critical to the development of the PSRs, but are also critical to the development of policy and research. At the time, SRTR staff suggested the OPTN consider closing data entry after a specified time period, auditing reported data, and removing unnecessary data elements.

The Committee considered several alternatives approaches to restricting or preventing data changes following submission. The processes discussed by the Committee included:

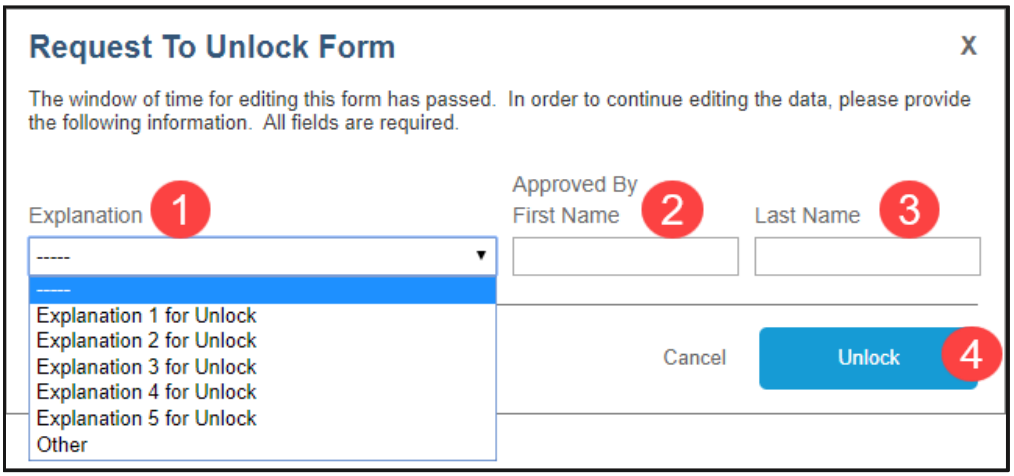
- Prospective review and approval by the OPTN before members could change previously submitted data
- Prospective review and approval by the Committee or a sub-committee before members could change previously submitted data
- Permit changes to previously submitted data by requiring an explanation of why the change is necessary, as well as official approval for the change from a designated administrator at the member

Appendix D contains the advantages and disadvantages the Committee identified for each alternative.

After substantial discussions about preventing or at least limiting data changes, the Committee opted for an approach that strikes a balance between the need to maintain accurate and stable data for policy development and performance measurement, and the need to allow members to correct known data errors. Under the process, which only applies to data values collected using the TIEDI data collection instruments, members will need to complete more steps than they currently do to make data changes as part of *Policy 18.1*. A member who identifies an error will be able to 'unlock' their data in order to make a correction. However, the member will no longer be able to simply change the data values. Instead, the Committee proposes requiring members to submit an explanation detailing why the data values are being changed. In addition, members are required to submit the name of an individual at their institution who has reviewed the proposed change and provided approval to make the change.

The screenshot in **Figure 2** is an example of what members may encounter when trying to change data in the system if the Committee's proposal is implemented. Members will first choose an explanation from the drop-down menu. As shown in the screenshot, the user will be able to select "Other" and then provide a written response. After completing the explanation screen, the member will add the first and last name of the organizational approver. The form can then be unlocked and the data can be changed.

Figure 2: Potential Way Members Will Have to Report a Reason for Changing Data and the Name of the Individual at the Member Institution Who Approved the Change



Source: Screenshot prepared by UNOS staff.

Requiring an approver is intended to help members develop institutional knowledge of why they are changing data. This knowledge should also help members identify systematic issues with their data entry and validation practices. By identifying their data challenges, members can better target their resources by providing additional data training or revises broken practices, for example.

The Committee received feedback from SRTR staff and its own members about the problems associated with implementing a strict data lock. For example, SRTR staff pointed out that data integrity is a primary principle of the project. Restricting changes to only rare or unusual circumstances would prevent members from correcting the single, data keying related errors that members claim are the largest cause of problems. As such errors accumulated in the OPTN dataset, so too would the questions about data accuracy and integrity.

The Committee also considered how preventing data changes might impact members and data integrity in cases when data are not available when the data collection instrument is due or new values are reported following the due date. This can be particularly true for the follow-up collection instruments, such as the Transplant Recipient Follow-up (TRF). Currently, transplant hospitals are required to submit the information collected using the TRF within 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure, or within 14 days from notification of the recipient's death or graft failure. Therefore, after learning of a recipient's death, the program has 14 days to update the TRF data fields and submit them to UNet. No data changes would be permitted following submission or after the due date. However, the Committee was told that in some cases, transplant programs may not receive final autopsy reports until six months following the recipient's death. The Committee was also told that the final autopsy report may have corrected data values, or may have values that were initially submitted as missing. Given this information, the Committee recognized the need to preserve members' ability to change data after the submission deadlines.

In 2016, DAC developed a standard checklist for committees to complete when considering adding new OPTN data elements. The checklist requires committees to describe how the new data elements address the OPTN Data Collection Principles, whether the data could be collected through an alternative

mechanism, and whether the data definition is clearly articulated, among other areas for consideration. **Appendix E** lists the responses to the Committee's Standard of Review checklist for new data elements.

Providing Members Additional Resources to Improve Data Quality

To assist members with integrating the new data submission requirements into their existing practices, UNOS Research staff identified ways existing data tools could be improved, as well as new resources that could be added. For instance, transplant programs and OPOs currently access monthly "Data Validation" reports through the Data Services portal in UNet. Research staff propose increasing the frequency to weekly reporting. The change would allow transplant programs, OPOs, and histocompatibility labs to easily identify and review any data elements with missing, unknown, or suspect values, in real time. These tools should help members quickly identify potential data discrepancies well before the submission deadlines. In addition, the reports will be expanded to cover all data elements on the TIEDI collection instruments.

Research staff also propose creating a new data quality dashboard to allow members to visually review their data quality in aggregate form. This will help members identify more global inconsistencies in reporting based on comparisons with national data. The dashboard is intended for use by the members' data quality manager, transplant administrator, or similar role with broad data quality oversight. Currently, members can only perform such a review by comparing individual data collection instruments. The change allows members to more easily identify systematic issues with their submitted data. For example, members will be able to see a comparison of their missing, unknown, or suspect values per data element and data collection instrument. They will also be able to see how the data they submitted compares to all other submitted data. The dashboard also allows them to identify how often data elements are modified following official submission along with the reason(s) for the modification(s). The actual dashboard and reporting resources are in development and will be validated by the Committee and selected groups.

