OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Member Evaluation Plan

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OPTN Member Evaluation Plan Introduction

OPTN members agree to comply with OPTN obligations, which are set forth in the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*., the OPTN Final Rule, 42 CFR Part 121, OPTN Bylaws, and OPTN Policies. The OPTN Member Evaluation Plan is provided as guidance for members on how the OPTN Contractor conducts its ***routine*** reviews and evaluations of members for performance and compliance with OPTN obligations.

Members are expected to comply with all obligations, regardless of whether an obligation is specifically described in the OPTN Member Evaluation Plan as one that is "routinely" monitored. Reports of non-compliance with any OPTN obligation will be investigated by the OPTN Contractor and are subject to review by the OPTN Membership and Professional Standards Committee (MPSC). The MPSC is authorized to take action against an OPTN member in accordance with OPTN Bylaws *Appendix L: Reviews and Actions*. OPTN Members must respond to all requests for information while investigating instances of potential non-compliance with OPTN Policies and Bylaws or potential threats to patient safety. In some instances of review, the MPSC will develop operational rules to maintain efficiency and guide the MPSC's workflow.[1]

Routine review and evaluation activities performed by the OPTN Contractor include, but are not limited to:

1. Reviewing applications submitted for OPTN membership and designation as an organ-specific transplant program or living donor recovery hospital
2. Reviewing applications for mandatory key personnel for maintenance of organ-specific transplant program or living donor recovery hospital designation
3. Monitoring member actions associated with transplant program inactivation or re-activation, and requests for withdrawal from the OPTN
4. Monitoring member transplant program and OPO performance-related data including graft and patient survival rates, transplant rates, and organ yield
5. Monitoring member compliance with IT security requirements for access to the OPTN Computer System
6. Site surveys of individual member compliance with OPTN obligations
7. Reviewing all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and investigating potential policy violations, including when:
    a. An organ is accepted for one candidate, but another candidate is transplanted
    b. Candidates on a match run are skipped or bypassed in order to allocate the organ to a candidate further down the match run
    c. An organ is transplanted into an individual who did not appear on the match run
    d. An organ is exported to a foreign country prior to exhausting the match run
8. Investigating issues reported to the OPTN Contractor or discovered during routine reviews of OPTN members, including:
    a. Potential patient safety events
    b. Potential donor-derived disease transmission events
    c. Living donor events
    d. Vessels recovered from a living donor or a donor positive for hepatitis B or hepatitis C that were transplanted into someone other than the recipient of that donor's organ
    e. Complaints
    f. Reports or allegations of potential member noncompliance with OPTN obligations

For more information on OPTN member requirements and obligations, see:

- National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.
- OPTN Final Rule, 42 CFR Part 121
- OPTN Bylaws *Article I: Membership*

[1] More information on the MPSC's operational rules can be found here: https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf.

- OPTN Bylaws *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*
- OPTN Bylaws *Appendix L: Reviews and Actions*

Policy 1.3: Variances

The OPTN Contractor will:

Monitor variances in an ad hoc and individualistic manner as variances are created. Each variance requires an evaluation plan and must meet OPTN standards to be approved. Any data submitted to the OPTN Contractor may be subject to review, and members are required to provide documentation as requested.

Policy 1.4: Allocation of Organs during Emergencies

The OPTN Contractor will:

Retrospectively review the allocation process for all deceased donor organs. Each organ will continue to be reviewed for compliance with the respective allocation policies. All allocations and reporting requirements will be reviewed appropriately.

Policy 2.2: OPO Responsibilities

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- An authorization to donate
- Reasons for excluding any donors from the eligible death definition
- Declaration of death note, including
    - Date and time of pronouncement of death
    - Signature(s) of the person(s) required under the relevant state's laws
- Blood specimen collection and storage noted in the donor chart, including a collection date that is no earlier than 1 day before the donor recovery date

Review a sample of deceased donors in the OPTN Computer System to verify that the following source documents were uploaded to the OPTN Computer System:

- ABO typing
- ABO subtyping (if applicable)
- Results for infectious disease tests that are required by *Policy 2.9: Required Deceased Donor Infectious Disease Testing*
- Death pronouncement
- Authorization for donation
- HLA typing

Review a sample of deceased donor records to verify that data reported through the OPTN Computer System are consistent with source documentation, including:

- Infectious disease test results

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 2.3: Evaluating and Screening Potential Deceased Donors

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- That the OPO attempted to obtain the donor's medical and behavioral history

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 2.4: Deceased Donor Medical and Behavioral History

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- The donor was assessed for the risk of acute HIV, hepatitis B (HBV), or hepatitis C (HCV) infection according to the criteria in the *U.S. Public Health Service (PHS) Guideline*
- Whether or not the OPO's assessment of the donor according to the *U.S. PHS Guideline* identified any risk criteria for acute HIV, HBV, or HCV infection
    - If the OPO identified any risk criteria for HIV, HBV, or HCV infection in the donor, that the OPO communicated this information to all receiving transplant programs
- Any evidence in the medical and behavioral history that the donor was exposed to or received HPDGH
    - If the donor was exposed to or received HPDGH, that this was communicated to the receiving transplant programs

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 2.5: Hemodilution Assessment

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- The calculations used to assess hemodilution
- The date and time of the blood draw for the blood used for the screening tests
- The date and time of the blood draw used to determine hemodilution
- If the donor samples are hemodiluted, that the following were communicated to the accepting transplant programs:
    - Any screening results from the hemodiluted specimens
    - The tests completed on the hemodiluted specimens
    - The hemodilution calculation used for the hemodiluted specimens, if requested

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 2.6: Deceased Donor Blood Type Determination and Reporting

During OPO site surveys, the OPTN Contractor will:

Review the OPO's internal policies, procedures, and protocols to verify that it has a written protocol(s) that includes:

- Determining blood type by testing at least two separate blood samples with different collection times
- A process for resolving conflicting or indeterminate primary blood types
- A definition of the qualified health care professionals who can participate in blood type verification and reporting
- That blood type verification and reporting occurs prior to the match run
- That the two individuals performing blood type reporting each consult source documents from all known available blood type tests

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for blood type determination and reporting.

OPOs will provide:

- The OPO's internal policies, procedures, and protocols for the management of deceased donors
- Access to relevant staff who can answer interview questions

Additional Guidance:

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 2.6.B: Deceased Donor Blood Subtype Determination

During OPO site surveys, the OPTN Contractor will:

Review the OPO's internal policies, procedures, and protocols to verify that it has a written protocol(s) that includes:

- Determining blood subtype by testing at least two separate blood samples with different collection times
- Only using pre-red blood cell transfusion samples for subtyping
- Not reporting subtype when there are conflicting or indeterminate subtyping results

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for blood subtype determination and reporting.

Review a sample of deceased donor records when subtype is reported, to verify that:

- Subtyping tests were completed on at least two separate blood samples
- Only pre-red blood cell transfusion samples were used for subtyping
- All samples used for the subtyping tests have different draw times
- All subtyping tests have identical results

OPOs will provide:

- The requested sample of deceased donor medical records
- The OPO's internal policies, procedures and protocols for the management of deceased donors
- Access to relevant staff who can answer interview questions

Policy 2.6.C: Reporting of Deceased Donor Blood Type and Subtype

Required Reporting:

OPTN Policy 18.5.C: *Required Reporting by OPOs* requires a host OPO to report if an ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in OPTN Policy 2.6.C*: Reporting of Deceased Donor Blood Type and Subtype,* and after the OPO has executed a match run. OPOs are required to report these events to the OPTN Patient Safety Reporting Portal within 72 hours after the OPO becomes aware of the event.

Policy 2.8: Required Deceased Donor General Risk Assessment

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for documentation that there are results or other evidence that the following were performed:

- Urinalysis within 24 hours before cross clamp

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 2.9: Required Deceased Donor Infectious Disease Testing

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for documentation of results or other evidence that the following were performed and that results reported through the OPTN Computer System are consistent with source documentation:

- HIV, HBV, and HCV testing using samples drawn no earlier than 4 days before the donor recovery date:
    - HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
    - HIV ribonucleic acid (RNA) screening or diagnostic nucleic acid test (NAT)
    - Hepatitis B surface antigen (HBsAg) screening test
    - Hepatitis B core antibody (total anti-HBc) screening test
    - Hepatitis B deoxyribonucleic acid (DNA) screening or diagnostic NAT
    - Hepatitis C antibody screening test (anti-HCV)
    - Hepatitis C RNA screening or diagnostic NAT
- Cytomegalovirus (CMV) antibody (anti-CMV) screening or diagnostic test
- Epstein-Barr Virus (EBV) antibody (anti-EBV) screening or diagnostic test
- Syphilis screening or diagnostic test
- Toxoplasma Immunoglobulin (IgG) antibody test

OPOs will provide:

The requested sample of deceased donor medical records.

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. In the event the OPTN Contractor identifies instances where deceased lung donors were not tested for SARS-CoV-2 by NAT performed on a lower respiratory specimen, the OPTN Contractor will inquire with the member.

Additional Resources:

FDA-approved screening and diagnostic tests: http://tinyurl.com/FDA-SCREENING

Policy 2.11.B: Required Information for Deceased Liver Donors

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased liver donor records for documentation of:

- Results or other evidence that direct bilirubin was performed
- Results or other evidence that total bilirubin was performed

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 2.11.E: Required Information for Deceased Pancreas Donors

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased pancreas donor records for documentation of:

- Serum amylase
- Serum lipase

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 2.12: Post Procurement Follow Up and Reporting

During OPO site surveys, the OPTN Contractor will:

Review the OPO's internal policies, procedures, and protocols to verify that it has a written protocol(s) for:

- Obtaining deceased donor test results and reporting them to the OPTN Contractor
- Reporting positive test results and relevant information to receiving transplant programs and, when required, to the OPTN Patient Safety Reporting Portal

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for post-procurement follow-up and reporting of deceased donor test results.

OPOs will provide:

- The OPO's internal policies, procedures, and protocols for the management of deceased donors
- Access to relevant staff who can answer interview questions

Policy 2.14.B: Pre-Recovery Verification

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- A verification for each organ containing:
    - Donor ID

    - Organ
    - Organ laterality (if applicable)
    - Donor blood type
- And when the intended recipient is known prior to recovery, verification for each organ containing:
    - Intended recipient unique identifier
    - Intended recipient blood type
    - Donor and intended recipient are blood type compatible or intended incompatible

Review the OPO's internal policies, procedures, and protocols to verify that it has a written protocol(s) that includes:

- Definition of qualified healthcare professionals to perform the pre-recovery verification
- Verification of the following by the on-site recovering surgeon and a qualified health care professional:
    - Donor ID
    - Organ
    - Organ laterality (if applicable)
    - Donor blood type
    - Donor blood subtype (if used for allocation)
- Verification of the following by two qualified health care professionals when the intended recipient is known prior to recovery:
    - Intended recipient unique identifier
    - Intended recipient blood type
    - Donor and intended recipient are blood type compatible or intended incompatible
- Sources used for verification

Interview OPO staff to verify that OPO staff practices align with OPTN policy and with the OPO's policies and procedures for pre-recovery verifications.

OPOs will provide:

- The requested sample of deceased donor medical records
- The OPO's internal policies, procedures and protocols for the management of deceased donors
- Access to relevant staff who can answer interview questions

Policy 2.14.C: Organ Procurement Procedures

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- All flush solutions and additives
- All flush solution and additive lot numbers

OPOs will provide:

The requested sample of deceased donor medical records.

Policy 3.1: Access to the OPTN Computer System

Required User Training

The OPTN Contractor will:

Assign required OPTN training annually and upon account creation for every OPTN Computer System User. The training will be information-security focused and based on policies and the system terms of use for the OPTN Computer System.

Users will be required to pass an exam at the end in order to complete the training. Users will have 45 days from assignment to complete the training and exam.

The OPTN Contractor will maintain documentation of user completion and testing status in the OPTN Learning Management System and provide this documentation to each user. This documentation is accessible to Site Security Administrators for all users at their organization.

OPTN Members will:

Ensure that their users complete the required training and exam within 45 days of assignment.

Policy 3.1.A: Security Requirements for Systems Accessing the OPTN Computer System

Security Framework Attestations

The OPTN Contractor will:

Send out requests for self-attestations from OPOs, Transplant Hospitals, and Histocompatibility Labs on each members' current security framework on an annual basis. The attestation questions will be based on NIST 800-171 Rev. 2 controls and will be delivered to the designated Information Security Contacts at the member organization. Documentation may be requested within the security framework assessment to support a given answer to a control question.

Provide timely review and follow up to attestations submitted by members. Discuss any identified gaps found in the attestation with the members' Information Security Contacts and support development of a plan for remediation.

OPOs, Transplant Hospitals, and Histocompatibility Labs will provide:

Attestations to the adherence to their established security framework through the official request delivered by the OPTN Contractor within the specified timeframe for response. Documented evidence will be included as requested to support assessment responses.

Timely responses to OPTN Contractor inquiries on submitted attestations. Engage in follow up conversation with OPTN Contractor to discuss and develop remediation plans for identified gaps.

Security Requests for Information

The OPTN Contractor will:

Send out requests for information to OPOs, Transplant Hospitals, and Histocompatibility Labs based on known exploited vulnerabilities. Documentation required for each request may vary, and the OPTN Contractor will provide the documentation needed and timeframe for response at the time the request is submitted.

OPOs, Transplant Hospitals, and Histocompatibility Labs will provide:

Responses to the requests for information and requested documentation on the specified timeframe for response.

Policy 3.1.B: Site Security Administrators

The OPTN Contractor will:

Periodically monitor to ensure that each OPO and histocompatibility lab has designated at least two site security administrators, and that each transplant hospital has designated at least two site security administrators per approved program.

Conduct periodic User Audits of OPTN Computer System users through assignment to member organization's site security administrators. Site security administrators will need to evaluate that all users have appropriately assigned permissions based on the Principle of Least Privilege.

OPOs, Transplant Hospitals, and Histocompatibility Labs will provide:

Timely updates to their site security administrators, including notification to the OPTN Contractor when individual(s) have either left their organization or relinquish their role as a site security administrator.

Routine audits to their OPTN Computer System users, verifying that all users are given the appropriate permissions based on the NIST principle of least privilege.

