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**Center for Clinical Standards and Quality**

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**Ref: QSO-25-03-Transplant**

**DATE:** October 10, 2024

**TO:** State Survey Agency Directors

**FROM:** Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

**SUBJECT:** Revisions to the State Operations Manual (SOM), Chapter 2- The Certification Process; SOM Appendix X, Guidance to Surveyors: Organ Transplant Programs; and SOM Chapter 9- Exhibits – Advance Copy

**Memorandum Summary**

- **Updates to the State Operations Manual** - The Centers for Medicare & Medicaid Services (CMS) is releasing updates to Chapters 2 and 9, and to Appendix X of the SOM for transplant programs. This guidance provides a consistent approach to the transplant survey process and certification activities and incorporates feedback previously received from stakeholders.
- **Survey tools and resources:** Following the release of these updates, additional tools and resources, e.g., transplant survey workbook, will be provided to aid the state survey team in navigating the survey process for organ transplant programs.
- **Several previously released QSO (previously S&C) memos are now obsolete.** Memos: [S&C 17-04-Transplant](#) (incorporated into the SOM), [S&C 17-13-Transplant](#) (outdated), [S&C: 16-24-Hospitals](#) (outdated), and [QSO-19-05-Transplant](#) (incorporated into the SOM) are now expired. CMS will note the expiration date on these memos, which are currently on the CMS website. This memo and the associated SOM updates will supersede the expired memos.

**Background:**

On January 1, 2019, CMS issued [QSO-19-11-Transplant](#) that transitioned all survey activities for transplant programs from a national contractor to the state survey agencies (SAs). On March 4, 2020, the COVID-19 Public Health Emergency necessitated the temporary suspension of non-emergency inspections - including routine inspections of transplant programs. Effective May 11, 2023, SAs resumed routine operations, and CMS has since identified several opportunities to implement enhancements and additional details to the interpretive guidance and survey protocol for transplant programs. These updates and revisions seek to ensure surveyors remain focused on matters of health and safety during their evaluation of transplant program compliance with Medicare's Conditions of Participation, provide brevity and clarity to frequently asked questions, and standardize operational procedures related to transplant program certification.

## **Discussion:**

CMS has revised Chapter 2 of the SOM to provide guidance to CMS staff, SAs, and the transplant provider community. A general summary of the changes is as follows:

- **Definitions:** added a definition for United Network for Organ Sharing and expand the definition for the Scientific Registry of Transplant Recipients.
- **Process for initial approval:** added SA procedures for processing initial transplant program approval requests before outcomes data is available. The updated guidance requires the availability of outcomes data before initiating an onsite survey. If the data is not yet available, an onsite survey CANNOT be initiated. State agencies should notify transplant providers that the initial survey will occur once the data becomes available and compliance with all requirements at §482.80 can be determined.
- **Survey and approval procedures:**
  - add a survey team composition and scope section; and
  - add a data submission, clinical experience, and outcome requirements for initial approval section.
- **Notification to CMS:** provide guidance on the types of changes that programs are responsible for notifying CMS about.
- **Transplant program inactivation:** provide operational procedures when receiving notifications of transplant program inactivation and the process for documenting them in the national surveyor database.
- **Mitigating factors applications:** provide additional guidance on requesting initial program approval, the application process, and possible review outcomes.
- **Combined transplant programs:** provide additional guidance on transplant programs that perform simultaneous, i.e., combined, transplants.
- **Organ Procurement and Transplantation Network (OPTN) Membership:** define what it means to be a member, how it impacts Medicare eligibility, and resources for determining transplant program member status with the OPTN.
- Expand the **regulatory background** section.

CMS has revised Appendix X of the SOM to include additional detail on clinical areas of the transplant survey process. A general summary of these changes is as follows:

- **Survey task changes:** provide added detail to the tasks for information gathering, e.g., medical record review and review of the program's Quality Assessment and Performance Improvement (QAPI) efforts.
- **Observations of care:** incorporate distinct opportunities to directly observe multidisciplinary care planning and coordination.
- **Tools and resources:** add resources that aid in reviewing a transplant program, e.g., entrance conference materials list.
- **Patient Sample Selection** redesign.
- **Interpretive guidance revisions** based on stakeholder feedback. This includes clarifying CMS' expectations for notifying key staff changes, the "phases" of transplantation, and the living donor advocate's role and responsibilities.

CMS has developed a new Exhibit 357, “Model Letter for a Transplant Program Inactivation,” that is added to Chapter 9 of the SOM. The letter is for SAs and CMS Location staff use when a transplant program is approaching the maximum 12 months of inactivity. SAs and CMS staff will use this template letter to notify the program that they should reactivate or voluntarily withdraw/terminate Medicare approval or the program will be terminated after 12 months of inactivity, as per 42 CFR 488.61(d).

### **Surveyor Tools and Resources**

Following the release of these updates, additional tools and resources will be provided to aid the SA survey team in navigating through the survey process for organ transplant programs. This will be released in a future QSO memo. As a reminder, the Transplant Program Basic Training (on-demand) is available on [CMS' Quality, Safety, & Education Portal](#).

### **Transplant Provider Data on Quality, Certification & Oversight Reports (QCOR) Website**

The [QCOR website](#) is an online reporting system that is open to the public. It provides timely data about Medicare and Medicaid providers and suppliers. **The QCOR data for transplant programs went live on June 16, 2022.** Users may generate and view data reports on transplant programs’ survey and certification activities. These reports can be accessed through the Hospitals link on QCOR. Reports available include the following:

1. Provider Reports for information on provider counts.
2. Survey Reports for information on survey activity and overdue surveys.
3. Deficiency Reports for information on deficiency counts, the average number of deficiencies, and citation frequency.

