CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 240 **Date: May 1, 2026**

SUBJECT: Technical revisions to the State Operations Manual (SOM) Appendix X for transplant programs.

SUMMARY OF CHANGES: The SOM is being updated to make technical revisions to the survey protocol in Appendix X. The table of contents is being updated to reflect the order of the survey protocol, reference to multidisciplinary "rounds" is being changed to multidisciplinary "meetings", and finally Task 6 title of the survey protocol is being changed to Quality "Assessment" and Performance Improvement to be consistent with regulatory references to this requirement. We are also reinserting survey procedures for an alternative survey protocol, as these procedures were inadvertently deleted in the previous SOM posting. This is existing procedure and no revisions have been made to the content that is being reinserted.

NEW/REVISED MATERIAL - EFFECTIVE DATE: May 1, 2026
IMPLEMENTATION DATE: May 1, 2026

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	SOM/Appendix X/Table of Contents
R	SOM/Appendix X/Survey Protocol/Task 4 Clinical Observations; "rounds" was replaced with "meeting".
R	SOM/Appendix X/Survey Protocol/Task 6 QAPI; "Assurance" was replaced with "Assessment".
R	SOM/Appendix X/Alternate Survey Protocol: Pediatric Heart Program

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.
Or
Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Appendix X – Guidance to Surveyors: Organ Transplant Programs

Table of Contents
(Rev. 240 Issued: 05-01-26)

Transmittals for Appendix X

The Standard Organ Transplant Program Survey Protocol

(Rev. 240; Issued: 05-01-26; Effective: 05-01-26; Implementation:05-01-26)

I. Introduction

Overview & Key Concepts

A transplant program must be located within a hospital that has a Medicare provider agreement and must meet the Conditions of Participation (CoPs) specified in §§482.72 through 482.104 in order to be granted approval from the Centers for Medicare and Medicaid Services (CMS) to provide transplant services. In addition, transplant programs must also meet the hospital CoPs specified in §§482.1 through 482.57. For more detailed information on CMS' certification process, please see Chapter 2 of the State Operations Manual.

Patients that receive care in a transplant program are unique in that each patient who is managed by the transplant program will receive such services at various points of care, e.g. pre-transplant evaluation, transplantation procedure, and post-discharge follow-up care. Additionally, patients seeking transplantation services will be managed for varying time periods, lasting months to potentially years due to their complexities and nature of the transplantation process, e.g., evaluation for transplant, management while on the waiting list, transplant procedure, and discharge planning. It is critical to ensure the survey process evaluates patient safety and compliance with the applicable CoPs throughout not only a patient's length of stay but also along the continuum of transplant and living donor care management.

This survey protocol provides a standardized framework for surveyors to fully evaluate patient safety and compliance with all transplant program CoPs. For complaint investigations, surveyors should also follow instructions found in Chapter 5 of the State Operations Manual (SOM). Hospitals may have more than one transplant program, and each program must be surveyed and approved individually.

Note: In order to observe care delivery in a manner which is not prompted nor influenced, all transplant program surveys must be unannounced. The unannounced survey allows the surveyor to review the transplant program, as well as the Hospital in which it is located, during their routine day-to-day operations and avoids the possibility of a transplant program's advanced preparation for a Federal survey.

The following transplant programs must meet Medicare CoPs in order to be granted Medicare approval to provide transplant services: kidney transplant program, pancreas transplant program, heart transplant program, lung transplant program, liver transplant program, and intestinal transplant program. Each program must meet the CoPs at §§482.72 through 482.104 and must be surveyed and approved separately unless otherwise noted.

Program	Abbreviation	Notes
Adult Kidney	AKO	
Adult Pancreas[1]	APA	In order to perform adult pancreas transplants, the program must have a Medicare-approved adult kidney program. This includes combined kidney/pancreas and pancreas-only transplants.
Adult Heart-only	AHO	
Adult Lung	ALO	
Adult Liver	ALI	
Adult Intestine/Multivisceral[2]	AIM	In order to perform adult intestinal/multivisceral transplants, the program must have an approved adult liver program.
Pediatric Kidney	PKO	
Pediatric Pancreas[1]	PPA	In order to perform pediatric pancreas transplants, the program must have an approved pediatric kidney program. This includes kidney/pancreas and pancreas-only transplants
Pediatric Heart	PHO	
Pediatric Lung	PLO	
Pediatric Liver	PLI	
Pediatric Intestine/Multivisceral[2]	PIM	In order to perform pediatric intestinal/multivisceral transplants, the program must have an approved pediatric liver program.

[1]An adult or pediatric pancreas transplant program may be Medicare-approved, with no independent survey activity, if the program operates as a component of an existing Medicare-approved kidney transplant program which is in compliance with the CoPs (§§482.72-482.104).

[2]An adult or pediatric intestine transplant program may be Medicare-approved, with no independent survey activity, if the program operates as a component of an existing Medicare-approved liver transplant program which is in compliance with the CoPs ((§§482.72-482.104).

Survey Team Size and Composition

The transplant program CoPs apply to each approved program. While multiple transplant programs may be approved within a certified hospital, the survey process must determine compliance with program requirements for each individual program, respectively. In order to ensure optimal resources allotted to perform survey activities and conduct a thorough review of each transplant program, survey team size and composition should be determined based on the number of transplant programs requesting approval, or approved in a certified hospital. For survey planning purposes, consideration should be given to existing transplant programs with upcoming re-approval surveys when requests for initial approval are processed. Initial approval, re-approval, and/or complaint surveys may be performed jointly, as appropriate.