Policy 3.1.C: Security Incident Management and Reporting

OPOs, Transplant Hospitals, and Histocompatibility Labs will provide:

Notification of security incidents within the timeframe required by policy.

If requested, members will also provide status updates on an agreed upon schedule, as well as control and verification requirements. Members may be directed to take specific actions based on the scope and severity of the security incident and the potential to impact the OPTN Computer System.

The OPTN Contractor will:

Communicate necessary status updates and control and verification requirements based on the scope and severity of the security incident(s) OPOs, Transplant Hospitals, and Histocompatibility Lab members report. The OPTN Contractor will also communicate any specific actions members may need to take based on the scope and severity of the security incident(s) and the potential to impact the OPTN Computer System.

The OPTN Contractor will monitor user and member activity in the OPTN Computer System to determine any potential risks to the OPTN Computer System and OPTN Data.

Policy 3.1.C.i: Information Security Contact

The OPTN Contractor will:

Periodically monitor to ensure there is at least one Information Security Contact designated per transplant hospital, OPO, and histocompatibility lab.

Contact this designated individual first in the event of a known security event.

Request annually that this individual complete a security framework attestation and respond to any further follow up discussion on identified security gaps.

Send information security requests for information to these designated individuals.

OPOs, Transplant Hospitals, and Histocompatibility Labs will provide:

The name and contact information for their Information Security Contact, which can be more than one individual if the member chooses. Individual(s) must be able to fulfill the responsibilities identified in policy: provide 24/7 capability for incident response and communications, receive relevant notifications of security incidents, communicate information regarding security incidents to the OPTN, and facilitate development and fulfillment of the security requirements for systems accessing the OPTN Computer System.

Prompt notification of new individual to this responsibility in the event existing Information Security Contact is removed.

Policy 3.2: Notifying Patients of Their Options

During transplant hospital site surveys, the OPTN Contractor will:

Interview relevant staff to verify that hospital staff practices align with OPTN policy.

Transplant hospitals will provide:

Access to relevant staff who can answer interview questions.

Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration

During transplant hospital site surveys, the OPTN Contractor will:

Review the hospital's internal policies, procedures, and protocols to verify that it has a written protocol(s) that includes:

- Testing two candidate blood samples before waiting list registration that:
  - Are drawn on separate occasions
  - Have different collection times
  - Are submitted as separate samples
- Reporting candidate blood type:
  - By two qualified healthcare professionals
  - Using all known available blood type determination source documents
- Definition of qualified health care professionals who can participate in blood type verification and reporting
- A process for resolving conflicting or indeterminate primary blood type results

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for blood type determination and reporting.

Transplant hospitals will provide:

- The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients
- Access to relevant staff who can answer interview questions

Additional Guidance:

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. In the event the OPTN Contractor identifies an instance where an active candidate is registered with the same hospital or another hospital with the same social security number but a different blood type, the OPTN Contractor will inquire with the member(s).

Policy 3.4.C: Candidate Registrations

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. In the event the OPTN Contractor identifies a recipient of a living donor organ who

was not registered as a candidate on the waiting list prior to being transplanted, the OPTN Contractor will inquire with the member.[2]

Policy 3.5: Patient Notification

During transplant hospital site surveys, the OPTN Contractor will:

Interview relevant staff to verify that hospital staff practices align with OPTN policy.

Transplant hospitals will provide:

Access to relevant staff who can answer interview questions.

Additional Resources:

Patient Information Letter: http://optn.transplant.hrsa.gov/resources/informing-patients

Policy 3.6.C: Individual Waiting Time Transfers

During transplant hospital site surveys, the OPTN Contractor will:

Interview relevant staff to verify that hospital staff practices align with OPTN policy.

Transplant hospitals will provide:

Access to relevant staff who can answer interview questions.

Policy 3.7.D Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

During transplant hospital site surveys, the OPTN Contractor will:

Interview relevant staff to verify that hospital staff practices align with OPTN policy.

Transplant hospitals will provide:

Access to relevant staff who can answer interview questions.

Policy 5.1.A: Kidney Minimum Acceptance Criteria

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. The OPTN Contractor will notify Kidney Transplant Programs of upcoming due dates and ensure the programs report to the OPTN annually their Kidney Minimum Acceptance Criteria. In the event the OPTN Contractor identifies a program is past due, the OPTN Contractor will inquire with the member.

[2] The MPSC set an operational rule for reviewing instances of noncompliance with this policy. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

Transplant hospitals will provide:

Timely review and updates to their Kidney Minimum Acceptance Criteria.

Policy 5.3.C: Informed Consent for Kidneys Based on KDPI Greater than 85%

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Kidney-alone transplant recipients who received a kidney with a Kidney Donor Profile Index (KDPI) score greater than 85% gave written informed consent to receive offers for kidneys with a KDPI score greater than 85%
- Multi-organ transplant recipients whose transplant included a kidney with a KDPI score greater than 85% gave written informed consent to receive the kidney before it was transplanted

If there is not a sample for review, site surveyors will interview relevant staff to verify that hospital staff practices align with OPTN policy.

Transplant hospitals will provide:

- The requested sample of medical records
- Access to relevant staff who can answer interview questions, if applicable

Additional Guidance:

Additional consent is not required to receive offers of kidneys with a KDPI greater than 85% for candidates who were registered on the kidney waiting list before December 4, 2014 and were consented to receive an ECD kidney.

Policy 5.4: Organ Offers

The OPTN Contractor will:

Conduct ongoing reviews of the allocation process for deceased donor organs that result in a transplant. Instances of noncompliance will result in an inquiry from the OPTN Contractor.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 5.4.B: Order of Allocation

The OPTN Contractor will:

Review all instances of deceased donor organs exported to hospitals in foreign countries to ensure that all potential transplant recipients (PTRs) on the match run have been offered the organ.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 5.4.E: Allocation to Candidates Not on the Match Run

The OPTN Contractor will:

Conduct ongoing reviews of directed donations and request the following information:

- Authorization to donate
- Name of recipient
- Organ type
- Recipient hospital

Members will provide:

The information listed above and any other supporting documentation necessary to verify compliance.

Policy 5.7: Organ Check-In

During transplant hospital site surveys, the OPTN Contractor will:

Review the hospital's internal policies, procedures, and protocols to verify that it has a written protocol for:

- Organ check-in including the following elements:
    - Timing:
        - Upon arrival at the transplant hospital
        - Before opening external container
    - Verification using OPTN external label of:
        - Donor ID
        - Organ type
        - Organ laterality (if applicable)
    - Notifying OPO within 1 hour if it is not an expected organ

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for organ check-in.

Transplant hospitals will provide:

- The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients
- Access to relevant staff who can answer interview questions

Required Reporting:

OPTN Policy 18.5.A: *Required Reporting by Transplant Hospitals* requires a transplant hospital to report if:

- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ

Transplant hospitals are required to report these events to the OPTN Patient Safety Reporting Portal within 72 hours after the transplant hospital becomes aware.

Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt

During transplant hospital site surveys, the OPTN Contractor will:

Review the hospital's internal policies, procedures, and protocols to verify that it has a written protocol(s) that includes:

- Pre-transplant verification prior to organ receipt that includes:
    - Participation by two licensed healthcare professionals

    - Timing of the pre-transplant verification
        - Recipient in the operating room
        - Either before induction of general anesthesia or before incision if the recipient is already under continuous sedation before arriving in the operating room
    - Verification of expected donor:
        - Donor ID
        - Organ
        - Lung laterality (if applicable)
        - Blood type
        - Blood subtype (if used for allocation)
    - Verification of recipient
        - Unique identifier
        - Blood type
    - Verification that the expected donor and intended recipient are blood type compatible or intended incompatible
    - Sources used for verification
- Pre-transplant verification upon organ receipt that includes:
    - Participation by the transplant surgeon and another licensed health care professional
    - Timing of the pre-transplant verification
        - Organ and recipient are in the operating room
        - Before anastomosis of the first organ
    - Verification of donor:
        - Donor ID
        - Organ
        - Organ laterality (if applicable)
        - Blood type
        - Blood subtype (if used for allocation)
    - Verification of recipient
        - Unique identifier
        - Blood type
    - Verification that the donor and intended recipient are blood type compatible or intended incompatible
    - Verification that the correct donor organ has been identified for the correct recipient
    - Sources used for verification

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for pre-transplant verifications.

Transplant hospitals will provide:

- The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients
- Access to relevant staff who can answer interview questions

Additional Guidance:

For purposes of this policy, a living donor organ is not considered "received" until it has been recovered.

Required Reporting:

OPTN Policy 18.5.A*: Required Reporting by Transplant Hospitals* requires a transplant hospital to report if:

- A donor organ is identified as incorrect during pre-transplant processes conducted according to OPTN Policy 5.8.A*: Pre-Transplant Verification Prior to Organ Receipt*

- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to OPTN Policy 5.8.A*: Pre-Transplant Verification Prior to Organ Receipt*
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to OPTN Policy 5.8.A*: Pre-Transplant Verification Prior to Organ Receipt*

Transplant hospitals are required to report these events to the OPTN Patient Safety Reporting Portal within 72 hours after the transplant hospital becomes aware.

Policy 5.8.B: Pre-Transplant Verification upon Organ Receipt

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The following were verified between organ arrival and anastomosis:
  - Donor ID
  - Organ
  - Laterality (if applicable)
  - Donor blood type
  - Recipient unique identifier
  - Recipient blood type
  - Donor and recipient are blood type compatible or intended incompatible
  - Correct donor organ has been identified for the correct recipient
- The following are documented:
  - Intended recipient arrival time in the operating room (OR) or documentation showing intended recipient present at time of verification
  - Organ arrival time in the OR or documentation showing organ present at time of verification
  - Verification time
  - Anastomosis time or documentation showing verification occurred prior to anastomosis

Transplant hospitals will provide:

The requested sample of medical records.

Additional Guidance:

For purposes of this policy, a living donor organ is not considered “received” until it has been recovered.

Required Reporting:

OPTN Policy 18.5.A*: Required Reporting by Transplant Hospitals* requires a transplant hospital to report if:

- A donor organ is identified as incorrect during pre-transplant processes conducted according to OPTN Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*
- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to OPTN Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to OPTN Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*

Transplant hospitals are required to report these events to the OPTN Patient Safety Reporting Portal within 72 hours after the transplant hospital becomes aware.

Policy 5.9: Released Organs

The OPTN Contractor will:

Conduct ongoing reviews of the released organ allocation process for deceased donor organs that are transplanted. In the event that an organ is not transplanted into the patient it was accepted for, the OPTN Contractor will inquire with the OPO and the transplant hospital.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 5.10.E: Allocation of Heart-Kidneys

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation available at the time of entry, including:

- For recipients receiving a heart-kidney transplant based on a diagnosis of CKD:
    - Regularly administered dialysis for ESRD
    - Measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 30 mL/min on either:
        - The date of the most recent result before registration on the kidney waiting list
        - A date after registration on the kidney waiting list
- For recipients receiving a heart-kidney transplant based on a diagnosis of sustained acute kidney injury:
    - Dates of dialysis received
    - Measured or estimated CrCl or GFR values less than or equal to 25 mL/min and the corresponding collection dates for each value

Transplant hospitals will provide:

The requested sample of medical records.

Policy 5.10.F: Allocation of Lung-Kidneys

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation available at the time of entry, including:

- For recipients receiving a lung-kidney transplant based on a diagnosis of CKD:
    - Regularly administered dialysis for ESRD
    - Measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 30 mL/min on either:
        - The date of the most recent result before registration on the kidney waiting list
        - A date after registration on the kidney waiting list
- For recipients receiving a lung-kidney transplant based on a diagnosis of sustained acute kidney injury:
    - Dates of dialysis received
    - Measured or estimated CrCl or GFR values less than or equal to 25 mL/min and the corresponding collection dates for each value

Transplant hospitals will provide:

The requested sample of medical records.

Policy 6.1.A: Adult Heart Status 1 Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in the OPTN Computer System to justify a candidate's status are consistent with documentation in the candidate's medical record, including:

- Evidence of admission to the transplant hospital that registered the candidate on the waiting list on each day registered at status 1
- Support by a required mechanical circulatory support device (MCSD), including:
    - Device type
    - Device brand (if applicable)
    - Implant/initiation date and time
    - Ventricle support (if applicable)
- Evidence that the candidate is supported by the required MCSD on each day registered at status 1
- Required lab values, including collection dates and times
- Required therapies, hemodynamic measurements, diagnoses, and clinical observations and events, including reported dates and times

Transplant hospitals will provide:

The requested sample of medical records.

Policy 6.1.B: Adult Heart Status 2 Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in the OPTN Computer System to justify a candidate's status are consistent with documentation in the candidate's medical record, including:

- Evidence of admission to the transplant hospital that registered the candidate on the waiting list, if required, on each day registered at status 2
- Support by a required mechanical circulatory support device (MCSD), if applicable, including:
    - Device type
    - Device brand (if applicable)
    - Implant/initiation date and time
    - Ventricle support (if applicable)
- Evidence that the candidate is supported by the required MCSD, if applicable, on each day registered at status 2
- Required lab values, including collection dates and times
- Required therapies, hemodynamic measurements, diagnoses, and clinical observations and events, including reported dates and times

Transplant hospitals will provide:

The requested sample of medical records.

Policy 6.1.C: Adult Heart Status 3 Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in the OPTN Computer System to justify a candidate's status are consistent with documentation in the candidate's medical record, including:

- Evidence of admission to the transplant hospital that registered the candidate on the waiting list, if required, on each day registered at status 3
- Support by a required mechanical circulatory support device (MCSD), if applicable, including:
    - Device type
    - Device brand (if applicable)
    - Implant/initiation date and time
    - Ventricle support (if applicable)
- Evidence that the candidate is supported by the required MCSD, if applicable, on each day registered at status 3
- Hemodynamic monitoring, if required
- Required lab values or results, including collection dates and times
- Required therapies, hemodynamic measurements, diagnoses, classifications, and clinical observations and events, including reported dates and times

Transplant hospitals will provide:

The requested sample of medical records.

