CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 227 **Date: December 13, 2024**

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix X, Transplant Program Interpretive Guidelines and Survey Procedures and Chapter 9 - Exhibits

I. SUMMARY OF CHANGES: The SOM Appendix X, transplant program survey procedures is revised to provide better clarification to the surveyors. In addition, updates are made to the interpretive guidance based on state agency and industry feedback. Also, references to data requirements for reapproval have been removed throughout the Appendix following changes in the Burden Reduction Final Rule [84 FR 51732], i.e., data submission, clinical experience, and outcome requirements for reapproval. Finally, Exhibit 357 is being added to Chapter 9 of the SOM for state agency use for inactive transplant programs.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: December 13, 2024
IMPLEMENTATION DATE: December 13, 2024

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	Appendix X/Table of Contents/The Standard Organ Transplant Program Survey Protocol
R	Appendix X/Table of Contents/The Standard Organ Transplant Program Survey Protocol/Introduction
R	Appendix X/Table of Contents/The Standard Organ Transplant Program Survey Protocol/Survey Protocol Tasks
R	Appendix X/Table of Contents/The Standard Organ Transplant Program Survey Protocol/Task 2 - Entrance Activities
R	Appendix X/Table of Contents/Alternate Survey Protocol: Pediatric Heart Program
R	Appendix X/Table of Contents/Interpretive Guidelines for Organ Transplant Surveys
D	Appendix X/Table of Contents/Interpretive Guidelines for Organ Transplant Surveys/42 C.F.R. 482.82 Data Submission, Clinical Experience and Outcome Requirements Re-approval

R	**Appendix X/The Standard Organ Transplant Program Survey Protocol**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol/Introduction**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol/Survey Protocol Tasks**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol/Task 1 - Pre-survey: Off-site Preparation**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol/Task 2 - Entrance Activities**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol /Task 3 - Sample Selection**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol/Task 4 – Clinical Observations**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol/Task 5 – Information Gathering: Medical Record Reviews and Interviews**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol /Task 6 – Quality Assessment and Performance Improvement (QAPI)**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol /Task 7 – Personnel Record Reviews**
R	**Appendix X/The Standard Organ Transplant Program Survey Protocol/Task 8 – Exit Conference**
R	**Alternate Survey Protocol: Pediatric Heart Program**
R	**Alternate Survey Protocol: Pediatric Heart Program/Task 2 - Entrance Activities**
R	**Alternate Survey Protocol: Pediatric Heart Program/Task 3 - Sample Selection**
R	**Alternate Survey Protocol: Pediatric Heart Program/Task 4 – Review of Transplant Patient Medical Records**
N	**Interpretive Guidelines for Organ Transplant Surveys**
R	**Appendix X/X-002/§482.72 Condition of Participation: OPTN Membership/Revised to add links to the OPTN website.**
R	**Appendix X/X-011/§482.74(a) Condition of Participation: Notification to CMS**
R	**Appendix X/X-012/§482.74(a)(1) Change in key staff members of the transplant team, such as a change in the primary transplant surgeon and primary transplant physician.**
R	**Appendix X/X-015/§482.74(a)(3) and §482.74(b). Inactivation of the transplant program.**
R	**Appendix X/X-021/§482.76 Condition of Participation: Pediatric Transplants.**
R	**Appendix X/X-023/§482.76(c) -A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.**

	(1) Loss of Medicare approval to perform pediatric transplant, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants. **(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform pediatric transplants.** **(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.**
R	**Appendix X/X-024/§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 center 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.100-203), as follows:** **(1)The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;**
R	**Appendix X/X-025/§482.76(d)(2) The unified program shares the same transplant surgeons and quality improvement program.**
R	**Appendix X/X-026/§482.76(d)(3) Specialized facilities, services, and personnel required by pediatric heart transplant patients.**
R	**No tag/§482.78 Condition of participation: Emergency preparedness for transplant programs.**
R	**Appendix X/X-031/§482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Programs.**
R	**Appendix X/X-032/§482.80(a) Standard: Data Submission.**
R	**Appendix X/X-033/§482.80(b) Standard: Clinical Experience.**
R	**Appendix X/X-035/§482.80(c) Standard: Outcome requirements.** **§482.80(d) Exceptions.**
R	**Appendix X/X-036/§482.80(d)(5) A kidney transplant program that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval**
R	**Appendix X/X-051/§482.90 Condition of Participation: Patient and Living Donor Selection. The transplant program must use written patient selection criteria in determining a patient's suitability for placement on the waiting list.**
R	**Appendix X/X-052/ §482.90(a) Standard: Patient Selection.** **Patient selection criteria must ensure fair and non-discriminatory distribution of organs.**
R	**Appendix X/X-053/§482.90(a)(1) Prior to placement on the program's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.**

R	**Appendix X/X-055/§482.90(a)(3) When a patient is placed on a program's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.**
R	**Appendix X/X-056/§482.90(a)(4) A transplant program must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.**
R	**Appendix X/X-058/§482.90(b) Standard: Living Donor Selection.**
R	**Appendix X/X-059/§482.90(b)(2) Document in the living donor's medical records the living donor's suitability for donation.**
R	**Appendix X/X-071/§482.92 Condition of Participation: Organ Recovery and Receipt. Transplant programs must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes.**
R	**Appendix X/X-073/§482.92(a) Standard: Organ Receipt. Verification that the donor's blood type and other vital data are compatible with transplantation of the intended recipient.**
R	**Appendix X/X-074/§482.92(b) Standard: Living Donor Transplantation. Verification that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient.**
R	**Appendix X/X-081/§482.94 Condition of Participation: Patient and Living Donor Management. Transplant programs must have written patient management policies for the transplant and discharge phases of transplantation.**
R	**Appendix X/X-082/§482.94(a) Standard: Patient and Living Donor Care. The transplant program must ensure that patient care is under a multidisciplinary team.**
R	**Appendix X/X-087/§482.94(c) Standard: Patient Records. Transplant program must maintain up to date medical records.**
R	**Appendix X/X-091/§482.94(c)(ii) Multidisciplinary discharge planning for post-transplant care.**
R	**Appendix X/X-092/§482.94(d) Standard: Social Services.**
R	**Appendix X/X-094/§482.94(e) Standard: Nutritional Services.**
R	**Appendix X/X-099/§482.96 -Condition of Participation: Quality Assessment and Performance Improvement (QAPI)**
R	**Appendix X/X-101/§482.96(a)(cont'd)**
R	**Appendix X/X-102/§482.96(b) Standard: Adverse Events.**
R	**Appendix X/X-112/§482.98(a)(1) Coordinating with the hospital in which the transplant program is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.**
R	**Appendix X/X-114/§482.98(a)(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon.**
R	**Appendix X/X-118/§482.98(c) Standard: Clinical Transplant Coordinator.**
D	**Appendix X/X-119**

R	**Appendix X/X-121/§482.98(d) Standard: Independent Living Donor Advocate or Independent Living Donor Advocate Team.**
R	**Appendix X/X-122/§482.98(d)(1) The independent living donor advocate or team must not be involved in transplantation activities on a routine basis.**
R	**Appendix X/X-123/§482.98(d)(2) The independent living donor advocate or independent living donor advocate team must demonstrate: (i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and (ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.**
R	**Appendix X/X-124/§482.98(d)(3) -The independent living donor advocate or independent living donor advocate team is responsible for:** **(i) Representing and advising the donor;** **(ii) Protecting and promoting the interests of the donor; and** **(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.**
R	**Appendix X/X-125/§482.98(e) Standard: Transplant Team.**
R	**Appendix X/X-139/§482.100 Condition of Participation: Organ Procurement.**
R	**Appendix X/X-150/§482.102(a) Standard: Informed Consent for Transplant Patients.**
R	**Appendix X/X-151/§482.102(a)(1) The evaluation process.**
R	**Appendix X/X-153/§482.102(a)(3) Alternative treatments.**
R	**Appendix X/X-154/§482.102(a)(4) Potential medical or psychosocial risks.**
R	**Appendix X/X-155/§482.102(a)(5) National and transplant program-specific outcomes, from the most recent SRTR program-specific report, including (but not limited to) the transplant program's observed and expected 1-year patient and graft survival, and national 1-year patient and graft survival;**
R	**Appendix X/X-156/§482.102(a)(6) Organ donor risk factors.**
R	**Appendix X/X-159/§482.102(b) Standard: Informed consent for living donors.**
R	**Appendix X/X-162/§482.102(b)(3) The surgical procedure, including post-operative treatment.**
R	**Appendix X/X-164/§482.102(b)(5) The potential medical or psychosocial risks to the donor.**
R	**Appendix X/X-165/§482.102(b)(6) The national and transplant program-specific outcomes.**
R	**Appendix X/X-169/§482.102(c) Standard: Notification to patients of information about the program that could impact the patient's ability to receive a transplant.**
R	**Appendix X/X-172/§482.102(c)(3) -As soon as possible prior to a transplant program's voluntary inactivation, the program must inform patients on the program's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list**

	of another Medicare-approved transplant program without loss of time accrued on the waiting list.
R	**Appendix X/X-188/§482.104(c) Standard: Participation in network activities.**
N	**Chapter 2/Table of Contents/Section 2060A – Citations**
N	**Chapter 2/ Table of Contents/Section 2060B.1 - Organ Procurement and Transplantation Network (OPTN)**
N	**Chapter 2/Table of Contents/Section 2060B.2 - Scientific Registry of Transplant Recipients (SRTR)**
N	**Chapter 2/Table of Contents/Section 2060B.3 - United Network for Organ Sharing (UNOS)**
N	**Chapter 2/Table of Contents/Section 2060C – Regulatory Background**
N	**Chapter 2/Table of Contents/Section 2061A – Transplant Services**
N	**Chapter 2/Table of Contents/Section 2061B - Organ Procurement and Transplantation Network Membership**
N	**Chapter 2/Table of Contents/Section 2062A – Survey Composition and Scope**
N	**Chapter 2/Table of Contents/Section 2062B.1 - Initial Survey for Medicare Approval**
N	**Chapter 2/Table of Contents/Section 2062B.2 - Re-approval Surveys**
N	**Chapter 2/Table of Contents/Section 2062B.3 - Complaint Surveys**
D	**Chapter 2/Table of Contents/Section 2062C - Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards:**
D	**Chapter 2/Table of Contents/Section 2062D - Post-Survey Activities**
D	**Chapter 2/Table of Contents/Section 2062E - Transmission of Program Approval Information**
D	**Chapter 2/Section 2062F-Mitigating Factors**
D	**Chapter 2/Section 2062F.1 Medicare Approval Based on Mitigating Factors**
D	**Chapter 2/Section 2062F.2 Mitigating Factors Application and Review Process**
D	**Chapter 2/Section 2062F.3 Processing Medicare Approval based on Mitigating Factors**
D	**Chapter 2/Section 2062F.4 Processing Denial of a Mitigating Factors Request**
D	**Chapter 2/Section 2062F.5 Systems Improvement Agreements (SIA)**
N	**Chapter 2/Table of Contents/Section 2064 – Notification to CMS**
N	**Chapter 2/Table of Contents/Section 2065 – Transplant Program Inactivation**
N	**Chapter 2/Table of Contents/Section 2066 - Mitigating Factors**
N	**Chapter 2/Table of Contents/Section 2067 – Transplant Resources**
R	**Chapter 2/Section 2060A – Citations**