A survey event for a transplant program must contain a minimum of two qualified transplant surveyors. See table below for survey team size based on number of transplant programs:

Number of transplant programs	Number of surveyors – minimum
1-3	2 surveyors
4-6	3 surveyors
6+	4 surveyors

Survey Protocol Tasks

(Rev. 240; Issued: 05-01-26; Effective: 05-01-26; Implementation:05-01-26)

The Components of the Standard Transplant Program Survey Protocol

TASK #	**Task**
1	Pre-survey: Off-site Preparation
2	Entrance Activities
3	Sample Selection
4	Clinical Observations
5	Information Gathering: Medical Record Reviews and Interviews
6	Quality Assessment and Performance Improvement
7	Personnel Record Review
8	Exit Conference
9	Post Survey Activities

TASK 1 - PRE-SURVEY: OFF-SITE PREPARATION

Prior to the survey, determine the number and types of transplant programs at the transplant hospital to be surveyed to determine survey team size.

Some portions of the survey process are to be conducted prior to entering the hospital. This gives the surveyor(s) an understanding of the information needed to navigate through certain tasks of the survey process. Surveyors should conduct a review of the below areas and make sure any material that needs to be provided to the transplant program is available as hard-copies, e.g., entrance conference materials list.

Review each program using the information below:

1. For initial approval surveys, review the **Initial Transplant Report** (see SOM Chapter 2) to determine compliance with the following:
   a. Data submission (X-032)
   b. Clinical experience (X-033)
   c. Outcome requirements (X-035)
2. OPTN membership. Verification of a transplant program's membership with the Organ Procurement and Transplantation Network (OPTN) can be found in the Initial Transplant Report (in the case of an initial approval) or on the OPTN's website: Full OPTN Member Directory. This directory contains all transplant programs designated as OPTN members.
3. Transplant program inactivation. If the transplant program had any **periods of inactivity,** determine whether the following occurred:

a. Any inactivation was reported to CMS within seven business (7) days of when the transplant program becomes aware that either a change will occur or has occurred; (X-011)
b. The program exceeded a 12 consecutive calendar month inactivation period; (X-172)

4. Complaints history. Any prior survey and certification issues, e.g. previous **complaints** that indicate further investigation or follow-up.

TASK 2 - ENTRANCE ACTIVITIES

Entrance Conference Considerations:

- All transplant program surveys are unannounced;
- The entire survey team should enter the hospital together;
- With the team present, the survey team lead will ask to speak to the hospital Administrator or the designated person in charge;
- All team members must display their surveyor identification badge during on-site surveys; and
- The entrance conference should begin within 20-30 minutes, or as soon as possible, upon entry to the facility.

*E*ntrance *C*onference Activities:

- Introduction of surveyors;
- Explain that the purpose of the survey is to determine the program's compliance with the Medicare CoPs for each transplant program being surveyed (list the programs to be surveyed);
- Discuss the projected survey schedule for the survey, including the projected time and date for the exit conference;
- Determine a point of contact at the transplant program for access to medical records and the UNet waiting list. Access to the UNet waiting list will be needed to perform certain tasks for determining compliance with waiting list management standards. The surveyor should determine how medical records will be accessed for survey activities, i.e. electronic health records or paper records;
- Provide the transplant program's point of contact a copy of the Entrance Conference Materials List (below). The surveyor should instruct the transplant program to submit all information listed below within 4 hours of their receipt of the list.
- Confirm that the primary transplant surgeon and primary transplant physician are consistent with the information on file with the state survey agency (SA); (if information is not consistent, the surveyor must confirm that the OPTN was notified of the change);
- Determine whether living donor transplants are performed at the transplant program;
- Determine whether the hospital uses any contracted services that also serve that transplant program. A review of the services provided under contract must occur to ensure such services are consistent and in compliance with the Medicare CoPs;

- As applicable, determine whether adult transplants are performed under an approved pediatric program or pediatric transplants are performed under an approved adult program (to enable sample selection); and
- Identify all areas of the hospital campus where transplant services are provided, including inpatient transplant care and outpatient care. Surveyors should ensure clinical observations are performed in all areas where transplant services are provided, e.g. inpatient transplant unit and outpatient transplant clinic (pre-transplant and post-transplant services).

Entrance Conference Materials List

Requested Items for Review for Each Organ Program Type			
Transplant Program		**Program Type:**	**Program Representative:**
Name:		Choose an item.	
The following is a list of documentation that the surveyors will need to review. If the records are electronic, it would be helpful to arrange for a staff member who is familiar with the electronic system, as well as the organization of the transplant medical records to assist surveyors in their review. The surveyors may ask for copies of various sections of the medical record, policies or other documents, as necessary. Please bring all charts related to the transplant or living donation from evaluation through post-transplant or living donation, including post discharge planning. This is not an exhaustive list. Actual findings during an onsite survey may necessitate review of additional documentation not listed below.			
Lists Of Transplant Candidates, Recipients And Living Donors (by organ type)			✓
1.	Each transplant program's **complete current active waiting list** including the following information: name, date of listing, waiting list status, medical record number, age, race and gender of each patient;total number of individuals on the waiting list.		☐
2.	List of all patients (including their medical record number) **removed from the waiting list** within the past 12 months of each program for reasons other than death or transplant.		☐
3.	List of all patients (including their medical record number) removed from the waiting list within the past 12 months of each program **due to death or transplant**.		☐
4.	List and number of persons **evaluated for transplant that were not placed on the waiting list** within the past 12 months; please include patient name, decision date, decision reason and medical record number. Do not include persons that are currently in the evaluation process.		☐
5.	List and number of the **transplants performed** within the past 18 months including patient name, date of transplant, medical record number, organ(s) transplanted, age, race, gender, address, country of primary residence, and the date of death or graft failure if applicable;		☐
6.	List and number of **living donors** who were evaluated during the past 12 months, denoting those potential donors who proceeded to donation. Include name, medical record number, the organ(s) donated, and date of donation within the designated time period.		☐
	Lists of Meeting Schedules, Scheduled Follow-up Visits and Current Transplant Inpatient Census		

