Crosswalk Guide to OPTN & CMS Transplant Programs Oversight

Supplemental Survey Method Information

CMS, HRSA and UNOS collaborated to develop a compliance resource for transplant professionals. Transplant programs are surveyed by both the OPTN and CMS for how well they comply with both OPTN Policies and Bylaws and federal regulations. The Crosswalk Guide to OPTN and CMS Transplant Programs Oversight Excel file allows program administrators who are preparing for site visits, to review the requirements of both organizations and see where they overlap. It also briefly summarizes what site surveyors from each organization will review on their visit.

This document contains supplemental information about survey methods that is useful to administrators but could not fit within the resource itself. Program administrators can link to this information from within the "Notes" column of the appropriate CMS or OPTN Crosswalk requirement.

Contents

CMS Tag X013: Notifying CMS of a Decrease in Volume or Survival Rates (Examples)

Survey Method: During their review, surveyors will note any significant changes that occurred over an extended period of time that could have an effect on your program's ability to conduct transplants or on the outcomes of those transplants. The reviewer should also be able to reasonably conclude that these changes could result in your program being out compliance with the transplant experience (volume) or outcome requirements under §482.82. CMS will also review information listed in the TPQR to confirm. CMS must be notified within seven (7) business days.

Clinical Experience Examples: For programs subject to clinical experience (volume) requirements (i.e., adult heart-only, adult lung-only, adult kidney-only, adult liver, and adult intestinal and/or multivisceral), examples of significant events include (but are not limited to):

1. The transplant program loses a significant number or type of personnel including the primary surgeon or primary physician, which decreases the ability of the program to perform transplants for any period exceeding 3 months; and could result in the clinical experience requirement (an average of 10 per year) not being met.
2. The program loses access to hospital resources or facilities (e.g., lab services, damages to the physical plant or infrastructure) to such an extent that the loss seriously limits or prevents transplants from being performed for any period exceeding 3 months; and could result in the clinical experience requirement (an average of 10 per year) not being met.
3. Cases in which a transplant program's team transferred to another hospital. It would be expected that recruitment of another transplant team would take a significant amount of time; or
4. A program seeking re-approval that has conducted 5 transplants in Year 1 and Year 2. The likelihood of performing 25 transplants in Year 3 is low.

Outcomes Examples: For programs subject to outcome requirements, requirements, examples of significant events include (but are not limited to):

1. Changes in patient selection criteria, patient care practices or protocols that had the unintended result of lowering patient or graft survival rates for a period exceeding 30 days that could result in the transplant program not meeting the outcome requirements.
2. The program
    a) loses access for more than 30 days to hospital resources or facilities (e.g., lab services, damages to the physical plant or infrastructure) that affect the program's outcomes, and
    b) the loss could lead a reasonable person to conclude that compliance with the outcomes under 482.82 may be jeopardized. Examples include but are not limited to the level of staffing or staffing coverage patterns, changes to the patient care practices, or immunosuppressant drug protocol.

Some examples of circumstances where notifications to CMS is not expected include:

1. A patient's death, as opposed to a pattern of deaths that is significantly higher than historical rates. Please note that programs may be required to report this type of event to other governing bodies; or
2. A program that has 8 transplants in year 1 of the re-approval period.

CMS Tag X024-X026: Pediatric Transplants: Pediatric Heart – OBRA 97 – Jointly Operated (Examples)

Survey Method: Prior to going onsite, surveyors review the TPQR to determine whether the pediatric heart program is seeking alternate approval under this section. They also review the joint operating agreement between hospital with the pediatric heart transplant program and the affiliated hospital with a Medicare-approved heart transplant program.

Examples of differences between the two programs in the transplantation process that the surveyor will need to assess could include:

- different transplant surgeons perform the surgeries for transplant recipients within the two programs;
- different processes for analyzing and reviewing adverse events;
- different patient and/or living donor informed consent protocols; and •different patient selection criteria or different processes for granting exceptions to those criteria.

The key question for surveyors in assessing differences is “Are these differences the result of the specialized services or needs for pediatric patients if other operations are unified among the two programs?” If the response is “yes,” then this would not be considered a deficiency.