The [QCOR FAQs](#) provide additional information on transplant programs, including how to interpret deficiency results from transplant program surveys.

### **List of Medicare-approved Transplant Programs**

A national list of Medicare-approved transplant programs is available on the [Resources tab](#) of QCOR’s main landing page. This Excel file is updated monthly.

### **Contact:**

For questions or concerns relating to this memorandum, please contact [QSOG\\_TransplantTeam@cms.hhs.gov](mailto:QSOG_TransplantTeam@cms.hhs.gov).

### **Effective Date:**

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz  
Director, Survey & Operations Group

David R. Wright  
Director, Quality, Safety & Oversight Group

Attachments-

State Operations Manual, Chapter 2 – Advance copy

State Operations Manual - Appendix X – Advance copy

State Operations Manual, Chapter 9, Exhibit 357– Advance copy

The updates in the attached advanced copies will be incorporated into the SOM in a future release.

**Resources to Improve Quality of Care:**

*Check out CMS’ new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to specific provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.*

*Learn to:*

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility’s standards of care*

*See the [Quality, Safety, & Education Portal Training Catalog](#), and select Quality in Focus.*

*Get guidance memos issued by the Quality, Safety and Oversight Group by going to [CMS.gov](#) page and entering your email to sign up. Check the box next to “CCSQ Policy, Administrative, and Safety Special Alert Memorandums” to be notified when we release a memo.*

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# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

Transmittal

Date: October 10, 2024

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**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\*:** Upon Issuance

**IMPLEMENTATION DATE:** Upon Issuance

*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
R	Appendix X/ The Standard Organ Transplant Program Survey Protocol. Extensive revisions made throughout the survey protocol to provide additional detail and better clarity to the state surveyors.
R	X-002/§482.72 Condition of Participation: OPTN Membership/Revised to add links to the OPTN website.
R	X-011/§482.74(a) Condition of Participation: Notification to CMS
R	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	X-015/§482.74(a)(3) and §482.74(b). Inactivation of the transplant program.
R	X-021/§482.76 Condition of Participation: Pediatric Transplants.

R	X-025/§482.76(d)(2) The unified program shares the same transplant surgeons and quality improvement program.
R	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	X-031/§482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Programs.
R	X-032/§482.80(a) Standard: Data Submission.
R	X-033/§482.80(b) Standard: Clinical Experience.
R	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	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	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	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	X-058/§482.90(b) Standard: Living Donor Selection.
R	X-059/§482.90(b)(2) Document in the living donor's medical records the living donor's suitability for donation.
R	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	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	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	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	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	X-087/§482.94(c) Standard: Patient Records. Transplant program must maintain up to date medical records.

R	X-091/§482.94(c)(ii) Multidisciplinary discharge planning for post-transplant care.
R	X-092/§482.94(d) Standard: Social Services.
R	X-094/§482.94(e) Standard: Nutritional Services.
R	X-114/§482.98(a)(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon.
R	X-118/§482.98(c) Standard: Clinical Transplant Coordinator.
R	X-121/§482.98(d) Standard: Independent Living Donor Advocate or Independent Living Donor Advocate Team.
R	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	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	X-125/§482.98(e) Standard: Transplant Team.
R	X-139/§482.100 Condition of Participation: Organ Procurement.
R	X-150/§482.102(a) Standard: Informed Consent for Transplant Patients.
R	X-151/§482.102(a)(1) The evaluation process.
R	X-153/§482.102(a)(3) Alternative treatments.
R	X-154/§482.102(a)(4) Potential medical or psychosocial risks.
R	X-156/§482.102(a)(6) Organ donor risk factors.
R	X-159/§482.102(b) Standard: Informed consent for living donors.
R	X-162/§482.102(b)(3) The surgical procedure, including post-operative treatment.
R	X-164/§482.102(b)(5) The potential medical or psychosocial risks to the donor.
R	X-165/§482.102(b)(6) The national and transplant program-specific outcomes.
R	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	X-188/§482.104(c) Standard: Participation in network activities.
R	Chapter 2/ Section 2060A – Citations
R	Chapter 2/ Section 2060B – Definitions
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

<b>R</b>	<b>Chapter 2/Section 2062B.3 - Complaint Surveys</b>
<b>R</b>	<b>Chapter 2/Section 2064 – Notification to CMS</b>
<b>R</b>	<b>Chapter 2/Section 2065 – Transplant Program Inactivation</b>
<b>R</b>	<b>Chapter 2/Section 2066 - Mitigating Factors</b>
<b>R</b>	<b>Chapter 2/Section 2067 – Transplant Resources</b>
<b>N</b>	<b>Chapter 9/Exhibit 357</b>

**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:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>One-Time Notification -Confidential</b>
	<b>Recurring Update Notification</b>

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



# State Operations Manual

## Chapter 2 - The Certification Process

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ADVANCE COPY

## Organ Transplant Programs

### 2060 - Organ Transplant Programs

(Rev. 190, Issued: 06-14-19, Effective: 06-14-19, Implementation: 06-14-19)

#### 2060A – Citations

*(Rev.)*

The Conditions of Participation (CoPs) for Transplant *Programs* 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 *programs*, 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 *programs* 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.)*

##### 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.)**

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.)**

*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 ([OSOG\\_TransplantTeam@cms.hhs.gov](mailto:OSOG_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 (Rev.)**