7.	List and number of transplant patients and living donors that are currently an inpatient and the location of the patient in the hospital (unit and floor).	☐
8.	List and number of post-transplant patients and post-donation individuals that are scheduled for follow-up visits during the survey timeframe.	☐
9.	A schedule of any multidisciplinary team meetings that will be held during the survey timeframe; include team rounding schedule.	☐
10.	A schedule of any selection committee meetings that will be held during the survey timeframe.	☐
11.	A schedule of any QAPI committee meetings that will be held during the survey timeframe.	☐
	List of Organ Offers	
12.	List and number of the organs that the transplant program received offers for within the past 18 months, and declined, and the reason for the declination/UNOS decline code.	☐
	Program Administration/Contracts	
13.	An organizational chart of the transplant program: that includes the chain of command and how the transplant program fits within the overall hospital structure.	☐
14.	Any contracts with external parties that the hospital or transplant program have for services relevant to transplantation, including but not limited to Anesthesiology, Blood Banking, Dialysis Services (inpatient or outpatient), Histocompatibility (HLA) or Immunology Laboratory, Infectious Disease, Internal Medicine, Living Donor including (Paired Exchange, Regional, Altruistic, Adult to Pediatric, or Pediatric to Adult donors), Nursing, Pathology, Radiology, Nutritional/Dietary Services or Surgery.	☐
	Personnel	
15.	List of all transplant-associated professional personnel, their titles, primary organ transplant program affiliations and any other transplant program affiliations, if applicable. (X-082, X-090, X-091, X-125)	☐
16.	The curricula, training plan, and/or training schedule for personnel (agenda, dates, evidence of attendance). (X-112)	☐
17.	On-call schedule for transplant surgeons and transplant physicians for the past 30 days.	☐
	Policies and Procedures	
18.	Patient selection criteria (transplant recipient and living donor), provide the criteria that your program uses to select patients for transplant and living donation (X-051-59)	☐
19.	Organ Receipt Policy for ABO and Other Vital Data Verification (include associated forms) (X-071, X-073)	☐
20.	Living Donor Recovery for ABO and Other Vital Data Verification (include associated forms) (X-074)	☐
21.	Transplant Recipient Patient Management Policies for Transplant and Discharge Planning Phases (X-082, X-090, X-091, X-125)	☐
22.	Living Donor Patient Management for Pre-Donation, Donation and Discharge Planning Phases (X-082, X-125)	☐
23.	Waiting List Management Policy (including patient notifications) (X-081-94)	☐

24.	Informed Consent Policy for Recipients (include associated forms) (X-149-158)	☐
25.	Informed Consent Policy for Living Donors (include associated forms) (X-060, X-124, X-149, X-159-168)	☐
26.	Ongoing communication with patients and dialysis centers (Informing patient and dialysis centers of patient's listing status) (X-120, X-186)	☐
27.	Procedure for informing patients on the waiting list of the availability of a transplant team that could impact the patients' ability to receive a transplant should an organ become available (X-169)	☐
28.	If a transplant program is served by a single transplant surgeon or physician, the potential unavailability of the transplant surgeon or physician (X-170)	☐
	Education Information	
29.	A copy of the written material that is distributed to potential transplant recipients and living donors to explain the selection criteria (X-051-056)	☐
30.	Any written educational materials used pre and post-transplant for transplant recipients (X-126)	☐
31.	Any written educational materials used pre and post-donation for living donors (X-126)	☐
	QAPI	
32.	The written copy of the transplant program's Quality Assessment and Performance Improvement (QAPI) plan (X-099-104)	☐
33.	The written copy of the hospital's Quality Assessment and Performance Improvement (QAPI) plan	☐
34.	Any QAPI reports, records and minutes of QAPI committee meetings, or consultation reports about the QAPI program (X-099-104)	☐
35.	Policy / Protocol on complaints, adverse events, and other occurrence or variance reporting issues (X-99-104)	☐
36.	Log of any reported adverse events for the past 24 months and documentation of the investigation, analysis of events, and any follow-up action taken (X-102 to X-104)	☐

TASK 3 – SAMPLE SELECTION

In this sample selection task, the survey team identifies a number of samples of medical records that will be reviewed during the survey. The selection should be accomplished very early in the survey process to allow the transplant program time to gather the records (unless the records are 100% electronic). Use the lists of recipients and living donors (if applicable) provided by the transplant program as the universe for sample selection. The goal is to choose, within the sample, a representation of the overall transplant program services and patients. Patients that will be available in-person during the survey should be prioritized, i.e. inpatients and patients presenting for evaluation or follow-up care.

