DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-10-Transplant
REVISED

DATE: **March 11, 2016 – Revised May 3, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy – Interpretive Guidelines for the Organ Transplant Conditions of Participation (CoPs)

Memorandum Summary

- **Organ Transplant Interpretive Guidelines Update:** The attached Interpretive Guidelines for the Transplant CoPs at 42 CFR §§ 482.68 through 482.104 are temporarily ON HOLD pending additional revisions, clarifications and corrections.

The attached Guidelines are temporarily on hold pending additional revisions, clarifications, and corrections to the Interpretive Guidelines (IGs) for the Organ Transplant Conditions of Participation at 42 CFR §§ 482.68 through 482.104.

The draft IGs will remain on the CMS web-site as a draft document for information only, with appropriate notations as to their draft status.

We appreciate the comments, questions, and suggestions we received since the original issuance in March 2016, as they alerted us to the need for revision and clarification. Once the IG revisions have been completed and comments addressed, this memorandum will be reactivated and the final IGs posted on the web-site. Until that time, the original Interpretive Guidelines issued in 2008 via policy memorandum SC-08-25, as updated through subsequent Survey and Certification (S&C) policy memoranda, will continue to guide the CMS surveys.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum with regard to the draft status of the attached IGs.

If you have additional questions or concerns, please send an email to the SCG Transplant team at SCG_TransplantTeam@cms.hhs.gov.

/s/
Thomas E. Hamilton

Attachment: Advance Copy- Organ Transplant Interpretive Guidelines

cc: Survey and Certification Regional Office Management

These Guidelines are temporarily on hold pending additional revisions and clarifications to the Interpretive Guidelines (IGs) for the Organ Transplant Conditions of Participation. These IGs will remain on the CMS web-site as a draft document for information only. Once the IG revisions have been completed and comments addressed, this memorandum will be reactivated and the final IGs posted on the web-site.

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal – ADVANCE COPY

Date: XXXX

SUBJECT: Addition of new Appendix X to Medicare State Operations Manual (SOM), Interpretive Guidelines and Survey Procedures for Organ Transplant Programs.

I. SUMMARY OF CHANGES: CMS has established a new appendix in the State Operations Manual that outlines the interpretive guidelines and survey procedures for the Conditions of Participation for organ transplant programs at 42 C.F.R. §§482.72 through 482.104.

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
N	Appendix X/Interpretive Guidelines and Survey Procedures for Organ Transplant Programs/Entire Appendix

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

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

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

These Guidelines are temporarily on hold pending additional revisions and clarifications to the Interpretive Guidelines (IGs) for the Organ Transplant Conditions of Participation. These IGs will remain on the CMS web-site as a draft document for information only. Once the IG revisions have been completed and comments addressed, this memorandum will be reactivated and the final IGs posted on the web-site.

State Operations Manual

Appendix X - Interpretive Guidelines and Survey Procedures for Organ Transplant Programs

Table of Contents
(Rev.)

DRAFT

Transmittals for Appendix X

Attachment A: Organ Transplant Surveys, Interpretive Guidelines:

Definitions	*Abbreviations*
American Board for Transplant Certification	*ABTC*
CMS Certification Number	*CCN*
The Centers for Disease Control	*CDC*
The Centers for Medicare & Medicaid Services	*CMS*
The Centers for Medicare & Medicaid Services Central Office	*CO*
The Centers for Medicare & Medicaid Services Regional Office	*RO*
Clinical Transplant Coordinator	*CTC*
Conditions of Participation	*CoPs*
Conditions for Coverage	*CfCs*
Contract Officer Representative	*COR*
End Stage Renal Disease	*ESRD*
Health Resources and Services Administration	*HRSA*
Hepatitis B Virus	*HBV*

These Guidelines are temporarily on hold pending additional revisions and clarifications to the Interpretive Guidelines (IGs) for the Organ Transplant Conditions of Participation. These IGs will remain on the CMS web-site as a draft document for information only. Once the IG revisions have been completed and comments addressed, this memorandum will be reactivated and the final IGs posted on the web-site.

Definitions	*Abbreviations*
Hepatitis C Virus	*HCV*
Human Leukocyte Antigen	*HLA*
Human Immunodeficiency Virus	*HIV*
Independent Living Donor Advocate	*ILDA*
Institutional Review Board	*IRB*
Licensed Clinical Social Worker	*LCSW*
Licensed Practical Nurse	*LPN*
Licensed Vocational Nurse	*LVN*
Living Donor	*LD*
Lung Allocation Score	*LAS*
Master of Social Work	*MSW*
Model for End Stage Liver Disease	*MELD*
Model for Pediatric End Stage Liver Disease	*PELD*
Organ Procurement Organization	*OPO*
Organ Procurement and Transplantation Network	*OPTN*
Other Vital Data	*OVD*
Peripheral Parenteral Nutrition	*PPN*
Program Specific Reports	*PSR*
Project Officer	*PO*
Potential Living Donor	*Potential LD*
Quality Assessment and Performance Improvement	*QAPI*
Social Worker	*SW*
Scientific Registry of Transplant Recipients	*SRTR*
State Operations Manual	*SOM*
State Survey Agency	*SA*
Statement of Work	*SOW*
Total Parenteral Nutrition	*TPN*
Transplant Program Quarterly Report	*TPQR*
Transplant Candidate	*TC*
Transplant Recipient	*TR*
United Network of Organ Sharing	*UNOS*
United Network of Organ Sharing Identification/OPTN (LD&TR)	*UNOS/OPTN ID*
Western Institutional Review Board	*WIRB*