R	**Chapter 2/Section 2060B.1 - Organ Procurement and Transplantation Network (OPTN)**
R	**Chapter 2/Section 2060B.2 - Scientific Registry of Transplant Recipients (SRTR)**
N	**Chapter 2/Section 2060B.3 - United Network for Organ Sharing (UNOS)**
R	**Chapter 2/Section 2060C - Regulatory Background**
R	**Chapter 2/Section 2061 – Request for Medicare Approval of an Organ Transplant Program**
R	**Chapter 2/Section 2061A – Transplant Services**
R	**Chapter 2/Section 2061B - Organ Procurement and Transplantation Network Membership**
R	**Chapter 2/Section 2062A – Survey Composition and Scope**
R	**Chapter 2/Section 2062B.1 - Initial Survey for Medicare Approval**
R	**Chapter 2/Section 2062B.2 - Re-approval Surveys**
R	**Chapter 2/Section 2062B.3- Complaint Surveys (Remove Outcomes Non-compliance)**
D	**Chapter 2/Section 2062B.4 – Clinical Experience**
D	**Chapter 2/Section 2062B.4 - Complaint Surveys**
D	**Chapter 2/Section 2062C - Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards:**
D	**Chapter 2/Section 2062D – Post-Survey Activities**
D	**Chapter 2/Section 2062E – Transmission of Program Approval Information**
D	**Chapter 2/Section 2062F-Mitigating Factors**
D	**Chapter 2/Section 2062F.1 Medicare Approval Based on Mitigating Factors**
D	**Chapter 2/Section 2062F.2 Mitigating Factors Application and Review Process**
D	**Chapter 2/Section 2062F.3 Processing Medicare Approval based on Mitigating Factors**
D	**Chapter 2/Section 2062F.4 Processing Denial of a Mitigating Factors Request**
D	**Chapter 2/Section 2062F.5 Systems Improvement Agreements (SIA)**
N	**Chapter 2/Section 2064 – Notification to CMS**
N	**Chapter 2/Section 2065 – Transplant Program Inactivation**
N	**Chapter 2/Section 2066 - Mitigating Factors**
N	**Chapter 2/Section 2067 – Transplant Resources**
N	**Chapter 9/Exhibit 357/Model Letter for a Transplant Program Inactivation**

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
Chapter 2 - The Certification Process

Table of Contents
(Rev. 227; Issued: 12-13-24)

Organ Transplant Programs

Organ Transplant Programs

2060 - Organ Transplant Programs

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

2060A – Citations

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

The Conditions of Participation (CoPs) for Transplant *Program*s were established under several statutory authorities. Section 1102 of the Social Security Act (the Act) authorizes the Secretary to publish rules and regulations "necessary for the efficient administration of the functions" with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title." Section 1881(b)(1) of the Act contains specific authority for prescribing the health and safety requirements for facilities, including renal transplant *program*s, that furnish end stage renal disease (ESRD) care to beneficiaries. Section 1861(e)(9) of the Act authorizes developing standards necessary for the health and safety of individuals furnished services in hospitals. Organ transplant programs are required to be in compliance with the federal requirements set forth in the Medicare CoPs in order to be eligible to receive Medicare payment. In addition to meeting the CoPs for transplant *program*s in 42 CFR Part 482, Subpart E, transplant programs must also meet the Hospital CoPs specified in §§482.1 through 482.57.

2060B – Definitions

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

2060B.1 Organ Procurement and Transplantation Network (OPTN)

The OPTN is a public-private partnership that links all professionals involved in the donation and transplantation system. The OPTN operates the national network for organ procurement and allocation and works to promote organ donation. The OPTN was established by the National Organ Transplant Act of 1984 and is operated by United Network for Organ Sharing (UNOS) under a contract from the Health Resources and Services Administration (HRSA) in accordance with section 372 of the Public Health Service (PHS) Act. Through its policies, the OPTN works to increase the number of transplants, provide equity in access to transplants, improve outcomes for waitlisted patients, living donors, and transplant recipients, and promote living donor and transplant recipient safety.

2060B.2 Scientific Registry of Transplant Recipients (SRTR)

The SRTR, founded in 1987, is a national database of transplant statistics that provides analytic support for the ongoing evaluation of the scientific and clinical status of solid

organ transplantation in the United States. It was established pursuant to section 373 of the PHS Act.

The SRTR produces Program-Specific Reports (PSR) to provide statistics on organ transplants. The reports contain information about candidates waiting for a transplant, outcomes on the waiting list, the transplant recipients, the donors, and the outcomes after a transplant. PSRs are produced twice each year for each organ transplant program (i.e., heart, intestine, kidney, liver, lung, and pancreas).

More information on finding and comparing transplant programs can be obtained through the SRTR website at https://www.srtr.org/. More information on the PSRs can be found here: https://www.srtr.org/reports/program-specific-reports/

2060B.3 United Network for Organ Sharing (UNOS)

UNOS is a private, nonprofit membership organization that coordinates the nation's transplant system under the OPTN federal contract. UNOS assists the transplant community and the patients it serves by:

- *maintaining the national organ transplant waiting list,*
- *coordinating the matching and distribution of donated organs,*
- *increasing public awareness of the need for donated organs,*
- *serving as a forum to create and define organ-sharing policies that maximize the use of donated organs,*
- *producing professional education tools, and*
- *providing extensive information about organ transplantation to patients and the public.*

2060C - Regulatory Background

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

The Conditions of Participation for transplant programs were published in the Federal Register on March 30, 2007 (72 FR 15198) and became effective 90 days after publication on June 28, 2007. *For the first time, this final rule established Medicare Conditions of Participation for heart, intestine, kidney, liver, lung, and pancreas transplant centers. This rule set forth clear expectations for safe, high-quality transplant services delivered in Medicare-participating facilities.*

Effective July 16, 2012, the Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation final rule (77 FR 29034, May 16, 2012) revised the requirement at §482.92. This final rule eliminated a duplicative requirement for an organ recovery team that is working for the transplant center to conduct a ''blood type and other vital data verification'' before organ recovery when the recipient is known. The verification continued to be completed at two separate times in the transplant process.

Effective July 11, 2014, the Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II rule (79 FR 27106, May 12, 2014) finalized changes to the transplant program Conditions of Participation. Specifically, it removed redundant data submission requirements and eliminated the automatic 3-year reapproval cycle.

Thereafter, the Omnibus Burden Reduction Final Rule, published September 30, 2019 (84 FR 51732), removed the requirements at §482.82 that transplant programs must meet all data submission, clinical experience, and outcome requirements in order to obtain Medicare re-approval. This final rule became effective on November 29, 2019. Transplant programs are still required to comply with the CoPs at §§482.72 through 482.104 and the data submission, clinical experience, and outcome requirements for initial Medicare approval under §482.80.

2061 – Request for Medicare Approval of an Organ Transplant Program

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

Hospitals seeking initial approval for a new organ transplant program must submit a revised CMS-855A to its Medicare Administrative Contractor (MAC) to indicate the addition of service.

The applicant transplant program must *also* submit a request for Medicare approval to the applicable State Survey Agency (SA) and *copy CMS Baltimore (QSOG_TransplantTeam@cms.hhs.gov).*

Upon receipt of the applicant transplant program's written request seeking initial approval, the SA will provide a packet of information to the applicant including a list of documents that must be submitted to the SA.

CMS Baltimore will provide the applicant transplant program's report specific to clinical experience, data submission, and outcomes requirements to the appropriate State Survey Agency and CMS Location. This will be reviewed prior to the onsite survey to determine compliance with initial approval requirements under §482.80. See Section 2062B.1 for additional guidance for determining compliance with the clinical experience, data submission, and outcome requirements at §482.80.

The SA should confirm receipt of all necessary documents with the applicant and inform the applicant that the initial survey will be scheduled upon notification from the MAC that the revised CMS-855A has been approved.

Office of Civil Rights clearance is not required separately for the transplant program located within the Medicare-certified hospital.

2061A - *Transplant Services*

Medicare-certified Transplant Programs

A transplant program located within a Medicare-approved hospital must meet the Conditions of Participation for transplant programs to be granted CMS approval to provide transplant services. These requirements apply to the following programs:

Heart transplant program
Lung transplant program
Kidney transplant program
Liver transplant program
*Pancreas transplant program**
*Intestine transplant program***

**In order to perform pancreas transplants, a hospital must have an approved kidney transplant program.*

***In order to perform intestinal transplants, a hospital must have an approved liver transplant program.*

Pediatric or adult pancreas and intestine transplant programs that apply for initial Medicare approval must operate as a component of an existing Medicare-approved kidney or liver transplant program, respectively, which is in compliance with the CoPs (§§482.72-482.104). An onsite survey for initial approval of an adult or pediatric pancreas or intestine transplant program is not required and compliance with applicable requirements listed at §482.80 must be verified prior to approval using procedures specified in Section 2062B.1 of this Chapter. Enforcement action taken by CMS against a kidney or liver transplant program may impact the Medicare approval of the hospital's pancreas and intestine transplant program.

Programs Serving both Adult and Pediatric Populations

Transplant hospitals may perform both adult and pediatric transplants, either under separate program approval or under a single transplant program approval. If a transplant program is seeking separate approval of its adult and pediatric programs, the programs will be surveyed separately.

If a program *plans to perform both adult and pediatric transplants under a single transplant program, e.g. adult kidney transplant program*, the program must seek approval for the primary age group, either adult or pediatric, that it serves and perform the majority of its transplants within that age group. That is, a program that provides more than 50 percent of its transplants in a 12-month period to pediatric patients must apply as a pediatric program. A program that provides more than 50 percent of its transplants in a 12-month period to adults must apply as an adult program.

Transplant Programs Performing Living Donation

CMS does not require separate approval for transplant programs that may also provide living donor services. If living donor services are provided by a hospital other than the transplanting hospital, these services are considered to be provided under arrangement. As such, there must be a formal arrangement between the hospital in which the transplant program is located and any other hospital which provides living donor services for the transplant program. It is the transplant program's responsibility to ensure that the CoPs applicable to living donors are met by the associated hospital providing the living donor services. The medical record of the living donor must confirm that all the requirements of the CoPs were met.

Combined or Simultaneous Transplants

In order for combined transplants to be performed in a transplant hospital, the Medicare-certified hospital must have separate approvals of transplant programs for each organ type to provide transplant services and meet the conditions of participation specified in §§482.72 through 482.104. For example, to perform a combined heart-lung transplant, the hospital must have an approved heart transplant program and a separately approved lung transplant program.

Note: §482.70 defines a heart-lung program as a transplant program that is located in a hospital with an existing Medicare-approved heart transplant program and an existing Medicare-approved lung program that performs combined heart-lung transplants. To perform combined (or simultaneous) heart-lung transplants, a transplant hospital must have a Medicare-approved lung and a Medicare-approved heart transplant program. Separate approval as a "heart-lung" transplant program is not required.

Combined transplants will be reviewed during the onsite survey of a transplant program. The transplant program survey protocol includes a review of individuals who received combined or simultaneous transplants during the survey process. See State Operations Manual, Appendix X for more information on the transplant program survey protocols and procedures.

2061B Organ Procurement and Transplantation Network Membership

Membership in the OPTN by the transplant hospital in which the transplant program is located is a requirement for Medicare approval. *OPTN membership means that the transplant hospital meets OPTN requirements and that it plays an active role in forming the policies that govern the transplant community. If a transplant program is determined to be non-compliant by the OPTN Board, it may deem the program a "Member Not in Good Standing" and refer the case to the Secretary for review.*

The OPTN maintains a member directory of transplant programs on its website, which can be accessed here: OPTN Member Directory.

Key personnel for transplant programs can be searched on the OPTN website through the following link, Transplant Program, Key Personnel Member Directory. Use the "Transplant Center by Organ," search option and choose the specific organ.