### **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** **(Rev.)**

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.*

## **2062 - Survey and Approval Procedures for Organ Transplant Programs** **(Rev.)**

### **2062A – Survey Composition and Scope** **(Rev.)**

#### ***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** ***(Rev.)***

### **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.)**

*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.)**

*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 11<sup>th</sup> 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**

### **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 [OSOG\\_TransplantTeam@cms.hhs.gov](mailto:OSOG_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 [OSOG\\_TransplantTeam@cms.hhs.gov](mailto:OSOG_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.)**

*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;*
- *Procedures for submission of request for consideration of mitigating factors; and*

### ***Surveyor Training***

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

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# State Operations Manual

## Appendix X – Guidance to Surveyors: Organ Transplant Programs

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# ***The Standard Organ Transplant Program Survey Protocol (Rev.)***

## **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.*

<b>Program</b>	<b>Abbreviation</b>	<b>Notes</b>
Adult Kidney	AKO	

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

<sup>1</sup>*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).*

<sup>2</sup>*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:*

<i>Number of transplant programs</i>	<i>Number of surveyors – minimum</i>
<i>1-3</i>	<i>2 surveyors</i>
<i>4-6</i>	<i>3 surveyors</i>
<i>6+</i>	<i>4 surveyors</i>

## Survey Protocol Tasks

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

### 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:

- For initial approval surveys, review the **Initial Transplant Report** (see SOM Chapter 2) to determine compliance with the following:*
  - Data submission (X-032)*
  - Clinical experience (X-033)*
  - Outcome requirements (X-035)*
- 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.*
- Transplant program inactivation. If the transplant program had any **periods of inactivity**, determine whether the following occurred:*
  - 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)*
  - The program exceeded a 12 **consecutive calendar** month inactivation period; (X-172)*
- 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

<b>Requested Items for Review for Each Organ Program Type</b>		
<b>Transplant Program</b>	<b>Program Type:</b>	<b>Program Representative:</b>
<b>Name:</b>	<b>Choose an item.</b>	
<p><i>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.</i></p>		
<b>Lists Of Transplant Candidates, Recipients And Living Donors (by organ type)</b>		✓
1.	<i>Each transplant program's <b>complete current active waiting list</b> 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.</i>	<input type="checkbox"/>
2.	<i>List of all patients (including their medical record number) <b>removed from the waiting list</b> within the past 12 months of each program for reasons other than death or transplant.</i>	<input type="checkbox"/>
3.	<i>List of all patients (including their medical record number) removed from the waiting list within the past 12 months of each program <b>due to death or transplant.</b></i>	<input type="checkbox"/>
4.	<i>List and number of persons <b>evaluated for transplant that were not placed on the waiting list</b> 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.</i>	<input type="checkbox"/>
5.	<i>List and number of the <b>transplants performed</b> 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;</i>	<input type="checkbox"/>
6.	<i>List and number of <b>living donors</b> 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.</i>	<input type="checkbox"/>
<b>Lists of Meeting Schedules, Scheduled Follow-up Visits and Current Transplant Inpatient Census</b>		
7.	<i>List and number of transplant patients and living donors that are <u>currently</u> an inpatient and the location of the patient in the hospital (unit and floor).</i>	<input type="checkbox"/>
8.	<i>List and number of post-transplant patients and post-donation individuals that are scheduled for follow-up visits during the survey timeframe.</i>	<input type="checkbox"/>
9.	<i>A schedule of any multidisciplinary team meetings that will be held during the survey timeframe; include team rounding schedule.</i>	<input type="checkbox"/>
10.	<i>A schedule of any selection committee meetings that will be held during the survey timeframe.</i>	<input type="checkbox"/>

11.	<i>A schedule of any QAPI committee meetings that will be held during the survey timeframe.</i>	<input type="checkbox"/>
<b>List of Organ Offers</b>		
12.	<i>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.</i>	<input type="checkbox"/>
<b>Program Administration/Contracts</b>		
13.	<i>An organizational chart of the transplant program: that includes the chain of command and how the transplant program fits within the overall hospital structure.</i>	<input type="checkbox"/>
14.	<i>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.</i>	<input type="checkbox"/>
<b>Personnel</b>		
15.	<i>List of all transplant-associated professional personnel, their titles, primary organ transplant program affiliations and any other transplant program affiliations, if applicable.</i>	<input type="checkbox"/>
16.	<i>The curricula, training plan, and/or training schedule for personnel (agenda, dates, evidence of attendance).</i>	<input type="checkbox"/>
17.	<i>On-call schedule for transplant surgeons and transplant physicians for the past 30 days.</i>	<input type="checkbox"/>
<b>Policies and Procedures</b>		
18.	<i>Patient selection criteria (transplant recipient and living donor), provide the criteria that your program uses to select patients for transplant and living donation (X-051-60)</i>	<input type="checkbox"/>
19.	<i>Organ Receipt Policy for ABO and Other Vital Data Verification (include associated forms) (X-071, X-073)</i>	<input type="checkbox"/>
20.	<i>Living Donor Recovery for ABO and Other Vital Data Verification (include associated forms) (X-074)</i>	<input type="checkbox"/>
21.	<i>Transplant Recipient Patient Management Policies for Transplant and Discharge Planning Phases (X-082, X-090, X-091, X-125)</i>	<input type="checkbox"/>
22.	<i>Living Donor Patient Management for Pre-Donation, Donation and Discharge Planning Phases (X-082, X-125)</i>	<input type="checkbox"/>
23.	<i>Waiting List Management Policy (including patient notifications) (X-081-94)</i>	<input type="checkbox"/>
24.	<i>Informed Consent Policy for Recipients (include associated forms) (X-149-158)</i>	<input type="checkbox"/>
25.	<i>Informed Consent Policy for Living Donors (include associated forms) (X-060, X-124, X-149, X-159-168)</i>	<input type="checkbox"/>
26.	<i>Ongoing communication with patients and dialysis centers (Informing patient and dialysis centers of patient's listing status) (X-120, X-186)</i>	<input type="checkbox"/>

