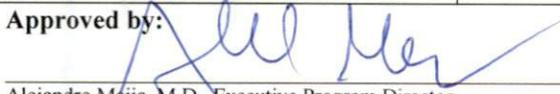


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|  Methodist Dallas Medical Center | Title: Data Submission Policy | Effective Date: 12/2007 |
| | Section: Liver, Kidney and Pancreas | |
| Approved by:  Alejandro Mejia, M.D., Executive Program Director | | Revision Date(s): 01/2015; 08/2019; 9/2022; 11/2025 |
|  Denise Harrington, Vice President Transplant Services | | |
|  Melody Holder, Director of Transplant Clinical Operations | | |
| | | Next review Date: 11/2028 |

Purpose: To meet data submission deadlines and thresholds required by OPTN and CMS

Policy: OPTN and CMS requirements for submission of general forms:

- 95% of required forms complete within three months of the due date and 100% of required forms complete within six months of the due date
- 100% of donor and recipient feedback forms within 30 days of the transplant date

Procedure:

| Form to be submitted: | Timeframe: | For the following groups: | Responsible person: |
|--|---|--|--|
| Living donor feedback | The time prior to donation surgery | For each potential living donor organ recovered at the hospital | Living donor coordinator/data analyst |
| Living donor feedback | 72 hours after 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 | Living donor coordinator/data analyst |
| Living donor registration (LDR) | 90 days after the Recovery Hospital submits the living donor feedback form | For each living donor organ recovered at the hospital | Living donor coordinator/data analyst |
| Living donor follow-up (LDF) | 90 days after the six-month, 1 year, and 2-year anniversary of the donation | For each living donor organ recovered at the hospital | Living donor coordinator and/or living donor advocate/data analyst |
| Organ specific transplant recipient registration (TRR) | 90 days after transplant hospital removes the recipient from the waiting list | For each recipient transplanted by the hospital | Transplant coordinator/data analyst |
| Transplant candidate registration (TCR) | 90 days after the transplant hospital registers the candidate on the waiting list | For each candidate on the waiting list or recipient transplanted by the hospital | Transplant Coordinator /data analyst |

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|---|--|--|---|
| Organ specific transplant recipient follow-up (TRF) | Either: 90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure OR 14 days from the notification of the recipient's death or graft failure | For each recipient followed by the hospital | Data Analyst with the assistance of the transplant coordinator |
| Waiting List Removal for Transplant | 1 day after the transplant | For each recipient followed by the hospital | Data Analyst/Transplant Coordinator involved in recipients transplant event |
| Liver Post-Transplant Explant Pathology | 60 days after transplant hospital removes candidates from waiting list | For each liver recipient transplant by the hospital | Liver coordinator and Data analyst |
| Recipient malignancy (PTM) | 30 days after the transplant hospital reports the malignancy on the transplant recipient follow-up form | For each recipient, with a reported malignancy, that is followed by the hospital | Data Analyst with the assistance of the transplant coordinator |

TIMELY COLLECTION OF DATA:

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary

| Form to be submitted: | Time period: | Responsible person: |
|--|--|--|
| Organ specific transplant recipient registration (TRR) | When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first | Data analyst with Inpatient transplant coordinator |
| Living donor registration (LDR) | When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first | Living donor coordinator/data analyst |
| Living donor follow-up (LDF) | 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date | Living donor coordinator and/or living donor advocate/data analyst |

CHANGES TO SUBMITTED DATA:

Upon expiration of the corresponding timeframe listed above, data submitted using the following instruments are considered final:

- Transplant Candidate Registration (TCR)
- Transplant Recipient Registration (TRR)
- Living Donor Registration (LDR)
- Transplant Recipient Follow-up (TRF)
- Living Donor Follow-up (LDF)

To make any changes after the submission deadline, approval must be obtained from either of the OPTN Representative designees (Transplant Clinical Program Manager or Transplant Quality Manager) and a reason for the changes must be documented, as per OPTN policy

LIVING DONOR DATA SUBMISSION REQUIREMENTS:

The follow up period for living donors will be a minimum of two years.

The OPTN Contractor will calculate follow-up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

REPORTING REQUIREMENTS AFTER LIVING KIDNEY DONATION:

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014

Required kidney donor status and clinical information includes all of the following:

- Patient status
- Working for income, and if not working, reason for not working
- Loss of medical (health, life) insurance due to donation
- Has the donor been readmitted since last LDR or LDF form was submitted?
- Kidney complications
- Regularly administered dialysis as an ESRD patient
- Donor developed hypertension requiring medication
- Diabetes
- Cause of death, if applicable and known

Required kidney laboratory data includes all of the following:

- Serum Creatinine
- Urine protein

Recovery hospitals must report these incidents through the OPTN Improving Patient Safety System within 72 hours of organ recovery. The MPSC will review and report all cases of redirected living donor organs to the OPTN Board of Directors.

LIVING DONOR ADVERSE EVENT REPORTING:

- A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia; must report within 72 hours after the aborted organ recovery procedure
- A living donor dies within 2 years after organ donation; must report within 72 hours after the program becomes aware
- A living donor is listed on the wait list within 2 years after organ donation; must report within 72 hours after the program becomes aware

- A living kidney donor begins regularly administered dialysis as and ESRD patient within 2 years after organ donation; must report within 72 hours after the program becomes aware
- A living donor organ is recovered but not transplanted into any recipient; must report within 72 hours after organ recovery
- A living donor organ is recovered and transplanted into someone other than the intended recipient; must report within 72 hours after organ recovery

POLICY VIOLATION

Any associate who fails to abide by this policy may be subject to disciplinary action, up to and including termination.

Reference: OPTN Policy 18