Definitions:

Phases

Transplant Candidate/Recipient Care Phases:

- *Pre-Transplant/Evaluation: (from the first presentation for evaluation of a potential recipient and placement on the program's waiting list until the time the transplant candidate enters the OR for the transplant surgery)*
- *Transplant Inpatient Stay: (from the time the transplant recipient enters the OR for the transplant surgery until the patient is discharged following the inpatient surgery stay)*
- *Discharge: (from the point the transplant recipient is awake and alert following surgery until actual discharge)*
- *Post-Transplant: (pertaining to QAPI)*

Living Donor Care Phases:

- *Pre-Donation: (from first presentation by the potential donor until the time they enter the operating room (OR) for the donation surgery)*
- *Donor Inpatient Stay: (from the time the donor enters the OR for the donation surgery until donor discharge from the inpatient surgery stay)*
- *Discharge: (from the time when the donor is alert and awake following surgery until discharge)*
- *Post-Donation: (pertaining to QAPI)(from the time of discharge until the care is transferred to donor's primary physician)*

TAG	Regulation	Interpretive Guidelines
X001	**§482.68 – Special Requirements for Transplant Centers**. A transplant center 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.	This tag should be cited as "not met" if any Condition at **§482.72 through §482.104** is found out of compliance. These requirements became effective on June 28, 2007. Survey Procedures Surveyors will only review documents from the three years prior to the date of survey. Kidney and pancreas programs will apply and be surveyed separately for Medicare approval; however, for the pancreas program to receive Medicare approval, the program must be co-located with a Medicare-approved kidney program. To perform combined heart/lung transplants, the transplant hospital must have separately Medicare-approved heart and lung programs. An intestinal/multi-visceral program must be co-located with a Medicare-approved liver program.

TAG	Regulation	Interpretive Guidelines
X001 (cont'd)	(b) In addition to meeting the conditions of participation specified in §482.72 through §482.104, a transplant center must also meet the conditions of participation specified in §482.1 through §482.57.	Transplant surveyors will only be authorized to survey a transplant program under the transplant regulatory requirements, but because the transplant Quality Assessment and Performance Improvement (QAPI) program is a component of the hospital-wide QAPI program, transplant program surveyors must have a clear understanding of the interrelated hospital and transplant program QAPI requirements. If surveyors believe hospital requirements are out of compliance (such as failure to fulfill executive responsibilities to adequately resource the QAPI program, or findings identified in the transplant program survey for the overall organizational QAPI infrastructure or functioning), those findings must be referred to the appropriate CMS Regional Office (RO) and Central Office (CO) Contract Officer Representative (COR) for consideration of an independent authorization to survey the hospital for compliance with the hospital Conditions of Participation (CoPs), which are cited under the Hospital "A Tags" in Appendix A of the SOM. Noncompliance with the hospital CoPs at 42 CFR §482.1 through §482.57 would be identified and cited in a separate Hospital Survey conducted by the State and/or RO after referral.
Blank	**General Requirements for Transplant Centers**	Blank

TAG	Regulation	Interpretive Guidelines
X002	**§482.72 Condition of Participation: OPTN Membership.** A transplant center 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.	The most recent CMS Transplant Program Quarterly Report (TPQR) will provide evidence of current Organ Procurement and Transplantation Network (OPTN) membership. As an OPTN member, the transplant hospital's membership status may fall into one of several possible categories: • Full member, • Conditional approval, • Probation, and/or • Member not in good standing. Transplant programs that are not approved by the OPTN (meaning that they do not have the ability to receive organ offers or to place candidates on the waiting list) are not considered to be operational programs and cannot be approved by CMS for Medicare participation. <u>Survey Procedures</u> Surveyors should review the TPQR during the offsite survey preparation for the program's OPTN membership status. The surveyors should verify this status onsite with the program and allow the program the opportunity to address any discrepancies in the TPQR data. If during the entrance conference the program states they are not a participating member of the OPTN, the surveyors must stop the survey and contact the RO and COR.

TAG	Regulation	Interpretive Guidelines
X002 (cont'd)	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.	Blank

TAG	Regulation	Interpretive Guidelines
X011	**§482.74 Condition of Participation: Notification to CMS** (a) A transplant center must notify CMS immediately of any significant changes related to the center'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:	*In relation to tags X012, X014 and X015, "significant change" for purposes of this section, means any event that is likely to have considerable impact on the program's operations, ability to perform transplants or conduct transplant care, or ability to meet the CoPs.* *Providers must notify CMS CO of the changes described below.* *Significant changes or events about which CMS must be notified include:* • *Personnel changes to the primary transplant surgeon or primary transplant physician;* • *Termination of the OPO agreement; or* • *Program inactivation* *See Tags X012, X014 and X015 for additional detail in each of the key areas.* *For purposes of this section, notifying CMS "immediately" means within seven business days of when the transplant program becomes aware that either a change has occurred or will occur.* *Note: In order to facilitate communication, it is helpful, but not a requirement, for programs to notify CMS when the Transplant Program Administrator or hospital Chief Executive Officer (CEO) changes.*