27.	<i>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)</i>	<input type="checkbox"/>
28.	<i>If a transplant program is served by a single transplant surgeon or physician, the potential unavailability of the transplant surgeon or physician (X-170)</i>	<input type="checkbox"/>
<b>Education Information</b>		
29.	<i>A copy of the written material that is distributed to potential transplant recipients and living donors to explain the selection criteria</i>	<input type="checkbox"/>
30.	<i>Any written educational materials used pre and post-transplant for transplant recipients (X-126, X-150-172)</i>	<input type="checkbox"/>
31.	<i>Any written educational materials used pre and post-donation for living donors (X-060, X-126, X-159-171)</i>	<input type="checkbox"/>
<b>QAPI</b>		
32.	<i>The written copy of the transplant program's Quality Assessment and Performance Improvement (QAPI) plan (X-099-104)</i>	<input type="checkbox"/>
33.	<i>The written copy of the hospital's Quality Assessment and Performance Improvement (QAPI) plan (X-099-104)</i>	<input type="checkbox"/>
34.	<i>Any QAPI reports, records and minutes of QAPI committee meetings, or consultation reports about the QAPI program (X-099-104)</i>	<input type="checkbox"/>
35.	<i>Policy / Protocol on complaints, adverse events, and other occurrence or variance reporting issues (X-102-104)</i>	<input type="checkbox"/>
36.	<i>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)</i>	<input type="checkbox"/>

### **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.*

<b>Category</b>	<b>Sample Size*</b>	<b>Comment</b>
<i>Waiting list patients</i>	<i>3</i>	<i>Patients can remain on a transplant program waiting list for varying periods of time before transplantation</i>



		<i>occurs. Include two (2) patients minimum that have been on the waiting list &gt;3 years and one (1) patient minimum on the waiting list &lt;3 years</i>
<i>Patients removed from waiting list for reasons other than death or transplant</i>	<i>3</i>	<i>”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</i>
<i>Patients removed from the waiting list due to death or transplant</i>	<i>3</i>	<i>“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</i>
<i>Patients evaluated but not placed on the waiting list</i>	<i>3</i>	
<i>Patients transplanted less than 6 months ago</i>	<i>3</i>	<i>If no patients have been transplanted within the last 6 months, add three (3) additional records to “Waiting list patients” category</i>
<i>Patients transplanted more than 6 months ago</i>	<i>3</i>	
<i>Living organ donors (if applicable)</i>	<i>3</i>	
<i>Patient adverse events</i>	<i>3</i>	
<i>*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.</i>		

#### **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 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 hospital at 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.)*



- 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**

*The surveyor should request specific personnel records and job descriptions from the Personnel or Human Resources Department (based on the list below) and review these records in a secure area. Try to choose personnel records of transplant staff other than those that were chosen for interview, if possible. The goal is to choose a sample that is representative of the overall transplant program; do not just focus on the primary transplant personnel (i.e., primary transplant surgeon or physician).*



<b>Position</b>	<b>Sample size per program</b>	<b>Education</b>	<b>Licensure/ Board Certification</b>	<b>Transplant-Specific Orientation</b>	<b>Ongoing Transplant-Specific Training</b>	<b>Job Description</b>
<i>Transplant Surgeons</i>	<i>1-2</i>		<i>X</i>			
<i>Transplant Physicians</i>	<i>1-2</i>		<i>X</i>			
<i>Transplant Coordinator</i>	<i>1</i>		<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>Dietitian</i>	<i>1</i>			<i>X</i>	<i>X</i>	<i>X</i>
<i>Pharmacist</i>	<i>1</i>			<i>X</i>	<i>X</i>	<i>X</i>
<i>Social Worker</i>	<i>1-2</i>	<i>X</i>		<i>X</i>	<i>X</i>	<i>X</i>
<i>Nurses</i>	<i>2 in the transplant unit</i>			<i>X</i>	<i>X</i>	
<i>Living Donor Advocate or Team</i>	<i>Up to 3</i>	<i>X</i>		<i>X</i>	<i>X</i>	<i>X</i>

*If concerns regarding staff education, qualifications, and training for staff providing transplant care are identified during personnel record review, expand the survey to identify any deficient practice, e.g. personnel interviews. For staff new to transplant, or who appear unfamiliar with the care of transplant patients, the surveyor validates the presence of orientation education and/or additional training to ensure that the staff are prepared to care for patients undergoing transplants.*

### ***PERSONNEL INTERVIEWS***

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

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

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

### **TASK 8 - EXIT CONFERENCE**

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

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

During the conference:

- Identify each deficiency found and restate those deficiencies being cited;
- Provide an opportunity for the transplant program to present additional information that may not have been presented during the survey (except for *a failure to meet requirements* at §482.80(a) and (c));
- Outline the next steps
  - The hospital administration will receive a written form (the CMS-2567 Statement of Deficiencies) from the state survey agency that describes the survey findings and cited noncompliance deficiencies. Findings for all programs that were surveyed together will be included on one CMS-2567. Each deficiency will be identified by the applicable program. Following receipt of the CMS-2567 (generally within 10 days of the exit conference), the transplant program must submit a plan of correction within 10 days of receipt of the CMS-2567 for each individually cited deficiency.
- Explain that all findings *discussed during the exit conference* are preliminary and subject to administrative review.