Projected Impact of the Proposal

The changes proposed by the Committee will result in improved data quality. High quality data are critical when it comes to measuring program performance and informing the public about patient outcomes. This is reflected in both the Final Rule and the OPTN's Principles of Data Collection. Improving data integrity will in turn increase user confidence that their decisions, such as allocation policy, are based on reliable evidence. Conversely, questions about data integrity can erode the public's trust in the research findings based on the data.

The proposed policy improves data integrity by establishing one set of data submission deadlines and by providing members with additional time to perform data quality assurance activities of their data prior to submission. By eliminating *Policy 18.4*, the proposal clearly states that member data is due to the OPTN by the dates established in *Policy 18.1*.

The proposal also addresses how OPTN members will make changes to their already submitted data. Members are now able to change submitted data under any circumstances. While this was intended to help members ensure their submitted data were correct, the lack of a formal data correction process has led to some instances where large volumes of changes are made well after the data have been submitted as final.

The proposal establishes a process that will slightly increase the burden on members to make such data changes. The change is intended, in part, to make members consider improving their data reporting and quality assurance efforts so that data are correct at the due date, and there is less reason for post-submission changes. By increasing the number of actions members must complete to change data, the proposal also seeks to restore the public's trust in the accuracy and completeness of the OPTN data. Furthermore, by requiring a leadership position at each member institution to review and approve all changes it should improve institutional awareness of issues. Greater transparency into their data-related processes should also help members identify and correct the root causes leading to their need to change data. Additionally, the proposed process should improve transparency by identifying and reviewing the reasons why members change submitted data, who is approving such changes, and how frequently changes are occurring.

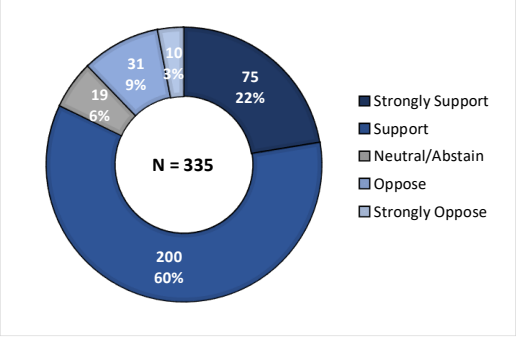
Because the proposed changes may pose challenges for some members, the Committee has also identified several types of assistance to help members implement the recommended changes. These include extending the amount of time members have to submit data collected on the TIEDI instruments, refining existing tools available in the Data Services portal to help members identify issues prior to submission, and creating new Data Services portal tools to provide members with a comparison of their own data quality versus aggregated data quality measures of all members.

Community Feedback and the Committee's Response

The proposal was available for public comment from August 2 through October 2, 2019. During that time, 41 comments were submitted to the OPTN website. The entries included summaries of the 11 regional meetings and nine OPTN committees where the proposal was discussed. The remaining 20 entries were submitted by individuals, organ procurement organizations, transplant programs, and four professional organizations. When combined with the sentiment votes cast during regional and committee meetings, and other sources, the proposal received more than 375 responses. The committee reviewed and discussed the results of public comment and concluded that public sentiment supports sending the proposal to the Board of Directors with no changes.

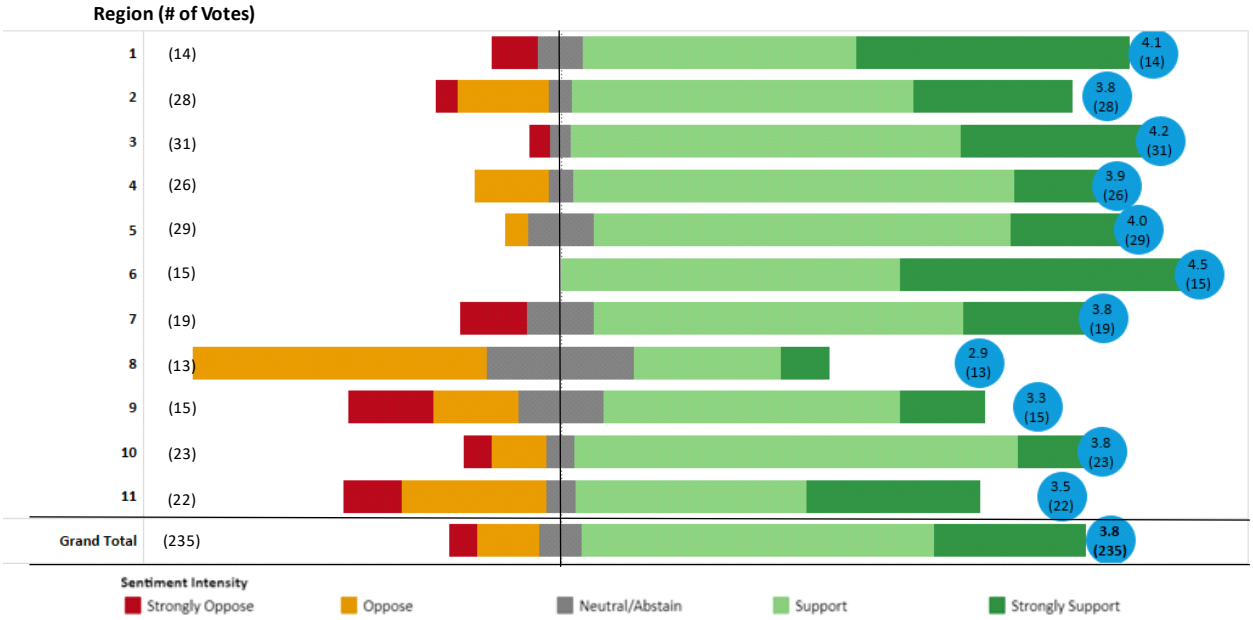
At regional meetings, member organizations send a representative who votes on the organization's behalf. During committee meetings, committee members vote on behalf of themselves. At both the regional and committee meetings, voters use a five-point Likert scale comprised of the following options: strongly oppose, oppose, neutral-abstain, support, and strongly support. As shown in **Figure 3**, the proposal received strong support across the regional and committee meetings based on sentiment voting results. Sentiment voting was 82 percent in support, and only 12 percent in opposition.

Figure 3: Overall Regional and Committee Sentiment Voting



The next three figures depict the broad support for the proposal. As shown in **Figure 4**, a total of 235 sentiment votes were submitted as part of the 11 regional meetings. Region 3 and Region 5 accounted for the most votes by region, 31 and 29 votes, respectively. Region 8 and Region 1 accounted for the fewest votes by region, 13 and 14 votes, respectively.