2062A – *Survey Composition and Scope*

Survey Team Composition

SAs should schedule a minimum of two (2) surveyors for review of abdominal transplant programs (kidney, liver, intestine and pancreas) and a minimum of two (2) surveyors for thoracic transplant programs (heart and lung). These are separate survey teams and should not be combined, even if the programs are all surveyed simultaneously. Refer to the transplant program survey protocol in Appendix X for additional discussion on team composition.

When more than one transplant program is surveyed at a hospital, all deficiency citations from all the programs may be entered onto one Form CMS-2567. However, the deficiencies cited for each program must be separate and clearly identifiable for the applicable program. The CMS survey database allows for the selection of distinct programs.

Scope

A transplant program must be located within a Medicare-certified hospital. In addition to meeting the transplant Conditions of Participation at §§482.72 through 482.104, the transplant program must also be in compliance with hospital CoPs at §§482.1 through 482.57.

Most hospitals seek Medicare certification through private, CMS-approved accrediting organizations. Unlike hospitals, there are currently no CMS-approved accrediting organizations that are authorized to deem transplant programs and therefore, transplant programs remain under the oversight of the State Survey Agency.

If a State Survey Agency conducts a hospital survey in conjunction with a transplant program survey, the transplant program and hospital survey findings are documented on separate CMS-2567 forms even though the surveys may be conducted together. During a stand-alone transplant program survey, a surveyor may also identify possible noncompliance with the hospital regulations. When hospital requirements are thought to be out of compliance and in need of investigation, the transplant program survey team must contact their supervisor to consult with the CMS Location.

> ***Non-deemed Hospital**: If the hospital in which the transplant program is located is not a deemed hospital, these concerns may be investigated by the State Survey Agency as a hospital complaint investigation. Findings of non-compliance should be cited on a separate Form CMS-2567 under the name and CCN of the hospital in which the transplant program is located.*

***Deemed Hospital**: If the hospital in which the transplant program is located is a deemed facility, the surveyor must contact his/her office and receive authorization from CMS to conduct a hospital complaint investigation. Any deficiencies cited under the hospital requirements must be entered onto a separate CMS-2567. Chapter 5, Section 5100 of the SOM provides additional information for handling complaints of deemed facilities.*

2062B Types of Surveys and Related Guidance

2062B.1 Initial Survey for Medicare Approval

See Section 2061 above for instructions on requesting initial approval.

Once the MAC notifies the SA of its approval of the *updated* CMS-855A, a survey may be scheduled. Initial surveys are unannounced. If the applicant transplant program is found to be in compliance with the CoPs, it is assigned a CCN. The program will not be issued a separate provider agreement. Once transplant program approval is completed, the *CMS Location* will forward a form CMS-2007 (Provider Tie-In Notice) to the MAC. *The ESRD Networks must also be notified for the initial approval of a kidney transplant program.*

Approved transplant programs operating within a single hospital are issued a CCN in the 9800 series. All approved programs that operate within a hospital fall under this transplant CCN. No separate or additional transplant CCN is issued for approved transplant programs under a single transplant center.

Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval

*Transplant programs must meet requirements for data submission, clinical experience, and outcomes at §482.80 to receive their **initial** Medicare approval or may seek mitigating factors review for noncompliance associated with this requirement in accordance with §488.61.*

Surveyors will need to request and obtain CMS' Initial Transplant Report (ITR) to determine whether the applicant program meets the criteria determined by §482.80. Upon receipt of a transplant program's request for initial approval, CMS Baltimore will provide the CMS Location and SA with the ITR. This report contains data that measures the program's data submission rate, volume (clinical experience), patient/graft survival rates (outcomes), and whether the transplant program under review has met these requirements.

Provisions under §488.61 authorize CMS to consider mitigating factors when determining approval for a transplant program that has not met the data submission,

clinical experience, or outcome requirements if the program submits a formal, written request for such a review.

If the applicant does not wish to apply for mitigating factors consideration for non-compliance at §482.80, the initial application will be denied, and the provider will be notified of the denial in writing. If the applicant is determined to be out of compliance with any Condition of Participation other than §482.80, the initial application should be denied and all usual certification processes for denials should be followed.

Determining the Level of the Deficiency for Non-Compliance

Clinical Experience Requirements at 42 CFR §482.80(b)**:** Compliance with the clinical experience (volume) standards at 42 CFR §§482.80(b) is determined by reviewing the program's performance compared to the objective standards outlined in the regulation. The goal of this section is to achieve consistency in determining the level of a deficiency citation, (i.e., condition level, or standard level) under these CoPs.

To be considered for initial approval, a transplant program must "generally perform 10 transplants over a 12-month period" (§482.80(b)). If the program performs at least eight transplants over a 12-month period, it may be approved with an acceptable plan of correction.

*If a transplant program other than a kidney transplant program has not performed at least eight transplants in the most recent 12 months at the time of the program's request for initial approval, an initial approval survey **cannot** be conducted. Kidney programs that have not performed at least three transplants over a 12-month period may not be surveyed for initial approval. The program should be instructed to notify the SA when it has met the minimum requirement to initiate an onsite survey.*

If the program has performed at least eight but less than 10 transplants in that 12-month time period, non-compliance at X-033 will be cited as a standard-level deficiency. The program may still be approved with a standard-level citation for Clinical Experience if an acceptable plan of correction is received and the program is in substantial compliance with all remaining CoPs. During an onsite survey, transplant programs may provide evidence of conducting additional transplants which are more recent than the information provided in the ITR. Surveyors should use this information when reviewing a program's compliance with CMS' clinical experience requirement.

The determination of condition-level non-compliance is made based upon the extent of any non-compliance findings with the standards under a CoP. A finding of non-compliance with the Clinical Experience standard alone with no other non-compliance with standards under the Condition would generally not result in condition-level non-compliance determination at §482.80.

Note: A program's inactivity does not create an exception to the clinical experience requirement. See section 2062B.5 for more information on transplant program inactivity.

Outcome Requirements at 42 CFR §482.80(c): *Transplant programs must meet or exceed national thresholds for one-year post-transplant patient and graft survival to be in compliance with CMS' outcome requirements for initial certification at 482.80(c). Determining compliance with this requirement is made using data from the Initial Transplant Report, which is provided to the CMS Location and SA by CMS Baltimore.*

If there is no outcome data available, this may mean that not enough time has passed to determine one-year patient and graft survival rates, or the program has not performed enough transplant surgeries to generate a report. Outcomes data must be available in order to determine compliance with the requirement at 482.80(c). If the data is not yet available, an onsite survey cannot be initiated and the SA should notify the provider that the initial survey will occur once the data becomes available.

The following transplant program types **are** subject to the outcome requirements, *i.e., one-year patient and graft survival:*

- Adult Kidney
- Adult Heart
- Adult Lung
- Adult Liver
- Pediatric Kidney (includes only 1-year graft survival)
- Pediatric Heart
- Pediatric Lung
- Pediatric Liver

The following transplant program types **are not** subject to the outcome requirements:

- Adult Pancreas
- Pediatric Pancreas
- Adult Intestine/Multivisceral
- Pediatric Intestine/Multivisceral

Initial Surveys after Outcomes Data Becomes Available

The SA will conduct a full onsite survey for initial approval once they verify that all required certification materials have been submitted, received, and determined complete, including data required to determine compliance with the data submission, clinical experience and outcome requirements at §482.80. Once this verification is completed, the state agency will proceed with scheduling an onsite survey to determine compliance with the CoPs at §§482.72 through 482.76 and §§482.90 through 482.104.

Results of the initial onsite survey for transplant programs:

- ***Initial approval:*** *If the SA determines that the transplant hospital is in substantial compliance with all CoPs or has standard-level deficiencies with an accepted plan of correction, CMS will notify the transplant hospital in writing of its approval and the effective date of the approval. The effective date of Medicare*

approval is determined using existing procedures in the State Operations Manual, Ch. 2, Section 2008D.

- ***Initial denial:*** *If the SA determines that the transplant program has failed to meet CoPs other than §482.80, CMS will notify the transplant hospital in writing of the denial. Mitigating factors will not be considered for condition-level deficiencies. The transplant hospital may reapply for Medicare approval after correcting any deficiencies. If the transplant hospital reapplies for initial Medicare approval, it will undergo a new initial onsite survey.*
- ***Initial approval or denial based on mitigating factors:*** *If CMS determines that the transplant hospital is in substantial compliance with all CoPs, i.e., no condition-level deficiencies, except for §482.80, or has standard-level deficiencies with an accepted plan of correction, CMS will* ***consider mitigating factors*** *using procedures specified in §488.61(e) in its consideration of initial approval. Upon review of the program's request to consider mitigating factors for failure to meet the outcome requirements, CMS will make a determination of Medicare-approval or denial. For more information on the mitigating factors process, see Section 2066.*

2062B.2 Re-approval Surveys

Once a transplant program has been approved to participate, it will be periodically re-surveyed for compliance with the CoPs. Re-approval surveys are unannounced surveys and are performed at a frequency consistent with the CMS Mission and Priority Document (MPD).

SAs may follow usual recertification procedures for non-deemed hospitals (SOM Chapter 2, Section 2021A) in cases where the survey results in a determination of substantial compliance with all Conditions of Participation.

2062B.3 - *Complaint Surveys*

Transplant program complaints may involve hospital CoPs, in addition to any transplant program CoPs. Additionally, most hospitals with transplant programs are deemed to meet CMS requirements based upon accreditation through an Accrediting Organization (AO) with a CMS-approved hospital program. If a transplant program complaint survey results in possible deficiencies with the hospital requirements at §§482.1 through 482.57, the CMS Location must approve any investigation of the hospital CoPs.

A transplant program is an integral part of the hospital and must meet all applicable hospital Conditions of Participation. Transplant programs and hospitals share most operations including nursing staff and nursing administration, rules for the operating room, credentialing, and quality of patient care. While the transplant program CoPs include specific requirements for evaluation for transplant, wait-listing, and allocation of organs, the requirements for many of the shared services, such as surgical services and nursing services, are specified in the hospital CoPs rather than the transplant program CoPs.

All complaints against a Medicare-certified transplant program will be referred to the applicable SA for triage and investigation by the SA hospital survey staff or applicable AO, if the hospital is deemed. If the nature of the allegations suggests non-compliance with any hospital CoPs, a hospital complaint survey would be performed.

See SOM, Chapter 5, for a description of the general complaint investigation process.

For complaint investigations of a transplant program, the scope of survey activities is generally limited to the specific transplant CoPs associated with the allegation(s). If allegations are substantiated, the scope may be expanded to review any associated CoPs.

Complaints related to disease transmission via an organ from a deceased donor should be communicated to the RO for their determination of the need for an OPO complaint investigation.

2064 – Notification to CMS

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

Under §482.74, approved transplant programs must immediately notify CMS of any significant changes related to the hospital's transplant program that could affect its compliance with the Conditions of Participation. These changes include, but are not limited to:

- *changes in the primary transplant surgeon, as designated to the OPTN;*
- *changes in the primary transplant physician, as designated to the OPTN; and*
- *inactivation of the transplant program.*

Beginning January 1, 2019, the applicable SA has received these notifications on CMS's behalf. Due to the nature of the information being reported and its relationship to survey activities, the SA must maintain these notifications for reference at the time of re-approval surveys. If the surveyor determines that the transplant program failed to notify the SA of these key changes, a deficiency should be cited at §482.74.