Listed below are examples of differences that may exist between two programs that a reasonable person would assess as being specific to the needs of pediatric patients, and would not be considered evidence that the program is not operating in a unified manner.

- Example 1: The review of medical records indicates that there is a designated transplant coordinator (with expertise in pediatric patients) that does not work with the adult patients from the associated heart transplant program. This is permissible and would not be considered out of compliance since this is an example of specialized services for pediatric patients, if other operations are unified between the two programs.
- Example 2: A transplant program informed consent practices for the pediatric heart program may be different than the adult heart program. One set of materials could be provided to pediatric patients (presented at a level understood by children) with more detailed information provided to parents/guardians. The adult program may not follow this same procedure. This is permissible. An example of a program operating in a non-unified manner would include a program that has two separate quality assessment and performance improvement (QAPI) programs that each monitor their own program and the QAPI reports and activities are not shared with one another and/or discussed.

CMS Tags X033 & X036: Clinical Experience (Volume) (Initial Approval) (More Details & Notes)

Crosswalk Requirement: Survey Method: Surveyors will review your most recent TPQR to determine the number of transplants you performed over the last 12-months and whether that number meets the clinical experience requirements.

More Details: The following types of programs are subject to a clinical experience requirement of 10 transplants performed over a 12-month period for initial approval:

- Adult Heart-Only
- Adult Lung-Only
- Adult Liver
- Adult Intestinal and/or Multivisceral
- Adult Kidney-Only (See note below.)

Note for adult kidney-only programs: If the program was Medicare-approved as of June 28, 2007, then the program must meet the clinical experience requirements of 10 transplants over the previous 12-month period. For programs that are not Medicare-approved as of that date, the program must perform at least 3 transplants within the 12 months prior to approval. Transplants performed on pediatric patients cannot be used to meet the adult clinical experience (i.e., volume) requirements.

A program's inactivity does not create an exemption from this regulatory requirement.
Cite a deficiency if a program has performed fewer than 10 transplants over a 12-month period unless:

1. The transplant program can provide more recent data that shows that the transplant program performed 10 transplants over a 12-month period, or
2. There were adult kidney/pancreas transplants performed by the same transplant team(s) s that routinely perform kidney transplants at the same hospital, that, when added to the number of adult kidney-only transplants, would total 10 or more and show compliance with this standard. For example, if there were 14 adult kidney/pancreas transplants performed, and 8 kidney-only adult transplants performed by the same team at the same transplant hospital, the deficiency would not be cited, because the kidney-only program would be considered to have performed 22 transplants.
3. An adult heart-only program may include the number of adult heart/lung transplants performed by the same transplant team(s) who routinely performs heart-only or lung-only transplants at the same hospital, for the purpose of compliance with this standard.
4. An adult lung-only program may include the number of adult heart/lung transplants performed by the same team(s) who routinely perform heart-only or lung-only transplants at the same hospital, for the purpose of compliance with this standard.

The surveyor should determine whether or not a transplant team that performs the multi-organ transplant can be considered "the same team" that performs the single organ transplant. Performance of the multi-organ transplant by the same surgeon(s) that perform the single-organ transplant can be considered as persuasive evidence in most cases, but there may be circumstances in which there are other substantial differences in the support teams and other key personnel involved in the transplantation process (e.g., physicians, clinical transplant coordinators, nurses, etc.), in which the determination could be that it is not "the same team."

Note about #2, #3, and #4 Above: The exceptions described above allow the clinical experience gained in a multi-organ transplant (generally, a more complex surgery) to be counted in the clinical experience requirements for a single-organ transplant (which would generally be less complex), provided that the same transplant team(s) performs both the single and multi-organ transplants.
The adult kidney-only, adult heart-only, and adult-lung programs were singled out for these exceptions because they have both clinical experience requirements and related multi-organ transplant programs (i.e., kidney/pancreas, and heart/lung).

Note: Consistent with OPTN policy, multi-organ transplants not covered under the combination types above would be counted as one for each organ type. For example, a liver/kidney transplant would be counted for both liver and kidney.