Figure 4: Sentiment Support for the Proposal, by Region



Overall, 79 percent of regional voters supported the proposal. About 14 percent of voters opposed the proposal, and about seven percent indicated they were neutral or chose to abstain. As Figure 4 also shows, ten of the 11 regions supported the proposal. In fact, at the ten regional meetings that supported the proposal, 182 of the 222 votes submitted, or 82 percent, were in strong support or support of the proposal. On a region-by-region basis, support ranged from 60 percent (Region 11) to 100 percent (Region 6) of sentiment votes cast among the ten regions that supported the proposal.

A plurality of voters in Region 8 opposed the proposal. Of the 13 votes cast, 46 percent were in opposition, while 31 percent supported the proposal, and 23 percent reported being neutral or abstaining. Some of those in attendance expressed different reasons for opposing the measure. At least one individual at the Region 8 meeting was concerned that members were being asked to do more without being provided additional resources. Another individual opposed to the proposal stated that extending the submission deadlines would only encourage members to wait even longer before submitting their data.[16]

All nine OPTN committees who heard the proposal were in favor of it, with 89 of the 100 sentiment votes cast supporting or strongly supporting the proposal (**Figure 5**). By committee, support ranged from 63 percent to 100 percent. There were no “strongly opposed” votes cast.

[16] Region 8 meeting notes, September 11, 2019.

Figure 5: Sentiment Support for the Proposal, by OPTN Committee

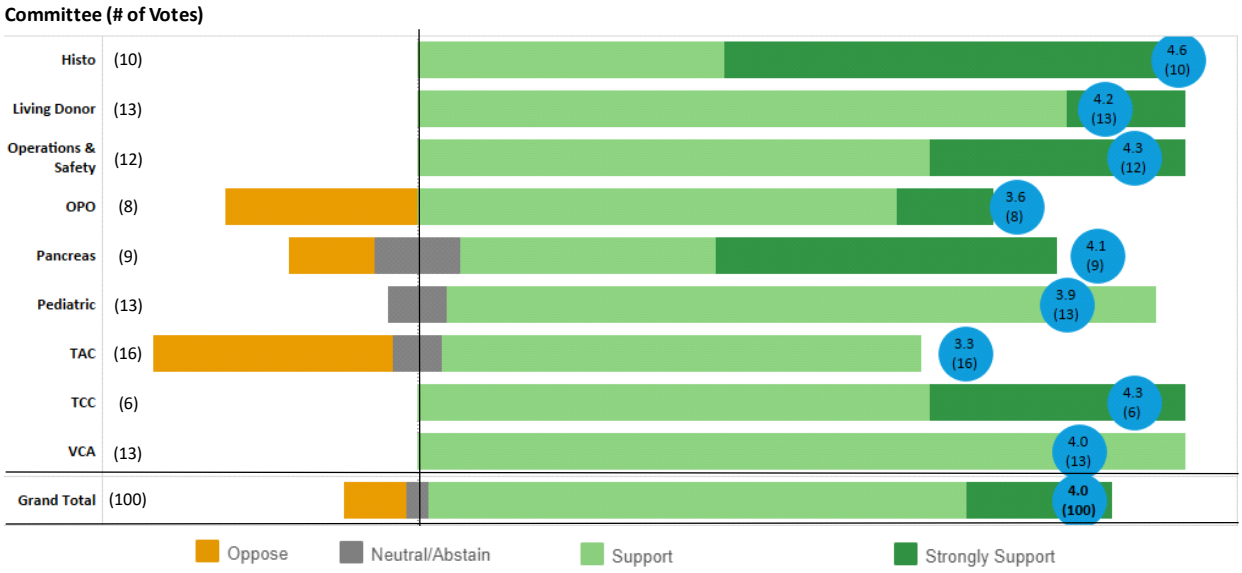
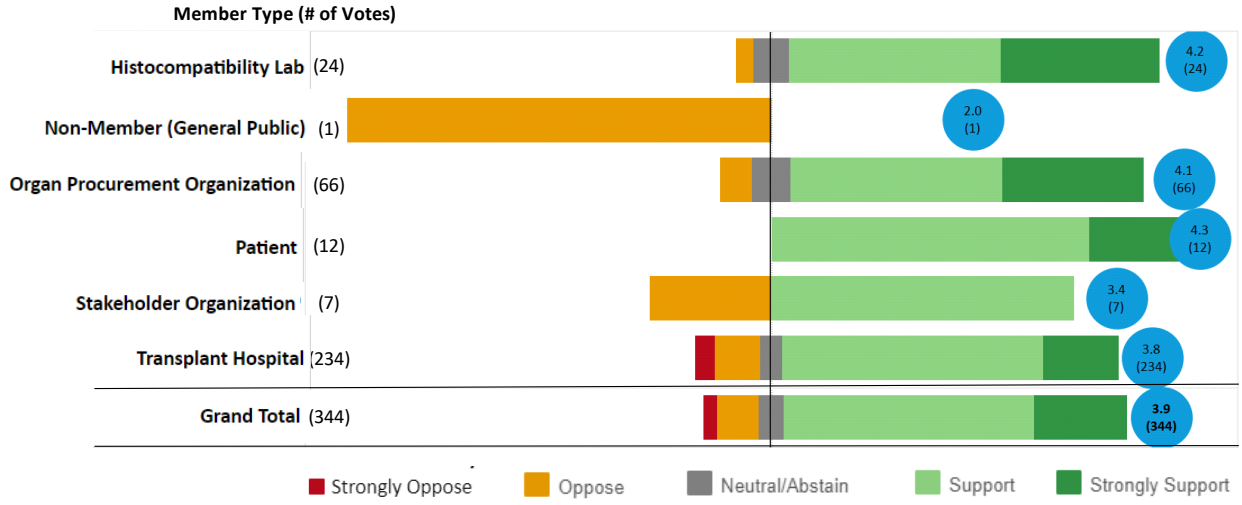


Figure 6 identifies sentiment support by OPTN member type. Transplant hospitals accounted for almost 70 percent of the total sentiment votes cast. Support among transplant hospital members was approximately 83 percent. OPOs accounted for the next most votes by member type, and their support for the proposal was approximately 85 percent. Only one vote was submitted by a non-member, although the graphic might suggest there was greater representation.

Figure 6: Sentiment Support for the Proposal, by Member Type



Four professional organizations submitted written comments (**Table 5**). The American Society of Transplantation (AST), the American Nephrology Nurses Association (ANNA), and the American Society for Histocompatibility and Immunogenetics (ASHI) provided written support. AST expressed support for all elements of the proposal, while indicating that some constituencies expressed concern about the potential for additional member burden meeting the new submission deadlines. The American Society

of Transplant Surgeons' (ASTS) written comment opposed the proposal based on its potential impact to transplant centers, while stating strong support for how OPO and HLA requirements are addressed.