TAG	Regulation	Interpretive Guidelines
X012	(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center's "primary transplant surgeon" or "primary transplant physician;"	Though the transplant program may have multiple transplant surgeons and/or physicians, OPTN requires that each program must designate a primary transplant surgeon and primary transplant physician. These individuals collectively are responsible for ensuring the ongoing operation of the program and compliance with the OPTN policies, and for notifying the OPTN contractor (the United Network for Organ Sharing, UNOS) if the program deviates from the OPTN policy. The transplant program must notify CMS of these changes by the time OPTN paperwork has been submitted and should not wait for the provisional or actual designation by the OPTN before notifying CMS. If the program notified CMS regarding a change in the primary transplant surgeon or primary transplant physician but has not notified the OPTN, do not cite the deficiency at this tag (which requires notification to CMS). Rather, refer to tag X115 which requires that a program report the designation of a primary transplant surgeon and primary transplant physician to the OPTN. If the program has not notified CMS of a change in the primary transplant surgeon or primary transplant physician, inform the transplant program that they must immediately (within 7 days) send a letter notifying CMS of the change, even though the citation has been recorded. CMS does not require information on personnel changes other than the primary transplant surgeon and primary transplant physician. If the program does have a personnel change that results in the inability to meet all OPTN requirements and CMS CoPs, the program must contact CMS to voluntarily inactivate the transplant program. Such personnel changes could include, but are not limited to, the absence of a key personnel function (such as absence of cardiology support, or nephrology support for kidney programs or hepatology support for liver programs). <u>Survey Procedures</u> Prior to going onsite, review the most recent TPQR and note the primary transplant surgeon and primary transplant physician for each transplant program. During the survey, verify that these designations remain current. Cite a deficiency if the existing designations are not consistent with the TPQR. In the cited deficiency, document the date the designation of the primary transplant surgeon or primary transplant physician actually changed for the transplant program. Do not cite a deficiency if the program can provide evidence in writing that CMS was immediately notified of the change.

TAG	Regulation	Interpretive Guidelines
X014	(2) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and	Notifying CMS "immediately" means within seven business days of when the transplant program becomes aware that a termination of the Organ Procurement Organization (OPO) agreement with the hospital within which the transplant program is located has occurred or will occur. Survey Procedures A deficiency should be cited if the transplant program failed to notify CMS of the termination in a timely manner. The surveyor informs the transplant program that they must also send a letter to CMS requesting a change in the OPO under the OPO Conditions for Coverage (CfCs) at 42 CFR §§486.301-486.348.

TAG	Regulation	Interpretive Guidelines
X015	(3) Inactivation of the transplant center. (b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to): (1) Requesting additional information; (2) Analyzing the information; or (3) Conducting an on-site review.	Please refer to 42 CFR section 488.61(e) Transplant Center Inactivity. A transplant program may not be inactive for more than 365 days within a 3 year period from the date of initial inactivation. Prior to the 365th day, the program may reactivate at any time if it is meeting all CoPs. After the 365th day, the transplant program will no longer be able to participate in the Medicare program. The transplant program may choose to voluntarily withdraw from Medicare participation, or approval will be revoked by CMS. A transplant program must timely notify CMS when it will not be or is not accepting organs for a period exceeding 14 consecutive days. Inactive programs are still surveyed for compliance with all CMS requirements. Even if the program is not accepting current organ offers, the program continues caring for transplant candidates and recipients and receiving payment from Medicare for such services. See 42 CFR §482.102(c)(3) for notifications to the patient. <u>Survey Procedures</u> CO will provide the TPQR report to the survey team, which will provide information about any notifications CMS has received regarding transplant program inactivity with CMS. Compare these inactive time periods with reported inactivity in the TPQR to assess whether or not CMS was notified of periods of inactivity as required.

TAG	Regulation	Interpretive Guidelines
X021	**§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.	This section of the regulation applies to programs that perform pediatric transplants. A transplant program can apply for and be approved for both an adult (age 18 and over) and a pediatric (under age 18) transplant program for the same organ type. If the transplant hospital has two separate programs, they must be surveyed separately. If the transplant hospital is seeking approval as a pediatric program and performing transplants on adult recipients, then a sample of those adult transplant recipients must be included in the survey sample for review. If a transplant hospital is seeking separate approval of an adult and a pediatric program, both of the programs will need to be surveyed separately and will include separate medical record samples for review. Transplant programs that serve both adult and pediatric recipients may choose to apply for separate approval as adult and pediatric programs, but are not required to do so. If a program seeks a single approval for both age groups, the program must apply for the primary age group that it serves. That is, a program that provides more than 50 percent of its transplants in a 12-month period to pediatric recipients must apply as a pediatric program. A program that provides more than 50 percent of its transplants in a 12-month period to adult recipients must apply as an adult program. <u>Survey Procedures</u> Review the CMS TPQR to determine if the program is seeking approval for separate adult and pediatric programs or a single program that provides both adult and pediatric transplants of the same organ type. Determine the survey sample. The survey of a single program providing adult and pediatric transplants must include both recipient types in the survey sample. Programs that are surveyed separately must have complete adult and complete pediatrics samples for survey.