CMS Tag X035: Outcome Requirements: Patient and Graft Survival (Initial Approval) (Details & Notes)

Survey Method: Surveyors will review your TPQR to determine if your program meets any applicable outcome requirements. If the TPQR indicates that the outcome requirements haven't been met, they will cite a deficiency.

More Details: The TPQR information already considers whether a program is required to meet outcome requirements, and the methodology that SRTR uses to calculate the CSR for each program-type.

The program types subject to this requirement include:

- Adult Kidney-Only
- Adult Heart-Only
- Adult Lung-Only (Includes ages 12 and over.)
- Adult Liver
- Pediatric Kidney-Only (Includes only 1-year graft survival)
- Pediatric Heart-Only
- Pediatric Lung-Only (Includes ages 12 and over.)
- Pediatric Liver

Note: The methodology of the SRTR Center Specific Report (CSR) for lung programs calculates one risk-adjusted report that includes transplant recipients ages 12 and over and another non-risk adjusted pediatric report for those under age 12. The regulation (482.80(c)) states that for lung programs, CMS will review adult and pediatric outcomes together. Therefore, this single risk-adjusted report (covering ages 12 and over) will be used to assess compliance for both the adult and pediatric lung programs.

CMS Tag X043: Clinical Experience (Re-Approval) (More Details & Notes)

Survey Method: Surveyors will review the most recent TPQR for the average number of transplants you performed during your re-approval period.

More Details: Transplant programs subject to clinical experience requirements must perform an average of 10 transplants per year. This means that a transplant program is not out of compliance with this requirement if they perform 30 transplants over the three-year re-approval period regardless of whether 10 transplants are performed in each calendar year. The TPQR information already considers whether a program is required to meet clinical experience requirements. If the TPQR indicates that this requirement has not been met, cite a deficiency.

Note: The timeframe for the re-approval period is from the previous approval of the program to the current survey. The following types of programs are subject to clinical experience requirements to be considered for re-approval:

- Adult Kidney-Only
- Adult Heart-Only
- Adult Lung-Only
- Adult Liver
- Adult Intestinal and/or Multivisceral

Transplants performed on pediatric patients cannot be used to meet the adult clinical experience (i.e., volume) requirements.

A program's inactivity does not create an exemption from this regulatory requirement.

If the program has clinical experience requirements and the average number of transplants performed is less than 10 per year (based on the information from the TPQR), cite the finding unless:

1. The transplant program can provide more recent data that shows that the transplant performed an average of 10 transplants per year during the re-approval period; or
2. An adult kidney-only transplant program demonstrates that a sufficient number of adult kidney/pancreas transplants were performed by the same transplant team(s) who are at the same hospital to bring the adult kidney-only program into compliance with this standard; or
3. An adult heart-only program may include the number of adult heart/lung transplants performed by the same transplant team(s) that routinely perform heart-only or lung-only transplants at the same hospital, for the purpose of compliance with this standard.
4. An adult lung-only program may include the number of adult heart/lung transplants performed by the same transplant team(s) that routinely perform heart- only or lung-only transplants at the same hospital, for the purpose of compliance with this standard.

Note about #2, #3, and #4 Above: The exceptions described above allow the clinical experience gained in a multi-organ transplant (generally, a more complex surgery) to be counted in the clinical experience requirements for a single-organ transplant (which would generally be less complex), provided that the same transplant team performs both single and multi-organ transplants.

The adult kidney-only, adult heart-only, and adult-lung programs were singled out for these exceptions because they have both clinical experience requirements and related multi-organ transplant programs (i.e., kidney/pancreas, and heart/lung).

Additional note: Paragraph (d) of this section refers to those programs that are exempt from clinical experience and/or outcome requirements. Since the items listed in paragraph (d) are not surveyed, they are not part of these guidelines. A description of these exceptions can be found in the regulation text.

CMS Tags X044 & X045: Outcome Requirements: Patient and Graft Survival (Note)

Crosswalk Requirement: Outcome Requirements: Patient and Graft Survival (Re-approval)
Survey Method: Surveyors will review the TPQR to determine if your program meets any applicable outcome requirements. If your outcome requirements have not been met, surveyors will cite a deficiency.