Table 5: Support For or Opposition To the Proposal, by Medical Society

Organization	Response	Comments
American Society of Transplant Surgeons	Oppose	Support for proposal as it applies to OPOs and Histocompatibility labs. However, proposal is problematic for transplant centers who are already strained to the maximum to complete a large number of forms with a large number of data elements
American Society of Transplantation	Support	Extended time to submit data helps ensure accuracy at submission and should reduce need to change data. Some AST members expressed concern about increased burden
American Nephrology Nurses Association	Support	Support
American Society for Histocompatibility and Immunogenetics	Support	Extended submission timelines and data locking will help improve accuracy of donor and recipient histocompatibility data

Three general themes were raised during public comment. The primary theme is support for extending the submission deadlines and requiring additional steps to change the data after the deadline. The second most cited theme involves concerns that the proposed requirements place additional burdens on member institutions' data activities. The third general theme consists of requests for additional resources to help members meet the requirements. Within the general comments were sub-categories, which are discussed in greater detail.

Theme 1: Support for extending the submission deadlines and requiring additional steps to change the data after the deadline

In addition to the widespread agreement with the proposed solutions found in the sentiment voting results, the public comments submitted to the OPTN website also favored the proposal. Several comments expressed support for all aspects of the proposal. For example, one respondent's comment read "this doesn't seem to be too big of a change, I am comfortable with the timeliness and requesting permission to make changes to the data." Another commenter stated support for the efforts to "increase timelines for the submission of TEIDI (sic) data and for limiting the ability to make changes."

Other comments expressed support for certain aspects of the proposal. An OPO expressed strong support for the increased accountability and oversight associated with changing data in the proposal. A transplant program supported extending the submission deadlines because it provides "additional time for [programs] to obtain more accurate information." The program also supported requiring an explanation for unlocking data because it will lead to a better understanding of why data are changed.

Other comments submitted to the OPTN website supported the proposal's focus on improving data quality, but wondered whether extending the submission timelines would only result in members continuing to wait until the new deadline, or later, to submit their data. At least one commenter opposed the proposal because it extended the deadlines which are "already incredibly generous and

there are no data elements that shouldn't be available within the already established timeframes." During the course of the project, Committee members discussed the possibility that members would not use the additional time to improve the quality of their submissions. However, the members still felt strongly that extending the deadlines was the appropriate decision.

Theme 2: Proposed changes will only exacerbate existing data entry burden

Multiple comments referred to the additional burden members would face as a result of the proposed changes. Commenters defined the burden in different ways. For example, some indicated that the volume of forms their organization must complete is a challenge. Others reported that limited staffing and/or frequent staff turnover make data reporting difficult. A few commenters pointed to the additional steps in the proposed process around unlocking data and requiring leadership approval as unnecessarily diverting resources from more important issues.

The public comment proposal asked respondents to report the most common factors preventing their organizations from submitting accurate data within the established timeframes. The answers help illustrate why members view the proposed changes as adding to their activities. Some respondents reported that they do not have enough personnel to adequately complete the data entry and data validation activities. For instance, one comment stated "We have a process for [a] nurse coordinator review of forms and with their work load it can take a few weeks for them to [perform the review]." Another response indicated the issues with not having the correct personnel, "[our] data submission [is] done by non-clinical team members. [L]ocating data points in various parts of the [electronic medical record] is challenging for non-clinical staff." One respondent stated that their data validation process involves a single staff person comparing each data value entered in TIEDI with the corresponding value in the electronic medical record (EMR).

Suggested improvements included eliminating data elements that are not useful or relevant. In its role as an operating committee, DAC will be performing a comprehensive, on-going review of existing data elements. As part of this review, the Committee will identify elements that should be modified or removed. While the review process is being developed, the Committee will rely on the OPTN Data Principles and Vision Statement as a guide.

A few of the comments addressed the proposal's requirement to have leadership approve the changes made after the data has been locked. A regional meeting participant stated that the policy is vague concerning what staff would be acceptable to approve changes. A transplant program stated that leadership approval seems unnecessary if documentation exists to verify the reason for the change. While maintaining documentation may be helpful for OPTN reviews after the fact, the DAC included the leadership requirement to help members be aware of the types of changes being made at their institutions, as well as the frequency of the changes. When proposing the requirement as part of the data lock, the Committee considered it as an opportunity for a member organization to address a potential training or process issue before the matter became systematic.

Similarly, an OPO expressed concern that requiring OPOs to "maintain documentation demonstrating the accuracy of all data submitted" places an unintended new burden on OPOs. The commenter pointed out that some data submitted by OPOs, such as donor lab values and hemodynamics, are not maintained specifically by the OPO, but rather obtained through DonorNet®. The concern is that OPOs will now be required to maintain source documentation that they do not currently collect. The Committee members had a lengthy discussion about this matter during their October 10, 2019 in-person

meeting. The members agreed that the proposal was not intended to require OPOs to maintain source documentation which they had not previously maintained. Instead, the proposed language is a revision and continuation of the existing provision for maintaining documentation.[17]

Several comments submitted to the OPTN website discussed how increasing the use of technology could potentially reduce the burden associated with data entry and validation, while increasing data accuracy. These comments took the form of calls for the increased use of Application Programming Interfaces (API) to integrate data reporting and data collection functions. The OPTN has implemented APIs for more than half of the required data elements to make it more efficient for members to submit their data electronically. However, members have been slower to implement similar APIs on their side for providing the information. Others commented on the need to be able to seamlessly upload the data in their transplant databases into TIEDI.

Theme 3: Education and training would help improve data submission activities

Respondents to the proposal on the OPTN website were asked to identify the tools that would help their organizations (a) submit data on time, and (b) quickly identify data discrepancies. A number of comments addressed a need for resources to guide members through the data entry requirements. For example, a commentator said that currently it is up to those who complete the forms to teach others how to do it. The effectiveness of this practice is highly dependent on the individuals, and likely to be inconsistent across member institutions. Additionally, system changes may not be consistently communicated to all users. During their consideration of the public comment feedback, the Committee members voiced strong support for addressing members' requests for education and training.[18]

Possibly in conjunction with the concerns of additional workload, several comments suggested that addressing the education and training needs of those entering the data would result in greater data accuracy. Some also suggested that an effective education effort might mitigate the need for the Committee's proposed changes.