Sample sizes reflect the minimum number of samples per category. If concerns are identified during the survey for a given area, surveyors should expand the sample size to determine trends and/or identify widespread issues.

The chart below reflects the minimum number of patients that must be selected randomly for each area.

Category	Sample Size*	Comment
Waiting list patients	3	Patients can remain on a transplant program waiting list for varying periods of time before transplantation occurs. Include two (2) patients minimum that have been on the waiting list >3 years and one (1) patient minimum on the waiting list <3 years
Patients removed from waiting list for reasons other than death or transplant	3	"Removed" for purposes of this criteria means removed from the waiting list in the previous 12 months. If no patients were removed from the waiting list in the previous 12 months, extend the time period for the sample
Patients removed from the waiting list due to death or transplant	3	"Removed" for purposes of this criteria means removed from the waiting list in the previous 12 months. If no patients were removed from the waiting list in the previous 12 months, extend the time period for the sample
Patients evaluated but not placed on the waiting list	3	
Transplant Recipients	6	Sample selection should be distributed among recipients whose transplant was 1) performed within the last 6 months and 2) more than 12 months ago. If no patients have been transplanted within the last 6 months, add those additional records to "Waiting list patients" category.
Living organ donors (if applicable)	3	
Patient adverse events	3	
*If the transplant program is performing pediatric transplants under an approved adult transplant program, surveyors should select two (2) additional records for each of the categories listed above for that population. Similarly, if the transplant program performs adult transplants under an approved pediatric transplant program, surveyors should select two (2) additional records for each of the categories listed above.		

TASK 4 – *CLINICAL OBSERVATIONS*

Observations provide direct knowledge of the transplant program's practices, which the surveyor can use when assessing compliance. A finding of non-compliance should not be based on a single observation and should be supported by a second source of information.

The transplant program survey process includes three (3) critical opportunities for direct observations to occur: multidisciplinary rounds, selection committee meeting(s), and routine quality improvement meeting(s) (see additional details below). Each of these observations offers the surveyor insight as to the composition of the transplant program, the culture within the program, and key clinical topics that are shared during these routine occurrences.

Observations can occur in any area or location where patient care is provided and should serve to identify potential patient safety and quality of care issues. Observational findings should be compared to findings in medical record documentation and/or through interviews.

As with written patient information, observations must be performed and reported in consideration of the privacy and protection of the patient.

1. **Selection Committee Meeting**: The purpose of selection committee meetings is to discuss patients who are undergoing evaluation for placement on the transplant program's waiting list and review patients who are already listed. These meetings generally occur weekly and will often include the transplant physician, transplant surgeon, transplant coordinator, social worker, nutritionist, and at times, a financial counselor. During the observation of the transplant program's selection committee meeting, note the following:

    a. Attendance and leadership of the selection committee meeting
    b. Team participation and involvement in patient selection discussion
    c. Selection criteria used to make patient determinations
    d. Process for making patient determinations
    e. Outcome of the selection committee meetings
    f. Results of any committee meeting discussions are conveyed to the patient and/or their family
    g. Review previous meeting minutes and attendance for consistency with observed meeting

    Relevant tags if concerns or deficient practices are observed: X-051-X-056

2. **Multidisciplinary *Meetings***: The purpose of the multidisciplinary *meetings* is to discuss clinical status and identify the clinical needs of transplant patients. Occurring on the inpatient unit, the multidisciplinary *meetings* generally occur daily and include all key staff members of the multidisciplinary team. Rounds may also include clinical staff responsible for direct patient care. During observations, note the following:

    a. Attendance and roles of the team members
    b. Leadership and collaboration within the team
    c. Communication among team members
    d. Involvement of recipient/family in care decisions
    e. Documentation and evidence of individualized implementation and evaluation of patient's plan of care to ensure they are meeting their goals

3. **Quality Improvement Meetings**: The transplant program is required to develop, implement and monitor an ongoing, data-driven QAPI program. The purpose of quality improvement

meetings is for the members of the transplant program QAPI team to raise topics, discuss plans, and/or identify issues with the elements in its QAPI program. Note: Any concerns that are identified during observations of routine transplant program quality improvement meetings should be further investigated in Task 6: QAPI. During observations, note the following:

a. Attendance and roles of the team members
b. Identification of QAPI leadership, as well as participation from all members of the team
c. Identification of issues and concerns relative to the transplant program activities
d. Follow-up and development of improvement plans to address gaps in care
e. Action items and/or results of the QAPI meeting

Relevant tags if concerns or deficient practices are observed: X-099-X-104

TASK 5 – *INFORMATION GATHERING: MEDICAL RECORD REVIEWS AND INTERVIEWS*

In this task, the team will be reviewing medical records for samples selected during Task 3: Sample Selection. The records will include pre-transplant evaluations, inpatient records, and post-transplant follow-up records. Because the transplant and donation process involves patients receiving services through various points of care, the program records may be found in different locations and may be a combination of electronic and paper medical records. Please ensure that the transplant program understands that the surveyors review records addressing the entire transplantation and donation process and that all requested records must be made available.

Components of the medical record review are detailed below and will be applied to all sampled patients, with additional areas of review that apply to a specific sample category. Surveyors should ensure the medical records are reviewed based on the review components below.