Note: The TPQR information already considers whether a program is required to meet outcome requirements, and the methodology that SRTR uses to calculate the CSR for each program-type.

The program types subject to outcome requirements include:

- Adult Kidney-Only;
- Adult Heart-Only;
- Adult Lung-Only (Include ages 12 and over.);
- Adult Liver;
- Pediatric Kidney-Only (Includes only 1-year graft survival);
- Pediatric Heart-Only;
- Pediatric Lung-Only (Include ages 12 and over.); and
- Pediatric Liver.

The methodology of the SRTR Center Specific Report (CSR) for lung programs calculates one risk-adjusted report that includes transplant recipients ages 12 and over and another non-risk adjusted pediatric report for those under age 12. The regulation (482.82(c)) also states that for lung programs, CMS will review adult and pediatric outcomes together. Therefore, this single risk-adjusted report (covering ages 12 and over) will be used to assess compliance for both the adult and pediatric lung programs.

CMS Tag X053: Psychosocial Evaluation for Transplant Candidates (More Details)

Survey Method: Surveyors will review your written patient selection policy to verify that it contains the following requirement: that a prospective transplant candidate will receive a psychosocial evaluation by a qualified healthcare professional BEFORE that candidate is placed on the waiting list.

More Details: The policy is expected to (1) indicate the length of time in which the psychosocial evaluation is deemed to be current, (2) identify the qualified healthcare professionals who may complete these evaluations (it is expected that these professionals would have knowledge of transplantation), and (3) include the follow-up and referral procedures if a transplant candidate requires such activities.

While the transplant program has flexibility in the specific psychosocial tool to be used, the psychosocial evaluation is expected to be completed and to be focused on the individual's suitability for transplantation. It is expected that a psychosocial evaluation of this nature would be conducted by transplant program personnel and would address the following:

1) social, personal, housing, vocational, financial, and environmental supports;
2) coping abilities and strategies;
3) understanding of the risks and benefits of transplantation;
4) ability to adhere to a therapeutic regimen; and
5) mental health history, including substance or alcohol use or abuse and how it may impact the success or failure of organ transplantation.

The psychosocial evaluation is expected to be age-appropriate. Similar to psychosocial evaluations in other areas, in cases of young pediatric patients, the evaluation would include interviews with the parents/guardians.

Verify in the sample of post-June 28, 2007, transplant recipient medical records that the psychosocial evaluation was completed by a person authorized under the program's policy before that potential recipient was placed on the UNET and transplant program's waiting lists. UNET is the secure Internet-based transplant database operated by the contractor for the OPTN (UNOS) for the nation's transplant programs and Organ Procurement Organizations to register patients and donors on the waiting list and for transplantation.

In each case, if a referral was made for further psychosocial evaluation before it could be determined whether an individual was to be placed on the UNET waiting list, verify that additional evaluation was completed as required by the transplant program's policies and procedures for follow-up and referral.

It is expected that in nearly all cases, a psychosocial evaluation is possible and should be conducted as part of the determination of whether or not someone would be a suitable transplant candidate. There are rare or emergency situations when a psychosocial evaluation cannot be completed prior to transplantation due to the patient's medical condition and with the absence of family or others that can provide information/insight into the psychosocial history of the patient.

In such cases, verify that documentation is included in the transplant patient's medical record that describes the reason a psychosocial evaluation was waived or unable to be completed, due to the need for emergency intervention or exceptional circumstances and that no family or others were available to address the psychosocial history of the patient. Examples of these exceptional or emergent circumstances may include untreatable encephalopathy, massive liver trauma, and acute (fulminant) liver failure (e.g., Tylenol overdose, mushroom poisoning).

CMS Tags X087; X088: Waitlist Management - Updating Clinical Information (More Details)

Survey Method: Surveyors will review your policies and procedures on updating both the waiting list and the pre-transplant clinical information for waiting list patients.

More Details: The policies and procedures should include the timeframe within which these updates must be completed, what type of information is updated, who is designated to update the clinical information, and how often the clinical information for waiting list patients is reviewed.