As part of the education discussion, many commentators identified a need to better define the data elements that are requested. This included a comment submitted by a transplant program recommending clearer variable definitions and better communication of data definition changes. Multiple comments stated that those entering the data do not understand what is being asked for on the TIEDI forms. Moreover, comments also indicated that data changes following submission were the result of confusion about the definitions of the TIEDI data elements.

Often, these comments also mentioned the need for clarifying and standardizing the data definitions. One commenter stated that there are not strict definitions of the variables or the circumstances in which answers should be submitted. Another commenter recommended eliminating the data elements with limited value or are subjective (such as functional status). During their October 2019 meeting, Committee members acknowledged these concerns and expressed their intentions to strengthen this activity as part of their new responsibilities under the new OPTN contract.

[17] Data Advisory Committee, Meeting Summary October 10, 2019, available at https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[18] Id.

Proposal Compliance

The proposal's emphasis on improving data accuracy is compliant with the requirements of the National Organ Transplantation Act and the OPTN Final Rule, particularly the Final Rule's requirements to make available timely and accurate data. The proposal aligns with the OPTN's Strategic Plan and to promote efficiency in donation and transplant.

Compliance Analysis with NOTA and the OPTN Final Rule

The Final Rule Requires that OPOs and transplant hospitals "shall…submit to the OPTN…information regarding transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed."[19] This proposal meets the requirements of the Final Rule by clarifying the conditions and deadlines by which OPTN members must provide data.

- **Make available to the public timely and accurate program-specific information on the performance of transplant programs:** The Committee recommends the proposed changes based on the principle that accurate data are necessary for determining allocation policies.
- **Such information shall be in the form required:** The Committee's intention behind eliminating *Policy 18.4 Data Submission Standard* and revising some of the language in *Policy 18.1 Data Submission Requirements* is to clarify for the OPTN members the information to be submitted.
- **Such information…shall be submitted in accordance with the schedule prescribed:** The Committee believes that extending the submission deadlines for TIEDI data will improve data integrity by providing OPTN members with additional time to enter and check their data values. The Committee also believes that implementing a process for locking data at its submission deadline will spur OPTN members to prioritize submitting accurate and timely data the first time.

Alignment with OPTN Strategic Plan

1. *Increase the number of transplants:* This proposal should not impact the number of transplants.
2. *Improve equity in access to transplants:* Improved data quality may lead to more accurate analysis of problems and better developed solutions that may help the OPTN and SRTR develop policies and practices that lead to more equitable organ allocation.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes*: Outcomes may improve as increased data accuracy and timeliness allow the transplantation community to identify beneficial treatments.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* This proposal's focus on assisting OPTN members with their efforts to initially submit accurately and timely data will reduce the need for members to spend time and staffing resources to correct mistakes later.

[19] 42 CFR §121.11(b)(2). (For additional discussion of the responsibilities, see "Organ Procurement and Transplantation Network." Federal Register 63:63 (April 2, 1998) p. 16320.

Implementation and Operational Considerations

The proposal is expected to entail substantial implementation efforts by the OPTN related to system reporting functionality, tool development to assist members, and communications. OPTN staff have reported a full 12 months may be necessary from an implementation perspective. Similarly, OPTN staff have estimated a considerable effort may also be needed because the changes impact all member types. Development and implementation of the member-specific resources to improve data quality will also require a substantial effort by OPTN staff.

Member organizations will also be impacted by the changes; however, because of the time the OPTN will need to implement the proposal, there is an opportunity to communicate about the changes with members and to provide the educational resources prior to implementation. The proposed changes clarify existing submission requirements and extend the due dates for data submitted using a TIEDI data collection instrument. The clarification and additional time should allow members to complete their data entry and data validation activities within the timeframes required for submission. Additionally, OPTN members will now be required to explain why data values are being changed following their official submission prior to making such changes. Members will also need to identify the individual responsible for approving the data changes as part of the process. Eventually, all transplant candidates, recipients, donors, and their families may be impacted as data quality improves and can be better used in all facets of transplantation.

Potential Fiscal Impact of Proposal

OPTN

Programming changes are required and will likely account for the majority of resources associated with this proposal. The changes may occur over a 12-month period and include changes to TIEDI forms with a team of five staff members. This is considered a “very large” effort at an estimated 2,600 hours to implement. The bulk of the programming effort involves modifying the current process used to import the forms. Other functions that must be programmed and tested include: implementing the new data submission deadlines, the process for unlocking data collection instruments, and capturing members’ data change reasons and approver information. Operationally, the existing data relationship between the Deceased Donor Registration and Death Notification Record forms will require re-programming to allow for the extension of the DDR deadline without adversely impacting members’ ability to comply with the DNR submission deadline.

Creating and enhancing reporting functionality to assist members with their data quality activities is expected to be a substantial effort. Members access existing data validation reports through the Data Services Portal. These will be expanded to address each organ by form type, and include all of the data fields captured on each form. Additionally, new data quality dashboards will be created for transplant programs, OPOs, and histocompatibility labs. The dashboards are being designed so that members can review the quality of their data across all forms, and make comparisons to national-level data. This level of detail should make it easier for members to identify systemic issues with their data, if they exist. Research implementation hours include development of the new data quality report and the Tableau dashboard. Ongoing hours include maintenance of those new tools.

The OPTN will provide educational and outreach materials to members explaining policy and system changes, introducing new data tools, and promoting best practices for ensuring timely and accurate data reporting. It is anticipated that at least one new training module may be required to assist members.

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. As part of the proposed policy changes, data are locked at the submission deadlines identified in *Policy 18.1.B: Timely Submission of Certain Data*. In order to change locked data, members must provide an explanation for the change, and provide the name of someone in a leadership position at their institution who approved the change. Currently, the OPTN does not collect an explanation of why data are changed, nor does it collect the name of the individual approving the change. The collection of new OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval from the federal Office of Management and Budget (OMB). The OMB approval process may impact the implementation timeline.

OPTN Members

Transplant centers without an already robust Quantitative Assurance (QA) process could experience financial burden to comply with new data submission policies. Centers may need to build out infrastructure to create additional screens and data collection fields. In most instances, build out may involve some aspects of the Electronic Health Record (EHR) and may also involve some transplant specific databases. Data for the proposal is likely collected from various repositories, so extracting it to comply may require more time depending on how easily it is extrapolated from the medical record. Staff at centers may perform the QA analysis function manually if the process is not already established electronically, although most centers do operate an electronic process. Burden is unique to each center, but may affect smaller centers disproportionately, since they may have less complex infrastructure. Different data elements would likely be entered by various staff members throughout the transplant process, with most of it being entered in the post-transplant phase. Any staff time associated with entering data collection post-transplant would likely *not* be reimbursed by payers. There is no mechanism to charge for data collection and entry into TIEDI.