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

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

## **TASK 9 - POST SURVEY ACTIVITIES**

Following the survey, the surveyor will complete the Form CMS-670 (Survey Team Composition and Workload) and the CMS-2567 forms.

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

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

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## **Alternate Survey Protocol: Pediatric Heart Program** (Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

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

Under §482.76(d), instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant program that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub.L.100-203).

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

1. The pediatric transplant program is operated jointly with another Medicare-approved facility. This joint operation may occur pursuant to a structured affiliation between the two hospitals or pursuant to a written agreement;
2. The surgeons who perform the heart transplants at the pediatric hospital are credentialed for cardiac surgery at both hospitals under the unified program;  
The QAPI programs must be shared by both hospitals and include review, analysis and recommendations for the pediatric transplants; Collaboration between both QAPI programs would consist of reviewing and evaluating the need for any changes between the jointly operated entities; and
3. Demonstrates to the satisfaction of CMS that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

### **TASK 1 – PRE-SURVEY PREPARATION OFF-SITE**

None required.

### **TASK 2 – ENTRANCE ACTIVITIES**

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

#### Requested Items for Review:

##### Lists of Transplant Candidates and Patients:

Log of the transplants performed including name and date of transplant for both the pediatric heart transplant program and the associated heart transplant program within the past *18 months*;

##### Program Administration: Policies, Procedures, Personnel, and QAPI

1. A copy of the joint operating agreement between the pediatric heart transplant program and the associated heart transplant program that is jointly operating this program;
2. An organizational chart of the pediatric heart transplant program and the associated program;
3. Credentials for cardiac transplant surgeons and physicians and confirmation they are permitted to practice at both facilities; and

4. Log of any reported adverse events (by the pediatric heart transplant program and the associated program) and corresponding documentation of the investigation and analysis of those events for the past 12 months.

### **TASK 3 – SAMPLE SELECTION**

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

#### Pediatric Heart Transplant Recipients Sample Selection

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

### **TASK 4 – REVIEW OF TRANSPLANT PATIENT MEDICAL RECORDS**

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

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

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

### **TASK 5 – STAFF INTERVIEW**

Follow standard protocol for interviews.

### **TASK 6 – PERSONNEL RECORD REVIEW**

Follow standard protocol for personnel file review.

## **TASK 7 – ADMINISTRATIVE REVIEW**

### Operating Agreement

Review the operating agreement between the pediatric heart transplant program and the associated heart transplant program to ensure that it meets the requirements of the guidelines (Tags X-024 through X-026).

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

## **TASK 8 – PRE-EXIT CONFERENCE**

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

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

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

## **TASK 9 – EXIT CONFERENCE**

Refer to the standard protocol for the exit conference. However, pediatric heart programs under the alternate approval are only required to meet tags X-024 through X-026. Therefore, the exit conference will be limited to findings on these requirements.

## **TASK 10 – POST SURVEY ACTIVITIES**

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

## Interpretive Guidelines for Organ Transplant Surveys

### X-001

(Rev.)

#### §482.68 – Special Requirements for Transplant Programs.

A transplant program located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§482.72 through 482.104, a transplant program must also meet the conditions of participation specified in §§482.1 through 482.57, except for §482.15.

#### Guideline §482.68

If any Condition of Participation is found to be out of compliance, then this Condition must also be cited as being out of compliance.

#### General Requirements for Transplant Programs

### X-002

(Rev.)

#### §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. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

### **§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.)**

**§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-014**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**



**§482.74(a)(2) Termination of an agreement between the hospital in which the transplant program is located and an OPO for the recovery and receipt of organs as required by section 482.100; and**

**Guideline §482.74(a)(2)**

Outside an approved waiver process, a hospital may not terminate its agreement with its designated OPO. Via a waiver request submitted to CMS, a hospital may request to work with an OPO in another OPO Donation Service Area. Should the waiver be granted, a hospital may then terminate the agreement with its designated OPO. See also 42 CFR 486.308. The transplant program must notify the applicable state survey agency (SA) of its hospital's intention to seek a waiver of its designated OPO. The hospital must submit the actual request for an OPO waiver to the Center for Medicare within CMS Central Office in Baltimore. Once the waiver is granted or denied, the hospital must provide a copy of the decisional document to the SA.

**X-015**

***(Rev.)***

**§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.)***

**§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-022**

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

**(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants.**

**(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform adult transplants.**

#### **Guideline §§482.76 (b)(1)-(2)**

A pediatric transplant program is permitted to perform adult transplants under its pediatric Medicare approval. But, if the pediatric program performs 50% or more of its total volume of transplants, in a 12 month period, on adults, the program must decide whether to seek an additional adult program approval or revise their single designation to an adult designation.

If the program elects to maintain its pediatric approval and to seek an additional adult program approval, there may be an impact in the event of a termination of one of the programs.

Termination of the pediatric program will trigger a review of the adult program. Termination of the adult program will result in the automatic termination of the pediatric program..