Policy 6.1.D: Adult Heart Status 4 Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in the OPTN Computer System to justify a candidate's status are consistent with documentation in the candidate's medical record, including:

- Support by a required mechanical circulatory support device (MCSD), if applicable, including:
    - Device type
    - Device brand (if applicable)
    - Implant/initiation date and time
    - Ventricle support (if applicable)
- Evidence that the candidate is supported by the required MCSD, if applicable, on each day registered at status 4
- Required therapies, hemodynamic measurements, diagnoses, classifications, and clinical observations and events, including reported dates and times

Transplant hospitals will provide:

The requested sample of medical records.

Policy 6.2.A: Pediatric Heart Status 1A Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in the OPTN Computer System to justify a candidate's status are consistent with documentation in the candidate's medical record, including:

- Evidence of admission to the hospital that registered the candidate on each day registered at status 1A, plus at least one of the following:
    - Administration of continuous mechanical ventilation on each day registered at status 1A
    - Assistance of an intra-aortic balloon pump on each day registered at status 1A
    - Ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion
    - Infusion of a qualifying high-dose IV inotrope or multiple qualifying IV inotropes on each day registered at status 1A, plus a qualifying congenital heart disease diagnosis
- Assistance of a mechanical circulatory support device

Transplant hospitals will provide:

The requested sample of medical records.

Policy 6.3: Status Updates

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, to verify:

- That a candidate's status or criteria used to justify the current status are updated in the OPTN Computer System within 24 hours of a change in the candidate's medical condition to accurately reflect the change in condition

Transplant hospitals will provide:

The requested sample of medical records.

Policy 6.4: Adult and Pediatric Status Exceptions

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in the OPTN Computer System to justify a candidate's status are consistent with documentation in the candidate's medical record, including:

- Evidence of admission to the hospital that registered the candidate on the waiting list, if required
- For candidates whose implanted mechanical circulatory support device (MCSD), or a component within, has been recalled by the U.S. Food and Drug Administration, support by a required MCSD, including:
    a. Device type
    b. Device brand
    c. Implant/initiation date
    d. Ventricle support (if applicable)
- For candidates whose implanted MCSD, or a component within, has been recalled by the U.S. Food and Drug Administration, evidence that the device was implanted at the time of the exception request, and the transplant physician has determined an entire device replacement or replacement of a component of the device is required to sufficiently mitigate the risks associated with the recall

Transplant hospitals will provide:

The requested sample of medical records

Policy 6.6: Heart Allocation Classifications and Rankings

The OPTN Contractor will:

Conduct ongoing reviews of match runs and allocation processes for deceased donor hearts that result in a transplant. These allocations are reviewed to ensure compliance with the appropriate allocation table and match run requirements. All allocations that deviate from the match run will be reviewed by the OPTN Contractor.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 6.6.F: Allocation of Heart-Lungs

The OPTN Contractor will:

Conduct ongoing reviews of match runs and allocation process for deceased donor heart-lung transplants to ensure the OPO placed the organs with the appropriate recipients in accordance with the policy requirements.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 7.3: Intestine Allocation Classifications and Rankings

The OPTN Contractor will:

Conduct ongoing reviews of match runs and allocation processes for deceased donor intestines that result in a transplant. These allocations are reviewed to ensure compliance with the appropriate allocation table and match run requirements. All allocations that deviate from the match run will be reviewed by the OPTN Contractor.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 8.3.A: Waiting Time for Candidates Registered at Age 18 Years or Older

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Measured or estimated creatinine clearance less than or equal to 20 mL/min
- GFR less than or equal to 20 mL/min
- Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)

Transplant hospitals will provide:

The requested sample of medical records.

Additional Guidance:

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

The dialysis start date from the CMS database, if displayed in the OPTN Computer System, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from the OPTN Computer System.

Policy 8.3.B: Waiting Time for Candidates Registered prior to Age 18

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)

Transplant hospitals will provide:

The requested sample of medical records.

Additional Guidance:

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

The dialysis start date from the CMS database, if displayed in the OPTN Computer System, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from the OPTN Computer System.

8.4, 8.5, 8.7: Kidney Allocation Classifications and Rankings, Allocation of Both Kidneys from a Single Deceased Donor to a Single Candidate, and Allocation of Released Kidneys

The OPTN Contractor will:

Conduct ongoing reviews of match runs and allocation processes for deceased donor kidneys that result in a transplant. These allocations are reviewed to ensure compliance with the appropriate allocation table and match run requirements. All allocations that deviate from the match run will be reviewed by the OPTN Contractor.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 8.4.A: Candidate Classifications

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System for candidates with an Expected Post-Transplant Survival (EPTS) in the top 20% are consistent with source documentation, including:

- Date of birth
- Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)
- Diabetes status
- Number of prior solid organ transplants

Transplant hospitals will provide:

The requested sample of medical records.

Additional Guidance:

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

The dialysis start date from the CMS database, if displayed in the OPTN Computer System, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from the OPTN Computer System.

Policy 8.4.D: Allocation of Kidneys by Blood Type

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Kidney transplant recipients with blood type B who received a kidney from a donor with blood type A, non-A_1 or blood type AB, non-A_1B provided written informed consent to accept a kidney from a donor with these blood types

Verify that the transplant program has a written policy regarding its titer threshold for transplanting blood type A, non-A_1 and blood type B, non-A_1B kidneys into candidates with blood type B.

Transplant hospitals will provide:

- The requested sample of medical records
- The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Policy 8.4.F: Prioritization for Liver Recipients on the Kidney Waiting List

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, of kidney recipients who received priority for a kidney due to a prior liver transplant, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including the most recent dates and results for any of the following:

- Measured or estimated creatinine clearance (CrCl)
- Glomerular filtration rate (GFR)
- Dialysis

Transplant hospitals will provide:

The requested sample of medical records.

Policy 8.4.G: Prioritization for Heart Recipients on the Kidney Waiting List

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, of kidney recipients who received priority for a kidney due to a prior heart transplant, for documentation that data reported

through the OPTN Computer System are consistent with source documentation, including the most recent dates and results for any of the following:

- Measured or estimated creatinine clearance (CrCl)
- Glomerular filtration rate (GFR)
- Dialysis

Transplant hospitals will provide:

The requested sample of medical records

Policy 8.4.H: Prioritization for Lung Recipients on the Kidney Waiting List

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, of kidney recipients who received priority for a kidney due to a prior lung transplant, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including the most recent dates and results for any of the following:

- Measured or estimated creatinine clearance (CrCl)
- Glomerular filtration rate (GFR)
- Dialysis

Transplant hospitals will provide:

The requested sample of medical records

Policy 9.1.A: Adult Status 1A Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Qualifying criteria reported on the status 1A justification form
- That all lab results reported for status 1A qualifying criteria were the most recent available at the time they were entered into the OPTN Computer System

Transplant hospitals will provide:

The requested sample of medical records.

Policy 9.1.B: Pediatric Status 1A Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Qualifying criteria reported on the status 1A justification form

Transplant hospitals will provide:

The requested sample of medical records.

Policy 9.1.C: Pediatric Status 1B Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Qualifying criteria reported on the status 1B justification form

Transplant hospitals will provide:

The requested sample of medical records.

Policy 9.1.D: MELD Score

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Creatinine
- Bilirubin
- Sodium
- INR
- Albumin
- Birth sex (or Sex for the Purpose of Adult MELD Calculation, if applicable)
- 24 hours of continuous veno-venous hemodialysis (CVVHD) or dialysis twice within the 7 days before the serum creatinine test, if applicable

Transplant hospitals will provide:

The requested sample of medical records.

Policy 9.1.E: PELD Score

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Candidate age
- Birth sex
- Height
- Weight
- Albumin
- Bilirubin
- INR

- Creatinine
- 24 hours of CVVHD or dialysis twice within the 7 days before the serum creatinine test, if applicable

Transplant hospitals will provide:

The requested sample of medical records.

Policy 9.2: Status and Laboratory Values Update Schedule

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- That all lab results for values detailed in Policies 9.1.D and 9.1.E were the most recent available at the time they were entered into the OPTN Computer System for recertification

Transplant hospitals will provide:

The requested sample of medical records.

Policy 9.5: Specific Standardized MELD or PELD Score Exceptions

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Qualifying criteria for standardized exceptions reported on the MELD or PELD exception or exception extension form

Transplant hospitals will provide:

The requested sample of medical records.

Policy 9.8: Liver Allocation, Classifications, and Rankings

The OPTN Contractor will:

Conduct ongoing reviews of match runs and allocation processes for deceased donor livers that result in a transplant. These allocations are reviewed to ensure compliance with the appropriate allocation table and match run requirements. All allocations that deviate from the match run will be reviewed by the OPTN Contractor.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 9.9 Liver-Kidney Allocation

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation available at the time of entry, including:

- For recipients receiving a liver-kidney transplant based on a diagnosis of CKD:
    - Regularly administered dialysis for ESRD
    - Measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 30 mL/min on either:
        - The date of the most recent result before registration on the kidney waiting list
        - A date after registration on the kidney waiting list
- For recipients receiving a liver-kidney transplant based on a diagnosis of sustained acute kidney injury:
    - Dates of dialysis received
    - Measured or estimated CrCl or GFR values less than or equal to 25 mL/min and the corresponding collection dates for each value
- For recipients receiving a liver-kidney transplant based on a diagnosis of metabolic disease:
    - Hyperoxaluria
    - Atypical HUS from mutations in factor H or factor I
    - Familial non-neuropathic systemic amyloidosis
    - Methylmalonic aciduria

Transplant hospitals will provide:

The requested sample of medical records.

Policy 10.1: Lung Composite Allocation Score

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Factors that can affect the lung composite allocation score (CAS):
    - Date of birth
    - Height
    - Weight
    - Diagnosis
    - Functional status
    - Assisted ventilation status
    - Oxygen status
    - Oxygen rate
    - 6 minute walk distance
    - Pulmonary artery systolic pressure, prior to any exercise
    - Cardiac index (CI), prior to any exercise
    - PCO_2
    - PCO_2 type
    - Serum creatinine
    - Total bilirubin

- For candidates less than 12 years old and assigned as Priority 1, at least one of the following:
    - Respiratory failure as evidenced by at least one of the following:
        - Requires continuous mechanical ventilation
        - Requires supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen levels greater than 90%
        - Has an arterial or capillary PCO_2 greater than 50 mm Hg
        - Has a venous PCO_2 greater than 56 mm Hg
    - Pulmonary hypertension as evidenced by at least one of the following
        - Has pulmonary vein stenosis involving 3 or more vessels
        - Exhibits any of the following, in spite of medical therapy:
            - Cardiac index less than 2 L/min/M^2
            - Syncope
            - Hemoptysis
            - Suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate

Transplant hospitals will provide:

The requested sample of medical records.

The OPTN Contractor will:

Conduct ongoing reviews of match runs and allocation processes for deceased donor lungs that result in a transplant. These allocations are reviewed to ensure compliance with the appropriate allocation table and match run requirements. All allocations that deviate from the match run will be reviewed by the OPTN Contractor.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 10.3: Clinical Values and Update Schedule

Last Updated: 9/3/2024

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Data reported at the time of the candidate's registration on the lung transplant waiting list, corresponding with the following factors outlined in Policies 10.1.A.1 and 10.1.B.1, is six months old or less from the date of the candidate's registration date:
    - Height
    - Weight
    - Diagnosis
    - Functional status
    - Assisted ventilation status
    - Oxygen status
    - Oxygen rate
    - 6 minute walk distance
        i. Oxygen titration test performed prior to the initial 6 minute walk test, including the final amount of supplemental O2, which must be the amount provided at the start of the six-minute walk test.

    - PCO_2
    - PCO_2 type
    - Serum creatinine
    - Total bilirubin
- When a transplant program reports that a candidate on the lung transplant waiting list is on continuous mechanical ventilation or ECMO, or requires supplemental oxygen provided via a high flow nasal cannula, that the following values are reported and assessed within the 28 days preceding the report, and continue to be assessed and reported every 28 days following the most recent assessment while the candidate remains on continuous mechanical ventilation or ECMO, or continues to require supplemental oxygen provided via a high flow nasal cannula:
    - Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)
    - Assisted ventilation status

Transplant hospitals will provide:

The requested sample of medical records.

Policy 11.3.B: Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through the OPTN Computer System are consistent with source documentation, including:

- Kidney criteria
    - Measured or estimated creatinine clearance less than or equal to 20 mL/min
    - GFR less than or equal to 20 mL/min
    - Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)
- Pancreas criteria
    - On insulin

Transplant hospitals will provide:

The requested sample of medical records.

Additional Guidance:

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

The dialysis start date from the CMS database, if displayed in the OPTN Computer System, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from the OPTN Computer System.

Policy 11.4: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings

The OPTN Contractor will:

Conduct ongoing reviews of match runs and allocation processes for deceased donor pancreas, kidney-pancreas, and islet that result in a transplant. These allocations are reviewed to ensure compliance with the appropriate allocation table and match run requirements. All allocations that deviate from the match run will be reviewed by the OPTN Contractor.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 11.7: Allocation of Released Kidney-Pancreas, Pancreas, or Islets

The OPTN Contractor will:

Conduct ongoing reviews of the released organ allocation process for deceased donor kidney-pancreas, pancreas, or islets that are transplanted. In the event that an organ is not transplanted into the patient it was accepted for, the OPTN Contractor will inquire with the OPO and the transplant hospital.

Members will provide:

Any information or documentation the OPTN Contractor requests to verify compliance.

Policy 13.4.A: Release of Protected Health Information (PHI)

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of KPD donor medical records, and any material incorporated into the medical record by reference, to verify:

- Written consent from paired donors to share protected health information (PHI) with all other transplant hospitals in the KPD exchange.

If there is not a sample for review, site surveyors will interview relevant staff to verify that recovery hospital staff practices align with OPTN policy.