The proposed changes will require all members to review their existing data collection, data entry and data validation work flows. Leadership at each member institution should be involved with the reviews. Not only will this raise general awareness, but it would also present an opportunity to quickly address any identified process, training, and performance issues. The level of knowledge regarding the type, frequency, and reasons for data changes likely varies by institution. A deeper understanding, could help members suggest ways to improve the quality of the data being submitted. Because of the significance of the proposed changes, even institutions with strong practices will want to perform a comprehensive review to identify areas of potential improvement.

Changes to processes, training, and staffing levels identified through the reviews could have a fiscal impact on some member institutions. Additionally, the current policies allow for some leeway with timeliness of data entry and members are accustomed to the current reporting timelines. As a result, changing member submission practices will likely require substantial outreach.

Implementation at centers could require four to five months, but it is dependent on the patient volume and capabilities of the existing infrastructure. This proposal may create efficiency for OPOs. It would reduce staff time to rework or change data entered by transplant centers, creating improved accuracy in submission. There are no implementation or ongoing costs for OPOs to comply with this proposal.

Extending submission dates throughout the year could allow for more opportunity to submit accurate and compliant data, but not necessarily create efficiency for transplant centers.

Monitoring and Evaluation Plan

Monitoring of OPTN members' data submission activities remain unchanged by the proposal. However, the reasons for and frequency of data changes will be collected for the first time and reviewed by the Committee, as well as reported to the Board of Directors at least annually.

Monitoring member compliance

The proposed language will not change the current routine monitoring of OPTN members. All policy requirements and data entered in UNet℠ may be subject to OPTN review, and members are required to provide source documentation as requested.

OPTN staff will continue to review rates of compliance with submission dates, as specified in *Policy 18.1.B*: *Timely Submission of Certain Data*, for the following data collection instruments:

- Deceased Donor Registration (DDR)
- Donor Organ Disposition
- Potential Transplant Recipient (PTR)
- Living Donor Registration (LDR)

For OPOs, OPTN staff will also continue to review a sample of deceased donor records to verify that data reported on the DDR are consistent with source documentation. For living donor recovery hospitals, the OPTN staff will continue to review a sample of living donor medical records to verify that data reported on the LDR are consistent with source documentation.

Policy evaluation

The proposed policy language requires the Committee to report at least annually to the Board of Directors the following:

- Data submission compliance rates
- Frequencies of data changes following submission, as well as the reported reasons associated with the changes; and
- Other relevant information identified by the Committee.

To assist in the Committee's reporting, UNOS Research and IT staff will provide regular reporting updates to the Committee.

Conclusion

As discussed throughout the document, there is broad public support for the changes recommended by the Committee to improve data quality. Members of the transplantation community raised important questions and concerns about the proposed changes during public comment. Members frequently stated concerns that the proposal creates additional work for an already overtaxed system. They point to unclear data definitions, duplicative data entry requirements, and submitting data that is not useful

as proof of the burden already placed on them. To address these issues, they request additional education and training opportunities before adding more requirements.

The Committee thoughtfully considered the concerns identified by the community. For example, as part of their deliberations, the Committee members discussed the advantages and disadvantages of extending versus maintaining the submission timeframes. Implementing a single policy addressing data submission requirements and deadlines addresses when data are due, and underscores the expectation that submitted data should be accurate. Implementing a multi-step process requiring members to "unlock" their submitted data and provide explanation for the changes prior to re-submission will improve data quality in several ways. First, members will likely seek to submit accurate data initially to avoid the steps required to make changes. Second, members' actions will be under greater scrutiny from the Committee when they must explain why submitted date are being changed as well as provide the name of an individual who approved the change. Third, because of the proposed data collection and reporting associated with the process, it benefits members to review their data entry and validation practices to identify and implement potential improvements. Members are also being provided additional tools and resources to help them meet the proposed requirements. By collecting the reasons members change their data will also help with future policy development, as the Committee will be able to consider the appropriateness of the explanations provided.

Opportunities exist to address some of the member questions and concerns raised during public comment. For example, an effort to clarify data definitions has been underway for some time and will likely grew as part of the Committee's transition to an operating committee of the Board of Directors. The Committee is now responsible for reviewing all OPTN data elements on a cyclical basis. As a result, the Committee is partnering with other OPTN committees in developing a process for identifying data elements for modification or removal, and then implementing the process.

These actions improve the widespread availability of trusted, complete, and accurate data for members seeking to use it for performance improvement. High-quality data will also improve the OPTN's policy development activities and evaluation of transplant system performance. Additionally, other researchers who study and assess transplant system performance will benefit from data quality improvements. It also aligns with the Final Rule's requirement that timely and institution-specific performance data be made publicly available in order to appraise the quality of transplantation programs

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

Policy 18 Data Submission Requirements

18.1 Data Submission Requirements

18.1.A Accurate Submission of Data

OPTN m~~M~~embers must ~~report~~ submit accurate data to the OPTN Contractor ~~according to *Table 18-1* below~~. Members ~~are responsible for providing~~ must maintain documentation ~~upon request to verify~~ demonstrating the accuracy of all data ~~that is~~ submitted to the OPTN ~~through the use of standardized forms~~.

18.1.B Timely Submission of Certain Data

Members must submit data to the OPTN Contractor according to Table 18-1.

Table 18-1: Data Submission Requirements

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Histocompatibility Laboratory	*Donor Histocompatibility* (DHS)	~~30~~60 days after the ~~OPO submits the deceased donor registration~~ DHS record is generated	Each ~~heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory~~ living and deceased donor
Histocompatibility Laboratory	*Recipient Histocompatibility* (RHS)	~~*Either* of the following:~~ • ~~30~~60 days after the transplant hospital removes the candidate from the waiting list because of transplant • ~~30 days after the transplant hospital submits the *recipient feedback*~~	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
OPOs~~, all~~	*Death Notification ~~records~~ Registration (DNR)*	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~~	*Monthly Donation Data Report: Reported Deaths*	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	*Potential Transplant Recipient* (PTR)	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	*Donor Organ Disposition (Feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	*Deceased Donor Registration* (DDR)	~~30~~60 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living Donor Feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to VCA donor organs