## **X-023**

*(Rev.)*

**§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.)*

**§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. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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.)***

**§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. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§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.)**

**§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. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§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. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§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.)***

**§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. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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.)*

**§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-054**

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

**§482.90(a)(2)** Before a transplant program places a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

**X-055**

*(Rev.)*

**§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.)*

**§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.)*

**§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.)**

**§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-060**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§482.90(b)(3) Document that the living donor has given informed consent, as required under §482.102.**

### **Guideline §482.90(b)(3)**

“Informed consent” means the individual participates in his or her health care decision-making through a process which:

- a) provides the living donor with information about the decision to donate and the procedures, alternatives, risks, benefits and other pertinent information;
- b) is provided to the living donor in a manner suitable for comprehension;
- c) includes documentation by the hospital that the living donor understood and can articulate his/her understanding of the information above; and
- d) ensures voluntary consent by the living donor.

## **X-071**

**(Rev.)**

**§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.)**

**§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.)***

**§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.)**

**§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.)*

### **§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 dietitian 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-083**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

### **§482.94(b) Standard: Waiting List Management.**

**Transplant programs must keep their waiting lists up to date on an ongoing basis, including:**

**X-084**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§482.94(b)(1) Updating of waiting list patients' clinical information;**

**Guideline §482.94(b)(1)**

Timely updates to clinical information for patients on the waiting list affect: (1) organ allocation priority based on medical urgency and (2) a candidate's ability to receive a transplant.

Transplant programs must update the waiting list with accurate, recent and timely clinical information to ensure that a candidate is able to receive a transplant should an organ become available. Transplant programs should determine how often waiting list patients should be evaluated and provided ongoing assessment.

**X-085**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.94(b)(2) Removing patients from the program's waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a program's waiting list; and**

**Guideline §482.94(b)(2)**

There may be instances where a recently transplanted recipient is placed back on the waiting list. In these instances, documentation must include the original date of removal and the date of the new placement on the list.

**X-086**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.94(b)(3) Notifying the OPTN no later than 24 hours after a patient's removal from the program's waiting list.**

**Guideline §482.94(b)(3)**

For the purpose of this Standard, the 24-hour period to notify the OPTN of a patient's removal begins at the time of the patient's death; transplantation; the patient's decision to be removed from the list; or notification of death or transplantation from an outside source (family or another transplant hospital if the patient was listed with more than one transplant program).

The OPTN is considered to have been automatically notified once the patient is removed from the waiting list in UNET by the transplant program. No additional notification is required by the transplant program to the OPTN.

## **X-087**

*(Rev.)*

### **§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-088**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.94(c)(1) For each patient who receives an evaluation for placement on a program's waiting list, the program must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of:**

- (i) The patient's placement on the program's waiting list;**
- (ii) The program's decision not to place the patient on its waiting list; or**
- (iii) The program's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.**

## **X-089**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.94(c)(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant program must document in the**

patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

**Guideline §482.94(c)(2)**

Transplant programs determine the most appropriate method for communication with the patient and the dialysis facility. The communication must be evidenced by documentation in the medical record.

**X-090**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.94(c)(3) In the case of patients admitted for organ transplants, transplant programs must maintain written records of:**

**(i) Multidisciplinary patient care planning during the transplant period; and**

**Guideline §482.94(c)(3)**

A multidisciplinary care plan includes ongoing assessments to identify any new patient needs and/or to determine if any currently identified patient needs have changed. A multidisciplinary team must be identified for each patient at the time the evaluation for wait listing begins. This multidisciplinary team participates in the patient care planning from evaluation through transplantation. At the time of the initial evaluation, each member of the team participates in the evaluation of the patient. It may not be necessary for all team disciplines to see the patient again until transplant is imminent unless there are identified needs. Following the transplant, each discipline must, as appropriate: 1) reassess the recipient following the surgery; 2) see the recipient as often as indicated by identified issues; and 3) see the recipient prior to discharge.

**X-091**

**(Rev.)**

**§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.)*

### **§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-093**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

### **§482.94(d)(cont'd)**

**...A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and**

**(1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or**

**(2) Is working as a social worker in a transplant program as of effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.**

**Guideline §§482.94(d)(cont'd) and (d)(1)-(2)**

Non-MSW employees functioning as a transplant program social worker prior to June 28, 2007, which is the effective date of the final rule, “Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants” (72 FR 15198, Mar. 30, 2007), must have a consultative relationship with an MSW who meets the requirements of §482.94(d)(1). The purpose of the consultative relationship is for the MSW to advise, support and often guide a social worker in their position. A consultative relationship generally would include:

- Meetings between the MSW and the non-MSW on a routine or re-occurring basis; and
- Evidence that the MSW is available and responsive for ad hoc consultation with the non-MSW employee.

**X-094**

***(Rev.)***

**§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 dietitian 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. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

## **§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-100**

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

### **§482.96(a) Standard: Components of a QAPI Program.**

**The transplant program's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights....**

**Guideline §482.96(a)**

This standard requires transplant QAPI programs to identify, implement, assess and re-assess objective measures to evaluate and improve both their transplantation outcomes as well as the quality, safety and performance of their transplantation activities, across all phases of transplant and living donation.

Transplantation and living donor care - including but not limited to the potential areas for measurement listed in this standard – involve multiple phases, activities and potential outcomes, each with various aspects that may be amenable to objective measurement. Objective measures can mean that a transplant program will select some measures for routine monitoring on an ongoing basis; others will be identified and implemented in order to address, evaluate and monitor a particular problem or opportunity for improvement. Each transplant QAPI program should identify and implement multiple objective measures that are relevant and meaningful for evaluating its own performance with regard to both transplantation activities and outcomes to:

- Collect and analyze data to assess its baseline performance and to track performance on the selected measures over time; and
- Use the information gained to evaluate and improve performance and to ensure that improvements are sustained over time.