Recovery hospitals will provide:

- The requested sample of living donor records
- Access to relevant staff who can answer interview questions, if applicable

Policy 13.4.C: Additional Requirements for KPD Donors

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of KPD donor medical records, and any material incorporated into the medical record by reference, to verify that the transplant hospital informed the paired donor of the following:

- The KPD program's matching requirements
- KPD donors and candidates do not choose their match
- A KPD donor or a candidate may decline a match

- The possibility of helping more than one candidate receive a transplant
- The possibility that the paired donor may have to wait to find a match
- The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues
- The possibility that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery
- The possibility that the paired donor's kidney might not be transplanted or the paired donor's matched candidate might not receive a transplant because of unexpected events
- The KPD program's remedy for failed KPD exchanges and that the remedy does not include any additional priority for the paired candidate on the deceased donor waiting list
- The possibility that personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation related costs.
- The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
- The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
- That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney
- That the paired donor may require additional testing, including multiple blood draws for crossmatching
- The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients
- The paired donor has the right to withdraw from participation in the KPD program at any time, for any reason.

Review a sample of KPD donor medical records, and any material incorporated into the medical record by reference, for documentation that the paired donor's transplant hospital obtained the paired donor's signature confirming that the donor has been informed that they may withdraw from participation in the KPD program at any time, for any reason.

If there is not a sample for review, site surveyors will interview relevant staff to verify that recovery hospital staff practices align with OPTN policy.

Recovery hospitals will provide:

- The requested sample of living donor records
- Access to relevant staff who can answer interview questions, if applicable

Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the donor psychosocial evaluation was completed and addressed the following:

- Psychosocial issues that might complicate the living donor's recovery
- Risks for poor psychosocial outcome
- An assessment of risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*
- The living donor's history of smoking, alcohol, and drug use, including past or present substance use disorder
- Factors that warrant educational or therapeutic intervention prior to the final donation decision
- The living donor's understanding of the short and long-term medical and psychosocial risks for both the living donor and recipient

- Whether the decision to donate is free of inducement, coercion, and other undue pressure
- The living donor's ability to make an informed decision
- The living donor's ability to cope with the major surgery and related stress
- Whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
- The living donor's occupation, employment status, health insurance status, living arrangements, and social support
- The living donor's understanding of the potential financial implications of living donation

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- That the person performing psychosocial evaluations of living donors is someone with the role/title of psychiatrist, psychologist, masters-prepared social worker, or licensed clinical social worker

Recovery hospitals will provide:

- The requested sample of living donor records
- The recovery hospital's internal policies, procedures and protocols for the care of living donors
- Evidence as needed to verify compliance
- Access to relevant staff who can answer interview questions

Policy 14.2.A: ILDA Requirements for Living Donor Recovery Hospitals

During living donor recovery hospital site surveys, the OPTN Contractor will:

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- To designate a key ILDA contact for each living donor
- That the ILDA is not involved with the recipient evaluation
- That the ILDA is independent of the decision to transplant the recipient
- That the ILDA discusses with each donor, the:
    - Informed consent process
    - Evaluation process
    - Surgical procedure
    - Follow-up requirements and the benefit and need for participating in follow-up

Recovery hospitals will provide:

- The requested sample of living donor records
- The recovery hospital's internal policies, procedures and protocols for the care of living donors
- Access to relevant staff who can answer interview questions

Additional Guidance:

The OPTN Contractor will examine the hospital's internal policies, procedures and protocols to verify the presence of a process by which the hospital ensures that the assigned ILDA for a given potential living donor patient is not involved in the evaluation of the associated transplant candidate, and is not involved in the decision to proceed to transplantation or approve the transplant candidate for transplantation.

Policy 14.2.B: ILDA Protocols for Living Donor Recovery Hospitals

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review the hospital's internal policies, procedures and protocols to verify that the hospital has developed and implemented written protocols that address:

- Composition of the ILDA team, if a team is used
- Qualifications and training of the ILDA
- Duties and responsibilities of the ILDA
- Grievance process for the ILDA

Recovery hospitals will provide:

The recovery hospital's internal policies, procedures and protocols for the care of living donors.

Policy 14.3: Informed Consent Requirements

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for a document signed by the living donor confirming that the donor:

- Is willing to donate
- Is free from inducement or coercion
- Has been informed that he/she may decline to donate at any time

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The living donor was offered an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential
- An ILDA was available to assist the living donor during the consent process
- The living donor was provided instruction about all phases of the living donation process, which includes consent, medical and psychosocial evaluations, pre- and post-operative care, and required post-operative follow-up according the OPTN policy requirements

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- To provide information to living donors in a language in which the donor is able to engage in a meaningful dialogue with the recovery program staff

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital disclosed the following to the living donor:

- It is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value including, but not limited to, cash, property, and vacations
- That the hospital must (or will) provide an ILDA
- Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation
- A deceased donor organ might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs
- Transplant hospitals determine candidacy for transplantation based on existing hospital-specific guidelines or practices and clinical judgment

- The recovery hospital will take all reasonable precautions to provide confidentiality for the living donor and the recipient
- Any transplant candidate may have an increased likelihood of adverse outcomes (including but not limited to graft failure, complications, and mortality) that:
    - Exceed local or national averages
    - Do not necessarily prohibit transplantation
    - Are not disclosed to the living donor
- The recovery hospital can disclose to the living donor certain information about candidates only with the permission of the candidate, including:
    - The reasons for a transplant candidate's increased likelihood of adverse outcomes
    - Personal health information collected during the transplant candidate's evaluation, which is confidential and protected under privacy law
- Health information obtained during the living donor evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state or federal public health authorities
- The recovery hospital is required to:
    - Report living donor follow-up information at six months, one year, and two years post-donation
    - Have the donor commit to post donation follow-up testing coordinated by the recovery hospital
    - Obtain and store a living donor blood specimen for ten years, only to be used for investigation of potential donor-derived disease
- Any infectious disease or malignancy pertinent to acute recipient care discovered during the first two years of the donor's post-operative follow-up care:
    - May need to be reported to local, state or federal public health authorities
    - Will be disclosed to their recipient's transplant hospital
    - Will be reported through the OPTN Patient Safety Reporting Portal
- The living donor will receive a medical evaluation
- The living donor will receive a psychosocial evaluation
- The hospital may refuse the living donor
- The following are inherent risks associated with evaluation for living donation:
    - Allergic reactions to contrast
    - Discovery of reportable infections
    - Discovery of serious medical conditions
    - Discovery of adverse genetic findings
    - Discovery of abnormalities that may require additional testing at the donor's expense or create the need for unexpected decisions by the transplant team

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided information or disclosure to the donor addressing the risk of the following:

- Death
- Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
- Abdominal symptoms such as bloating, nausea, and bowel obstruction
- The morbidity and mortality of the living donor may be impacted by age, obesity, hypertension, or other donor-specific pre-existing conditions
- Problems with body image
- Post-surgery depression or anxiety
- Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the recipient dies
- Changes to the living donor's lifestyle from donation

- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed
- Need for life-long follow-up at the living donor's expense
- Loss of employment or income
- Negative impact on the ability to obtain future employment
- Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance
- Risks may be temporary or permanent
- Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided the following information to the living donor regarding recipient outcome and survival data, unless the living donor *only* donated a covered VCA:

- When the recipient transplant hospital is known or is the same as the recovery hospital:
    - SRTR's national 1-year patient and transplanted organ survival rates for the organ being donated
    - SRTR's most recent hospital-specific 1-year patient and transplanted organ survival rates for the recipient's transplant hospital for the organ being donated
- When the recipient transplant hospital is not known:
    - SRTR’s national 1-year patient and transplanted organ survival rates for the organ being donated

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living kidney donor regarding:

- Education about expected post-donation kidney function and the potential impact on chronic kidney disease (CKD) and end-stage renal disease (ESRD) on the living kidney donor in the future, including:
    - On average, donors will have a 25-35% permanent loss of kidney function after donation
    - Although risk of ESRD for living kidney donors does not exceed that of members of the general population with the same demographic profile, risk of ESRD for living kidney donors may exceed that of healthy non-donors with medical characteristics similar to living kidney donors
    - Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young donor cannot predict lifetime risk of CKD or ESRD
    - Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney
    - The development of CKD and subsequent progression to ESRD may be faster with only one kidney
    - Dialysis is required if the living donor develops ESRD
    - Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN policy
- Potential surgical risks:
    - Decreased kidney function
    - Acute kidney failure and the need for dialysis or kidney transplant for the living donor in the immediate post-operative period
    - Risks may be temporary or permanent
    - Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional disclosure to female living kidney donors that:

- Risks of preeclampsia or gestational hypertension are increased in pregnancies after donation

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living liver donor regarding:

- Potential surgical risks:
    - Acute liver failure with need for liver transplant
    - Transient liver dysfunction with recovery
    - Risk of red cell transfusions or other blood product transfusions
    - Biliary complications, including leak or stricture, that may require additional intervention
    - Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks
    - Risks may be temporary or permanent
    - Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living donor of covered VCAs other than covered genitourinary organ VCAs regarding:

- Potential surgical risks:
    - Loss of function
    - Physical disability
    - Physical disfigurement
- Potential psychosocial risks:
    - Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional or cosmetic outcome
- Potential financial impacts:
    - Procedure may not be covered by health insurance
- Risks may be temporary or permanent
- Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living donor of covered genitourinary organ VCAs regarding:

- Potential surgical risks:
    - Bowel injury
    - Need for hormonal replacement therapy
    - Pain or discomfort with intercourse
    - Partial or complete loss of organ-specific function, including reproductive function
    - Physical disfigurement
    - Urinary tract injury or dysfunction
- Potential psychosocial risks:
    - Feelings of emotional distress or grief if the transplant recipient does not experience a successful functional, cosmetic, or reproductive outcome
- Potential financial impacts:
    - Procedure may not be covered by health insurance
- Risks may be temporary or permanent
- Risks may include those listed, but are not limited to those listed

Recovery hospitals will provide:

- The requested sample of living donor records
- The recovery hospital's internal policies, procedures and protocols for the care of living donors

- Evidence as needed to verify compliance
- Access to relevant staff who can answer interview questions

Policy 14.4.A: Living Donor Medical Evaluation Requirements

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the donor medical evaluation was completed.

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- That the medical evaluation of the living donor performed by the recovery hospital is reviewed by a physician or surgeon

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the donor included assessment of:

- Personal history of:
    - Hypertension
    - Diabetes
    - Lung disease
    - Heart disease
    - Gastrointestinal disease
    - Autoimmune disease
    - Neurologic disease
    - Genitourinary disease
    - Hematologic disorders
    - Bleeding or clotting disorders
    - Cancer, including melanoma
- History of infections
- The donor's active and past medications
- The donor's allergies
- Coronary artery disease
- Whether the donor has a family history of:
    - Coronary artery disease
    - Cancer
- Occupation
- Employment status
- Health insurance status
- Living arrangements
- Social support
- Smoking, alcohol and drug use/abuse
- Psychiatric illness
- Depression
- Suicide attempts
- Risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. Public Health Service (PHS) Guideline*

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Height
- Weight
- BMI
- Vital signs
- A review of major organ systems
- Complete Blood Count (CBC) with platelet count
- Blood type (and subtype if tested)
- Prothrombin Time (PT) or International Normalized Ratio (INR)
- Partial Thromboplastin Time (PTT)
- Metabolic testing, including:
    - Electrolytes
    - BUN
    - Creatinine
    - Transaminase levels
    - Albumin
    - Calcium
    - Phosphorus
    - Alkaline phosphatase
    - Bilirubin
- HCG quantitative pregnancy test (for premenopausal women without surgical sterilization)
- Chest X-ray
- Electrocardiogram (ECG)
- CMV (Cytomegalovirus) antibody testing
- EBV (Epstein Barr Virus) antibody testing
- Syphilis testing
- HIV, hepatitis B (HBV), and hepatitis C (HCV) testing performed no earlier than 28 days before the organ recovery date:
    - HIV antibody (anti-HIV) test or HIV antigen/antibody (Ag/Ab) combination test
    - HIV ribonucleic acid (RNA) nucleic acid test (NAT)
    - Hepatitis B surface antigen (HBsAg) test
    - Hepatitis B core antibody (total anti-HBc) test
    - HBV deoxyribonucleic acid (DNA) NAT
    - Hepatitis C antibody (anti-HCV) test
    - HCV RNA NAT

Review the hospital's internal policies, procedures and protocols to verify that the hospital has developed and implemented written protocols that address:

- Identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease
- Cancer screening for:
    - Cervical cancer
    - Breast cancer
    - Prostate cancer
    - Colon cancer
    - Lung cancer

Recovery hospitals will provide:

- The requested sample of living donor records
- The recovery hospital's internal policies, procedures and protocols for the care of living donors

- Evidence as needed to verify compliance
- Access to relevant staff who can answer interview questions

Policy 14.4.B: Additional Requirements for the Medical Evaluation of Living Kidney Donors

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the donor included assessment of:

- A kidney-specific personal history including:
    - Genetic renal diseases
    - Kidney disease
    - Proteinuria
    - Hematuria
    - Kidney injury
    - Diabetes, including gestational diabetes
    - Nephrolithiasis
    - Recurrent urinary tract infections
- Whether the donor has a family history of:
    - Kidney disease
    - Diabetes
    - Hypertension
    - Kidney cancer
- The donor's anatomy, including:
    - Whether kidneys are of equal size
    - Whether kidneys have masses, cysts, stones or other anatomical defects
    - Which kidney is more suitable for transplantation

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Blood pressure measured in one of the following ways:
    - Taken on two occasions
    - 24-hour monitoring
    - Overnight monitoring
- Metabolic testing, including:
    - Fasting blood glucose
    - Fasting lipid profile, including:
        - Cholesterol
        - Triglycerides
        - HDL Cholesterol
        - LDL Cholesterol
    - Glucose tolerance test or glycosylated hemoglobin, if indicated (in first degree relatives of diabetics and in high risk individuals)
- Urinalysis or urine microscopy
- Measurement of urinary protein and albumin excretion
- Measurement of glomerular filtration rate (GFR) by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
- 24-hour urine stone panel (if indicated according to policy)

Review the hospital's internal policies, procedures and protocols to verify that the hospital has developed and implemented written protocols that address:

- PKD screening

Recovery hospitals will provide:

- The requested sample of living donor records
- The recovery hospital's internal policies, procedures and protocols for the care of living donors
- Evidence as needed to verify compliance

Policy 14.4.C: Additional Requirements for the Medical Evaluation of Living Liver Donors

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the donor included assessment of:

- Whether the donor has a family history of:
    - Liver diseases
    - Bleeding or clotting disorders
- The donor's anatomy via radiological assessment, including:
    - Assessment of projected graft volume
    - Donor's remnant volume
    - Vascular anatomy
    - Presence of steatosis

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Hepatic function panel
- Ceruloplasmin, if indicated (in donors with a family history of Wilson's disease)
- Iron, iron binding capacity and ferritin
- Alpha-1-antitrypsin level
    - Phenotype for living donors with low alpha-1-antitrypsin levels

Review the hospital's internal policies, procedures and protocols to verify that the hospital has developed and implemented written protocols that address:

- Hypercoagulable state evaluation
- Testing for genetic diseases
- Screening for autoimmune disease
- Pre-donation liver biopsy

Recovery hospitals will provide:

- The requested sample of living donor records
- The recovery hospital's internal policies, procedures and protocols for the care of living donors
- Evidence as needed to verify compliance

Policy 14.4.D: Additional Requirements for the Medical Evaluation of Living Donors of Covered VCAs

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Transmissible disease screening for a living donor of any covered VCA:
    - Toxoplasma immunoglobulin G (IgG) antibody test
- Additional transmissible disease screening for a living uterus donor:
    - Bacterial vaginosis (Gardnerella vaginalis)
    - Chlamydia nucleic acid test (NAT)
    - Gonorrhea NAT
    - Herpes simplex virus (HSV) 1/2 immunoglobulin G (IgG) antibody test
    - Human papilloma virus (HPV) cervical specimen DNA or mRNA test
    - Trichomoniasis
    - Fungal screenings to include vaginal candidiasis performed two times:
        - At evaluation
        - At time of donation
- Pap smear for a living uterus donor

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the living uterus donor included assessment of:

- The donor's gynecological and obstetric history, including prior childbirth
- The donor's anatomy, including:
    - Pelvic exam
    - Radiological assessment to determine if the uterus is anatomically suitable for transplantation

Recovery hospitals will provide:

The requested sample of living donor records.