2065 – Transplant Program Inactivation

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

A transplant program may voluntarily declare an "Inactive Status" with CMS and may remain inactive and retain its Medicare approval for a period ***not to exceed 12 consecutive calendar months****. See §488.61(d). Transplant programs that have declared inactive status are not receiving organ offers and/or performing transplants. Transplant programs* ***must notify*** *their waitlist patients of any inactivation or plan to inactivate their program as this affects their ability to receive a transplant. See §482.102(c) for more information.*

The program must provide written notification to its SA (on behalf of CMS) of the anticipated inactivity period as required at §482.74(a)(3). Notification to the SA and to

the potential recipients must occur prior to the start of any planned inactivity period. During its inactivity period, the program must continue to comply with all Medicare CoPs.

Once the SA receives notice of the transplant program's intent to inactivate, a letter or electronic communication should be sent acknowledging receipt of the notification, ensuring the transplant program is aware of its responsibility to notify the SA when the inactivation ends, and that the voluntary inactivation may be no longer than 12 consecutive calendar months for the program to retain its approval.

The SA should enter the transplant program's inactivation start date in the provider details table of the national surveyor database.

Routine surveys or complaint investigations will continue and should not be delayed based on a transplant program's "Inactive Status."

Prior to going on-site for a re-approval survey, the survey team should determine if the program has had any voluntary inactivation since the last survey. If so, confirm during the survey that patients on the program's waitlist were notified of the inactivation and that assistance was provided as discussed above.

If during a survey it is determined that the transplant program implemented a voluntary inactivation but did not notify CMS (through the SA), a deficiency should be cited for §482.74(a)(3). If a surveyor finds that patients were not notified properly of inactivation or were not provided requested assistance, a deficiency should be cited for §482.102(c)(3). Notification to patients is expected to occur within 30 calendar days of the planned inactivation. Documentation of the notification may be evidenced in the patient's medical record or a separate record maintained by the program.

The SA must monitor all inactive transplant programs to ensure that the inactivation does not exceed the 12-month limitation. Once the program reaches its 11th month of voluntary inactivation, the SA should contact the program again to inquire as to the intentions of the program. A model letter for transplant program notification can be found in the SOM, Chapter 9: Exhibit 357.

Once a transplant program voluntarily withdraws or is terminated following their inactive period, they must apply for initial approval and meet all applicable CoPs, including the data submission, clinical experience, and outcome requirements at 482.80.

2066 - Mitigating Factors

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

Background

Under 42 CFR §488.61(e), a transplant program may request that the CMS consider mitigating factors for the initial approval of a transplant program that does not meet the CoP at §482.80 for data submission, clinical experience, or outcome requirements.

Mitigating factors will not be considered in situations of immediate jeopardy or any other cited deficiency.

The regulation describes general considerations that will be reviewed in determining whether a program can be approved based on mitigating factors at 42 CFR §488.61(e)(1). These areas include (but are not limited to):

1. The extent to which outcome measures are not met or exceeded;
2. Availability of Medicare-approved transplant *programs* in the area;
3. Extenuating circumstances (for example, natural disasters) that have a temporary effect on meeting the CoPs;
4. Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available Scientific Registry of Transplant Recipients (SRTR) report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at §482.80(c)(2)(ii);
5. Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone a Fontan procedure, where CMS finds that the innovative practices are supported by evidence-based published research literature or nationally recognized standards or Institution Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and
6. Whether the program's performance, based on the Organ Procurement and Transplantation Network (OPTN) method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

Requesting Initial Approval Based on Mitigating Factors

Once a survey has been performed and the applicant transplant program is determined to be out of compliance with §482.80, it may request consideration of mitigating factors to address this non-compliance.

A transplant program requesting initial approval based on the presence of mitigating factors must complete the following steps:

1. *Send Timely Letter of Intent to Apply for Mitigating Factors: if CMS determines a transplant program has not met the data submission, clinical experience, or outcome requirements for initial approval, CMS may deny the request for initial approval. The program will receive a letter notifying the program of its denial.*

The transplant program must respond to CMS's letter with its intent to apply for mitigating factors review. Within 14 calendar days after CMS has issued to the program a formal written notice of a condition-level deficiency under §482.80, CMS must receive notification of the program's intent to seek mitigating factors review. All requests for consideration of mitigating factors should be sent electronically to the CMS Location where the hospital is certified and CMS Baltimore at QSOG_TransplantTeam@cms.hhs.gov.

2. *Send Timely and Complete Mitigating Factors Application: all information necessary for consideration must be received within **120 calendar days** of CMS' written notification of noncompliance at §482.80. See the Mitigating Factors Web Instructions in the "Downloads" section of the CMS Transplant page for additional information on the required contents to deem an application complete. The complete mitigating factors application should be sent electronically to both the CMS Location where the hospital is certified and CMS Baltimore at QSOG_TransplantTeam@cms.hhs.gov.*

Failure to meet *any of* these timeframes may be the basis for denial of mitigating factors.

Preparing the Mitigating Factors Application

A request for consideration of mitigating factors must include sufficient information to permit an adequate review and understanding of the transplant program, the factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and in the case of extenuating circumstances, such as a natural disaster, fire, or a pandemic, the recovery actions planned. In order to ensure a complete and thorough application, the following criteria should be followed:

- *The application must include all elements noted in the mitigating factors application checklist. See the Mitigating Factors Web Instructions in the "Downloads" section of the CMS Transplant page for additional information on the required contents to deem an application complete and ready for submission to CMS. The mitigating factors application checklist that was used must also be submitted as part of the application record.*
- *The pages of application documents should be sequentially numbered and sent as a single Adobe Portable Document Format (.pdf) or Microsoft Word (.doc or .docx) file. CMS strongly suggests the mitigating factors application be sent electronically, without the use of encryption or password protection. This will ensure that CMS is aware of all supporting documentation provided and will help facilitate the review process.*
- *Mitigating factors application materials must have all Personally Identifiable Information (PII) removed prior to submission to ensure a timely review.*
- *The application narrative should be concise and the supporting documentation relevant to the rationale and mitigating factors requested. See the Mitigating*

Factors Web Instructions in the "Downloads" section of the CMS Transplant page for more information on Mitigating Factors: Areas for Consideration.

- *The program should limit the file size to a maximum of 200 pages.*

Outcomes of a Mitigating Factors Application Review

All mitigating factors applications will be reviewed by CMS Baltimore. The CMS review will include analysis by CMS staff and technical experts with programmatic and clinical expertise for each transplant program on a case-by-case basis. Following the review, CMS Baltimore will provide a recommendation to the respective CMS Location for approval or denial of the mitigating factors application based on review criteria and elements for approval.

Following the recommendation, the respective CMS Location may take the following actions:

1. *Grant initial approval of a program's Medicare participation based upon mitigating factors.*
2. *Deny the program's request for Medicare approval based on mitigating factors.*
3. *Offer a time-limited Systems Improvement Agreement (SIA) in accordance with 42 CFR §488.61(g), when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the SIA or a CMS finding that the hospital has failed to meet the terms of the SIA, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval based on mitigating factors.*

2067 – Transplant Resources

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

It is recommended that SAs maintain the following transplant program information on their websites:

- *Current Conditions of Participation (§§482.68 through 482.104). Note: the Medicare regulations for transplant programs are in Subpart E, Requirements for Specialty Hospitals;*
- *Current Interpretive Guidance and Transplant Survey Protocol;*
- *List of information and materials that must be submitted for initial applications;*
- *Contact person or mailbox for:*
  - *submission of changes in information and inactivation*
  - *requests for verification of Medicare-approval*
  - *submission of questions by transplant providers*
- *Survey training hyperlink for Transplant Basic Course; and*
- *Procedures for submission of request for consideration of mitigating factors.*

Surveyor Training

The Transplant Program Basic Surveyor Course may be accessed via https://qsep.cms.gov/welcome.aspx.

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

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(Rev. 227; Issued: 12-13-24)

The Standard Organ Transplant Program Survey Protocol

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

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. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

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.

Entrance Conference 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 Rounds**: The purpose of the multidisciplinary rounds is to discuss clinical status and identify the clinical needs of transplant patients. Occurring on the inpatient unit, the multidisciplinary rounds 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 ASSURANCE 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.

Alternate Survey Protocol: Pediatric Heart Program

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

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."

Interpretive Guidelines for Organ Transplant Surveys

General Requirements for Transplant Programs

X-002

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.72 Condition of Participation: OPTN Membership.

A transplant program must be located in a transplant hospital that is a member of, and abides by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary pursuant to §121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

Guideline §482.72

The hospital in which the organ transplant program(s) is a part of must be a member of the Organ Procurement and Transplantation Network (OPTN) prior to Medicare approval and for as long as it is approved. In the event that the Secretary issues formal notice of *their* approval of a recommendation for the exclusion of a program from the OPTN, the associated Medicare approval will be terminated pursuant to non-compliance with 42 CFR 482.72.

The OPTN maintains a member directory of all transplant programs, both active and inactive.

- *Member directory can be searched by member status or state here: Search Member Directory*
- *Full member directory can be accessed here: Full OPTN Member Directory*

X-011

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.74 Condition of Participation: Notification to CMS

(a) A transplant program must notify CMS immediately of any significant changes related to the hospital's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow-up, as appropriate, include, but are not limited to:

Guideline §482.74

For purpose of this condition and its relative tags at X-012, X-014 and X-015, "immediately" means within seven business days of when the transplant program becomes aware that either a change will occur or has occurred.

Transplant program notifications to CMS relating to the changes specified in tags X-012, X-014, and X-015 must be made to the respective state survey agency. Survey activities for the transplant program were transitioned from Federal contractors to the state survey agencies in January 2019. As a result of this change, the state survey agency will be collecting these notifications on behalf of CMS and such notifications will adequately demonstrate compliance with CMS' notification requirements.

X-012

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.74(a)(1) Change in key staff members of the transplant team, such as a change in the individual the transplant program designated to the OPTN as the program's "primary transplant surgeon" or "primary transplant physician;"

Guideline §482.74(a)(1)

CMS requires notification of changes of the following key staff member(s):

- *Primary transplant surgeon, as designated to the OPTN*
- *Primary transplant physician, as designated to the OPTN*

X-015

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.74(a)(3) Inactivation of the transplant program.
§482.74(b) Upon receiving notification of significant changes, CMS will follow up with the transplant program as appropriate, including (but not limited to):
(1) Requesting additional information;
(2) Analyzing the information; or
(3) Conducting an on-site review.

Guideline §482.74(a)(3)

Upon notification of a program's plan for inactivation, CMS may request additional information from the program pertaining to the reason for the inactivation and the communications that have occurred to notify and assist the patients on the program's waiting list in association with the inactivation period.

Per §488.61(*d*) Transplant Program Inactivity, "A transplant program may remain inactive and retain its Medicare approval for a period not to exceed 12 months." Program inactivity does not preclude a program from survey for compliance with the Conditions of Participation during the inactivation period. If a program's inactivity period exceeds 12 *consecutive calendar* months, it must*:* reactivate, voluntarily withdraw from Medicare participation, or be subject to termination of its Medicare approval.

X-021

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.76 Condition of Participation: Pediatric Transplants.

A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at §488.61 of this chapter.
(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at §§482.72 through 482.74 and §§482.80 through 482.104 with respect to its pediatric patients.

Guideline §482.76(a)

Upon application to the Medicare program, a transplant program must specify whether it requests approval as an adult or pediatric program.

Note: In effort to address differences in health and organ transplantation issues between children and adults, the OPTN bylaws were updated to require that a designated transplant program have a pediatric component approved by the OPTN in order to perform kidney, liver, and heart transplants in patients less than 18 years old. To be OPTN-approved for a pediatric component, the designated transplant program must identify a qualified primary pediatric transplant surgeon and a qualified primary pediatric transplant physician who will serve as key personnel. These OPTN bylaws were updated on December 08, 2020.

