OPTN

Notice of OPTN Policy Change

Modify Data Submission Policies

Sponsoring Committee:	**Data Advisory**
Policies Affected:	***18.1: Data Submission Requirements***
	18.4: Data Submission Standards
Public Comment:	**August 2 – October 2, 2019**
Board Approved:	**December 3, 2019**
Effective Date:	**Pending programming and notice to OPTN members**

Purpose of Policy Change

Under the National Organ Transplant Act, the OPTN is required collect, analyze, and publish data concerning organ donation and transplants. *Policy 18: Data Submission Requirements* establishes OPTN data requirements, including that members must complete and submit data on transplant candidates, recipients, and donors. OPTN members and other data users have raised concerns about the integrity of the submitted data. The policy changes address the concerns by clarifying what information must be submitted and when it is due, and limiting members' ability to make post-deadline changes to data.

Proposal History

- The Committee started working on the proposal in early 2019.
- It went through public comment August 2-October 2, 2019.
- The proposal was supported in ten regions and by the majority of professional associations.

Summary of Changes

Submission deadlines are clarified and extended for certain data collection instruments used by the Transplant Information Electronic Data Interchange® (TIEDI). Data values will be "locked" after the established deadlines. Members' can "unlock" data after the deadlines to make changes, by describing why the changes are needed and acknowledging leadership awareness of the changes. The OPTN will provide annual reporting to the Board detailing the frequency of and reasons for the data changes.

Implementation

Members need to ensure data are entered accurately and within the new deadlines established for the TIEDI data collection forms. In support of this objective, members should review their existing data collection, entry, and validation practices to ensure submission of timely and accurate data. Members will need to educate staff on the revised deadlines and the new process for making data changes after the deadlines.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

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
OPO~~s, 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

The following member:	***Must submit the following instruments to the OPTN Contractor:***	***Within:***	***For:***
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
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

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
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
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

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
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 Registration (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.~~