Policy 14.5: Living Donor Blood Type Determination and Reporting

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review the hospital's internal policies, procedures, and protocols and interview staff to verify that it has a written protocol(s) that includes:

- Testing two donor blood samples before generating the donor ID that:
    - Are drawn on separate occasions
    - Have different collection times
    - Are submitted as separate samples
- Reporting subtype only when:
    - Tests are completed on two separate blood samples
    - The draw times for the samples used for the two tests are at different times
    - Samples used are pre-red blood cell transfusion
    - There are no conflicting or indeterminate subtype results
- Reporting candidate blood type:
    - By two qualified healthcare professionals
    - Using all known available blood type determination source documents

- Definition of qualified health care professionals who can participate in blood type verification and reporting
- A process for resolving conflicting or indeterminate primary blood type results

Interview recovery hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for living donor blood type determination and reporting.

Recovery hospitals will provide:

- The recovery hospital's internal policies, procedures and protocols for the care of living donors
- Access to relevant staff who can answer interview questions

Additional Guidance:

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 14.7: Living Donor Pre-Recovery Verification

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review the hospital's internal policies, procedures, and protocols to verify that it has a written protocol that includes:

- Participation by the recovery surgeon and another licensed health care professional
- Timing of verification:
    - Before induction of general anesthesia
    - On the day of the organ recovery
- Verification of the donor:
    - Donor ID
    - Organ
    - Organ laterality (if applicable)
    - Blood type
    - Blood subtype (if used for allocation)
- Verification of the intended recipient:
    - Unique identifier
    - Blood type
- Verification that the donor and intended recipient are blood type compatible or intended incompatible
- Verification that the correct donor organ has been identified for the correct intended recipient
- Sources used for verification

Interview recovery hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for living donor pre-recovery verification.

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The following were verified:
    - Donor ID
    - Organ
    - Organ laterality (if applicable)
    - Donor blood type
    - Intended recipient unique identifier
    - Intended recipient blood type
    - Donor and intended recipient are blood type compatible or intended incompatible
    - Correct donor organ has been identified for the correct intended recipient

- The verification took place:
    - Before the induction of general anesthesia
    - On the same date as the living donor recovery

Recovery hospitals will provide:

- The requested sample of living donor records
- The recovery hospital's internal policies, procedures and protocols for the care of living donors
- Access to relevant staff who can answer interview questions

Required Reporting:

OPTN Policy 18.5.B: *Required Reporting of Living Donor Events by Recovery Hospitals* requires a recovery hospital to report if a living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia. Recovery hospitals are required to report these events to the OPTN Patient Safety Reporting Portal within 72 hours after the aborted organ recovery procedure.

Policy 14.8.B: Living Donor Specimen Collection and Storage

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records for the following documentation:

- Blood specimen collection and storage noted in the medical record
- A collection date for stored blood specimens that is no earlier than one day before the donor recovery date

Recovery hospitals will provide:

The requested sample of living donor medical records

Policy 14.10: Living Donor Organ Check-In

During transplant hospital site surveys, the OPTN Contractor will:

Interview transplant hospital staff to verify that hospital staff practices align with OPTN policy and with the hospital's policies and procedures for living donor organ check-in.

Transplant hospitals will provide:

- The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients
- Access to relevant staff who can answer interview questions

Policy 14.11: Living Donor Pre-Transplant Verification

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that pre-transplant verifications were performed for transplants of living donor organs as required by OPTN Policy 5.8: *Pre-Transplant Verification*.

Required Reporting:

OPTN Policy 18.5.A: *Required Reporting by Transplant Hospitals* requires a transplant hospital to report if:

- A donor organ is identified as incorrect during pre-transplant processes conducted according to OPTN Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or OPTN Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*
- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to OPTN Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or OPTN Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either OPTN Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or OPTN Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*

Transplant hospitals are required to report these events to the OPTN Patient Safety Reporting Portal within 72 hours after the transplant hospital becomes aware.

Policy 15.1: Patient Safety Contact

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. The OPTN Contractor will notify OPOs and transplant programs if there is not a patient safety contact identified in the OPTN Computer System. If an OPO or transplant program fails to identify a Patient Safety Contact, the OPTN Contractor will inquire with the member.

Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- HIV, hepatitis B (HBV), and hepatitis C (HCV) tests, using blood samples collected prior to first anastomosis:
    - HIV, using a CDC-recommended laboratory testing algorithm
    - Hepatitis B surface antigen (HBsAg)
    - Hepatitis B core antibody (total anti-HBc)
    - Hepatitis B surface antibody (HBsAb)
    - Hepatitis C antibody (anti-HCV)
    - Hepatitis C ribonucleic acid (RNA) nucleic acid test (NAT)

  For all candidates 12 years or older at the time of anastomosis of the first organ, blood samples must be drawn during the hospital admission for transplant.
- For candidates 12 years or older at the time of anastomosis of the first organ: HIV, HBV, or HCV tests demonstrating that the candidate was already known to be infected with HIV, HBV, or HCV, if testing for one or more of these infections was not completed during hospital admission for transplant and prior to first anastomosis
- For candidates less than 12 years old at the time of anastomosis of the first organ: HIV, HBV, or HCV tests demonstrating that the candidate was already known to be infected with HIV, HBV, or HCV, if testing for one or more of these infections was not completed prior to first anastomosis

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation of:

- An assessment for the need to provide HBV vaccination prior to transplant
- If the transplant program determines that vaccination cannot be initiated or completed prior to transplant, the reason for not initiating or completing HBV vaccination
- The vaccination status prior to transplant in the medical record is consistent with the vaccination status reported through the OPTN Computer System

Transplant hospitals will provide:

The requested sample of medical records.

Additional Guidance:

HCV NAT is required for all candidates pre-transplant, regardless of the results of the Hepatitis C antibody test, unless the candidate was already known to be infected with HCV.

Guidance for Reporting Results from the HIV Laboratory Diagnostic Testing Algorithm for Serum and Plasma Specimens: https://stacks.cdc.gov/view/cdc/50872

Policy 15.3.B: Donors with Risk Identified Pre-Transplant

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The intended recipient or recipient's agent gave consent after the organ offer but before transplant when:
    - The accepted organ was from a donor who tested positive for:
        - Hepatitis B surface antigen (HBsAg)
        - Hepatitis B (HBV) nucleic acid test (NAT)
        - Hepatitis C (HCV) NAT
    - The accepted kidney or liver was from an HIV positive donor, and the transplant hospital participates in an approved variance according to *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*
- The intended recipient or recipient's agent was informed after the organ offer but before transplant that risk criteria for acute HIV, HBV, or HCV infection were present in the donor, when the accepted organ was from a donor with any risk criteria according to the *U.S. Public Health Service (PHS) Guideline*

Transplant hospitals will provide:

The requested sample of medical records.

Policy 15.3.C: Required Post-Transplant Infectious Disease Testing

During transplant hospital site surveys, the OPTN Contractor will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- HIV, hepatitis B (HBV), and hepatitis C (HCV) tests performed between 28 and 56 days after the date of transplant:
    - HIV ribonucleic acid (RNA) nucleic acid test (NAT)
    - HBV deoxyribonucleic acid (DNA) NAT

    - HCV RNA NAT
- HIV, HBV, or HCV tests demonstrating that the recipient was already known to be infected with HIV, HBV, or HCV, if testing for one or more of these infections was not performed between 28 and 56 days after the date of transplant

Transplant hospitals will provide:

The requested sample of medical records.

Policy 15.4: Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- Evidence of follow-up on deceased donor test results post-procurement
- Evidence that positive test results and other required relevant information received post-procurement are reported to each recipient hospital via phone call or email within 24 hours of the OPO's receipt, including:
    - The date and time the OPO received the results
    - The name of the individual at the recipient hospital who received the OPO's report
    - The mode or method of the report (by either telephone or email)
- Evidence that any results received post-procurement indicating malignancy or the presence of a Pathogen of Special Interest are reported through the OPTN Patient Safety Reporting Portal within 24 hours of the OPO's receipt of the results[3,4]

OPOs will provide:

The requested sample of deceased donor medical records.

Additional Guidance:

In the event that the OPTN Contractor identifies a test result or information received post-procurement that indicates donor-derived disease is possible and the result or information was not reported to the OPTN Patient Safety Reporting Portal, the OPTN Contractor will request that the OPO report the result or information to the OPTN Patient Safety Reporting Portal.

Policy 15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Disease or Malignancy

Additional Guidance:

In the event that the OPTN Contractor identifies a test result or information received post-procurement that indicates donor-derived disease is possible and the result or information was not reported to the OPTN Patient Safety Reporting Portal, the OPTN Contractor will request that the transplant program report the result or information to the OPTN Patient Safety Reporting Portal.

[3] The MPSC set an operational rule for reviewing instances of noncompliance with this policy. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

[4] The Ad Hoc Disease Transmission Advisory Committee (DTAC) reviews and updates the Pathogens of Special Interest annually: https://optn.transplant.hrsa.gov/media/yyhnrkar/special_pathogens_list.pdf.

Policy 15.6: Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy

Additional Guidance:

In the event that the OPTN Contractor identifies a test result or information received post-procurement that indicates donor-derived disease is possible and the result or information was not reported to the OPTN Patient Safety Reporting Portal, the OPTN Contractor will request that the living donor recovery hospital report the result or information to the OPTN Patient Safety Reporting Portal.

Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

The OPTN Contractor will:

Review the detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the requirements in the HHS research criteria and IRB data safety monitoring reports at each deadline in the schedule. The OPTN Contractor will send out reminders 60 and 30 days before IRB expiration.

Review information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. The OPTN Contractor will review all instances of HIV-positive organ transplants to ensure compliance with all policy requirements. In the event the OPTN Contractor identifies:

- Instances where an HIV positive living donor ID is generated at a hospital that does not have HOPE Act IRB approval
- Instances where a candidate listed as not willing to receive a HIV-positive organ receives the transplant of an HIV-positive organ
- Instances where a candidate is registered for multiple organs and has discrepant responses between the organ registrations on willingness to receive an HIV-positive organ

The OPTN Contractor will inquire with the member.

Policy 16.2: Packaging and Labeling Responsibilities

Required Reporting:

OPTN Policy 18.5.C: *Required Reporting by OPOs* requires a host OPO to report to the OPTN Patient Safety Reporting Portal if transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required. These events are required to be reported within 72 hours after the host OPO becomes aware.

Policy 16.5: Verification and Recording of Information before Shipping

During OPO site surveys, the OPTN Contractor will:

Review a sample of deceased donor records for the following documentation:

- Someone at the OPO, other than the individual who initially performed the labeling and documentation, has verified the accuracy of each label

Interview relevant staff to verify that OPO staff practices align with OPTN policy, including that the OPO has established and implemented a protocol, for verification of information before shipping.

OPOs will provide:

- The requested sample of deceased donor medical records
- Access to relevant staff who can answer interview questions

Policy 16.6.A: Extra Vessels Use and Sharing

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns.. In the event the OPTN Contractor identifies instances where HIV positive vessels are transplanted into a recipient that received an organ from a different donor, the OPTN Contractor will inquire with the member. In the event that the OPTN Contractor identifies instances where an extra vessel was reported to the OPTN Computer System with disposition of "other", the OPTN Contract may inquire with the member.

Policy 16.6.B: Extra Vessels Storage

During transplant hospital site surveys, the OPTN Contractor will:

Review compliance rates for:

- Destruction of extra vessels within 14 days after recovery

Transplant hospitals will provide:

Evidence as needed to verify compliance.

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. In the event the OPTN Contractor identifies instances where prohibited vessels are stored, the OPTN Contractor will inquire.[5]

Policy 16.6.C: Reporting Requirements for Extra Vessels

During transplant hospital site surveys, the OPTN Contractor will:

Review compliance rates for:

- Reporting extra vessel disposition within 7 days after use, sharing, or destruction

Transplant hospitals will provide:

Evidence as needed to verify compliance.

Additional Guidance:

All vessels shared between hospitals must be reported, even if they are not used.

The receiving transplant hospital is not required to report vessels as shared when it receives vessels directly from the recovering OPO.

[5] The MPSC set an operational rule for reviewing instances of noncompliance with this policy. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

Policy 18.1: Data Submission Requirements

During OPO site surveys, the OPTN Contractor will:

Review rates of compliance with submission dates for the following forms submitted to the OPTN within the review timeframe:

- Deceased Donor Registration (DDR)
- Deceased Donor Feedback
- Potential Transplant Recipient (PTR) refusal codes

Review a sample of deceased donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through the OPTN Computer System on the DDR and Donor Summary are consistent with source documentation.