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Recovery Hospitals	*Living Donor Feedback* ~~Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Living Donor Adverse Events*~~	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	*Living Donor Registration* (LDR)	~~60~~90 days after the Recovery Hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	*Living Donor Follow-up* (LDF)	~~60~~90 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, domino donor, and non-domino therapeutic donor organs
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up* (TRF)	*Either* of the following: • ~~30~~90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure • 14 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ Specific Transplant Recipient Registration* (TRR)	~~60~~90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital ~~submits the *recipient feedback* form~~ removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	~~*Recipient feedback*~~ *Waiting List Removal for Transplant*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	*Recipient Malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital
Transplant hospitals	*Transplant Candidate Registration* (TCR)	~~30~~90 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

18.1.C Changes to Submitted Data

Upon expiration of the corresponding timeframe listed in Table 18-1, data submitted using the following instruments are considered final:

- Deceased Donor Registration (DDR)
- Donor Histocompatibility (DHS)
- Recipient Histocompatibility (RHS)
- Transplant Candidate Recipient (TCR)
- Transplant Recipient Registration (TRR)
- Living Donor Registration (LDR)
- Transplant Recipient Follow-up (TRF)
- Living Donor Follow-up (LDF)

Changes to final data will not be permitted unless the member reports, within the data collection system prior to making the changes, both the approval of the member's official OPTN Representative (or designee) and the reason for the changes.

18.1.D Reporting

The Data Advisory Committee must report to the Board of Directors at least annually all of the following:

- Data submission compliance rates;
- The frequencies of data change following submission and reasons reported; and
- Other relevant information identified by the Committee.

~~18.4 Data Submission Standard~~

~~18.4.A Timely Data Submission~~

~~*Table 18-3* below sets standards for Members' data submission.~~

Table 18-3: Data Submission Standard

~~The following members:~~	~~Must submit:~~	~~Of their:~~	~~Within:~~
~~OPOs, transplant hospitals and Histocompatibility Laboratories~~	~~95%~~	~~Required forms~~	~~Three months of the form due date~~
~~OPOs, transplant hospitals and Histocompatibility Laboratories~~	~~100%~~	~~Required forms~~	~~Six months of the form due date~~
~~OPOs~~	~~100%~~	~~PTR refusal code forms~~	~~30 days of the match run date~~
~~OPOs and transplant hospitals~~	~~100%~~	~~Donor and recipient feedback forms~~	~~30 days of the transplant date~~

~~If a member fails to submit forms by the standards above, then the OPTN Contractor will attempt to assist the member. However, if this is unsuccessful, the Membership and Professional Standards Committee (MPSC) may review the members' actions. If the MPSC determines that the member continues to be non-compliant with data submission requirements, then the MPSC may recommend an onsite audit to retrieve the missing data at the members' expense.~~

#

Appendix A: Letter from Health Resources and Services Administration Acting Associate Administrator to UNOS Executive Director, Dated June 10, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration

Healthcare Systems Bureau

JUN 15 RECD

Rockville, Maryland 20857

JUN 10 2005

Mr. Walter K. Graham
Executive Director
United Network for Organ Sharing
700 North 4th Street
Richmond, Virginia 23219

Dear Mr. Graham:

The purpose of this letter is to inform the United Network for Organ Sharing (UNOS) that data submitted to the Organ Procurement and Transplantation Network (OPTN) by organ procurement organizations (OPOs) and transplant hospitals are considered mandatory under § 121.11(b)(2) of the OPTN final rule. Failure of an OPO or transplant hospital to submit the data accurately and completely could be considered in violation of this section.

The final rule governing the operations of the OPTN became effective March 16, 2000. Section 121.11(b)(2) provides that:

> "[a]n organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital."

Additional notice of the enforceability of this provision under section 1138 of the Social Security Act can be found in the preamble of the April 2, 1998, final rule discussing the definition of "rule or requirements of the OPTN" for purposes of implementation of section 1138 (63 Fed. Reg. 16296 (1998)). On page 167301, the Department states that it considers a "rule or requirement of the OPTN" to be those rules developed as provided for in the regulations. The Department uses the data submission requirement found in §21.11(b)(2) as an example:

> "an OPO or transplant hospital participating in Medicare or Medicaid could be considered in violation of section 1138 if the Secretary found that it did not provide information to the OPTN as required specifically by § 121.11(b)(2) ...."

Data "specified by the Secretary" include the data found on the OPTN forms and applications reviewed and approved by the Office of Management and Budget (OMB) (OMB packages No. 0915-0157, expiration on August 31, 2007, and No. 0915-0184, expiration on December 31, 2007). Violations of the accuracy and completeness of the data submission requirements provided in the final rule could subject an OPO or transplant hospital to appropriate sanctions including, but not limited to, those relating to participation in or reimbursement under Medicare and Medicaid programs and removal of designation as a transplant program.

Given the potential consequences of violating this requirement, UNOS should provide OPOs and transplant hospitals with adequate notice of this mandatory data submission requirement and the potential consequence of violations under section 1138. This notice can be achieved through a message on the UNet system at the time of user entry into the system and any other appropriate methods.

If you have any questions, please contact Jim Burdick, M.D., Director, Division of Organ Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, at (301) 443-7577.

Sincerely,

Joyce G. Somsak
Acting Associate Administrator

Appendix B: Generation Information Associated With TIEDI Data Collection Instruments and Current Submission Requirements (As of November, 2019)

Title	Responsible Member	Generating Event	Generation Frequency	Generation Timing	Submission Requirement Within…
Deceased Donor Registration	OPO	Organ Disposition form completed in DonorNet	Once	After organ recovery	30 days of generation date
Donor Histo-compatibility	Histocompatibility Lab	Organ Disposition from completed in DonorNet Living donor status update completed	Once	Post-transplant	30 days after feedback completed
Living Donor Follow-up	Transplant Hospital	6 months after transplant	6 months; 1 year; 2 years	Post-transplant	60 days of generation date
Living Donor Registration	Transplant Hospital	Living donor status update completed Candidate removed from waiting list using donor's DonorID	Once	Post-transplant	60 days of generation date
Recipient Histo-compatibility	Histocompatibility Lab	Recipient status update completed Living donor status update completed	Once	Post-transplant	30 days after waiting list removal because of transplant
Transplant Candidate Registration	Transplant Hospital	Candidate added to waiting list	Once	Pre-transplant	30 days of generation date
Transplant Recipient Follow-up	Transplant Hospital	Transplant date entered removing recipient from waiting list	6 months; 1 year; Annually	Post-transplant	30 days after 6-month and annual anniversary of transplant until death or graft failure; or 14 days from notification of death or graft failure
Transplant Recipient Registration	Transplant Hospital	Recipient removed from waiting list	Once	Post-transplant	60 days after waiting list removal

Source: OPTN *Policy 18: Data Submission Requirements* and discussions with UNOS staff.