TAG	Regulation	Interpretive Guidelines
X021 (cont'd)	(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.	Blank

X022	*(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*	*The transplant hospital has the option to apply for separate adult and pediatric programs or for a single program that performs both adult and pediatric transplants. However, this section applies only if the adult and pediatric transplant programs are seeking Medicare approval as a single adult program. If the program performs more transplants for adult recipients, then the adult program is the primary program; and if the program performs more transplants for pediatric recipients, then the primary program is the pediatric program. If the adult program is the primary program, then the adult program must be approved in order for the pediatric transplants to occur.* *Programs must be approved for the majority age group. Programs are required to be approved for the majority age group as long as the group that does not have its own Medicare approval does not exceed 50-percent of the total number of transplants, based on TPQR data.* *A program approved only for adult transplant may perform pediatric transplants as long as the number of pediatric cases remains fewer than 50-percent of the total number of transplants.* *Conversely, a program approved only for pediatric transplant can perform transplants on adults as long as the adult cases do not exceed 50-percent of the total number of transplants.* *It is the program's choice for which age group it will seek approval for (adult or pediatric). If, however, the balance between the age groups varies from year-to-year (i.e., sometimes adult transplants are more than 50-percent and sometimes pediatric transplants are more than 50-percent), the program might want to consider Medicare approval for each age group separately. However, a program that exceeds the 50-percent level in a single, 12-month period, and does not expect such an occurrence to continue, will not be required to obtain approval separately for the two age groups.* *If an adult transplant program that performs some pediatric transplants either voluntarily withdraws or is terminated from the Medicare program thus losing its approval, it cannot perform adult or pediatric transplants on Medicare beneficiaries. Conversely, if a pediatric program that performs some adult transplants either voluntarily withdraws or is terminated from the Medicare program, it cannot perform pediatric or adult transplants on Medicare beneficiaries.* *Surveyors should consider any additional or more recent information the transplant program may provide to supplement the TPQR report on the number of transplants performed over the previous 12-months.* • *Adult only >50% and Pediatric <50% is compliant* • *Adult only <50 and Pediatric >50 cite deficiency* • *Pediatric only >50 and Pediatric <50 cite deficiency* • *Pediatric only <50 and Pediatric >50 is compliant* *Separate adult and pediatric programs: Balance of pediatric and adult is not a consideration. Any number that meets the volume requirement is compliant.*

TAG	Regulation	Interpretive Guidelines
	transplants.	

TAG	Regulation	Interpretive Guidelines
X022 (cont'd)		*Note: Adult programs should be aware that even if their pediatric cases are under 50-percent of the total cases, pediatric outcomes will be viewed separately, and if pediatric outcome requirements are not met, the approved adult program (even if in compliance with outcome requirements for adults) could be cited for noncompliance with outcomes requirements.* *Survey Procedures* *In reviewing a pediatric transplant program, determine:* *1. Whether or not there is a separate adult program for this organ type; and* *Based on the TPQR data, whether or not the pediatric program performed 50-percent or more of all transplants on pediatric patients over the previous 12-months. If the answer to this is "yes," then the single pediatric program must be approved as a pediatric program in order to perform any adult transplants.*
X023	*(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.*	*Refer to guideline at X022.*

TAG	Regulation	Interpretive Guidelines
X023 (cont'd)	(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.	Blank

TAG	Regulation	Interpretive Guidelines
X024	(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;	Tags X024, X025, and X026 apply only to transplant programs that are approved through the alternative approval process defined in the Omnibus Budget Reconciliation Act of 1987. <u>Survey Procedures</u> Prior to going onsite, review the TPQR to determine whether the pediatric heart program is seeking alternate approval under this section. The TPQR will provide the CMS certification number (CCN) and name of the hospital (associated facility) with a Medicare-approved heart transplant program that is jointly operating the approved pediatric transplant program. Review the joint operating agreement between the hospital with a pediatric heart transplant program and the affiliated hospital with a Medicare-approved heart transplant program to ensure that the agreement clearly delineates the responsibilities of each party. This agreement must include, but is not limited to: • A commitment by the affiliated heart transplant hospital seeking approval under the Omnibus Budget Reconciliation Act of 1987 and the associated Medicare-approved facility to jointly operate the pediatric heart transplant program; and, • Confirmation that the affiliated facility is Medicare-approved to perform heart transplants.

TAG	Regulation	Interpretive Guidelines
X025	(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and	For pediatric transplant programs that are operated jointly by the hospital and another Medicare-approved facility, the program should share the same transplant surgeons, QAPI program, patient protocol, and selection criteria. The program must be jointly operated by the hospital and another Medicare-approved heart transplant program and the two programs must be operating in a unified manner. If areas of key differences exist in how the two programs are operated, cite a deficiency under this tag unless the differences are the result of the specialized services or needs for pediatric transplant candidates/transplant recipients as required in Tag X026 below. Examples of differences between the two programs in the transplantation process that the surveyor will need to assess could include: • Different transplant surgeons perform the surgeries for transplant recipients; • Different processes for analyzing and reviewing adverse events; • Different transplant candidate informed consent protocols; and • Different transplant candidate selection criteria or different processes for granting exceptions to those criteria. The key question for surveyors in assessing differences is, "Are these differences the result of the specialized services or needs for pediatric transplant candidates/transplant recipients if other operations are unified among the two programs?" If the response is "yes," then this would not be considered a deficiency. Listed below are examples of differences that may exist between two programs that a surveyor would assess as being specific to the needs of pediatric transplant candidates/transplant recipients, and would not be considered evidence that the program is not operating in a unified manner. Example 1: The review of medical records indicates that there is a designated transplant coordinator (with expertise in pediatric transplant candidates/transplant recipients) that does not work with the adult transplant candidates/transplant recipients from the associated heart transplant program. This is permissible and would not be considered out of compliance since this is an example of specialized services for pediatric transplant candidates/transplant recipients. Example 2: A transplant program's informed consent practices for the pediatric heart program may be different than the adult heart program. One set of materials could be provided to pediatric transplant candidate/transplant recipients (presented at a level understood by children) with more detailed information provided to parents/guardians. The adult program may not follow this same procedure.