OPOs will provide:

- The requested sample of deceased donor medical records
- Evidence as needed to verify compliance

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through the OPTN Computer System are consistent with source documentation, including:

- The following donor information reported on the Living Donor Registration (LDR):
    - Social Security Number
    - Donor type
    - Did the donor have health insurance
    - Working for income
    - Viral detection test results for HIV Status; CMV Total, IgG, and IgM; HBV DNA, Core Antibody, and Surface Antigen; HCV RNA and Antibody; EBV Total, IgG, and IgM
    - Pre-donation height
    - Pre-donation weight
    - Pre-donation Diabetes
    - Pre-donation history of hypertension
    - Pre-donation serum creatinine
    - Pre-donation urine protein or protein-creatinine ratio
    - Conversion from laparoscopic
    - Date of initial discharge
    - Organ recovery date
    - Organ(s) recovered
    - Donor recovery facility
    - Donor workup facility

Review rates of compliance with submission dates for LDRs submitted to the OPTN within the review timeframe.

Recovery hospitals will provide:

- The requested sample of living donor records
- Evidence as needed to verify compliance

During transplant hospital site surveys, the OPTN Contractor will:

Review rates of compliance with submission dates for the following forms submitted to the OPTN within the review timeframe:

- Transplant Recipient Registration (TRR)
- Transplant Recipient Follow-up (TRF) 6-month, 1-year, and 2-year forms

Review a sample of recipient medical records, and any material incorporated into the medical record by reference, to verify that data reported through the OPTN Computer System are consistent with source documentation, including:

- The following test results reported on the 6-month Transplant Recipient Follow-up (TRF):
    - HIV NAT
    - HBV NAT
    - HCV NAT
- Transplant date and time

Transplant hospitals will provide:

- The requested sample of medical records
- Evidence as needed to verify compliance

Additional Guidance:

When calculating the due date for deceased donor feedback, the procurement date is defined as the date the donor entered the operating room for purposes of organ recovery.

Policy 18.4.A: Reporting Requirements after Living Kidney Donation

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review compliance rates of reporting complete and timely donor status, clinical information, and laboratory data on the Living Donor Follow-up (LDF).

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through the OPTN Computer System are consistent with source documentation, including:

- Presence of supporting documentation in the donor chart for answers to each of the following:
    - Most recent donor status since [date of last follow-up form submission]
    - Working for income
    - Loss of insurance due to donation
- Presence of supporting documentation in the donor chart when any of the following are answered on the LDF:
    - Cause of death
    - If [not working for income], not working due to
    - If [loss of insurance due to donation], loss of:
        - Health insurance
        - Life insurance
- Presence of supporting documentation in the donor chart when any of the following are answered on the living kidney donor LDF:
    - Donor readmitted since LDR or last LDF was submitted?
    - Kidney complications
    - Regularly administered dialysis as an ESRD patient
    - Donor developed hypertension requiring medication
    - Diabetes

- The lab values entered on the living kidney donor LDF for:
    - Serum creatinine
    - Urine protein or protein-creatinine ratio

Recovery hospitals will provide:

- The requested sample of living donor records
- Evidence as needed to verify compliance

Required Reporting:

OPTN Policy 18.5.B: *Required Reporting of Living Donor Events by Recovery Hospitals* requires a recovery hospital to report if:

- A living donor dies within 2 years after organ donation
- A living donor is listed on the wait list within 2 years after organ donation
- A living kidney donor begins regularly administered dialysis as an ESRD patient within 2 years after organ donation

These events are required to be reported to the OPTN Reporting Patient Safety Portal within 72 hours after the recovery hospital becomes aware.

Policy 18.4.B: Reporting Requirements after Living Liver Donation

During living donor recovery hospital site surveys, the OPTN Contractor will:

Review compliance rates of reporting complete and timely donor status, clinical information, and laboratory data on the Living Donor Follow-up (LDF).

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through the OPTN Computer System are consistent with source documentation, including:

- Presence of supporting documentation in the donor chart for answers to each of the following:
    - Most recent donor status since [date of last follow-up form submission]
    - Working for income
    - Loss of insurance due to donation
- Presence of supporting documentation in the donor chart when any of the following are answered on the LDF:
    - Cause of death
    - If [not working for income], not working due to
    - If [loss of insurance due to donation], loss of:
        - Health insurance
        - Life insurance
- Presence of supporting documentation in the donor chart when any of the following are answered on the living liver donor LDF:
    - Donor readmitted since LDR or last LDF was submitted?
    - Liver complications, including:
        - Abscess
        - Bile leak
        - Hepatic resection
        - Incisional hernia due to donation surgery
        - Liver failure
        - Registration on the liver candidate waiting list
- The lab values entered on the living liver donor LDF for:

- Alanine aminotransferase
- Alkaline phosphatase
- Platelet count
- Total bilirubin

Recovery hospitals will provide:

- The requested sample of living donor records
- Evidence as needed to verify compliance

Required Reporting:

OPTN Policy 18.5.B: *Required Reporting of Living Donor Events by Recovery Hospitals* requires a recovery hospital to report if:

- A living donor dies within 2 years after organ donation
- A living donor is listed on the wait list within 2 years after organ donation

These events are required to be reported to the OPTN Patient Safety Reporting Portal within 72 hours after the recovery hospital becomes aware.

Policy 18.5: Reporting of Patient Safety Events

Required Reporting:

Transplant hospitals, recovery hospitals, and host OPOs are required to report these events to the OPTN Patient Safety Reporting Portal within 72 hours of the member becoming aware of the event.[6]

Policy 18.5.A: Required Reporting by Transplant Hospitals

During transplant hospital site surveys, the OPTN Contractor will:

Interview relevant staff to verify that hospital staff practices align with OPTN policy

Transplant hospitals will provide:

Access to relevant staff who can answer interview questions

Policy 18.5.B: Required Reporting of Living Donor Events by Recovery Hospitals

During living donor recovery hospital site surveys, the OPTN Contractor will:

Interview relevant staff to verify that hospital staff practices align with OPTN policy

Living donor recovery hospitals will provide:

Access to relevant staff who can answer interview questions

[6] Information on the OPTN's required reporting of safety events to HRSA can be found here: https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf.

Policy 18.5.A: Required Reporting by OPOs

During OPO site surveys, the OPTN Contractor will:

Interview relevant staff to verify that hospital staff practices align with OPTN policy

OPOs will provide:

Access to relevant staff who can answer interview questions

Policy 20: Travel Expense and Reimbursement

The OPTN Contractor will:

Review all requests for travel arrangements, accommodations, and reimbursements. Travel arrangements, accommodations, and reimbursements are only approved when the requirements outlined in OPTN Policy are met.

Bylaws Article 1.1.E: Member Compliance

The OPTN Contractor will:

Monitor OPTN members are acting to avoid risks to patient health or public safety. Concerns of patient health and public safety reported to the OPTN will be investigated and, if substantiated, sent to the MPSC for review and potential member action in line with Appendix L.[7]

Members must:

Cooperate with inquires and other requests regarding the investigation process and outcomes. This may include:

- Responding to inquiries regarding patient health, public safety, or policy violations
- Providing access to information, documentation, or personnel
- Complying with MPSC recommendations
- Participating in an informal discussion
- Participating in a peer visit to identify opportunities for improvement
- Formulating a plan for quality improvement
- Participating in ongoing monitoring

Bylaws Article 2.7: OPTN Code of Conduct

OPTN Directors must:

Sign the OPTN Code of Conduct prior to the start of their term and annually thereafter for the duration of their term.

The OPTN Contractor will:

Maintain a record of Directors who have signed the OPTN Code of Conduct and assist Directors with maintaining compliance through reminders prior to the start of their term and annually thereafter for the duration of their term.

Additional Guidance:

Code of Conduct forms will be provided to Directors at the time of their appointment or election to the OPTN Board of Directors and will be available on the OPTN website at all times.[8]

Failing to comply with *Bylaws Article 2.7: OPTN Code of Conduct* will disqualify a Director from serving in the appointed or elected position at that time but will not preclude them from serving in the future if all OPTN obligations are met.

Bylaws Article 7.8: OPTN Code of Conduct

OPTN Committee members and volunteers must:

Sign the OPTN Code of Conduct prior to the start of their term and annually thereafter for the duration of their term.

The OPTN Contractor will:

Maintain a record of Committee members and volunteers who have signed the OPTN Code of Conduct and assist Committee members and volunteers with maintaining compliance through reminders prior to the start of their term and annually thereafter for the duration of their term.

[7] The MPSC set an operational rule for reviewing instances of self-reporting issues with no concern. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

Additional Guidance:

Code of Conduct forms will be provided to Committee members and volunteers at the time of their appointment or election to an OPTN committee or other volunteer role and will be available on the OPTN website at all times.[9]

Failing to comply with *Bylaws Article 7.8: OPTN Code of Conduct* will disqualify a Committee member or volunteer from serving in the appointed or elected position at that time but will not preclude them from serving in the future if all OPTN obligations are met.

Bylaws Article 9.5: Review Boards

OPTN Review Board members must:

Sign the OPTN Code of Conduct prior to the start of their term and annually thereafter for the duration of their term.

The OPTN Contractor will:

Maintain a record of review board members who have signed the OPTN Code of Conduct and assist review board members with maintaining compliance through reminders prior to the start of their term and annually thereafter for the duration of their term.

Additional Guidance:

Code of Conduct forms will be provided to review board members at the time of their appointment or election to an OPTN review board and will be available on the OPTN website at all times.[10]

Failing to comply with *Bylaws Article 9.5: Review Boards* will disqualify a review board member from serving in the appointed or elected position at that time but will not preclude them from serving in the future if all OPTN obligations are met.

Bylaws Appendix A.1.C: MPSC Review of the Completed Membership Application

To support the MPSC's review of membership applications, the MPSC has codified the process through operational rules for the following membership applications:

- Late Key Personnel change applications
- Non-Institutional Member Renewal Applications and Key Personnel Changes
- Application rejections on the consent agenda[11]

Bylaws Appendix B.1: OPO Compliance

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The OPTN contractor learns of a final adverse action taken by a regulatory agency against an OPO which was not reported to the OPTN contractor in writing as defined in the bylaws

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[8-10] The OPTN Code of Conduct can be found here: https://optn.transplant.hrsa.gov/about/how-to-get-involved/

[11] The MPSC set an operational rule for reviewing membership applications that meet all of the Bylaw requirements. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

OPOs must:

Notify the OPTN contractor when any regulatory agency takes action against the OPO. Notification must:

- Be in writing
- Be received by the OPTN contractor within 10 business days after the OPO receives notification of the final adverse action
- Include all documents relating to the final adverse action

Definitions:

Final adverse actions by an agency include, but are not limited to, any of the following:

- Decertification by the Center for Medicare and Medicaid Services (CMS)
- Any action by a state licensing authority that affects the organization's ability to function
- Any action by the state health department that affects the organization's ability to function
- Loss of accreditation by the Association of Organ Procurement Organizations (AOPO), American Association of Tissue Banks (AATB), or Joint Commission on Accreditation of Healthcare Organizations

Bylaws Appendix B.2: OPO Performance Requirements

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- An OPO meets or falls below all of the following thresholds for a single organ or all organs taken together:
    - Expected organ yield per 100 donors - observed organ yield per 100 donors > 10
    - Ratio of observed to expected yield < 0.90
    - Two-sided p-value less than 0.05
- An OPO is noncompliant with MPSC requests or fails to adopt and implement a plan for improvement

The MPSC will review blinded data derived from the OPTN Computer System to:

- Identify whether observed organ yields fall below the expected yield, given individual OPO donor characteristics
- Evaluate overall (or aggregate) organ yield
- Evaluate organ-specific yields

Staff will send inquiries on behalf of the MPSC:

- When an OPO is identified as having experienced lower than expected yields during a specified 2.5 year cohort
- That may include a request for continued reporting until observed organ yields improve
- That may include a requirement for the OPO to promptly adopt and implement a plan for improvement
- That may lead to consideration for adverse action, if the OPO does not comply

MPSC monitoring may include:

- A request for continued reporting until observed organ yields improve
- A requirement for the OPO to promptly adopt and implement a plan for improvement

OPOs must:

Cooperate with the performance review process if yields meet or fall below thresholds. This may include:

- Responding to inquiries regarding performance
- Complying with MPSC recommendations regarding performance
- Participating in an informal discussion regarding a performance review
- Participating in a peer visit to identify opportunities for improvement
- Formulating a plan for quality improvement

Bylaws Appendix B.3: Quality Assessment and Performance Improvement (QAPI) Requirement

During OPO site surveys, the OPTN Contractor will:

Discuss with staff about how quality assessment and performance improvement requirements are performed. The OPTN Contractor will assess the QAPI program to ensure it includes ongoing comprehensive and data-driven monitoring and that the program maintains documentation of monitoring elements.

Additional Guidance:

The In addition to routine monitoring, MPSC may request information about an OPO's QAPI program in instances where the MPSC has a serious concern about the OPO's ability to independently improve and maintain compliance with OPTN obligations, such as repeated violations of the same or similar policies or prolonged periods of underperformance.

Bylaws Appendix B.5: OPO Personnel

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- A member fails to inform the OPTN contractor of a change in key personnel within 30 days of departure
- A member fails to submit the replacement's name and curriculum vitae no less than 30 days before the change will take effect

OPOs must:

Submit written notice immediately (and within 30 days) after learning that the OPO administrative director or medical director plans to leave or otherwise change positions and no longer serve in one of these roles. Written notice of a change in key personnel must include:

- Name of new director
- Status of appointment (interim or permanent)
- Effective date of the change
- A current curriculum vitae

Notify the OPTN contractor if it has not filled a vacant administrative or medical director position permanently within six months. The notification must include the steps taken to fill the position and the timeline for completing the hiring process.