If a transplant program performs pediatric transplants under an approved adult transplant program, no separate approval is required by CMS as long as the number of pediatric transplants performed is less than the number of adult transplants performed.

X-023

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.76(c) A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

(1) Loss of Medicare approval to perform pediatric transplant, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants.
(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center*'s* Medicare approval to perform pediatric transplants.
(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.

Guideline §§482.76(c)(1), (2) and (3)

An adult transplant program is permitted to perform pediatric transplants under its Medicare approval. However, if the number of pediatric transplants performed exceeds 50% of the total volume of transplants performed under the adult approval within a 12 month period, the program is required to seek separate pediatric approval. The pediatric transplant program would now represent the majority of transplants performed and therefore must maintain its Medicare approval in order for the adult program to continue to perform adult transplants.

If the pediatric program becomes the majority population served, loss of this approval would also mean a loss of the programs ability to perform adult transplants.

If the approval for the adult program is lost, the pediatric program may continue to perform transplants, but could be subject to a program review.

X-024

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§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 center 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.100-203), as follows:
(1)The center*'s* pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;

Guideline §482.76(d)(1)

In order for a pediatric heart transplant program to be approved under the OBRA of 1987 criteria rather than the Conditions of Participation, there must be evidence that it is being operated jointly by the hospital in which it's located and another Medicare hospital. Joint operation means that services and staff from both hospitals are required to accomplish the transplants performed at the pediatric hospital. See standards and guidance at §482.76(d)(2) and §482.76(d)(3) below. This joint operation may occur pursuant to a structured affiliation between the two hospitals or pursuant to a written agreement.

X-025

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.76(d)(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

Guideline §482.76(d)(2)

The surgeons who perform the heart transplants at the pediatric hospital are credentialed for cardiac surgery at both the *pediatric* Medicare-approved hospital and the other approved hospital. The surgeons may be employed full time by the other Medicare-approved facility.

The pediatric heart transplant program must be able to provide evidence that the QAPI programs for both hospitals are shared and would include review, analysis and recommendations for the pediatric transplants. The other Medicare-approved facility reviews data as regards the pediatric surgical services and the pediatric hospital reviews the data concerning evaluation, pre and post-operative care. Both QAPI programs would review and evaluate the need for any changes in the collaboration between the two entities.

X-026

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.76(d)(3) The center demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

Guideline §482.76(d)(3)

Facilities include (for example): surgical suites; recovery rooms; inpatient rooms.

Services include (for example): laboratory services; radiology.

Personnel include (for example): all required members of the Multidisciplinary Team; pre-operative and post-operative medical and nursing services.

§482.78 Condition of participation: Emergency preparedness for transplant programs.

A transplant program must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in

which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

Guideline §482.78

The Transplant Program must comply with all Emergency Preparedness requirements under this condition. This condition consists of multiple standards. Please refer to State Operations Manual, Appendix Z – Emergency Preparedness Requirements for All Providers and Suppliers.

Transplant *Program* Data Submission, Clinical Experience, and Outcome *Requirements*

X-031

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Programs.

Except as specified in paragraph (d) of this section, and §488.61 of this chapter, transplant programs must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

Guideline §482.80

The Standards of this Condition are evaluated by the surveyor off-site, prior to the survey. The determination of compliance or non-compliance will be communicated to the program at the time of the survey. Since *the findings for data submission and outcome requirements are* based on data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data during the survey to change the compliance determination*. Additional guidance for processing initial surveys can be found in the SOM, Chapter 2.*

X-032

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.80(a) Standard: Data Submission.

No later than 90 days after the due date established by the OPTN, a transplant program must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up and living donor registration and follow-up.

Guideline §482.80 (a)

The determination of compliance or non-compliance with this Standard is made prior to the on-site survey. The determination is shared with the program at the time of the survey. Since this finding is based upon data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data during the survey to change the compliance determination. *Additional guidance for processing initial surveys can be found in the SOM, Chapter 2.*

X-033

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.80(b) Standard: Clinical Experience.

To be considered for initial approval, an organ-specific transplant program must generally perform 10 transplants over a 12-month period.

Guideline §482.80(b)

*"*Generally*"* means in all instances except where specifically exempted by the regulations.

A transplant program will not be considered for initial approval until it has performed a minimum of eight transplants over a 12-month period at the time of its request for Medicare-approval. Kidney transplant programs must perform a minimum of three transplants before an initial certification survey can be performed, as specified by §482.80(d)(5).

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

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

For purposes of the clinical experience requirement, multi-organ transplantation will be included as separate transplants for each organ. For example, a combined liver-kidney transplant will account for one liver transplant and one kidney transplant.

X-035

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.80(c) Standard: Outcome requirements. CMS will review outcomes for all transplants performed at a program, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately

when a program requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant program's observed number of patient deaths and graft failures 1-year post-transplant to the program's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific report.

(2) CMS will not consider a program's patient and graft survival rates to be acceptable if:
(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and
(ii) All three of the following thresholds are crossed over:
(A) The one-sided p-value is less than 0.05,
(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and
(C) The number of observed events divided by the number of expected events is greater than 1.85.

No Tag

(d) Exceptions
(1) A heart-lung transplant program is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the program.
(2) An intestine transplant program is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multivisceral transplants performed at the program.
(3) A pancreas transplant program is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the program.
(4) A program that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant program.

X-036

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.80(d)(5) A kidney transplant program that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval

Transplant *Program* Process Requirements

X-051

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.90 Condition of Participation: Patient and Living Donor Selection.
The transplant program must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a program performs living donor transplants, the program also must use written donor selection criteria in determining the suitability of candidates for donation.

Guideline §482.90

In order to be eligible for transplantation or donation, candidates must meet the transplant program's selection criteria to determine suitability based on their medical and/or psychosocial health status. A transplant program's selection criteria contains indications and contraindications, which permit or exclude a candidate from donation or transplantation. Contraindications may be absolute or relative – meaning further evaluation on a case-by-case basis would be warranted.

Transplant programs are required to develop hospital-approved selection criteria to determine suitability for organ transplantation and living donation. *Each approved transplant program must use developed, written selection criteria for its respective organ type.* There must be evidence that the written selection criteria are followed for the selection of transplant candidates to be placed on the transplant waiting list and, if applicable, potential living donors. *Transplant candidates who are placed on the waiting list using criteria that are outside the written patient selection criteria would not be the sole basis for a deficiency citation. However, any deviations from the written selection criteria must be documented in the medical record.*

Any changes to the hospital-approved, written selection criteria are approved according to the hospital policy approval process.

The selection criteria (medical, psychosocial, financial, etc.) must clearly define all the factors that are considered in determining suitability for transplantation or living donation. These criteria may not exclude groups or individuals without documentation supporting the exclusionary foundation(s).

X-052

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.90(a) Standard: Patient Selection.
Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

Guideline §482.90(a)

The patient selection criteria must be followed consistently in a fair and non-discriminatory manner for all potential transplant candidates and living donors. For candidates that are placed on a transplant program's waiting list outside of the patient selection criteria, documented evidence must be present to support the exception.

Discrimination can mean *the* exclusion of those who meet the transplant program's hospital approved selection criteria and should be included on the waiting list as well as inclusion on the waiting list of those who do not meet the hospital-approved selection criteria.

X-053

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.90(a)(1) Prior to placement on the program's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

Guideline §482.90(a)(1)

An evaluation of each candidate's psychosocial status must be conducted in all situations in which it is possible to do so in order to determine suitability for transplantation and/or identify resources that potentially will be needed for the safe care and discharge of the patient post-discharge. The transplant program must conduct and document the psychosocial evaluation performed on a potential recipient before their placement on the waiting list. *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 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.

While the transplant program has flexibility in the selection of a specific psychosocial evaluation tool(s) to be used, it is expected that the psychosocial evaluation would be conducted by transplant program personnel who have the professional qualifications to administer psychosocial evaluations, make resultant assessments and make recommendations to the multidisciplinary team. Evaluations should include, at a minimum, the following:

- Social, personal, housing, vocational, financial, and environmental supports;
- Coping abilities and strategies;
- Understanding of the risks and benefits of transplantation;
- Ability to adhere to a therapeutic regimen; and
- Ongoing psychological issues that may impact the success or failure of organ transplantation.

The transplant program policy should include the following operational guidelines for ensuring that the psychosocial evaluation is completed, documented, and reflects the patient's current psychosocial status:

- *The length of time in which the psychosocial evaluation is deemed to be current and/or frequency of re-evaluation to determine continued appropriateness;*
- *The type of qualified professional healthcare personnel (MSW, LCSW, psychiatrist or psychologist) who may complete these evaluations;*
- *The follow-up and referral procedures if a transplant candidate requires such activities; and*
- *The method of communicating the psychosocial evaluation findings into the selection process.*

X-055

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.90(a)(3) When a patient is placed on a program's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

Guideline §482.90(a)(3)

The medical record must contain evidence of the components of the selection criteria that were applied to each individual transplant candidate to deem them an appropriate candidate for placement on the waiting list for transplantation. The *transplant candidate's* medical record must contain documentation that the multidisciplinary team considered all evaluations in the context of the hospital-approved selection criteria. If the *transplant candidate* does not meet the hospital-approved selection criteria but was placed on the waiting list anyway, the exception justification for listing must be clearly documented in the medical record.

X-056

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.90(a)(4) A transplant program must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

Guideline 482.90(a)(4)

Transplant programs must make available a copy of their patient selection criteria to any patient who makes this request so they may better understand what the program is using to determine eligibility for transplantation. Transplant programs should provide the patient an opportunity to obtain and review the program's selection criteria early in the evaluation process to enable their understanding of the selection process.

X-058

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.90(b) Standard: Living Donor Selection.

The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant programs must:
(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

Guideline §482.90(b)(1)

To be eligible for donation, prospective living donors must be determined as a suitable candidate for living donation. Each prospective living donor must receive a medical and psychosocial assessment prior to donation to ensure *appropriateness and suitability for donation*.

To maintain the privacy and integrity of patient evaluations, donor evaluations should be conducted independently of the potential recipient and the recipient's evaluation.

It is expected that a psychosocial evaluation for living donors would address the following:

- Social, personal, housing, vocational, financial, and environmental supports;
- Coping abilities and strategies;
- Understanding of the risks and benefits of donation;
- Ability to adhere to a therapeutic regimen; and
- Mental health history, including substance and alcohol use or abuse and how it may impact the success or failure of organ transplantation.

The transplant program policy should include the following operational guidelines for ensuring that the psychosocial evaluation is completed, documented, and reflects the potential donor's current psychosocial status:

1. *The length of time in which the psychosocial evaluation is deemed to be current and/or frequency of re-evaluation to determine continued appropriateness;*
2. *The type of qualified professional healthcare personnel (MSW, LCSW, psychiatrist or psychologist) who may complete these evaluations;*
3. *The follow-up and referral procedures if a transplant donor requires such activities; and*
4. *The method of communicating the psychosocial evaluation findings into the donor selection process.*

X-059

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.90(b)(2) Document in the living donor's medical records the living donor's suitability for donation, and

Guideline §482.90(b)(2)

The medical record needs to contain evidence of the components of the donor selection criteria applied to each prospective living donor to deem them an appropriate candidate for living donation. The potential living donor medical record must contain documentation that the multidisciplinary team considered all evaluations and made a determination as to donation suitability. If the potential donor is deemed not suitable for donation by the team, no donation may occur.

X-071

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.92 Condition of Participation: Organ Recovery and Receipt.

Transplant programs must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant program is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

Guideline §482.92

"Other vital data" include the OPTN Identification Number.