TAG	Regulation	Interpretive Guidelines
X025 (cont'd)	Blank	An example of a program operating in a non-unified manner would include a program that has two separate QAPI programs that each monitor their own program, and the QAPI reports and activities are not shared or discussed with one another. Survey Procedures Surveyors will need to visit both programs to verify that the programs are jointly operated by the hospital and another Medicare-approved heart transplant program and that the two programs are operating in a unified manner. Review the policies and procedures for the unified pediatric heart transplant program and the policies and procedures for the associated heart transplant program to identify any differences in the areas of staffing, quality improvement programs such as, but not limited to, transplant candidate/transplant recipient protocols, oversight of the program, and/or transplant candidate selection criteria. Review a sample of medical records for pediatric heart transplant candidates/transplant recipients, and heart transplant candidates/transplant recipients from the associated heart transplant program to determine if there are any differences between the two programs in the transplantation process (from pre-transplant to post-transplant follow-up) that indicate that the two programs are not operating in a unified manner.

TAG	***Regulation***	***Interpretive Guidelines***
X026	*(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.*	*Survey Procedures* *Review the joint operating agreement to ensure that it contains a sufficient description of the specialized facilities, services, and personnel that the associated facility and the pediatric heart transplant program are required to commit for pediatric heart transplant candidates/recipients.* *This description may include, but is not limited to:* *1. What specialized facilities (e.g., equipment, transplant candidate/transplant recipient areas) will be provided for pediatric heart transplant candidate/transplant recipients;* *2. What special services are available for pediatric heart transplant candidate/transplant recipients (e.g., a designated transplant coordinator for pediatric candidate/transplant recipients, a pediatric psychologist, or child life specialist); and* *3. What are the unique qualifications and competencies that the transplant personnel must have to care for pediatric heart transplant candidate/transplant recipients, such as expertise or training in pediatric transplantation (e.g., surgical issues, anesthesia protocols, or surveillance of organ rejection in infants or young children)?* *Review the last survey of the associated heart transplant program to see if any deficiencies cited for that program indicate problems in providing the specialized facilities, services and personnel required by pediatric heart transplant candidate/transplant recipients under the jointly-operated program.*
Blank	***Transplant Center Data Submission, Clinical Experience, and Outcome***	*Blank*

TAG	Regulation	Interpretive Guidelines
X031	**§482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Centers.** Except as specified in paragraph (d) of this section, and §488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.	Note: Paragraph (d) of 42 CFR §482.80 refers to those programs that are exempt from clinical experience and/or outcome requirements. Since the items listed in paragraph (d) are not surveyed, they are not part of these guidelines. A description of these exceptions can be found in the regulation text. During the survey process, all transplant recipients served by the transplant program will be included in the sample for review. For example, the onsite review for a pediatric program must also include any adults served by that program in the sample of transplant recipient records, interviews, etc. The survey process will also assess the program's compliance with the requirements for data submission and the outcome report(s) that encompass all transplant recipients regardless of age that are served by that program. The outcomes measurements for adult and pediatric transplant recipients will be reviewed separately for all programs using the Scientific Registry of Transplant Recipients (SRTR) Program Specific Report (PSR). If a program chooses to apply as a single program that includes both adult and pediatric transplant recipients, any outcome requirements that apply must be met separately for patient and graft survival for each age group (both pediatric and adult transplant recipients) served by that transplant program.

TAG	Regulation	Interpretive Guidelines
X032	(a) Standard: Data Submission. No later than 90 days after the due date established by the OPTN, a transplant center 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.	Programs must submit accurate required data to the OPTN. This includes submitting the completed OPTN forms for transplant candidate registration, transplant recipient registration and follow up, post-transplant malignancy, and living donor (LD) registration and follow up as required by OPTN. The regulation requires that at least 95-percent of the required data are submitted within 90 days of the due date established by the OPTN. Survey Procedures Prior to the onsite survey, review the most recent TPQR for the program. Cite a deficiency if the submission percentage of the required forms recorded on the TPQR is less than 95-percent. The transplant program cannot provide data to surveyors onsite to demonstrate they are in compliance with data submission requirements. If a program was not required to submit any forms during the time period assessed in the TPQR, the number of forms due will be listed as 0, and the percentage compliance will be listed as 0-percent. This is not considered a deficiency.

TAG	Regulation	Interpretive Guidelines
X033	(b) Standard: Clinical Experience. To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a12-month period.	"Initial approval" means the transplant program is new to Medicare and has not been previously approved, or if approved in the past, is not currently Medicare-approved. The following types of programs are subject to a clinical experience requirement of 10 transplants performed over a 12-month period for initial approval: • Adult Heart-Only • Adult Lung-Only • Adult Liver • Adult Intestinal and/or Multivisceral Note: For kidney transplant programs, refer to tag X036. Survey Procedures Review the most recent TPQR for the number of transplants performed over the previous 12-month period. Cite a deficiency if a program has performed fewer than 10 transplants over a 12-month period unless the transplant program can provide more recent data than the current TPQR data that shows that the transplant program performed 10 transplants over a 12-month period. A program may also meet this requirement as follows: • An adult heart-only program may include the number of adult heart/lung transplants performed by the same transplant team(s) who routinely performs heart-only or lung-only transplants at the same hospital, for the purpose of compliance with this standard. • Transplants performed on pediatric transplant recipients can be considered for adult clinical experience, but only when a recipient warrants adult treatment as determined by the transplant program.