Bylaws Appendix C.1: Histocompatibility Laboratory Compliance

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The OPTN contractor learns of a final adverse action taken by a regulatory agency against a histocompatibility laboratory, and the histocompatibility laboratory did not report this action to the OPTN contractor as defined in the bylaws

Histocompatibility laboratories must:

Notify the OPTN contractor when any regulatory agency takes action against the laboratory. Notification must:

- Be in writing

- Be submitted within 10 business days after the histocompatibility laboratory receives notification of the final adverse action
- Include all documents relating to the final adverse action

Definitions:

Final adverse actions by an agency include, but are not limited to, any of the following:

- Decertification by the Center for Medicare and Medicaid Services (CMS)
- Any action by a state licensing authority that affects the organization's ability to function
- Any action by the state health department that affects the organization's ability to function
- Loss of accreditation by the Association of Organ Procurement Organizations (AOPO), American Association of Tissue Banks (AATB), or Joint Commission on Accreditation of Healthcare Organizations

Bylaws Appendix C.5: Changes in Key Laboratory Personnel

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- A member fails to inform the OPTN contractor of a change in key personnel within seven business days of laboratory knowledge of the departure or extended absence
- A member fails to submit a completed personnel change application in the time and manner required
- A member fails to submit an updated laboratory coverage plan in the time and manner required

Histocompatibility laboratories must:

Notify the OPTN contractor in writing within seven business days of learning that the primary laboratory director, technical supervisor, general supervisor, or clinical consultant plans to leave or end active participation in the laboratory. Written notice of a change in key personnel must include:

- The nature of the change
- The effective date
- If a change in laboratory director, indicate if the technical supervisor, general supervisor, and clinical consultant roles also changed
- Confirmation that either ASHI or CAP (consulting subcontractors) have also been notified

Submit an updated laboratory coverage plan at least 30 days before the effective date of the change in key personnel or coverage.

Submit a completed personnel change application any time the laboratory wishes to designate a new laboratory director, technical supervisor, general supervisor, or clinical consultant. The completed application must:

- Demonstrate that the proposed individual meets the requirements for that position
- Be received by the OPTN contractor at least 30 days before the effective date of the change in key personnel

  If the laboratory received less than 60 days advance notice of the key personnel's departure or need for temporary leave, the application and coverage plan must be submitted to the OPTN contractor within 30 days of the date of departure.

Definitions:

Changes in laboratory key personnel: A change in key personnel occurs when an individual in a key personnel role:

- Departs
- Is unavailable to perform responsibilities for more than 30 days (temporary basis)
- Changes position so that he/she no longer serves in a key personnel role
- Accepts additional responsibilities for more than 30 days at another histocompatibility laboratory

Bylaws Appendix D.1: Transplant Hospital Compliance

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The OPTN contractor learns of a final adverse action taken by a regulatory agency against a transplant hospital, and the transplant hospital did not report this action to the OPTN contractor as defined in the bylaws

Transplant hospitals must:

Notify the OPTN contractor when any regulatory agency takes action against the transplant hospital. Notification must be:

- In writing
- Received by the OPTN contractor within 10 business days after the transplant hospital receives notification of the final adverse action
- Include all documents relating to the final adverse action

Definitions:

Final adverse actions by an agency include, but are not limited to, any of the following:

- Decertification by the Center for Medicare and Medicaid Services (CMS)
- Any action by a state licensing authority that affects the organization's ability to function
- Any action by the state health department that affects the organization's ability to function
- Loss of accreditation by the Association of Organ Procurement Organizations (AOPO), American Association of Tissue Banks (AATB), or Joint Commission on Accreditation of Healthcare Organizations

Bylaws Appendix D.4: Quality Assessment and Performance Improvement (QAPI) Requirement

How the OPTN contractor will evaluate member compliance with this bylaw:

MPSC monitoring may include:

- Review of a transplant hospital’s QAPI program, including documentation that all elements of the program have been implemented

Additional Guidance:

The MPSC may request information about a transplant hospital's QAPI program in instances where the MPSC has a serious concern about the hospital's ability to independently improve and maintain compliance with OPTN obligations, such as repeated violations of the same or similar policies or prolonged periods of underperformance.

Bylaws Appendix D.7: Transplant Program Key Personnel

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The OPTN contractor learns of an active and approved transplant program performing organ transplants without having both a qualified primary surgeon and a qualified primary physician for the organ type in question

Transplant hospitals must:

Apply for and receive OPTN program designation and approval for any organs being transplanted. A major criterion which must be met requires the submission and approval of applications for a designated primary surgeon and physician who must meet the organ-specific criteria found in the bylaws. All approved transplant programs must:

- Obtain initial primary surgeon and physician approval through initial program application
- Replace any departing approved primary surgeon or physician with another qualified individual by submitting a key personnel change application
- Voluntarily inactivate or withdraw a transplant program with the loss or extended unavailability of its designated primary surgeon or physician until this requirement can be met with a qualified individual

Additional Resources:

Sample membership application forms: https://unos.org/community/members/how-to-apply/

Bylaws Appendix D.7.B: Surgeon and Physician Coverage (Program Coverage Plan)

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review materials submitted by members, including coverage plans. Coverage plans will be:

- Reviewed by an ad-hoc committee of the MPSC when submitted with an application
- Reviewed by the MPSC when requested
- Reviewed by an MPSC subcommittee when requested

Transplant hospitals must:

Submit the program's written coverage plan to the OPTN contractor when:

- There is a key personnel change
- Applying for a new transplant program
- Applying for new transplant hospital membership
- Requested by staff

Notify candidates when:

- There are significant program or personnel changes, including:
    - Change in primary transplant physician or surgeon
    - Becoming a single surgeon or single physician program
    - Previously being a single surgeon or single physician program and now are able to again provide 365/24/7 coverage
    - Any other major or substantial programmatic changes that the program feels will impact or alter patients' ability to receive transplant services

Inform patients, if staffed by a single surgeon or physician, that:

- The individual may not be available to the program at all times
- The individual's unavailability may impact patient care, including the program’s ability to:

    - Accept organ offers
    - Procure organs
    - Perform transplants

Address each of the following requirements in the program coverage plan:

- The program's ability to have at least one transplant surgeon and transplant physician available 365 days a year, 24 hours a day, 7 days a week
- The program provides candidates with a written summary of the program coverage plan
    - When the candidates are listed
    - When there are significant or substantial program or key personnel changes
- That the transplant surgeons and transplant physicians on call for the program cannot be simultaneously on call for another hospital's transplant program that is more than 30 miles away (unless the circumstances have been reviewed and approved by the MPSC)
- That a transplant surgeon or transplant physician is readily available in a timely manner to:
    - Facilitate organ acceptance
    - Facilitate organ procurement
    - Facilitate organ transplantation
    - Address urgent patient issues
    - That the primary transplant surgeon and primary transplant physician are not designated as the primary transplant physician or surgeon at another transplant hospital unless both hospitals have additional transplant surgeons and physicians for those programs

Bylaws Appendix D.8: Changes in Key Transplant Program Personnel

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- A member fails to inform the OPTN contractor of a change in key personnel within seven business days of transplant program knowledge of the departure or extended absence
- A member fails to submit a completed personnel change application in the time and manner required
- A member fails to submit a written notification that the program plans to inactivate or withdraw[12]

Transplant hospitals must:

Notify the OPTN contractor in writing of a change in key personnel within seven business days of transplant program knowledge of the departure or extended absence of the program's primary surgeon or physician (including primary living donor surgeons).

Submit a completed personnel change application any time they wish to designate a new primary physician or surgeon. The completed application must:

- Demonstrate that the proposed surgeon or physician meets the primary surgeon or physician requirements for that organ
- Be received by the OPTN contractor at least 30 days before the effective date of the change in key personnel (due date will be provided by staff)

If the program received less than 60 days advance notice of a primary physician or surgeon's departure or need for temporary leave, the application must be submitted to the OPTN contractor within 30 days after the program notifies the OPTN contractor of the pending change (due date will be provided by staff).

[12] The MPSC set an operational rule for reviewing instances of noncompliance with this policy. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

Voluntarily inactivate or withdraw its designated transplant program status, if:

- The transplant program's primary surgeon or physician ends active involvement with the program on a permanent or temporary basis, and
- The program is unable to:
    - Submit a completed key personnel application by the due date
    - Demonstrate in the application that the proposed replacement meets the primary surgeon or physician requirements

Additional Resources:

Sample membership application forms: https://unos.org/community/members/how-to-apply/

Bylaws Appendix D.8.D: Reinstatement of Previously Designated Primary Surgeon or Primary Physician

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review written reinstatement requests.

Transplant hospitals must:

Submit a written reinstatement request if the program wishes to reinstate a previously designated primary surgeon or primary physician who left the hospital and returned. The request must:

- Be submitted within a year of the individual's departure from the hospital
- Include the following documents:
    - A letter from the transplant program director, department chair, or chief of the division, verifying the individual's current working knowledge and experience
    - A letter from the individual confirming the individual's on-site availability and commitment to the program
    - A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume as primary surgeon or primary physician

Bylaws Appendix D.11: Review of Transplant Program Functional Activity

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- A kidney, liver, heart, or lung transplant program has been identified as functionally inactive because it has not performed a transplant during a defined period:
    - Kidney, liver or heart: 3 consecutive months
    - Lung: 6 consecutive months
- A pancreas transplant program has been identified as functionally inactive because it has not performed two transplants in 12 consecutive months *and* has one of the following:
    - A median waiting time of the program's kidney-pancreas and pancreas candidates that is above the 67th percentile of the national waiting time
    - No kidney-pancreas or pancreas candidates registered at the program
- A kidney, liver, pancreas, heart, or lung transplant program at a stand-alone pediatric hospital has not performed a transplant in 12 consecutive months
- The member does not respond to MPSC inquiries regarding functional inactivity

Transplant hospitals must:

Provide written notice when a transplant program is notified by the MPSC that the program has been identified as functionally inactive to all of the program's potential candidates and candidates registered on the waiting list.

Include the following in the written notice for kidney, liver, heart, and lung transplant programs:

- The dates identified in the MPSC notification during which no transplants were performed
- The reason no transplants were performed
- The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital
- A copy of the OPTN Contractor's Patient Information Letter

Include the following in the written notice for pancreas transplant programs:

- The dates identified in the MPSC notification during which fewer than two transplants were performed
- The reason fewer than two transplants were performed
- The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital
- A copy of the OPTN Contractor's Patient Information Letter
- The names and contact information of all pancreas programs within the same state or commonwealth and all pancreas programs within 125 nautical miles of the functionally inactive program regardless of state or commonwealth boundaries
- Either or both of the following, as applicable:
    - The program's median waiting time in the consecutive 12 month period for kidney-pancreas and pancreas candidates compared to the 67th percentile of the national waiting time, if the program was identified by median waiting time
    - That the program had no kidney-pancreas or pancreas candidates on the waiting list in the consecutive 12 month period, if the program was identified for a lack of candidates on the waiting list

Respond to inquiries regarding periods of functional inactivity.

Participate in informal discussion with the MPSC or a subcommittee, if requested.

Additional Guidance:

Programs will not be identified for functional inactivity and referred to the MPSC during the first year after approval or reactivation of the program.[13]

Bylaws Appendix D.12.A: Transplant Program Performance

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member is above the established thresholds for review of pre-transplant mortality
- The member is below the established thresholds for review of offer acceptance
- The member is above the established thresholds for review of post-transplant graft survival
- The member does not respond to MPSC inquiries regarding program performance
- The member fails to promptly adopt and implement a plan for quality improvement
- The member fails to inactivate a program or a component of a program or withdraw designated transplant program status when recommended by the MPSC

[13] The MPSC set an operational rule for reviewing instances of noncompliance with this policy. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

The MPSC will review blinded data derived from the OPTN Computer System to:

- Identify transplant programs for review that meet any of the criteria for adult transplants:
    - A probability greater than 50% that the program's pre-transplant mortality rate ratio is greater than 1.75 during a 2 year period.
    - A probability greater than 50% that the transplant program's offer acceptance rate ratio is less than 0.30 during a 1 year period.
    - A probability greater than 50% that the program's 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year period. For pancreas programs, that 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.
    - A probability greater than 50% that the program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year period. For pancreas programs, that 1-year post-transplant patient survival conditional on 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.
- Identify transplant programs for review that meet any of the criteria for pediatric transplants:
    - A probability greater than 50% that the program's pre-transplant mortality rate ratio is greater than 1.75 during a 2 year period.
    - A probability greater than 50% that the program's offer acceptance rate ratio is less than 0.35 during a 1 year period.
    - A probability greater than 50% that the program's 90-day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.
    - A probability greater than 50% that the program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.

Staff will send inquiries on behalf of the MPSC:

- To programs identified as having experienced lower than expected outcomes during a specified cohort

Transplant hospitals must:

- Respond to inquiries and submit all requested documentation
- Participate in an informal discussion when requested by the MPSC
- Promptly adopt and implement a plan for quality improvement
- Participate in an on-site peer visit to identify opportunities for improvement when requested by the MPSC
- Inactivate a program or component of a program or withdraw designated transplant program status when recommended by the MPSC based on patient safety concerns

Bylaws Appendix D.12.B: Patient Notification Requirements for Waiting List Inactivation

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. When a program has inactivated its waiting list for either 15 or more consecutive days or 28 or more cumulative days during a calendar year, the OPTN Contractor will request and review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Transplant programs have provided written notice to candidates each time the program has reached either or both of the inactive waiting list thresholds
- Each element listed in the bylaws was addressed in the notification letter

A copy of the actual letter sent, filed in the medical record, will be sufficient for this documentation provided it contains all required elements.

Transplant hospitals will provide:

The requested sample of medical records.

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member fails to notify the patients in the time and manner required

Transplant hospitals must:

Respond to inquiries regarding periods of waiting list inactivity.