Measuring an outcome means measuring the health status of a patient resulting from health care. For example, the SRTR reports contain a number of objective outcome measures useful for performance monitoring and improvement (such as patient and graft survival), but additional patient outcomes not reported by the SRTR may also be important for a program to measure (for example, rates of specific intra- and post- operative complications for transplant recipients and living donors).

In addition to measuring relevant outcomes, other types of clinical quality measures are needed to evaluate transplantation activities. Each program must critically examine its own services and performance to determine which activities (and which aspects of the activity) within each phase of transplantation or donation should be evaluated and monitored using objective measures.

**X-101**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§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. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

#### **§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-103**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.96(b)(2) The transplant program must conduct a thorough analysis of and document any adverse event... .**

### **Guideline §482.96(b)(2)**

A thorough analysis is a planned, systematic investigative process that considers all of the phases of transplantation/living donation in identifying the causes of and factors contributing to an adverse event. The scope and depth of analysis, as well as the extent of multi-disciplinary involvement, may be scaled in proportion to the scope and severity of the harm experienced and/or the risk of harm involved.

A thorough analysis would include, but is not limited to:

- A description of the key facts of the event in enough detail so that one can clearly understand the facts and chronology of what occurred, the severity of the event, and how the potential recipient or potential living donor was affected;
- A review of whether similar events have occurred in the past;
- All of the information needed to identify factors that may have caused or contributed to the outcome, directly or indirectly;
- Analysis of the information to identify actual and potential vulnerabilities and opportunities to reduce risks and improve care;
- Use of the results of the analysis to design improvement actions to address the factors that caused or contributed to the event's occurrence, including factors and processes; and
- Specific plan for implementing, evaluating and monitoring improvement actions (timeframes, responsible parties, measurement strategy to assess effectiveness, etc.).

## **X-104**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

### **§482.96(b)(2)(cont'd)**

**...and must utilize the analysis to effect changes in the transplant program's policies and practices to prevent repeat incidents.**

### **Guideline §482.98(a)**

## **X-109**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

### **§482.98 Condition of Participation:**

**The transplant program must ensure that all individuals who provide services and/or**

supervise services at the program including individuals furnishing services under contract or arrangement are qualified to provide or supervise such services.

## **X-110**

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

### **§482.98(a) Standard: Director of a Transplant Program.**

The transplant program must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant program need not serve full-time and may also serve as a program's primary transplant surgeon or transplant physician in accordance with §482.98(b)... .

#### **Guideline §482.98(a)**

The designated director of a transplant program must be either a transplant surgeon credentialed in the hospital for transplant surgeries or a qualified physician. "Qualified physician" means a physician that is credentialed in the hospital to provide transplant medical services for the specific organ program type.

Serving as the director on a less than full time basis means that the director may continue his/her clinical responsibilities in addition to his/her role in general supervision of the program.

See Tags X-111 through X-114 for the responsibilities of the director of a transplant program.

## **X-111**

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

**§482.98(a)(cont'd) ... The director is responsible for planning, organizing, conducting, and directing the transplant program and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:**

## **X-112**

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

**§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-113**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§482.98(a)(2) Ensuring that tissue typing and organ procurement services are available.**

### **X-114**

**(Rev.)**

**§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-115**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.98(b) Standard: Transplant Surgeon and Physician.**

The transplant program must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

### **X-116**

(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)

**§482.98(b)(1)** The transplant surgeon is responsible for providing surgical services related to transplantation.

#### **Guideline §482.98(b)(1)**

The transplant surgeon determines when consultation from other surgical specialists is indicated and ensures all indicated services are provided.

### **X-117**

(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)

**§482.98(b)(2)** The transplant physician is responsible for providing and coordinating transplantation care.

#### **Guideline §482.98(b)(2)**

Transplant programs may operate differently in regard to the provision of care for transplant recipients. In most cases, the transplant physician is the primary provider of non-surgical transplant services associated with pre-surgical medical issues as well as post-transplant non-surgical services. In this role, the transplant physician has the primary responsibility for ensuring that all non-surgical services required by the recipient are provided. However, in some cases, the transplant surgeon may also serve in this role, which may also be acceptable.

### **X-118**

***(Rev.)***

**§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-120**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

### **§482.98(c)(cont'd)**

... **The clinical transplant coordinator's responsibilities must include, but are not limited to, the following:**

- (1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and**
- (2) Acting as a liaison between a kidney transplant program and dialysis facilities, as applicable.**

### **Guideline §§482.98(c)(cont'd) and (c)(1)-(2)**

Clinical transplant coordinators are important links between transplant recipients/living donors and the transplant program and dialysis facilities, as applicable. A transplant coordinator is often the patient's primary contact for communication and direction on transplantation or donation related activities. This communication involves patients, families, medical team, organ procurement organizations, donor hospitals, and all other members of the transplant team.

The primary purpose of the coordinator is to ensure that all the multidisciplinary needs of the patients are met in all phases of transplantation or donation.

The coordinator is also the primary contact with the ESRD facility in the case of kidney transplant patients. Evidence of the collaboration between the coordinator and the ESRD includes waiting list changes; laboratory results; and changes in medical condition.

## **X-121**

**(Rev.)**

**§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.*

*Advocacy 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.)**

**§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.)***

**§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.)***

**§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.)**

**§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-126**

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

### **§482.98(f) Standard: Resource Commitment.**

The transplant program must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services.