TAG	***Regulation***	***Interpretive Guidelines***
X033 (cont'd)	*blank*	*The surveyor should determine whether or not a transplant team that performs the multi-organ transplant can be considered "the same team" that performs the single organ transplant. Performance of the multi-organ transplant by the same surgeon(s) that perform the single-organ transplant can be considered as persuasive evidence in most cases, but there may be circumstances in which there are other substantial differences in the support teams and other key personnel involved in the transplantation process (e.g., physicians, clinical transplant coordinators, nurses, etc.), in which a determination could be made that this is not "the same team."* *Note about #2, and #3 above: The exceptions described above allow the clinical experience gained in a multi-organ transplant (generally, a more complex surgery) to be counted in the clinical experience requirements for a single-organ transplant (which would generally be less complex), provided that the same transplant team(s) performs both the single and multi-organ transplants.* *Note: Consistent with OPTN policy, multi-organ transplants not addressed under the combination types noted above (Adult Heart-Only, Adult Lung-Only, Adult Liver, Adult Intestinal and/or Multivisceral) would be counted as one for each organ type. For example, a combined liver/kidney transplant would be counted as one liver and one kidney separately.* *To determine the level of deficiency for the clinical experience (i.e., volume) requirement for initial approval under §482.80(b):* • *If the transplant program has performed 8 or more transplants in the past 12-months, cite a **standard** level deficiency.* • *If the transplant program has performed less than 8 transplants in the past 12-months, cite a **condition** level deficiency.*

X035	*(c)Standard: Outcome requirements. CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.* *(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center'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 Beneficiaries (SRTR) center-specific report.* *(2) CMS will not consider a center's patient and graft survival rates to be acceptable if:*	*Programs must meet outcome requirements for one year patient and graft survival. Survival data is analyzed to compare the expected one year survival for grafts and patients to the actual survival of grafts and patients. Comprehensive statistical analysis ensures the expected survival rates are risk-adjusted based on various risk factors among the patient population in each program.* *The three outcome thresholds for compliance are as follows: observed survival rate divided by the expected survival rate (O/E) is <1.5, the observed survival rate minus the expected survival rate (O-E) is <3.0, and the one-sided p-value is < 0.05.* *The program types subject to this requirement include:* *• Adult Kidney-Only* *• Adult Heart-Only* *• Adult Lung-Only* *• Adult Liver;* *• Pediatric Kidney-Only (Includes only 1-year graft survival)* *• Pediatric Heart-Only* *• Pediatric Lung-Only* *• Pediatric Liver* *Survival Procedures* *Review the TPQR to determine if the program does or does not meet both outcome requirements for patient and graft survival. If the TPQR indicates that the outcome requirements have not been met, cite a deficiency. The transplant program cannot provide data onsite during a survey to demonstrate past or current compliance with outcomes. Programs that do not meet the outcome requirements have an opportunity to provide data and supporting documentation related to non-compliant outcomes if they elect to apply for consideration of mitigating factors. For initial applications, mitigating factors consideration may be requested only for the outcomes, clinical experience or data submission requirements, and not for any other program deficiencies.*

X035 (cont'd)	*(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 1.5.* *(d) Exceptions(1) A heart-lung transplant center 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 center.*	*For information about the Mitigating Factors Process: Consideration of Mitigating Factors: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Transplant.html*

X035 (cont'd)	*(2) An intestine transplant center 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 center.* *(3) A pancreas transplant center 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 center.* *(4) A center 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*	*Blank*

TAG	Regulation	Interpretive Guidelines
	transplant center.	
X035 (cont'd)	*(4) A center 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 center.*	*Blank*
X036	*(5) A kidney transplant center that is not Medicare-approved on the effective date of this rule (June 28, 2007) is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.*	*For new kidney programs that are not Medicare-approved as of June 28, 2007, the program must perform at least 3 transplants within the 12-months prior to requesting initial approval.* *<u>Survey Procedures</u>* *Review the most recent TPQR for the number of transplants performed over the previous 12-month period. Cite a deficiency if a program has performed fewer than 3 transplants over a 12-month period unless: There were adult kidney/pancreas transplants performed by the same transplant team(s) that routinely perform kidney transplants at the same hospital, that, when added to the number of adult kidney-only transplants, would total 3 or more and show compliance with this standard. For example, if there were 2 adult kidney/pancreas transplants performed and 1 kidney-only adult transplant performed by the same team at the same transplant hospital, a deficiency would not be cited, because the kidney-only program would be considered to have performed 3 transplants. (Kidney-only programs require 3 kidney transplants for initial approval).*

TAG	Regulation	Interpretive Guidelines
X041	**§482.82 Condition of participation: Data Submission, Clinical Experience, and Outcome Requirements for Re-approval of Transplant Centers.** Except as specified in paragraph (d) of this section, and §488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.	As detailed in the guidance below for Tags X042, X043, and X045, programs must submit required data, meet clinical experience thresholds (minimum number of transplants), and maintain outcomes compliance for one year patient and graft survival. Note that §482.82(d) refers to those programs that are exempt from clinical experience and/or outcome requirements. Since the items listed in paragraph (d) are not surveyed, they are not part of these guidelines. A description of these exceptions can be found in the regulation text. During the survey process all patients, both adult and pediatric, served by the transplant program will be included in the sample of patient records and interviews used to assess the program's compliance with the requirements for data submission and outcome requirements. The outcomes data for adult and pediatric patients will be reviewed separately for all programs using the SRTR PSR. If a program is approved as a single program, including both adult and pediatric patients, the outcome requirements must be met for patient and graft survival for both pediatric and adult patients served by that transplant program.