Please note that different types of organ programs will likely have different policies and procedures for updating clinical information. In addition OPTN has certain requirements for updating clinical information based on the patient's characteristics. Differences in policies/procedures are permitted. The surveyors should assess whether or not the program is following its policies/procedures.

During interviews with transplant program staff, request information about the process and frequency with which the transplant program reviews and updates the clinical information of waiting list patients, both in the patient's medical record and on the transplant program's waiting list. Using the transplant program's policy of providing UNet access to certain personnel, ask one of these designees for a demonstration of updating both the UNET and transplant program's waiting list (if different from the list of patients on UNET).

Review the post-June 28, 2007, medical records for a sample of transplant candidates currently on the program's waiting list (these may be inpatient or outpatient records) to ensure that the clinical information in the medical record corresponds to the transplant program's waiting list information identified in UNet.

CMS Tag X092: Social Services (Examples)

Survey Method: Surveyors will review the medical records of a sample of post-transplant patients and living donors from after June 28, 2007. This review is to verify that the social worker participated in the initial assessment, care planning, intervention, reassessment, and discharge planning and that this work is reflected in the social work consultation and progress notes. Surveyors will also interview a sample of transplant recipients and living donors about the assistance counseling they or members of their family received from the transplant social worker.

Examples of social services include:

1) Acknowledgement of the risks and benefits of transplantation and/or living donation as appropriate;
2) Assessment of patients' ability to adhere to therapeutic regimens;
3) Assessment of patient's mental health history, including degree of substance and alcohol use and how it may impact the success or failure of organ transplantation or the donor's mental health post-transplant. .
4) Assessment of patient's and living donor's (if applicable) coping abilities and strategies;
5) Assessment of patient's financial capabilities and resources, including who will pay for post-discharge medical care for the donor, if necessary; and
6) Provision of adequate social, personal, housing and environmental support.

CMS Tag X099: QAPI Program (More Details)

Survey Method: Surveyors will ensure that you have a written and comprehensive QAPI program.

More Details: The transplant program's portion of the QAPI program must:

- Specifically address the individual components of the transplant program; and
- Include the participation of the transplant program's key personnel (Director, primary transplant surgeon, primary transplant physician, clinical transplant coordinator, and nursing personnel). Examples of their participation include participation in QAPI committee meetings, presenting topics to the QAPI committee, authoring reports or updates for the QAPI committee about the program's status.

The transplant program's QAPI program must be written and comprehensive. A comprehensive QAPI program is expected to include the following:

a. Individual members identifiable by name, title, role, and responsibilities;
b. QAPI methods of operating and decision-making (e.g., by committee, sub-committee, other);
c. Objective measures by which the quality-related data will be collected and analyzed (including the measures described in §482.80 and §482.82);
d. Established frequencies for review of program performance, and reporting to the QAPI Committee and to the hospital-wide QAPI program;
e. Method by which key findings and recommendations are reported to QAPI transplant members, to the hospital-wide QAPI, and to individuals determined by the QAPI program as instrumental to action on important analyses, findings, and recommendations;
f. Designation of an individual who will be responsible for monitoring the transplant program's QAPI program (i.e., QAPI coordinator);
g. Evidence of tracking and implementing recommendations for improvement;
h. Evidence of ongoing compliance with changes implemented as a result of recommendations by the QAPI Committee; and
i. Broad representation of transplant program issues relevant for the disciplines represented in the multidisciplinary team (e.g., surgical, nursing, social services). This means that the QAPI would not solely be focused on a single discipline (e.g., the surgeon) and would include performance measures relevant for other disciplines.

CMS Tag X100: Components of a QAPI Program (Examples)

Survey Method: Surveyors will confirm that your QAPI program uses objective measures for review. These measures must render a comprehensive evaluation of your transplant program's performance, including services provided under contract or arrangement.

Examples of objective measures may include (but are not limited to):
Review of survival outcomes and fluctuations in outcomes over a designated period of time;

- Frequency of the use of exceptions in the patient/donor selection process;
- Blood type compatibility errors over a designated period of time;
- Consistency between the OPTN waiting list and transplant program's waiting list as measured by periodic comparisons for accuracy;
- Number of patient rights and patient/family complaints (received, investigated, confirmed, satisfactory disposition);
- Number of complaints related to consent practices;
- Percentage of organs refused over a given period of time;
- Percentage of organ rejection over a given period of time;
- Number of post-transplant or post-living-donation infections and other complications;
- Measurements of the effectiveness of patient/donor/family education.