MEDICAL RECORD REVIEW:

For all sampled patients, review the medical record for the following:

- Patient Evaluation
    - Confirm that the each transplant candidate received a **psychosocial evaluation** prior to placement on the transplant program's waiting list. There are rare or emergency situations when a psychosocial evaluation cannot be completed prior to transplantation due to the transplant candidate's medical condition. Justification for not conducting a psychosocial evaluation prior to a potential recipient's placement on the waiting list must be documented in the medical record. (X-053)
    - Confirm that each living donor received a **medical and psychosocial evaluation** prior to donation (X-058)

- Confirm that verification **of blood type occurred** prior to placement on the waiting list (surveyor may need to review both labs section and progress note section in the medical record to confirm this information) (X-054)

- Patient Selection Criteria
  - The medical record must contain the **patient selection criteria used by the transplant program** when determining the appropriateness for placing a patient on its waiting list. Selection criteria must be written, approved by the hospital, and used consistently in the evaluation of each transplant candidate. (X-051, X-055)
  - Patient selection criteria must be **fair and non-discriminatory** (X-052)
- Confirm transplant candidates were informed of the following components of **informed consent prior to transplantation**:

  - The evaluation process (X-151)
  - The surgical procedure (X-152)
  - Alternative treatments (X-153)
  - Potential medical or psychosocial risks (X-154)
  - National and transplant program-specific outcomes (X-155)
  - Organ donor risk factors (X-156)
  - Their right to refuse transplantation (X-157)
  - Potential out-of-pocket costs of immunosuppressive medications if the surgery is not performed in a Medicare-approved transplant program (X-158)

  Note: A surgical consent for the actual transplantation surgery does not confirm the informed consent process.
- Multidisciplinary Care Planning, including waiting list management, patient care, and discharge planning
  - Progress notes on patient care, established care plans, staff activities, etc. Surveyor should verify involvement of all key personnel (X-081, X-090);
  - Identify patient needs and the extent to which appropriate follow-up action was taken;
  - Copies of notification or patient education materials provided;
  - Discharge planning including social worker notes, discharge summary, and discharge instructions provided to the patient (X-091). Effective discharge planning should be confirmed through inpatient and/or outpatient records.

Additional Review Components

Patient Sample: Persons evaluated; not placed on the waiting list

In instances where a patient was evaluated but not placed on the waiting list, there should be documentation of the reason for not placing the patient on the waiting list and whether the patient was informed of the decision not to place him/her on the waiting list based on the evaluation. If there is evidence that the potential candidate meets the waiting list criteria but was not listed, there must be documentation by the facility as to why they were not placed on the waiting list. Relevant tags if concerns or deficient practices are identified: X-083, X-087 and X-0X-88.

Patient Sample: Living Donor

A transplant program may provide living donor services either directly or under contract or arrangement with another hospital. For living donor samples, verify the following occurred:

- The transplant program used written donor selection criteria in determining the suitability of candidates for donation. (X-051)
- The donor candidate was informed of the fact that communication between the donor and the transplant program will remain confidential, consistent with 45 CFR parts 160 and 164. (X-160)
- Donor candidate was fully informed about aspects of and outcomes from living donation. (X-159)
- Every living donor has received a medical evaluation prior to donation. (X-058)
    - The evaluation must include a final recommendation and justification as to whether the living donor is suitable for donation. (X-059)
    - The evaluation must include evidence that the donor was notified as to suitability and rationale for the decision. (X-059)
- Every living donor has an Independent Living Donor Advocate (ILDA) identified for their care.
    - Every living donor must have an interview with the ILDA or ILDA team prior to the initiation of the evaluation and throughout the donation phase. (X-121)
- The donor was informed of their right to opt out of donation at any time during the donation process. (X-168)

If potentially deficient practices are identified for living donor services provided under contract or arrangement, review the transplant program's monitoring and quality assurance activities for contracted services during Task 6: QAPI.

Organ offers received but declined: Based on the entrance conference materials list, the transplant program provides the surveyor with a list of organ offers it has received from the OPTN but declined in the past 18 months. Review this list to determine any extended periods of time where organ offers were consistently declined. This may indicate changes within the transplant program that affect a waitinglist candidate's ability to receive a transplant, e.g., unavailability of qualified surgeons to perform the procedure. If significant instances of organ declinations are observed, determine whether:

a. The transplant program was active. If the transplant program was inactive, verify notification to CMS. (X-015)
b. Patients were notified of changes within the transplant program that would affect their ability to receive a transplant. (X-169-170)

INTERVIEW:

Interviews provide a method to collect valuable information and validate and verify the accuracy of information obtained through observations, record reviews, and review of other documents when assessing the transplant program for compliance with Medicare CoPs. Patient interviews should be conducted for, at a minimum, all sampled patients in order to obtain patient experience and validate any information discovered during the medical record

review. The surveyor or survey team should introduce themselves and state the purpose of the interview as soon as patient contact is established. It is possible to interview inpatients and outpatients of the hospitalat the time of survey. In-person interviews are preferred if the patient is available during the survey period. When this is not possible, the surveyor should contact the patient by phone and obtain permission to conduct a patient interview. If an interviewed patient was part of the original sample, then compare the information received from the patient with the information reviewed in their medical record. If an interviewed patient is not part of the original sample, the medical record must be reviewed and the information compared to the information provided by the patient regarding their patient experience.