TAG	Regulation	Interpretive Guidelines
X042	(a) Standard: Data Submission No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed during the prior 3 years. 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.	Programs must complete and submit accurate data to the OPTN. This includes submitting the completed OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, post-transplant malignancy and living donor (LD) registration and follow-up. The regulation requires that at least 95-percent of the required data are submitted within 90 days of the date established by the OPTN. <u>Survey Procedures</u> Prior to the onsite survey, review the most recent TPQR for the program. Cite a deficiency if the submission percentage of the required forms recorded on the TPQR is less than 95-percent. The transplant program cannot provide data to surveyors onsite to demonstrate they are in compliance with data submission requirements. If a program was not required to submit any forms during the time period assessed in the TPQR, the number of forms due will be listed as 0, and the percentage compliance will be listed as 0-percent. This is not considered a deficiency.

X043	*(b) Standard: Clinical Experience. To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the prior 3 years.*	*Programs as listed below must perform an **average** of 10 transplants per year. The timeframe for the re-approval period is from the previous approval of the program to the current re-approval survey. A program's inactivity does not create an exemption from this regulatory requirement.* *The following types of programs are subject to clinical experience requirements to be considered for re-approval:* *• Adult Heart-Only* *• Adult Lung-Only* *• Adult Liver* *• Adult Intestinal and/or Multivisceral* *• Adult Kidney-Only* *Survey Procedures* *Review the most recent TPQR for the **average** number of transplants performed during the re-approval period.* *If the program is subject to the clinical experience requirements and the **average** number of transplants performed is less than 10 per year (based on the information from the TPQR), cite a deficiency unless:* • *The transplant program can provide more recent data that shows an average of 10 transplants per year during the re-approval period; or* • *An adult kidney-only transplant program demonstrates, that a sufficient number of adult kidney/pancreas transplants were performed by the same transplant team(s) who routinely performs kidney-only transplants. Additionally, this team performs all of the above mentioned transplants at the same hospital.* *Transplants performed on pediatric transplant recipients can be considered for adult clinical experience (i.e. volume), but only when a recipient warrants adult treatment as determine by the transplant program.* *The surveyor must determine whether or not a transplant team that performs the multi-organ transplant can be considered "the same team" that performs the single organ transplant. Performance of the multi-organ transplant by the same surgeon(s) that perform the single-organ transplant can be considered as persuasive evidence in most cases, but there may be circumstances in which there are other substantial differences in the support teams and other key personnel involved in the transplantation process (e.g., physicians, clinical transplant coordinators, nurses, etc.), in which the determination could then be made that it is not "the same team."* *Note about #2, #3, and #4 Above: The exceptions described above allow the clinical experience gained in a multi-organ transplant (generally, a more complex surgery) to be counted in the clinical experience requirements for a single-organ transplant (which would generally be less complex), provided that the same transplant team performs both single and multi-organ transplants.*

TAG	***Regulation***	***Interpretive Guidelines***
X043 (cont'd)	*Blank*	*Note: Consistent with OPTN policy, multi-organ transplants not addressed under the combination types noted above would be counted as one for each organ type. For example, a liver/kidney transplant would be counted for both liver and kidney.* *To determine the level of deficiency for the clinical experience (i.e., volume) requirement for program re-approval under §482.82(b):* • *If the transplant program has performed an average of 8 or more transplants per year over the re-approval period and has performed at least 4 transplants in the past 12-months, cite a deficiency at the standard level.* • *If the transplant program has performed an average of 7 or fewer transplants per year over the re-approval period, cite the deficiency at the* ***condition*** *level. Please note that a program's inactivation does not create an exception to the clinical experience requirements.*

TAG	Regulation	Interpretive Guidelines
X045	(c) Standard: Outcome requirements. CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants. (1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTR center-specific report. (2) CMS will not consider a center's patient and graft survival rates to be acceptable if:	Programs must meet outcome requirements for one-year patient and graft survival. Survival data is analyzed to compare the expected survival for grafts and patients to the actual survival of grafts and patients. Comprehensive statistical analysis is used by the SRTR to calculate the expected survival rates which are risk adjusted based on various risk factors for the patient population in each program, and the donor and organ characteristics. The three outcome thresholds for compliance are as follows: observed survival rate divided by the expected survival rate (O/E) is <1.5, the observed survival rate minus the expected survival rate (O-E) is <3.0, and the one-sided p-value is < 0.05. The program types subject to outcome requirements include: • Adult Kidney-Only; • Adult Heart-Only; • Adult Lung-Only; • Adult Liver; • Pediatric Kidney-Only (Includes only 1-year graft survival); • Pediatric Heart-Only; • Pediatric Lung-Only; and • Pediatric Liver. To determine the level of deficiency for transplant program outcomes (i.e., patient and graft survival) requirement for program re-approval under §482.82(c): • Cite a program at **standard** level if they are out of compliance with the CoP outcomes in the most recent SRTR report. • Cite a deficiency at the **condition** level if the program is out of compliance during the most recent SRTR and 1 other report in the last four cohorts.