Note: Effective July 16, 2012, CMS amended § 482.92 to remove the requirement that the transplant program verify blood type before organ recovery (77 FR 29034, at 29058 (May 16, 2012)). "The Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation" final rule (CMS-3244-F) revised the requirement by eliminating a duplicative requirement for an organ recovery team that is working for the transplant program to conduct a "blood type and other vital data verification" before organ recovery when the recipient is known. The verification will continue to be completed at two other times in the transplant process, i.e., organ receipt (X-073) and living donor transplantation (X-074).

X-073

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.92(a) Standard: Organ Receipt. After an organ arrives at a transplant program, prior to transplantation, the transplanting surgeon and another licensed healthcare professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient.

Guideline §482.92(a)

The verification occurs once the organ arrives in the operating room, prior to transplantation.

The verification must be completed by the transplanting surgeon and another licensed healthcare professional. The second person verifying the blood type (and other data) may be any licensed health care professional who is in the operating room at the time of the verification. The transplant program should identify in its protocols which categories of health care professional(s) may do the second verification.

Verification by the transplanting surgeon and another licensed healthcare professional must be documented. The documentation must include signatures and the corresponding date and time of the verification. To ensure that verification is completed prior to transplantation, documentation must include the time that the organ arrived at the transplant program's operating room or suite.

If the transplant surgeon is already scrubbed and gloved, he/she may do a visual verification and sign that verification in the medical record at the end of the surgery. The time of the visual verification should be entered into the recipient's record by the second person at the time it is done and should state that the verification was visual by the transplant surgeon. The second person will sign their verification at that time. After the case is concluded, the surgeon confirms his visual verification in the record by either co-signing the verification entry by the second person or writing a separate progress note, which chronicles the verification (including times).

X-074

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.92(b) Standard: Living Donor Transplantation.

If a program performs living donor transplants, the transplanting surgeon and another licensed healthcare professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

Guideline §482.92(b)

Verification occurs onsite, after the donor*'s* arrival in the operating room, but prior to the induction of general anesthesia.

The verification must be completed by the transplanting surgeon and another licensed healthcare professional. *The second person verifying the blood type (and other data) may be any licensed health care professional who is in the operating room at the time of the*

verification. The *transplant* program should identify in its protocols which categories of health care professional(s) may do the second verification.

Verification by the transplant surgeon and another licensed healthcare professional must be documented. The documentation must include signatures and *the* corresponding date and time of the verification. To ensure that verification is completed immediately before the removal of the donor organ(s), documentation must include the time of donor arrival into the operating room, time of organ verification, and time general anesthesia was started.

If the donor organ recovery surgeon is also the transplanting surgeon, verification prior to removal of the living donor organ(s) and verification prior to transplantation must occur separately.

X-081

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.94 Condition of Participation: Patient and Living Donor Management.

Transplant programs must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant program performs living donor transplants, the program also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

Guideline §482.94

Transplant patient management policies for the transplant and discharge phases of transplantation are critical to protect the rights of any potential transplant recipient.

Policies for transplantation must incorporate, at a minimum, all patients who have chosen to undergo all or any portion of the evaluation process. The Medicare standards for transplant programs require programs to manage any patient that has received an evaluation, has been placed on the program's waiting list, and/or received a transplant (e.g., Patient Selection requirements for Transplantation at 482.90, Waiting List Management requirements at 482.94(b), and Informed Consent requirements for Transplant Patients at 482.102(a)). As such, transplant programs should define the structure of their evaluation and transplant processes and ensure that it maintains documentation of any patient who receives services from the transplant program.

Patient management policies for the discharge phase of transplant should have mechanisms in place to identify, assess, and meet the medical and psychosocial needs of the patient to ensure they have the resources necessary to care for their transplant. Organ transplant recipients have complex medical needs, including existing chronic disease(s), multiple comorbidities, complex medication regimen post-transplant, and lifestyle changes following surgery necessary to maintain the health and life of the organ.

These patients will require discharge planning at an early stage of their hospitalization to ensure their discharge needs are identified and addressed prior to actual discharge. Transplant programs should ensure its discharge policies are based on the hospital policies for discharge planning. See §482.43 (Tags A-0799 to A-0843) for more information on CMS' requirements for hospital discharge planning.

Transplant programs that provide living donor transplant services must develop and implement living donor policies that direct the care and management of donors through their evaluation, donation, and discharge after donation. The transplant program must determine the structure of its evaluation and donation processes and ensure that it maintains documentation of any potential transplant donor that receives services from the transplant program. The evaluation policies must ensure it incorporates at a minimum, all potential donors that have chosen to undergo all or any portion of the transplant program's evaluation process. Transplant programs should ensure its discharge policies for living donors are based on the hospital policies for discharge planning. See § 482.43 (Tags A-0799 to A-0843) for more information on CMS' requirements for hospital discharge planning.

Some transplant programs perform living donor services under arrangement with other hospitals. *See below for additional information.* In these cases, the transplant program retains all responsibility for compliance with management of the living donor. The transplant program must communicate the donor management activities that are required as a part of the living donor organ recovery to the hospital under the arrangement and ensure that the activities are completed appropriately.

Living Donor Services under Contract or Arrangement

There are requirements for transplant recipient programs providing living donor services under contract/arrangement. There are *several types of arrangements in which a transplant program* provides living donor services *under contract or arrangement with another transplant program.* This enables a transplant program to offer living donor services and *receive donor organs from a separate hospital that does not provide services to the organ recipient. There may be an ongoing arrangement between two transplant programs, such as children and adult programs. There are also episodic arrangements as part of a single donation or multi-organ exchange where more than two transplant programs are "swapping" organs.*

The CoPs for organ transplant programs include several provisions that apply to any program that is performing transplants with an organ from a living donor. If the services for a living donor for the recipient transplant program are provided by a transplant program located at another hospital, these services are considered to be provided by the recipient transplant program under contract or arrangement. The transplant program providing services to the transplant recipient is responsible for certain activities to ensure that the program is Medicare-approved and that certain basic services are provided to those living donors.

A recipient's transplant program that has its living donor services provided by one or more programs under contract or arrangement on either an ongoing or episodic basis must:

1) *Have written evidence of a contract or agreement with the living donor transplant program(s). This may be a specific contract or agreement between two hospitals or programs, or it may include participation in a transplant registry for paired donation of living donors and recipients.*

2) *Have a copy of the Medicare-approval letter for the living donor transplant program with which it has a contract or agreement, or have documented evidence that the CMS website listed below was reviewed prior to accepting the living donor organ to ensure that the program was a Medicare-approved program.*
   CMS Approved Transplant Program List Link:
   https://qcor.cms.gov/default.jsp?referer=https://qcor.cms.gov/main.jsp

3) *Retain copies of the medical records up to the point of admission to the hospital for the donation of any living donors whose organs were transplanted by the recipient transplant program. These records must be kept separate from the recipient's medical record. It is not expected that the medical record would include those records that occur on the day of donation such as labs and the anesthesia report. The recipient transplant program must review the records in advance of the donation to ensure the following minimum requirements are met:*
   a) *There is a complete medical and psychosocial evaluation in the medical record completed by the relevant professionals of a multidisciplinary team which has determined that the individual is a suitable living donor. (42 CFR §482.90)*
   b) *An Independent Living Donor Advocate (ILDA) has met and worked with the potential living donor and has been included in the discussions of the potential donor's suitability. (42 CFR §482.98)*
   c) *There is a fully documented informed consent process in the living donor's medical record that meets the minimum Medicare requirements. (42 CFR §482.102)*

   Note: This is not an exhaustive list of the requirements that apply to living donor services. The identification of this subset does not mean that the other CoPs for living donors are waived. This subset of CoPs is outlined because the recipient's transplant program must verify that these requirements have been met for any given living donor prior to the donation occurring.

4) *As part of the Quality Assessment and Performance Improvement (QAPI) requirement, ensure that there is a feedback system between the recipient and donor hospital to address any adverse events that occur in the donor or the recipient for a specific donation or transplant.*

If the recipient's program does not perform any living donor services directly (i.e., all living donor services are contracted), the program is still expected to track objective indicators to review the quality of the contracted service.

Additional Clarification

CMS requires the receiving transplant programs ensure that the requirements described above are met prior to accepting a living donor organ. It is not CMS' intention to establish a single standard of practice in how living donors are evaluated, provided with informed consent, or the specific activities of the independent living donor advocate. It is permissible for a transplant recipient's program to use another hospital's policies and procedures for any given living donor as long as the minimum standards described above are met. For example, if a transplant recipient program usually requires a nutritional evaluation by a dietitian for any living donor candidate with a BMI over 30, but a living donor organ is available through a "swap" where the individual has a BMI over 30, the transplant recipient hospital does not have to require a full nutritional evaluation before accepting that individual as a suitable living donor.

X-082

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.94(a) Standard: Patient and Living Donor Care.

The transplant program's patient and donor management policies must ensure that:
(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and
(2) If a program performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

Guideline §482.94(a)

Each transplant program must have a multidisciplinary team of healthcare professionals with expertise in different fields to determine an individual's care plan according to the individual's clinical and psychosocial needs. A transplant program's multidisciplinary team must involve at least a licensed medical and a licensed surgical physician (X-115 to X-117), nurse (X-125), clinical transplant coordinator (X-118 to X-120), registered dietician for all patients and living donors that require such services (X-094), social worker (X-092 to X-093), pharmacist (X-125), and ILDA (X-121 to X-124) if applicable.

The physician must direct this multidisciplinary team to be involved and provide the necessary services, respective to the area of clinical practice. The multidisciplinary team is responsible for the assessment, consultation, and development of the patient's care plan. Participation and involvement by the multidisciplinary team must be evidenced by documentation in the medical records.

In those instances where it is determined that the transplant recipient or living donor is not receiving or did not receive the services needed as identified by assessment, consultation and the multidisciplinary plan of care, the resulting deficiency should be cited at this regulatory *citation*.

X-087

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.94(c) Standard: Patient Records.

Transplant programs must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a program's waiting list and who is admitted for organ transplantation.

Guideline §482.94(c)

Complete medical records must be maintained for all patients who have chosen to undergo all or any portion of the evaluation process. Transplant programs are expected to define the structure of their evaluation processes and ensure that it maintains documentation of any patient that receives services from the transplant program.

Transplant programs are also expected to maintain documentation of each patient who is referred to their program for transplantation as a potential treatment for their organ failure. For example, this could be a referral from a medical physician, or it could be a potential candidate who is requesting an evaluation by the program for consideration for transplantation. The program must be able to show evidence of the plans for transplant and any determinations that are made for placing the patient on the program's waiting list, or if the referral is not appropriate for transplantation based on the program's criteria.

X-091

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.94(c)(ii) Multidisciplinary discharge planning for post-transplant care.

Guideline §482.94(c)(ii)

Programs need to ensure discharge planning occurs at an early stage of the patient's stay to allow for a thorough assessment of the patient's needs by each member of the multidisciplinary team, as well as validation of the patient's understanding of their responsibilities upon discharge. Each member of the dedicated multidisciplinary team must be involved in assessing the needs of the patient in preparation for discharge from the hospital. Areas of assessment for discharge planning include medical, psychosocial

and financial.

The recipient's medical record must contain documentation that the dedicated multidisciplinary team participated in the development of the discharge plan to address the individual needs of the recipient.