At a minimum, patient interviews should determine the following:

1. Patient made an informed decision to proceed with transplantation or donation.
2. Transplant program communicated any information that could affect the patient's ability to receive a transplant.
3. Patient received all discharge information in a timely manner using methods that validate the patient's understanding of information received, e.g. medication management, follow-up appointment details, contact information for transplant-related issues.
4. Any issues with discharge plans were identified and addressed before actual discharge.

Interviews with transplant staff in general should be conducted pursuant to medical record findings, patient interview findings, or specific observations.

Interviews with both patients and staff should be conducted one-on-one with the surveyor when possible. It is acceptable for surveyors to conduct telephone interviews with key personnel in the event that they are unavailable during the survey. If the interview is done in person, locate a private place for the interview. Interviews are conducted in private unless the recipient or donor expresses a preference to have a family member or staff member present during the interview. Discuss with the recipient/donor that their answers may be written down, and confirm that this is acceptable to them.

In interviewing inpatients, as with other types of surveys, all patient interviews are voluntary, and surveyors should focus on those patients whose condition is sufficiently stable to permit being interviewed (e.g., not in the intensive care unit).

TASK 6 – QUALITY *ASSESSMENT* AND *PERFORMANCE* IMPROVEMENT

The QAPI CoP requirements ensure that transplant programs have systems to identify and address areas of concern or risk for patient safety and well-being. The surveyor must review the transplant program's QAPI program, including the analysis of adverse actions, to ensure that the transplant program meets regulatory requirements (X-099 through X-104).

QAPI Review

QAPI is integral to each task in the survey protocol. Anytime a deficient practice or potential harm is identified, surveyors will consider if it has been addressed in the QAPI program. Considerations include:

1. *Comprehensive QAPI program (X-099):*

    a. *Does the program have a written, detailed, transplant-specific QAPI program with policies and procedures focused on transplant data and outcomes?*
    b. *Does the QAPI program cover all organ types?*
    c. *Is the QAPI transplant committee identified? How often do they meet? Is there evidence that individuals with authority to make decisions about the transplant program's policies and practices are routinely participating in the QAPI meetings or process?*
    Note: Larger transplant programs may have multiple quality improvement committees that all focus on individual components of a comprehensive QAPI program, respectively. Ensure there is communication of information between all quality improvement committees that monitor and address performance of the transplant program.
    d. *Is there a clear linkage between the transplant program's QAPI program and the overall hospital's QAPI program? Is the method for communication between the transplant QAPI and the hospital QAPI program defined?*

2. *Evaluation and Monitoring of the Transplant Program by the QAPI (X-100)*

    a. *Is the process to determine what objective measures the transplant QAPI program will look at on a regular basis defined?*
    b. *Is there evidence that the QAPI staff and committee members are reviewing and discussing the results of the objective measures, e.g., meeting agendas, presentations, minutes, and progress notes? (Please note this is different from a case review of an adverse event.)*
    c. *Do the transplant program's objective measures address transplant activities and outcomes throughout the continuum of transplant and/or living donor process?*
    d. *Are there benchmarks? If not, how does the program evaluate its performance for each objective measure?*
    e. *Is data missing from any of the objective measures? If yes, why?*
    f. *Are there any instances where other survey information (e.g., interviews, records) show something different from what the program is reporting in the objective measures?*

3. *Performance Improvement Actions/Activities (X-101)*

    a. *Is the process to identify and track performance improvement activities defined?*
    b. *Is there evidence that the transplant program has taken actions that result in performance improvements and are those tracked and sustained?*

4. *Transplant Program's Adverse Event Policies/Procedures and Analysis (X-102)*

CMS defines an adverse event as an untoward, undesirable, and usually unanticipated event ***that causes death or serious injury, or the risk thereof****. 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 beneficiaries, and unintended transmission of infectious disease to a beneficiary.*

a. *Are there transplant hospital written adverse event policies and procedures specific to transplant?*
b. *Does the policy address communicating reportable adverse events to the respective organization, as appropriate or as required, e.g., within the hospital system, to the state survey agency, OPTN/UNOS, CDC & local OPOs?*
c. *Does the written adverse event policy address the following:*

    i. *Inclusion of all approved organ types*
    ii. *A process for the identification of adverse events*
        Note: If the transplant program uses a hospital adverse event reporting system, what is their method to identify events relating to the transplant program?
    iii. *Mechanism to track and analyze adverse events*
    iv. *Method to determine who will be responsible to analyze the event.*
    v. *Process for incorporating adverse events into the QAPI program.*
        Note: If a concern is identified during the survey which meets CMS' definition of an adverse event and the concern was not identified by the transplant program, or if it was identified but not addressed in QAPI, the surveyor should determine what the program's mechanism is for discovery and referral to the QAPI program.