Notify candidates when a program inactivates its waiting list for either:

- 15 or more consecutive days
- 28 or more cumulative days during a calendar year

The written notice must include:

- The reasons for the inactivity
- The expected length of time the waiting list will be inactive
- The explanation that no organs will be accepted by this program for the candidates during the inactive period
- The candidate's options (must include multiple listing and transferring to another transplant hospital)
- How the candidate will be notified of reactivation or if the period of inactivation is extended
- A copy of the OPTN Contractor's Patient Information Letter
- The dates of each instance of waiting list inactivation (if notice is based on cumulative periods of inactivation)

Document and retain the written notices.[14]

Bylaws Appendices E, F, G, H, I, J: Conditional Approvals

How the OPTN contractor will evaluate member compliance with these bylaws:

The OPTN contractor will review materials submitted by members:

- The progress of each program toward meeting the requirements for full approval
- Any reports provided by the transplant program before the end of the conditional approval period, documenting the member's progress or ability to meet the requirements for full approval
- Key personnel change applications proposing a new surgeon or physician that fully meets the key personnel criteria if the surgeon or physician does not meet criteria at the end of the conditional approval

Conditionally approved programs must:

Comply with any interim operating policies and procedures required by the MPSC.

Comply with all applicable policies and procedures.

Demonstrate continuing progress toward full compliance with criteria for institutional membership.

Comply with all OPTN bylaw requirements for the conditionally approved program or component.

Provide any required reports by the documented deadlines prior to the conclusion of conditional approval if the program is still unable to meet all requirements for full approval. The report must document:

- The surgeon's or physician's progress toward meeting the bylaw requirements, or

[14] The MPSC set an operational rule for reviewing instances of noncompliance with this policy. Information on the MPSC's operational rule can be found here: https://optn.transplant.hrsa.gov/media/czblgosq/20231101_mpsc_meeting_minutes_public.pdf

- That the program is making sufficient progress in recruiting a transplant surgeon or physician who meets the criteria for full approval

Submit the following at least one month before the conclusion of conditional approval:

- A report documenting that the surgeon or physician can fully meet the key personnel requirements, or
- A key personnel change application proposing a replacement surgeon or physician who can fully meet the key personnel requirements and who will be on-site and credentialed by the end of the conditional approval period

Stop performing transplants by voluntarily inactivating or relinquishing the program or component if the program or component is unable to meet the requirements for full approval at the end of the conditional approval period.

Definitions:

Interim operating procedures may be required by the MPSC, and may include:

- Submission of reports describing the surgeon's or physician's progress towards meeting the requirements
- Other operating conditions to demonstrate ongoing quality and efficient patient care

Bylaw Appendices E.5, F.7, G.8, H.4, I.4: Transplant Programs that Register Candidates Less Than 18 Years Old

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns.. In the event the OPTN Contractor identifies instances where candidates less than 18 years old are registered at a transplant program that does not have an approved pediatric component, the OPTN Contractor will inquire.

Bylaws Appendix F.7.E: Emergency Membership Exceptions for Candidates Less than 18 Years Old

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. In the event the OPTN Contractor identifies instances where candidates less than 18 years old are registered at a transplant program that does not have an approved pediatric component, but the conditions detailed in this section of the Bylaws are met, the OPTN Contractor will request documentation to support the confirmation by the primary pediatric physician or primary pediatric surgeon at an approved pediatric liver component confirmed that it was not medically advisable to transport the patient to a liver transplant program with an approved pediatric component.

Bylaws Appendix H.4.E Emergency Membership Exceptions for Candidates Less than 18 Years Old

The OPTN Contractor will:

Conduct ongoing reviews of information submitted to the OPTN Computer System to monitor for compliance and potential patient safety concerns. In the event the OPTN Contractor identifies instances where candidates less than 18 years old are registered at a transplant program that does not have an approved pediatric component, but the conditions detailed in this section of the Bylaws are met, the OPTN Contractor will request documentation to support

the confirmation by the primary pediatric physician or primary pediatric surgeon at an approved pediatric heart component confirmed that it was not medically advisable to transport the patient to a heart transplant program with an approved pediatric component.

Bylaws Appendix K.1.A: Program Component Cessation

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review patient notification letters and refer the matter to the MPSC for consideration when:

- The OPTN contractor is notified of transplant program cessation
- Transplant program component cessation notifications do not meet bylaw requirements

Transplant hospitals must:

Notify potential living donors and potential and waitlisted candidates who have expressed interest in living donation when a living donor component of a transplant program is stopped.

Notify potential and waitlisted candidates when a deceased donor component of a transplant program is stopped.

Notify potential and waitlisted pediatric candidates when a pediatric component of a transplant program is stopped.

Notify potential and waitlisted adult candidates and potential and waitlisted pediatric candidates who may turn 18 during the cessation period when an adult component of a transplant program is stopped.

Maintain documentation supporting patient notification occurred and provide a copy of the patient notification and a list of the patients notified when requested.

The written notice must include:

- The reasons for program component cessation
- Explanation that during this period, the candidate cannot receive an organ offer
- Options for affected patients to transfer to another transplant program
- The phone number to the program's administrative office that can help with transferring to another transplant program

If a program stops transplanting a subset of patients within a program component, the affected group would be further defined to only include that specific subset (e.g., infants in a pediatric component).

Bylaws Appendix K.3.A: Notice to the OPTN Contractor of Long-term Inactive Status

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review materials submitted by members:

- Written notice to the OPTN contractor of inactivation

Transplant hospitals must:

Send written notification to the OPTN contractor, which must include:

- The reason(s) for inactivation
- The effective date of the inactivation

Bylaws Appendix K.3.B: Notice to the Patients of Long-term Inactive Status

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member fails to submit the required information in the time and manner required
- The member fails to notify the patients in the time and manner required

The OPTN contractor will review materials submitted by members:

- Draft copies of patient notification letters

Transplant hospitals must:

Send to the OPTN Contractor:

- A sample of each type of patient notice
- A list of potential candidates, candidates, recipients, and living donors who received the notice

Send written notification to patients (including potential candidates, candidates, recipients, and living donors currently being treated by the transplant program) at least 30 days prior to the planned inactivation date, or no later than seven days after the effective inactivation date.

The written notice must include:

- The reasons for inactivating the transplant program
- Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program while it is inactive
- Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program
- Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration
- The phone number of the inactive program's administrative office that can help with transferring to another transplant program

Additional Guidance:

If a natural disaster adversely affects the function of a transplant program, the patient notification requirements will be applied reasonably and flexibly.

Bylaws Appendix K.4.A: Notice to the OPTN Contractor

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review materials submitted by members:

- Written notice of withdrawal

Transplant hospitals must:

Send written notification to the OPTN contractor, which must include:

- The reason(s) for withdrawal
- The effective date of the withdrawal

Bylaws Appendix K.4.B: Notice to the Patients

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member fails to submit the required information in the time and manner required
- The member fails to notify the patients in the time and manner required

The OPTN contractor will review materials submitted by members:

- Draft copies of patient notification letters

Transplant hospitals must:

Send to the OPTN Contractor:

- A sample of each type of patient notice
- A list of potential candidates, candidates, recipients, and living donors who received the notice

Send written notification to patients (including potential candidates, candidates, recipients, and living donors currently being treated by the transplant program) at least 30 days prior to the planned withdrawal/termination date, or no later than seven days after the effective withdrawal or termination date.

The written notice must include:

- The reasons for withdrawing or terminating the transplant program
- Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program while it is withdrawn
- Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program
- Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration
- The phone number of the withdrawing program's administrative office that can help with transferring to another transplant program

Bylaws Appendix K.5: Transition Plan during Long-term Inactivity, Termination, or Withdrawal

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate any allegations of noncompliance. The OPTN contractor will review materials submitted by members:

- Transition plans
- Routine reports

Transplant hospitals must:

Submit a transition plan to the OPTN contractor within seven days of the effective date (may be submitted separately from the initial notice) that must include:

- A list of candidates on the transplant hospital's waiting list, with the following information on each candidate:
    - If the candidate chose to transfer to another hospital, the hospital to which the candidate is transferring
    - If the candidate chose not to transfer to another hospital:
        - The reason why the candidate chose not to transfer
        - Whether the candidate was informed of the implications of removal from the waiting list

- A list of the most urgent candidates, including:
    - Individualized plans for transfer
    - Potential alternative transplant programs
    - Timeline for transferring those candidates according to priorities and deadlines listed in Bylaw K.5(6)

Submit routine reports to the OPTN contractor until the program has completely cleared its waiting list of both active and inactive candidates. In general, these reports are due on the 1st and 15th of each month.

Immediately stop organ transplantation.

Help potential candidates and candidates transfer to other programs.

Transfer candidates to another hospital when either:

- Requested by the candidate
- The candidate is active and currently hospitalized at the transplant program. Then the transplant program must:
    - Initiate the transfer within 14 days after inactivation, withdrawal or termination, unless any of the following:
        - Transfer would be unsafe
        - Discharge is anticipated within the 14 day time period
        - Circumstances outside the transplant hospital prevent transfer within 14 days
    - Document all efforts to transfer these candidates and submit that documentation to the OPTN Contractor if a program cannot meet these deadlines

Bylaws Appendix K.6: Transferred Candidates Waiting Time

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- No written progress report is received within 90 days after the actual patient transfer date
- It appears that the member has not complied with their submitted plan
- The OPTN has requested, but not received, an updated progress report

The OPTN contractor will review materials submitted by members:

- The written collective patient transfer agreement and plan submitted by the transplant programs to confirm that it contains all required elements
- Progress reports submitted by the accepting transplant program to confirm that the program is complying with the submitted plan

Transplant hospitals must:

Send to the OPTN Contractor:

- A complete written agreement with each accepting transplant program that will be receiving candidates via a collective transfer that includes:
    - Request for collective transfer of candidates' waiting times
    - List of patient names and identifiers to be transferred
    - Mutually agreed upon transfer date
    - Assurance of notification and patient consent to transfer
    - List of active candidates that the transferring program agrees to change to inactive status if requested by the accepting transplant program
    - Acknowledgement that all patient information and records available to the OPTN Contractor will be transferred without modification

    - Acknowledgement that the transplant program accepting the patients accepts responsibility for patient notification and management according to all applicable OPTN Policies and Bylaws
- A plan from each accepting transplant program for evaluation of all collectively transferred candidates that includes:
    - A timeline and procedure for reviewing each candidate's waiting list status and amending it as appropriate until the candidate has been evaluated in accordance with the program's selection and listing criteria
    - A process and timeline for notifying candidates whose status is changed from active to inactive as part of either the collective transfer agreement or the accepting program's plan
    - An expected timeline for completing the candidates' evaluations and any subsequent waiting list status adjustments needed as a result of the new evaluations
- A progress report from each accepting transplant program:
    - Updating the evaluation status of each collectively transferred candidate as of day 90 post-collective transfer
    - Submitted to the OPTN Contractor within 14 days following day 90 post-collective transfer
- Additional progress reports from each accepting transplant program as requested by the OPTN Contractor

Evaluation Plan Appendix 1: Policies No Longer Under Active, Routine Monitoring

In various scenarios, the MPSC may decide that a policy or a component of a policy no longer requires active, routine compliance monitoring during site survey. These decisions are made based on high levels of compliance to improve review efficiency during site surveys and refocus monitoring on areas of improvement. The OPTN expects members to be compliant with all policies and can still request documentation if any compliance concerns arise. The decision to adjust active, routine monitoring at site survey are discussed during open session and voted on by the MPSC.

Policy 2.11.C: Required Information for Deceased Heart Donors

Effective date: 8/1/2022

Due to previous and maintained high compliance, the MPSC decided that Site Survey no longer needs to actively and routinely monitor this policy.

Policy 2.11.D: Required Information for Deceased Lung Donors

Effective date: 8/1/2022

Due to previous and maintained high compliance, the MPSC decided that Site Survey no longer needs to actively and routinely monitor this policy.

Policy 2.13: Deceased Donor Management

Effective date: 8/1/2022

Due to previous and maintained high compliance, the MPSC decided that Site Survey no longer needs to actively and routinely monitor this policy.

Policy 16.6.A: Extra Vessels Use and Sharing

Effective date: 8/1/2022

Due to high rate of compliance and understanding of the policy requirements based on information submitted through TIEDI, the MPSC decided that Site Survey no longer needs to actively and routinely monitor this policy.

Policy 16.6.B: Extra Vessels Storage

Effective date: 8/1/2022

Due to high rate of compliance, the MPSC decided for Site Survey to no longer review the location and requirements for storing vessels.

COVID-19 Related Requirements in OPTN Policies

Effective Date: 3/19/2024

This language has been removed from the OPTN Policy Evaluation Plan because the time period is no longer relevant for OPTN Site Survey monitoring. The impacted Policies are:

- OPTN Policy 6.1.A: Adult Heart Status 1 Requirements
- OPTN Policy 6.1.B: Adult Heart Status 2 Requirements
- OPTN Policy 6.1.C: Adult Heart Status 3 Requirements
- OPTN Policy 6.1.D: Adult Heart Status 4 Requirements
- OPTN Policy 6.2.A: Pediatric Heart Status 1A Requirements
- OPTN Policy 8.4.F: Prioritization for Liver Recipients on the Kidney Waiting List
- OPTN Policy 8.4.G: Prioritization for Heart Recipients on the Kidney Waiting List
- OPTN Policy 8.4.H: Prioritization for Lung Recipients on the Kidney Waiting List

- OPTN Policy 9.1.A: Adult Status 1A Requirements
- OPTN Policy 9.1.B: Pediatric Status 1A Requirements
- OPTN Policy 9.1.C: Pediatric Status 1B Requirements
- OPTN Policy 9.2: Status and Laboratory Values Update Schedule
- OPTN Policy 9.5: Specific Standardized MELD or PELD Score Exceptions
- OPTN Policy 9.9: Liver-Kidney Allocation
- OPTN Policy 10.1: Lung Composite Allocation Score
- OPTN Policy 10.3: Clinical Values and Update Schedule
- OPTN Policy 18.4.A: Reporting Requirements after Living Kidney Donation
- OPTN Policy 18.4.B: Reporting Requirements after Living Liver Donation

COVID-19 Related Requirements in OPTN Bylaw Appendices

Effective Date: 8/1/2024

This language has been removed from the OPTN Bylaw Evaluation Plan because the time period is no longer relevant for OPTN monitoring. The impacted Bylaw Appendices are:

- Bylaw Appendix D.11: Review of Transplant Program Functional Activity
- Bylaw Appendix D.12.B: Patient Notification Requirements for Waiting List Inactivation
- Bylaw Appendix K.1.A: Program Component Cessation
- Bylaw Appendix K.3.B: Notice to the Patients of Long-term Inactive Status