Components of a multidisciplinary discharge plan may include, but are not limited to:

- A description of the recommended follow-up appointments and the practitioners expected to perform the follow-ups (such as the transplant program, a local physician, or both);
- Contact numbers of transplant program staff that can be contacted for questions;
- The clinical signs and symptoms indicative of a potential complication from transplantation that would necessitate a call to the doctor;
- A transplant recipient/living donor specific nutrition plan, as applicable;
- A plan for addressing psychosocial issues (for example available supports, adaptation to stress of transplant, etc.);
- Activity restrictions and limitations (for example driving after taking pain medication);
- Need for coordination of other health services (for example physical or occupational therapies, home care, etc.) and assistance in securing these health services;
- Medication and administration, including the transplant recipient's schedule for taking medication and the process to obtain the medication; and
- Any assistance required to access local medical care, equipment or support.

X-092

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.94(d) Standard: Social Services.

The transplant program must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families….

Guideline §482.94(d)

Making social services available means that if a social service need for a recipient/donor/family is identified at any point from evaluation through discharge, the program must provide a qualified social worker to address the need/issue, and documentation in the medical record should confirm the social worker intervention.

A request for social services can be made by the patient, family member(s)/caretakers, and/or the patient's multidisciplinary team.

X-094

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.94(e) Standard: Nutritional Services.

Transplant programs must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

Guideline §482.94(e)

Many published medical articles have recognized the need for nutritional management after transplantation in order to prevent complications associated with immunosuppressive medications, as well as optimize wound healing and organ function. Transplant programs must have a process in place to ensure *each patient's nutritional needs are assessed and* that a qualified dietician is available to provide nutritional assessments or diet counseling to all transplant patients and living donors. Nutritional services include consultation, assessment, intervention(s) and education.

A request for nutritional services can also be made by the patient, family member(s)/caretakers, and/or the patient's multidisciplinary team. If a need is identified by any member of the multidisciplinary team, and a request is made for nutritional services, but the requested services are not provided due to the lack of nutritional staff available in the hospital, a deficiency would be cited.

X-099

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.96 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)

Transplant programs must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

Guideline §482.96

The transplant *program* develops its transplant program-specific quality assessment and performance improvement (QAPI) program either individually or collaboratively with the transplant hospital QAPI program and functions as a component of the associated hospital QAPI program required at 42 CFR §482.21. There should be evidence of communication between the two entities to ensure that both entities are actively involved in QAPI activities which address the specific requirements of the transplant CoPs. If the

transplant program has a separate QAPI program, it must provide evidence that it is interrelated with the hospital QAPI plan.

A comprehensive transplant QAPI program evaluates and monitors performance of transplantation services across every aspect of the program from the evaluation of a potential recipient/donor candidate through his/her discharge from the hospital. A comprehensive QAPI program approach embraces a broad, multidisciplinary, system-wide perspective. It encompasses all aspects of clinical care and all relevant hospital services and includes input from a broad representation of staff at all levels, including individuals with authority to make decisions about the transplant program's policies, practices and resources. It continuously monitors, evaluates and improves all organ transplantation services for transplant candidates, *transplant recipients, donor candidates, and living donors* across all phases of transplantation and living donation, including transplant services provided under contract or arrangement.

A data-driven transplant QAPI program continually uses data to guide quality assessment and performance improvement activities with respect to all transplantation services. The program proactively, systematically and at regular specified intervals:

- Identifies, implements, assesses and re-assesses the data to be collected for each measure and other information needed to monitor and evaluate performance of transplantation services in all areas;
- Collects, records and reviews the data for accuracy;
- Analyzes the data and uses the data/analyses to assess the program's performance; and
- Uses the results of its analyses to monitor, evaluate and improve the quality and safety of all transplantation/donation services on an ongoing basis.

X-101

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.96(a)(cont'd)
…The transplant program must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

Guideline §482.96(a)(cont'd)

The transplant program must use what it learns from monitoring the objective measures described under Tag X-100 to identify and implement actions to improve its performance.

The program should review the available evidence, if any, for particular performance improvement strategies and implement activities that are most likely to be effective in addressing the specific factors that are contributing to the program's performance. If successful, performance will need to be monitored over time to verify that improvements

are sustained. If not, the program will need to re-evaluate, determine an appropriate alternative course of action, and track performance.

X-102

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.96(b) Standard: Adverse Events.

A transplant program must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.
(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

Guideline §482.96(b)(1)

An adverse event is defined at 42 CFR §482.70 as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof."

The facility policies should include:

- A clear definition of what the transplant program considers an adverse event incorporating the CMS regulatory definition;
- The procedures for internal reporting of adverse events in all phases of transplant recipient or living donor care within the hospital;
- The process(es) used for analyzing adverse events in the transplant program;
- The process for developing, evaluating and tracking actions to prevent recurrence; and
- The required timeframe for reporting, investigating and analyzing adverse events.

The policies should also address any external adverse event reporting obligations, such as:

- External reporting of events to the OPTN, ESRD Network, etc. as required and applicable;
- Reporting to other federal or state *survey/health* agencies as required by law (e.g., for suspected medical device-related deaths or serious injury, transmission of an infectious disease, etc.); and
- Reporting to the OPO if a transplant recipient infection is related to an infectious disease present in a transplanted organ to ensure that other recipients who received organs from the same donor can be notified.

X-112

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(a)(1) Coordinating with the hospital in which the transplant program is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

Guideline §482.98(a)(1)

Care of transplant patients and living donors is unique and complex, requiring clarification of roles and responsibilities and appropriate training for nursing staff and clinical transplant coordinators. The director of the transplant *program* is responsible for coordination with the hospital's Nursing Department to determine the appropriate depth and type of orientation and training that will be provided to nursing staff that care for the transplant patients.

Evidence of coordination should include:

1. The transplant director has participated in the development of training and orientation plans for nurses who work or will work with transplant recipients and living donors;
2. The transplant director offers ongoing training opportunities for nursing staff; and
3. The transplant director provides feedback to the Nursing Department on the clinical competency of those nursing staff working with transplant recipients or living donors.

X-114

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(a)(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).

Guideline §482.98(a)(3)

Transplant surgeries are performed by qualified transplant surgeons, as well as residents/fellows under the direction of a supervising physician. To ensure patient safety, a supervising physician assumes the responsibility of the decisions being made and procedures being performed. A transplant surgeon must be credentialed by the hospital in which the transplant program is located to perform transplant surgeries *and must have surgical privileges delineated by the hospital in which the transplant program is approved.*

The supervision requirements are consistent and implemented in conjunction with the hospital surgical privileges at §482.51(a)(4). Therefore, when a resident or fellow participates in transplantation surgery, the specific tasks or procedures and level of supervision for each procedure would be specified in their surgical privileges and included on the surgical roster. For example, if a transplant surgeon's surgical privileges require direct supervision during surgical procedures, the supervising

physician must be physically present in the operating room where the procedure is being performed with the resident and patient throughout the performance of the procedure.

X-118

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(c) Standard: Clinical Transplant Coordinator.

The transplant program must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. ***The clinical transplant coordinator must be a registered nurse or clinician licensed by the State in which the clinical transplant coordinator practices, who has experience and knowledge of transplantation and living donation issues….***

Guideline§482.98(c)

The expectations of the coordinator *are defined* by the individual transplant program *and* will determine the particular professional clinical background required for the coordinator. However, regardless of the clinical background of the coordinator, the most critical factor of this Standard is the requirement for experience and knowledge. Clinical coordinators must have experience working with *donors and recipients* in any setting.

X-121

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(d) Standard: Independent Living Donor Advocate or Independent Living Donor Advocate Team. The transplant program that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

Guideline §482.98(d)

An independent living donor advocate role can consist of one individual or a team of individuals. Throughout this guidance, ILDA or ILDA team is referred to interchangeably as ILDA. Advocation for the wishes and challenges faced by a living donor is instrumental in ensuring the protection of rights for each potential living donor.

If a transplant program performs living donation, it must assign a living donor advocate or advocate team to each potential donor that is being evaluated for donation. The transplant program must ensure the ILDA remains independent of transplant program operations. Each potential donor must be informed of the ILDA assigned to them and how their role is integrated with donor's evaluation process, i.e. promoting the rights of

the donor through discussions and assessments of the donor's comprehension of the aspects of organ donation.

"Independent"means that the ILDA individual(s) function independently from the transplant team to avoid conflicts of interest, such as pressures for increasing a program's transplantation rates. An ILDA is not required to be employed or supervised by someone outside of the hospital.

The transplant program must ensure the independent operating ability of the ILDA, which may be achieved by incorporating the following factors:

a. *Independently operates: The position must allow the ILDA to provide independent representation to the potential LD/LD.* The transplant program must create a structure for the *ILDA* that allows independent evaluations and avoidance of conflict of interest.
b. *Informed consent: The job description of the ILDA must outline clear expectations that their position is to represent and advise the donor; and to promote his/her interests. This ILDA must be focused on ensuring that the rights of potential LDs/LDs are protected and that the potential LD's/LD's decision is informed and free from coercion.*
c. *Chain of command: While the ILDA performs their functions independent of the transplant team, there must be a chain of command for the communication of findings and/or donor needs based on their discussions and assessments. The ILDA has the ability to file a complaint/grievance with a third party if the ILDA believes that the rights of the potential LD/LD are not being properly protected.*

Note: To facilitate open discussions and avoid any bias towards a potential donor's decision to donate, the potential transplant recipient should not be present during any discussion between the ILDA and the potential donor.

X-122

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(d)(1) The independent living donor advocate or independent living donor advocate team must not be involved in transplantation activities on a routine basis.

Guideline §482.98(d)(1)

In order to maintain an unbiased approach to evaluating a donor's understanding of their decision to donate, a program's assigned ILDA must not have routine involvement in transplant-related activities for any given organ type. "Routine" means any active involvement in transplant activity that are regularly performed or transplant activities that occur on a fixed schedule for any given organ type. Performing transplant activities on special occasions would not be considered routine, however if the assigned ILDA takes on responsibilities towards transplantation, he or she would no longer meet this requirement.

X-123

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(d)(2) The independent living donor advocate or independent living donor advocate team must demonstrate:

(i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and
(ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

Guideline §482.98(d)(2)

The *ILDA* must be able to provide evidence of successful training which addressed the topics listed in the standard.

Interviews with living donors confirm that the *ILDA* provided information concerning:

- The organ donation process;
- The requirements of the informed consent process;
- The immediate and long-term expectations following donation;
- The immediate and long-term risks of donation;
- The expected outcomes for the recipient;
- The potential financial responsibilities related to donation; and
- Any alternative treatment(s) for the potential transplant recipient, if available.

The living donor medical record should fully chronical the interactions between the advocate or advocate team and donor candidate including the assessed level of understanding by the donor candidate during interactions.

The CoPs do not specify requirements for a donor advocate's background, education, or training or the donor advocate team's composition. Instead, it specifies their duties and the skills they must be able to demonstrate in 482.98(d)(2) (Tag X-123) and 482.98(d)(3) (Tag X-124).

X-124

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(d)(3) The independent living donor advocate or independent living donor advocate team is responsible for:

(i) Representing and advising the donor;
(ii) Protecting and promoting the interests of the donor; and

(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

Guideline §482.98(d)(3)

The ILDA is primarily the representative of the donor candidate. There may be instances where the *ILDA* advises the donor candidate where to seek additional information, encourages the candidate to ask pertinent questions, encourages the candidate to have additional discussions with the family or advises the donor candidate to delay the decision to donate at any point without reprisal if they choose. However, the *ILDA* does not advise as to a decision on donation.

All discussions and meetings between the donor candidate and the *ILDA* must center upon the needs, interests and choices of the donor *candidate*. These discussions must not address the needs of the potential recipient. If at any point in the process the donor changes his/her mind and decides not to donate, the *ILDA* must support and intercede on behalf of the donor candidate if indicated.

X-125

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.98(e) Standard: Transplant Team.