5. *Thorough Analysis to Effect Change and Prevent Repeat Incidences (X-103-X-104):*

    a. *Critical elements of a thorough analysis include, but are not limited to, the following:*

        i. *Specific chronology of the incident*
        ii. *Interview with all relevant staff involved*
        iii. *Interview with relevant external parties (e.g., OPO, referring physicians). If available, interviews with the transplant patient/living donor*
        iv. *Review of all relevant policies and procedures and identification of any deviation from standard procedures that occurred*
        v. *Any contextual factors related to the environment (e.g., staff schedules, bed availability, equipment, systems)*
        vi. *Rate of occurrence and common factors for the same/similar events*

    b. *As a result of the thorough analysis, were the following identified:*

        i. *Primary root cause(s)*
        ii. *Contributing factors to the event*

iii. *Potential areas to prevent repeat incidences, or after analysis determined that no opportunities for improvement exist.*
iv. *Specific recommendations/action steps that resulted from the analysis. If not, is there a sound rationale for not making changes?*

QAPI Inclusion of Contract Services

Refer to the list of the hospital's contractual services provided during the entrance conference. The contracted services list should be utilized to confirm that appropriate contractual personnel, policies and procedures, and other operational infrastructure are included in QAPI processes as though it were a direct component of the transplant program itself. The surveyor will assess if effective monitoring and feedback systems are in place regarding the quality of those contracted services. The actual contract should be available for review if concerns are identified during the survey and those concerns involve services that were provided under contract or arrangement.

When a transplant program performs living donor organ transplants under a contract with another hospital's living donor program (i.e. the certified transplant program being surveyed does not have its own living donor program and relies on another institution to manage the process for the living donor), the transplant program's QAPI program should ensure:

1. *There is a feedback system to address any adverse events that occur from a donation and subsequent transplant.*
2. *There is notification to the recipient or donating hospital for any adverse event, and identified actions taken to prevent recurrences. It is not expected that the transplant programs would share their analysis of the adverse event.*
3. *The recipient's transplant program QAPI plan includes a requirement for the donor's program to have an up to date QAPI plan that is designed to monitor any quality-related concerns and a review of the completeness of the donor records received.*

TASK 7 – *PERSONNEL RECORD REVIEWS*

If the surveyor identifies personnel concerns during observations or interviews, the surveyor should request relevant personnel records from the Personnel or Human Resources Department (based on the list below) and review these records in a secure area. Inquire as to how the program trains new staff and provides continuing transplant education to the staff.

Position	***Number of Records for Each Program***	***Qualifications***
Transplant Director	*1*	*X-110*
Transplant Surgeons	*3 (if less than 3, review all)*	*X-114*

Transplant Physicians	*2*	*Concerns with transplant physician qualifications should be referred for a review of the Hospital requirements for §481.12(a).*
Transplant Coordinators (Recipient and living donor, if applicable)	*1*	*X-118*
Dietitian	*1*	*X-094*
Pharmacist	*1*	*Concerns with transplant pharmacist qualifications should be referred for a review of Hospital requirements for §481.12(a).*
Social Worker(s)	*1-2*	*X-093*

PERSONNEL INTERVIEWS

For concerns identified during any personnel record review, interview the individual to gather additional information. Inform the hospital administrator and the transplant program that any staff may be selected for an individual interview. These interviews will be conducted one-on-one with the surveyor. A surveyor may interview more than the minimum number of transplant staff to make an appropriate assessment of the transplant program's ability to provide safe, quality care.

It is appropriate for surveyors to conduct telephone interviews with key personnel, in the event that they are unavailable during the survey, to prevent delays in the survey process. If certain staff have responsibilities in more than one type of organ transplant program, it is permissible to cover both programs in a single interview. Be sure to provide an opportunity for the interviewee to discuss any differences between the programs.

The staff interviews should elicit knowledge of the transplant program operations and the program's ability to provide safe and appropriate care to transplant patients.

TASK 8 - EXIT CONFERENCE

Prior to conducting an exit conference with the transplant program staff members, all members of the survey team should take the opportunity to convene as a group to discuss findings, seek any clarifications needed, and confirm next steps. Each team member will review and share the gathered evidence with the other team members. The team should determine any non-compliance and document any such findings including making photocopies of medical records or other documents needed to support the non-compliance. Make all copies prior to the exit conference.

A single exit conference will be held regardless of the number of programs surveyed. At the beginning of the exit conference, each participant will identify him/herself.

During the conference:

- Identify each deficiency found and restate those deficiencies being cited;

- Provide an opportunity for the transplant program to present additional information that may not have been presented during the survey (except for a failure to meet requirements at §482.80(a) and (c));
- Outline the next steps

    - The hospital administration will receive a written form (the CMS-2567 Statement of Deficiencies) from the state survey agency that describes the survey findings and cited noncompliance deficiencies. Findings for all programs that were surveyed together will be included on one CMS-2567. Each deficiency will be identified by the applicable program. Following receipt of the CMS-2567 (generally within 10 days of the exit conference), the transplant program must submit a plan of correction within 10 days of receipt of the CMS-2567 for each individually cited deficiency.

- Explain that all findings discussed during the exit conference are preliminary and subject to administrative review.

Although it is CMS' general policy to conduct an exit conference, be aware of situations that would justify refusal to continue an exit conference. For example, if the hospital administrator or transplant program administrator is represented by counsel, surveyors may refuse to continue the conference if the lawyer tries to turn it into an evidentiary hearing.

If the program records the conference, the surveyor should request a copy for the survey file.

TASK 9 - POST SURVEY ACTIVITIES

Following the survey, the surveyor will complete the Organ Transplant Hospital Worksheet, Form CMS-670 (Survey Team Composition and Workload), and the CMS-2567 forms. Form CMS-670 and the CMS-2567 are entered into the Automated Survey Process Environment System (ASPEN).

There will be a single CMS-2567 form prepared, even if the survey included multiple transplant programs within a hospital. Each regulation that is cited must specify the applicable transplant program to which it applies. ASPEN has been modified to include this information.