## **X-139**

*(Rev.)*

### **§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-149**

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

### **§482.102 Condition of Participation: Patient and Living Donor Rights.**

In addition to meeting the condition of participation “Patients rights” requirements at §482.13, the transplant program must protect and promote each transplant patient’s and living donor’s rights.

## **X-150**

*(Rev.)*

### **§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.)**

#### **§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-152**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

### **§482.102(a)(2) The surgical procedure;**

#### **Guideline §482.102(a)(2)**

Discussions by the transplant surgeon with the potential recipient would include:

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

## **X-153**

**(Rev.)**

### **§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.)**

### **§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. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§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.)**

**§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 immunodeficiency 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-157**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§482.102(a)(7) His or her right to refuse transplantation; and**

**Guideline §482.102(a)(7)**

The transplant program must inform all transplant candidates of their right to withdraw consent for transplantation any time during the process.

**X-158**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.102(a)(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant program it could affect the transplant recipient's ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.**

**X-159**

***(Rev.)***

**§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 policies 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-160**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.102(b)(1) The fact that communication between the donor and the transplant program will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.**

### **Guideline §482.102(b)(1)**

Requirements in 45 CFR part 160 and subparts A and E of part 164 relate to the privacy of individually identifiable health information and prevention from fraud and abuse related to the provision of or payment for health care for the purpose of protecting the privacy of health information.

Requirements in subpart C of 45 CFR part 164 relate to the security standards for the protection of electronic protected health information, notification procedures in the case of breach of unsecured protected health information, and the privacy, uses, and disclosure of individually identifiable health information.

Accordingly, any information shared between the living donor candidate and the transplant program may not be shared with the potential recipient and/or their families except as permitted by 45 CFR parts 160 and 164.

## **X-161**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§482.102(b)(2) The evaluation process;**

### **Guideline §482.102(b)(2)**

The informed consent process ensures that the donor understands what the evaluation process entails prior to its initiation. Prior to a donor candidate making a decision to undergo an evaluation for donation, they must understand what the process demands, patient and transplant program responsibilities, what determination(s) can be made as the result of an evaluation, and what factors could determine their non-candidacy for donation.

The evaluation process is ongoing, beginning at the time an individual is identified as a possible

candidate for donation and continues until donation. Routine re-assessments, as determined by the program's protocols must be conducted to ensure continued suitability for donation.

## **X-162**

*(Rev.)*

### **§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-163**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

### **§482.102(b)(4) The availability of alternative treatments for the transplant recipient;**

#### **Guideline §482.102(b)(4)**

A potential donor must be made aware of all alternative treatments that are available for the potential recipient which may include the possibility of a deceased donor transplant.

## **X-164**

*(Rev.)*

### **§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.)*



**§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-166**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§482.102(b)(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected;**

**X-167**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§482.102(b)(8) The donor's right to opt out of donation at any time during the donation process; and**

**X-168**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.102(b)(9) The fact that if a transplant is not provided in a Medicare-approved transplant program it could affect the transplant recipient's ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.**

**X-169**

***(Rev.)***

**§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-170**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.102(c)(1) A transplant program served by a single transplant surgeon or physician must inform patients placed on the program's waiting list of:**

- (i) The potential unavailability of the transplant surgeon or physician; and**
- (ii) Whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician.**

### **Guideline §482.102(c)(1)**

The absence of a transplant surgeon or physician may impact a transplant candidate's ability to receive a transplant if an organ becomes available. Transplant programs must disclose the possibility of such an event as well as whether the program has a process to provide an alternate transplant surgeon or transplant physician in such an event prior to the potential recipient undergoing evaluation. Any changes that occur following the informed consent process must also be shared with each candidate on the waiting list.

## **X-171**

**(Rev. )**

**§482.102(c)(2) At least 30 days before a program's Medicare approval is terminated, whether voluntarily or involuntarily, the program must:**

- (i) Inform patients on the program's waiting list and 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; and**
- (ii) Inform Medicare recipients on the program's waiting list that Medicare will no longer pay for transplants performed at the program after the effective date of the program's termination of approval.**

## **X-172**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§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.

**X-184**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.104 Condition of Participation: Additional Requirements for Kidney Transplant Programs.**

**X-185**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.104(a) Standard: End stage renal disease (ESRD) services.**

**Kidney transplant programs must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients... .**

**X-186**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.104(a)(cont'd) ... A kidney transplant program must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.**

**Guideline §482.104(a)(cont'd)**

Transplant programs must have policies in place on how information is shared with dialysis facilities for patients currently receiving dialysis. Transplant programs must have bi-directional communication with the dialysis facility about any waiting list status changes or changes in patient condition. The communications usually include laboratory values and change in inpatient status. There will be communication periodically between the two entities, however, the frequency is determined by patient status changes and the policies of the transplant program.

**X-187**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§482.104(b) Standard: Dialysis services.**

**Kidney transplant programs must furnish inpatient dialysis services directly or under arrangement.**

**X-188**

**(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)**

**§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.*

**Transmittals Issued for this Chapter**

<b>Rev #</b>	<b>Issue Date</b>	<b>Subject</b>	<b>Impl Date</b>	<b>CR#</b>
<u>R200SOMA</u>	02/21/2020	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric	02/21/2020	N/A

Rev #	Issue Date	Subject	Impl Date	CR#
		Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X-Organ Transplant Program and Appendix Z - Emergency Preparedness		
<u>R189SOMA</u>	05/24/2019	New to State Operations Manual (SOM), Appendix X, Survey Protocol and Interpretive Guidelines for Organ Transplant Programs	05/24/2019	N/A

ADVANCED

## 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 its 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]

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