The transplant program must identify a multi-disciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

Guideline §482.98(e)

Patients that have undergone transplantation or are waiting to receive a transplant have many complex medical and psychosocial needs. To ensure an interconnected approach to identifying and assessing a patient's care plan, the transplant program's multidisciplinary team must consist of individuals with appropriate qualifications, training and experience in the specified areas, which should include the following individuals:

- *Medical physician and/or surgeon*
- *Registered nurse*
- *Registered dietician*
- *Social worker*
- *Transplant coordinator*
- *Pharmacist*

The transplant program's policy should detail the role and necessary documentation, which exemplifies the qualifications of each representative of the multidisciplinary team.

If a program performs LD transplants, the team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of donation.

X-139

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.100 Condition of Participation: Organ Procurement.

The transplant program must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

Guideline §482.100

The hospital in which the transplant program is located must have a written agreement with their designated OPO for cooperation with the OPO in the recovery of donor organs *unless the hospital has been granted a waiver by CMS to work with another OPO*. The agreement must meet the requirements of §482.45 *and §486.322.*

X-150

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(a) Standard: Informed Consent for Transplant Patients.

Transplant programs must implement written transplant patient informed consent policies that inform each patient of:

Guideline §482.102(a)

As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide a transplant *candidate* with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose all available information to a *transplant candidate* who makes the voluntary choice to accept or refuse treatment. The transplant physician must ensure each *candidate* that is considered for organ transplantation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to them.

For each of the required components of the informed consent policies identified in standards §482.102(a)(1) through (8), the transplant program's policies and procedures should delineate:

1. *who is responsible for discussing the informed consent process with the transplant candidate;*
2. *where the discussions concerning the informed consent process are documented in the medical record;*
3. *the methods used by the program to ensure and document the transplant candidate's understanding of the information being delivered; and*
4. *when the discussion(s) will take place, if the information is provided at different points of the transplant process.*

Any transplant candidate who receives the education and information necessary in preparation to undergo an evaluation for placement on a transplant program's waiting list, and eventual transplantation, must have documented evidence of this informed consent.

The signed hospital surgical consent form alone is not considered evidence that the informed consent process for transplant patients was completed to include the requirements of §482.102(a)(1)-(8).

X-151

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(a)(1) The evaluation process;

Guideline §482.10(a)(1)

A part of the informed consent process is ensuring the candidate understands what the evaluation process entails prior to its initiation. *During the evaluation process, transplant candidates need to be educated on factors that may affect their decision to undergo transplantation as a treatment of choice. Organ transplantation is a complex medical procedure that requires long-term changes in lifestyle, potential financial responsibilities, as well as strict adherence to a medication regimen in order to ensure the success of their organ function and quality of life.* Prior to a potential recipient making a decision to undergo an evaluation for transplantation, they must understand all that is involved in the evaluation process, which includes what the potential recipient and transplant program responsibilities will be; all possible decisions regarding waitlisting and transplantation that could be reached as a result of the evaluations; and what factors could result in their removal from the waiting list.

X-153

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(a)(3) Alternative treatments;

Guideline §482.102(a)(3)

Each potential recipient's options for treatment will vary based on organ type and individual medical condition(s). It is expected that discussions related to alternative treatments occur during an evaluation for transplantation.

These discussions should be presented broad in focus and narrow in focus as options change or become available.

The discussions of alternative treatments should be reviewed any time the candidate has significant changes in their medical condition, *including changes that increase or limit options available.*

X-154

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(a)(4) Potential medical or psychosocial risks;

Guideline §482.102(a)(4)

There are general risks applicable to all organ transplant types and there are risks specific to each organ type. The transplant program must address both categories of risk with the *transplant candidate* prior to his/her decision to proceed with the evaluation process.

X-155

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(a)(5) National and transplant program-specific outcomes, from the most recent SRTR program-specific report, including (but not limited to) the transplant program's observed and expected 1-year patient and graft survival, and national 1-year patient and graft survival;

Guideline §482.102(a)(5)

Prior to undergoing an evaluation, the transplant program informs the *transplant candidate* of the location of the SRTR website and explains how the website may be used to periodically review the transplant data pertaining to the program's performance. The *transplant candidate* should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website. This information allows the patient to make an informed decision about listing with the program.

X-156

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(a)(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immune-deficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;

Guideline §482.102(a)(6)

During the pre-evaluation period, the program informs the potential recipient of the general risks as listed in this regulation. At the time an organ is offered, the potential recipient must be informed of any risk factors specific to the organ recovered or to be recovered.

The transplant program should utilize the *PHS guideline for Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020* to identify those instances where the potential recipient must be informed as to increased risk with a particular organ condition. The *PHS guideline for Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020* is available at: *https://www.cdc.gov/mmwr/volumes/69/rr/rr6904a1.htm*

X-159

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(b) Standard: Informed consent for living donors.

Transplant programs must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant programs must ensure that the prospective living donor is fully informed about the following:

Guideline §482.102(b)

As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide patients with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose appropriate information to a patient which allows them to make the voluntary choice to accept or refuse treatment. The physician must ensure each patient that is considered for organ donation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to the recipient.

Transplant programs must develop and implement informed consent policies for living donors that delineate the information to be shared and the responsibilities of any transplant staff member that will consult with the patient.

For each of the required components of the informed consent policies identified in standards §482.102(b)(1) through (9), the transplant program's polices and procedures should delineate:

1. *who is responsible for discussing the informed consent process with the potential donor;*
2. *where the discussions concerning the informed consent process are documented in the medical record;*
3. *the methods used by the program to ensure and document the potential donor's understanding of the information being delivered; and*
4. *when the discussion(s) will take place, if the information is provided at different points of the donation process.*

Any potential donor who receives the education and information necessary in preparation to undergo an evaluation for donation, must have documented evidence of this informed consent.

The signed informed consent form and/or hospital surgical informed consent form alone is not considered evidence that the informed consent process for the prospective living donor is complete. Transplant programs must provide documentation that ensures the living donor candidate was informed of subparagraphs (1) through (*9*) of this standard.

X-162

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(b)(3) The surgical procedure, including post-operative treatment;

Guideline §482.102(b)(3)

Discussions by the transplant surgeon with the potential donor candidate would include:

- What is the surgical procedure to be performed?
- What are the risks of the surgery?
- How is the surgery expected to *effect* the potential *donor's* health or quality of life?
- How long will the potential *donor* be hospitalized?
- What is the expected recovery period?
- When may normal daily activities be resumed?

X-164

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(b)(5) The potential medical or psychosocial risks to the donor;

Guideline §482.102(b)(5)

There are general risks applicable to all organ transplants and there are risks specific to each organ type. The transplant program must address both categories of risk with the potential donor prior to his/her decision to proceed with the evaluation process.

The informed consent discussion should include information regarding long term medical implications of organ donation *that cannot be* fully identified.

X-165

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(b)(6) The national and transplant program-specific outcomes for recipients, and the national and program-specific outcomes for living donors, as data are available;

Guideline §482.102(b)(6)

Prior to undergoing an evaluation, the transplant program informs the potential donor of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program performance. The potential recipient should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website.

There are currently no national or *program*-specific outcomes for living donors calculated by the SRTR.

X-169

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(c) Standard: Notification to patients.

Transplant programs must notify patients placed on the program's waiting list of information about the program that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

Guideline §482.102(c)

The transplant program's policies must address communication methods to inform patients of situations or events that would impact the program's ability to perform transplants.

If the event is related to an emergency situation, which may or may not require transfer of patients to another hospital, the transplant program is expected to notify patients on the waiting list of the emergency plan in accordance with the program's emergency preparedness protocol in place. See § 482.78(b) (Appendix Z, Tag E-0014) for more information on the transplant program requirements for the development of protocols that address the duties of the transplant program, hospital, and the OPO designated by the Secretary during an emergency.

X-172

(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.102(c)(3) As soon as possible prior to a transplant program's voluntary inactivation, the program must inform patients on the program's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant program without loss of time accrued on the waiting list.

Guideline §482.102(c)(3)

Transplant programs that intend to become inactive must notify the patient group that will be affected by the inactivity. If the determination is made to inactivate a transplant program or a component of a transplant program, all potential recipients on the waiting list would be unable to receive an organ offer during the time period of inactivity. As such, transplant programs must notify all affected patients of the upcoming inactivation. It must also inform the potential recipients of the expected time period of inactivation, if known, and options for waiting list patients to transfer to another facility.

Waiting list patients should receive notification of the program's voluntary inactivation at least 30 days prior to the planned inactivation date. Transplant programs determine the method of communication with the potential recipients and the program must be able to document the communication.

If a transplant candidate elects to be transferred to another transplant program, the inactivating transplant program must facilitate communication and help with the exchange of information. The transplant program should coordinate with the receiving facility to place the patient on their waiting list.

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(Rev. 227; Issued: 12-13-24; Effective: 12-13-24; Implementation: 12-13-24)

§482.104(c) Standard: Participation in network activities.

Kidney transplant programs must cooperate with the ESRD Network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.

Guideline §482.104(c)

The ESRD Network organizations are uniquely positioned to coordinate with dialysis professionals, providers, and patients to promote goals for healthcare quality improvement. There are currently 18 ESRD Network Organizations across the United States and its territories. CMS directs the ESRD Network Organizations through the development of a contract, which delineates the goals and quality improvement activities. Kidney transplant programs must cooperate with the ESRD Network for their region to ensure full participation and support in achieving the aims and goals set by the statement of work.

For more information on the ESRD Networks, visit https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations. For more details on the current statement of work, information can be requested from the designated ESRD Network.

Medicare State Operations Manual
Chapter 9 - Exhibits

Exhibits
(Rev. 227; Issued: 12-13-24)

Exhibit 357

Model Letter for a Transplant Program Inactivation

[Instructions: Medicare regulations at §488.61(d) allow a transplant program to voluntarily become inactive and retain its Medicare participation for a period not to exceed 12 consecutive calendar months. The program must notify CMS of its voluntary inactivation. This model letter should be used when a transplant program has notified CMS of its inactivation, is nearing its 12-month term AND has not notified CMS of its plans for reactivation.]

[Date]

[Hospital name]
[Hospital Address]

[CCN]*[Transplant Program(s)]*

Dear [Hospital Administrator]:

Under 42 CFR §488.61(e), the Centers for Medicare & Medicaid Services (CMS) may allow a transplant program to remain inactive and retain its Medicare transplant program approval for a period not to exceed 12 months.

We received notification that the [organ type] transplant program(s) at [Hospital] *declared its inactive status on* [Date] and will reach the maximum 12-month period of inactivity on [Date]. CMS does not have the authority to provide an extension beyond this 12-month period.

CMS must receive written notice of the transplant program's intent with respect to its inactive status prior to [Date]. It must either (1) reactivate or (2) voluntarily withdraw from the Medicare program. If you fail to take either action voluntarily and continue to be inactive beyond 12 months, the ***[ORGAN TYPE]*** *transplant program at [HOSPITAL] will lose is Medicare approval. Under separate notice, CMS will initiate termination of the Medicare approval of the [organ type] transplant program(s) at [Hospital].*

If the transplant program has no plans to reactivate, the program must notify all patients on the waitlist of its inactivation and assist those patients who choose to transfer to the waitlist of another Medicare-approved transplant center without loss of time accrued on the waiting list *as required at 42 CFR §482.102(c).*

Once a transplant program voluntarily withdraws or is terminated following its inactive period, it must apply for initial approval and meet all applicable CoPs, including the data submission, clinical experience, and outcome requirements at 482.80.

If you have any questions please contact [Name] at [phone], [e-mail].

Sincerely,

[Name, Title of Authorized Representative]