CMS Tag X102: Adverse Events (More Details & Notes)

Survey Method: Surveyors will review your current written policy and procedures for identifying, reporting, investigating and analyzing adverse events.

More Details: Adverse Event Definition 482.70: "Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant programs, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient."

Note: Transplant programs are not required to report adverse events to CMS.

The policies should address:
1. Procedure for reporting an adverse event by transplant program personnel, the hierarchy of reporting, and for conducting analysis based on the reports;
2. The required timeframe for reporting, investigating and analyzing adverse events;
3. The corrective action process after the completion of the analysis and the timeframes for the action;
4. Use of analysis of reported adverse events in prevention;
5. External reporting of events to OPTN, ESRD Network, and States, etc. as required and applicable.
6. Reporting to, or inclusion of, Institutional Review Board (IRB)/Western Institutional Review Board (WIRB) if the adverse event occurred within the context of an approved study;
7. For suspected medical device-related deaths or serious injury, reporting to the Food and Drug Administration (FDA) and the device manufacturer as required by federal law.
8. Reporting to the OPTN if the adverse event caused, or may have caused, transmission of an infectious disease, and reporting to the Centers for Disease Control (CDC), if CDC requires such reporting to them.
9. Reporting to the OPO if the adverse event was related to an infectious disease present in a recovered organ from a deceased donor that could have been transmitted to other recipients who received organs from that same donor, or an otherwise compromised organ that was not detected either through the donor screening or organ transport processes.

CMS Tag X103: Analysis of Adverse Events (Examples)

Survey Method: Surveyors will request a log of adverse events that you reported over the past 12 months. They will also verify that your program followed its policies on investigation, reporting and analysis.

Examples of systemic factors that may contribute to adverse events include:
- Human Factors (for example, communication procedures, staff training, scheduling)
- Environment (for example, location of needed equipment, systems for organizing/labeling medication)
- Equipment (for example, technology that does not warn of pending error)
- Policies (for examples polices that may exist but are unclear, or where no policies exist)
- Procedures (for example, there are no procedures for verification of blood type)
- Organizational (for example, the transplant program may not be monitoring adherence to or reinforcing care protocols)

CMS Tag X118: Clinical Transplant Coordinator (More Details)

Survey Method: Surveyors will identify the designated clinical transplant coordinator for your program. They will also review your policies that detail the coordinator's role in all phases of transplantation and donation. See description of phases.

More Details: Transplant Recipient: Consider the pre-transplant phase to be from the evaluating a potential recipient and placing the individual on the program's waiting list to the pre-surgery preparation.

- Consider the transplant phase to be from pre-surgery preparation until the patient is awake and alert following surgery.
- Consider the discharge phase to be from the point the patient is awake and alert following surgery through post-transplant clinical management and post-discharge follow-up.
  Living Donor
- Consider the donor evaluation phase to be from first presentation by the potential donor until the pre-surgery preparation for the donation.
- Consider the donation phase to be from pre-surgery preparation until the donor is awake and alert following surgery.
- Consider the discharge phase to be from the point the donor is alert and awake following surgery through discharge from post-donation clinical management and follow-up.

CMS Tag X121: Independent Donor Advocate/Team Role (Notes)

Survey Method: Your policies and procedures must require that you designate an independent living donor advocate or living donor advocate team and outline the qualifications and training required for this role. After viewing a sample of living donor medical records, surveyors will verify that you identified an independent living donor advocate or team for each living donor. Their review of medical records and policies and procedures, as well as the answers to their interview questions, must confirm that the independent living donor advocate operated independently from the transplant team.

Notes on Independent Donor Advocate: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA: (a) promotes the best interests of the potential living donor;(b) advocates the rights of the potential living donor; and (c) assists the potential donor in obtaining and understanding information regarding the: (i) consent process;(ii) evaluation process;(iii) surgical procedure; and(iv) benefit and need for follow-up.