Appendix C: Percentage of TIEDI Forms Changed After the Due Date, By the Number of Days After the Due Date

TIEDI Form	Due Date	Number of Forms	Form was changed before or on due date	Form was changed within 30 days after due date	Form was changed from 31 to 60 days after the due date	Form was changed from 61 to 90 days after the due date	Form was changed more than 90 days after the due date
DDR	30 days after feedback completed	10,334	59%	17%	7%	5%	13%
DHS	30 days after feedback completed	16,402	82%	14%	2%	1%	1%
RHS	30 days after waitlist removal	31,246	73%	20%	3%	1%	3%
LDR	60 days after living donor feedback	6,084	76%	12%	2%	1%	9%
TCR	30 days after registering on waitlist	59,051	33%	9%	5%	5%	49%
TRR	60 days after waitlist removal	34,743	56%	13%	4%	4%	24%
LDF	60 days after anniversary date	17,870	79%	14%	3%	1%	3%
TRF	30 days after anniversary date	342,516	66%	19%	7%	6%	2%

Note: Percentages may not sum to 100 percent due to rounding.
Source: UNOS staff analysis of submitted TIEDI date, May 1, 2019.

Appendix D: Advantages and Disadvantages Associated With Implementing a Process for Changing Officially Submitted Data

Alternative	Advantages	Disadvantages
Prior review and approval by the OPTN required before member may change previously submitted data	• Changes permitted only under circumstances defined by the Committee or OPTN contactor • Public comment can obtain feedback about legitimacy of circumstances under which changes will be permitted • Could be modeled after Regional Review Board process • Underscores importance of submitting accurate and timely by the due date • Establishes a clear process for changing submitted data	• Requires new project form because proposal goes beyond scope of this project • Requires additional staffing or assignment of additional duties to existing staff to review and adjudicate requests • Requires additional programming to create a Regional Review Board-like process • Subjectivity of change requests positions the Committee and/or OPTN for charges of bias and inconsistency • Database may contain known errors because change requests do not meet established criteria • Volume and complexity of change requests could delay resolutions
Prior review and approval by the Data Advisory Committee or designated sub-committee required before member may change previously submitted data	• Changes permitted only under circumstances defined by the Committee or OPTN contactor • Public comment can obtain feedback about legitimacy of circumstances under which changes will be permitted • Could be modeled after Regional Review Board process • Underscores importance of submitting accurate and timely by the due date • Establishes a clear process for changing submitted data	• Requires new project form because proposal goes beyond scope of this project • Requires additional staffing or assignment of additional duties to existing staff to review and adjudicate requests • Requires additional programming to create a Regional Review Board-like process • Subjectivity of change requests positions the Committee and/or OPTN for charges of bias and inconsistency • Database may contain known errors because change requests do not meet established criteria • Volume and complexity of change requests could delay resolutions • Requires additional staffing or assignment of additional duties to existing staff to collect, review, and summarize members' requests for the Committee

Selected Proposal	• Advantages	• Disadvantages
Members make changes and provide explanation for change and name of individual at member institution approving change	• Improves data accuracy • Requires members to explain reason for change and assign responsibility for change to an individual at the institution • Creates data warehouse of change reasons • Permits analysis and reporting of submitted information • Permits detailed reporting of member behavior, including change reasons, frequency of changes, and elements being changed • Does not delay data changes • Increases member oversight of data changes • Position titles in EMPIR can be associated with specific individuals at member institutions who are likely responsible for data quality	• Changes to submitted data still permitted • Process may not provide expected level of deterrence • Level of detail needed to adequately analyze member behavior is unclear • Maintenance of position titles used to identify individuals with data quality responsibilities could require extensive resources

Appendix E: Data Standard of Review Checklist

Component or Measure	Criteria	Outcome of Review
Purpose, Population, Outcomes	Have the purpose, population, and intended outcomes of collecting this element been clearly articulated?	Yes. The purpose of collecting the data elements is to inform the Committee and the OPTN of the frequency of and reasons for data changes after the submission deadlines
OPTN Data Collection Principles	Is the proposal for collection of this element consistent with the principles? Policy development & compliance Member-specific performance evaluation Patient safety evaluation (no alternative source) Fulfill OPTN Final Rule requirements	Yes. Collecting the reasons why data are changed after submission can serve as a metric for OPTN and program performance as required by the Final Rule. Additionally, the steps required to change data after the deadline may improve the accuracy at the time of entry.
Alternative Data Sources	Have alternatives to collecting this by the OPTN been explored? Is this element available via an external source? Do we have to program data collection within the OPTN system, or can we acquire external data? Is a survey a viable option to collect these data, or must it be programmed within the system?	The proposed process for collecting why data are changed is likely the most efficient method of collecting the data. It impacts only those who want to change data after the deadlines. It is collected in the OPTN system, and does not require members to access another system.
Consistency Within System	Do we already collect this element within another part of our system? If so, is the proposal to collect this in a consistent manner or justifiably different?	The data are not collected elsewhere in the system.
Interoperability	Is this element collected in a standard format to enable data exchange opportunities with an electronic health record (EHR) or other health data system? Is there an objective surrogate commonly available in an EHR that should be considered?	The data have not been previously collected, and there has not been a comprehensive effort previously to identify all the reasons for date changes. The data will be collected in a standard format.
Validity	Is the element capable of eliciting the data we seek? Is it appropriately sensitive and specific? Is the prevalence sufficient for the intended purpose?	The intention is to collect information identifying why the data are being changed. Programs must provide specific reasons for changing their data. As appropriate numbers of reasons are collected, the Committee will consider revisions to the permissible reasons
Reliability	Is the element and collection mechanism designed to consistently reproduce the same results? Are there variations in interpretation that would reduce the utility?	The process has been designed to consistently collect the reasons for data changes.
Definition	Is the data element definition sufficiently clear to allow entry by the broad group of people currently entering OPTN data?	The data elements are designed to be clear and understandable by the users.

Component or Measure	Criteria	Outcome of Review
Usability	Is the form usable? Does the arrangement / grouping of fields on the form make sense to the users? Are the right fields on the right forms? Is the label data-oriented or clinically oriented; is it intuitive to user?	Yes. While not fully programmed, the grouping of the data elements for identifying the reasons for data changes will make sense to users.
Quality	How will we measure and assess data quality, with respect to: Availability (complete / missing, uptime / access), Timeliness, Accuracy, and Relevance?	Initially, there will be specific categories for users to choose from; however, there will also be an “other category.” The “other” category is necessary to capture all potential reasons. As data collection becomes more robust, the Committee will consider potential revisions to the list of acceptable reasons.