Once the CMS-2567 is finalized, the SA is responsible for sending the CMS-2567 to the hospital administrator and requesting a plan of correction (note the plan of correction may address more than one type of transplant program). Once an acceptable plan of correction has been submitted, the SA is responsible for scheduling the follow-up visit (if applicable) to ensure that any cited deficiencies have been corrected.

Alternate Survey Protocol: Pediatric Heart Program

(Rev. 240; Issued: 05-01-26; Effective: 05-01-26; Implementation:05-01-26)

Survey Protocol for Pediatric Heart Transplant Programs Operating Jointly with Associated Heart Transplant Program

Under §482.76(d), instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant program that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub.L.100203).

The pediatric heart transplant program is responsible for providing evidence that:

1. The pediatric transplant program is operated jointly with another Medicare-approved facility. This joint operation may occur pursuant to a structured affiliation between the two hospitals or pursuant to a written agreement.

2. The surgeons who perform the heart transplants at the pediatric hospital are credentialed for cardiac surgery at both hospitals under the unified program; The QAPI programs must be shared by both hospitals and include review, analysis and recommendations for the pediatric transplants; Collaboration between both QAPI programs would consist of reviewing and evaluating the need for any changes between the jointly operated entities; and

3. Demonstrates to the satisfaction of CMS that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

TASK 1 – PRE-SURVEY PREPARATION OFFSITE

None required.

TASK 2 – ENTRANCE ACTIVITIES

Meet with the program administrator upon entrance and explain the purpose of the review. Provide an estimated timeframe for the survey and list the materials that will be reviewed.

Requested Items for Review:

Lists of Transplant Candidates and Patients:
Log of the transplants performed including name and date of transplant for both the pediatric heart transplant program and the associated heart transplant program within the past 18 months;

Program Administration: Policies, Procedures, Personnel, and QAPI

1. A copy of the joint operating agreement between the pediatric heart transplant program and the associated heart transplant program that is jointly operating this program;
2. An organizational chart of the pediatric heart transplant program and the associated program;

3. Credentials for cardiac transplant surgeons and physicians and confirmation they are permitted to practice at both facilities; and
4. Log of any reported adverse events (by the pediatric heart transplant program and the associated program) and corresponding documentation of the investigation and analysis of those events for the past 12 months.

TASK 3 – SAMPLE SELECTION

Using the lists of recipients of the pediatric heart transplant program and the associated heart transplant program, select the samples as early in the survey as possible so that the transplant program has time to obtain all the records requested. At any time, the surveyor may add additional records to any sample based on observations or interviews.

Pediatric Heart Transplant Recipients Sample Selection

Based on the list of transplants done over, but not prior to, the past three years by the pediatric heart transplant program, select a minimum of five or if less than 5 transplants have been completed, all available records of pediatric heart transplant recipients and request their medical records for review.

TASK 4 – REVIEW OF TRANSPLANT PATIENT MEDICAL RECORDS

Task 3 describes the number of transplant patient medical records that must be selected for review both in the pediatric heart transplant program and the associated program. Surveyors will focus the review of medical records on the following sections:

1. Evaluations: psychosocial and medical;
2. Patient selection criteria;
3. Informed consent documentation;
4. Blood type, ABO and UNOS ID verification;
5. Operative reports;
6. Progress Notes for patient care, staff activities, informed consent discussions, etc.;
7. Multidisciplinary care plan and patient teaching tools for involvement of all key personnel;
8. Discharge planning; and
9. Follow-up (outpatient) chart or section of record.

Surveyors will make photocopies of any documents needed to support survey findings. If requested, the surveyor will make the hospital a copy of all items photocopied. The photocopies must include the recipient's anonymous code, the type of document and the date and time the photocopy was made, for example, "Patient #3, Progress Notes, 2-25-07, 1400."

TASK 5 – STAFF INTERVIEW

Follow standard protocol for interviews.

TASK 6 – PERSONNEL RECORD REVIEW

Follow standard protocol for personnel file review.

TASK 7 – ADMINISTRATIVE REVIEW

Operating Agreement

Review the operating agreement between the pediatric heart transplant program and the associated heart transplant program to ensure that it meets the requirements of the guidelines (Tags X024 through X026).

Refer to the QAPI Administrative Review in the standard protocol. Ensure that the QAPI program is a single, unified program between the jointly operating hospitals.

TASK 8 – PRE-EXIT CONFERENCE

Review and analyze all the information collected from any observations, interviews, and record reviews to determine whether or not the program meets the requirement of 42 CFR 482.76(d) for approval of a pediatric heart transplant program. The team identifies any non-compliance that may prohibit the alternative approval.

Refer to the standard survey protocol for discussion by the survey team, determining compliance, and ensuring that any non-compliance is adequately supported.

If the program is not in compliance with the requirements of 42 CFR 482.76(d), then the pediatric heart transplant program cannot be approved under the alternate approval requirements.

TASK 9 – EXIT CONFERENCE

Refer to the standard protocol for the exit conference. However, pediatric heart programs under the alternate approval are only required to meet tags X024 through X026. Therefore, the exit conference will be limited to findings on these requirements.

TASK 10 – POST SURVEY ACTIVITIES

Refer to standard survey protocol. Approval of a pediatric heart transplant program does not require a separate form CMS-2567, and may be listed with other types of transplant programs surveyed simultaneously.