CMS Tag X139: Organ Procurement (More Details)

Survey Method: Surveyors will review your hospital's written agreement with your designated OPO, which must identify the specific responsibilities of both the hospital and the OPO and how they will work collaboratively.

More Details: Common responsibilities for the transplant hospital are expected to include (but are not limited to):

1. Providing current personnel contact information to the OPO, and notification of changes in key personnel;
2. Reporting inactivation and reactivation of transplantation services to the OPO;
3. Describing the method of communication with the OPO regarding organ acceptance or declinations;
4. Notifying the OPO of adverse events that would indicate that the donor may have had a transmissible disease which could impact the morbidity or mortality of recipients of other organs or tissues from the same donor;
5. Updating the UNet^{sm} data system in a timely manner with information about patient status and determinations regarding organ offers;
6. Providing a surgical recovery team to recover organs from donors, as appropriate, and transmitting licensure and/or credentialing information for the recovering surgeons to the OPO; and
7. Outlining a process for identifying and resolving issues, complaints, and concerns.

Common responsibilities for the OPO are expected to include (but are not limited to):

1. Determining the medical suitability of the donor;
2. Describing the method and timeliness of communication with the transplant hospital;
3. Notifying the transplant program of policy and procedure changes by the OPO that may affect organ recovery, placement, packaging, labeling, perfusion, and transport;
4. Ensuring the proper composition and credentialing of the organ recovery team;
5. Ensuring that proper documentation is provided to the transplant program about the recovered organ(s) which includes the blood type and other identifying information; and
6. Outlining a process for identifying and resolving issues, complaints and concerns.

CMS Tag X156: Informed Consent – Organ Donor Risk Factors (More Details)

Survey Method: Surveyors will review medical records and interview a sample of pre- and post-transplant patients to verify that the transplant program obtained fully-informed consent related to the organ donor risk factors that could affect the success of the graft or the health of the patient.

More Details:
Before a donor is identified and the transplant candidate is on a waiting list, these discussions should involve a general discussion of the implications of the transplant. These discussions should include the possibility of graft failure and/or other health risks related to the health status of the organ donor including:

a) the medical and social history and age of the donor,
b) the condition of the organ(s), and
c) the risk of contracting HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), cancer or malaria if the donor is infected, but the infection is not detectable at the time of donation.

After an organ offer is made for a patient, the transplant program must discuss with the patient the possible risks associated with transplantation of that specific organ. The discussion of risks should include any issues that could affect the success of the organ transplant (the condition of the organ), and any issues that could potentially place the health of the patient at risk (for example, known high-risk behaviors in the donor's background).

OPTN: Candidates 12+ with LAS (More Details)

Survey Method: OPTN-07: Surveyors will verify information entered into UNet℠ that was used to calculate the LAS score for your lung patients.

More Details: Surveyors review a sample of patients and a maximum of three (3) modifications per patient. The variables reviewed include: diagnosis, height, weight, functional status/NYHA class, assisted ventilation, 02 use, FVC actual, FVC percentage, 6 minute walk distance, cardiac cath values, diabetes status, PCO2, and creatinine. Site surveyors verify the information (lab values as well as dates) entered in UNet with medical record documentation.

OPTN: Status 1A/1B Pediatric – Heart (More Details)

Survey Method: Surveyors will review specific information on a sample of pediatric patients listed with the following: ventilator, ECMO, balloon pump, congenital or acquired heart disease, inotropes, exceptions.

More Details:

- For patients on a ventilator, surveyors verify that the candidate is on the ventilator each day of the listing.
- For patients with ECMO, surveyors verify that ECMO is in place for each day of the listing.
- For patients with a balloon pump, surveyors verify that the balloon pump is in place for each day of the listing.
- For patients listed with congenital or acquired heart disease, surveyors review the including the narrative.
- For candidates listed with inotropes. Surveyors verify the inotropes given as well as the doses for each day of the listing.
- For any candidate listed with an exception, surveyors review the information entered in the narrative.

OPTN: Status 1A Adults – Heart (More Details)

Survey Method: OPTN-32: Surveyors will review specific information on a sample of patients listed with the following: VAD, total artificial heart, ECMO, device-related complications, ventilators, exceptions.

More Details:

- For patients listed with a VAD. Surveyors verify the VAD implant date using the operative report. They also verify that the VAD is in place at the beginning and the end of the listing.
- For patients listed with a total artificial heart. Surveyors verify the total artificial heart implant date using the operative report. They also verify that the total artificial heart is in place at the beginning and the end of the listing.
- For patients with ECMO, surveyors verify that ECMO is in place for each day of the listing.
- For patients with device related complications, surveyors verify the information the program enters into the narrative.
- For patients on a ventilator, surveyors verify that the candidate is on the ventilator each day of the listing.
- For candidates listed with inotropes. Surveyors verify the inotropes given as well as the doses for each day of the listing. Surveyors also verify the presence of a swan ganz cathedar for each day of the listing.
- For any candidate listed with an exception, surveyors review the information entered in the narrative.

OPTN: Vessel Storage (More Details)

Survey Method: Surveyors will review your policies and interview individuals responsible for vessel storage to verify that they understand vessel disposition must be reported to the OTPN. They will also review all vessel inventory logs during review period to confirm storage did not exceed 14 days and verify disposition in only transplant surgical cases or destruction. Surveyors will also review temperature monitoring logs to confirm operation temperatures of storage refrigerator within permitted tolerances.

More Details:

- Surveyors review center policies and interview the individual responsible for vessel storage to verify that they understand vessels must be stored in FDA approved preservation solution.
- Surveyors review center policies and interview the individual responsible for vessel storage to verify that they understand vessel packaging and labeling. Surveyors also ask to see the refrigerator where vessels are stored. If there are vessels stored, surveyors will ask staff member to remove the container so they can verify the labeling meets the policy requirements.
- Surveyors review a sample of refrigerator logs to verify the temperature was maintained and verified on a daily basis.
- Surveyors review a sample of vessel disposition logs to verify that all vessels were destroyed or transplanted within 14 days of recovery.
- Surveyors review a sample of logs of stored vessels.
- Surveyors review the center's policy and interview the individual responsible for vessel storage to make sure they understand the policy requirements.

OPTN: Data Submission Requirements (More Details)

OPTN Survey Method: Noncompliance can be discovered through many avanues, including MPSC performance reviews and site surveys. If the 95% submission requirement is not met, the program may be contacted and requested to come into compliance. If compliance is still not achieved, the program is referred to the MPSC for possible action. This information is reported to CMS quarterly.

More Details: The SRTR provides the MPSC PAIS with analyses for each meeting. Any programs that are identified with lower than expected outcomes need to submit documentation regarding more recent outcomes, details of program operations, raw data, and a summary/status update on improvements they have made. The PAIS will continue to monitor the program until its survival rates improve or its status changes. The PAIS may refer a program to the MPSC for more serious actions if the program is noncompliant with requests for information and/or does not institute a plan for quality improvement.

NOT a requirement for OPTN membership: The MPSC will review a Transplant Program if it has a low survival rate compared to the expected survival rate for that Transplant Program. The review will be to determine if the low survival rate can be explained by patient mix or some other unique clinical aspect of the Transplant Program. The MPSC may conduct a peer visit to the Program at Member expense and may require the Member to adopt a plan for quality improvement. The MPSC may also require, at its discretion, that the Member participate in an informal discussion. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The discussion will be conducted according to the principles of confidential medical peer review, as described in Appendix L: Reviews, Actions, and Due Process of these Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

While the precise statistical criteria may be selected by the MPSC, the initial criteria used to identify programs with low patient or graft survival rates will include all of the following:

1. The finding that observed events minus expected events is greater than three (3).
2. The finding that the observed events divided by expected events is greater than 1.5.
3. There exists a one-sided p value less than 0.05.

Observed events are deaths or graft losses as reported in UNET database. Expected events are deaths or graft losses as calculated using organ-specific transplant models.

Those programs whose actual observed patient or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

If a Program's performance cannot be explained by patient mix or some other unique clinical aspect of the Transplant Program in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The Member’s failure to do so will constitute a violation of OPTN membership requirements.