X045 (cont'd)	*(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and 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 1.5.* *(d) Exceptions(1) A heart-lung transplant center 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 center.*	*Survey Procedures* *Review the TPQR to determine if the program does or does not meet both outcome requirements. If the TPQR indicates that the outcome requirements have not been met, cite a deficiency. The program cannot provide data onsite to surveyors to demonstrate they are in past or current compliance with the outcome requirements. The TPQR information already considers whether a program is required to meet outcome requirements, and uses the SRTR PSR for each program type. Programs that do not meet the outcome requirements have an opportunity to provide additional documentation related to noncompliant outcomes for consideration if they elect to apply for mitigating factors. For information about the Mitigating Factors Process: Consideration of Mitigating Factors, available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Transplant.html*

X045 (cont'd)	*(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 1.5.* *(d) Exceptions(1) A heart-lung transplant center 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 center.* *(2) An intestine transplant center is not required to comply with the outcome requirements in paragraph (c) of this section for intestine, combined liver-intestine, and multivisceral transplants performed at the*	*Blank*

TAG	Regulation	Interpretive Guidelines
	center.	
X045 (cont'd)	*(3) A pancreas transplant center 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 center.* *(4) A center that is approved to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section to be re-approved.*	*Blank*
Blank	***Transplant Center Process Requirements***	*Blank*

X051	***§482.90 Condition of Participation: Patient and Living Donor Selection***. *The transplant center 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 center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.*	*Transplant programs must have written selection criteria for the selection of transplant candidates to be placed on the transplant waitlist and, if applicable, potential LDs. The program must have policies in place to document how the program will apply the written selection criteria.* *The transplant program's policies and procedures must contain at least the following:* • *A requirement that transplant candidates receive a psychosocial evaluation, if possible, before placement on the waitlist,* • *A requirement for mandatory blood typing which is documented in the patient's medical record prior to placement on the waitlist,* • *Specific selection criteria used by the program for the potential transplant candidate/LD are documented into the medical record,* • *The process and documentation in the medical records for approving exceptions outside of the selection criteria,* • *A requirement that transplant candidates and, if applicable, their dialysis facilities, must be provided copies of the program's selection criteria when requested by either or both, and* • *A fair and non-discriminatory process for determining suitability for transplantation and organ acceptance.* *LD selection criteria must be must be consistent with general principles of medical ethics, in writing, and contain at least the following:* • *A requirement that a prospective LD receives a psychosocial evaluation prior to donation,* • *A requirement to document in the LD's medical records his/her suitability for donation, and* • *A requirement to document that the LD was given the information needed in order to be able to provide informed consent.* *Survey Procedures* *Review the written patient selection criteria to ensure that the items listed above are included in the transplant program policies and procedures. Ask to attend the selection committee meeting or the discussion of selecting a transplant candidate for the wait list to determine if the program is following its policy with respect to application of the selection criteria.* *In surveying the standards at X052 through X060 of the Condition at X051 (42 CFR §482.90), surveyors will evaluate whether or not each standard under this Condition is addressed and followed by the program. Review each program's policies and procedures. Each program must have written selection criteria for potential transplant recipients and LDs, if LD transplants are performed. The selection criteria are the factors specific to each organ type that the program has determined to be key factors for determining a candidate's suitability for transplant, for placement on the waiting list, and in the case of LD transplants, suitability for donation.*

X052	*(a) Standard: Selection. Patient selection criteria must ensure fair and non-discriminatory distribution of organs.*	*The selection criteria (medical, psychosocial, financial, etc.) must clearly define the characteristics of the transplant candidates for whom the program will and will not provide transplant services. These criteria may not exclude groups of individuals based on factors such as, but not limited to, race, ethnicity, religion, national origin, gender, or sexual orientation.* *A review of patient selection criteria in relation to fair and non-discriminatory distribution of organs requires consideration of the impact of transplant program policies and procedures that may create unfairness or discrimination.* *Discrimination can mean exclusion of those who should be included on the waitlist, or inclusion of those who do not meet selection criteria.* *The distribution of organs is not a CMS responsibility; however, policies and procedures, and actions by the transplant program can impact how transplant candidates are affected by the allocation system.* *Survey Procedures* *Review the process of transplant candidate selection, including the application of written selection criteria. The following scenarios describe a potential concern for fairness and non-discrimination:* *1. Patients were evaluated, determined to meet the selection criteria, but were not listed.* *2. Patients were evaluated, determined not to meet the selection criteria, but were listed.* *Review the transplant program's written patient selection criteria and medical records to ensure that individual factors such as race, ethnicity, religion, national origin, gender, or sexual orientation are not used to exclude potential transplant candidates from selection for the waitlist. The selection criteria (medical, psychosocial, financial, etc.) must clearly define the characteristics of the transplant candidates for whom the program will and will not provide transplant services. Programs may apply clinical judgment to reach a selection decision, and in each case that decision should be documented in the medical record. Exceptions that are made to include individuals that do not meet the selection criteria, or to exclude individuals who do meet selection criteria, must be clearly documented with the justification for the decision in the medical record.* *Review the complete list of the transplants performed by the program within the last re-approval period. The list should include, at a minimum: name, address, country of primary residence, race, and gender. Compare the transplant program's transplant candidate selection criteria and the list of transplants performed during the last re-approval period for any cases that suggest the program's selection criteria are not being followed or that the selection criteria are unfair or discriminatory.*

TAG	***Regulation***	***Interpretive Guidelines***
X052 (cont'd)	*Blank*	*If cases of unfair or discriminatory distribution of organs by the program are identified, those patterns may indicate that the national organ allocation OPTN policy is not being followed appropriately. In those cases, surveyors must contact the appropriate CMS project officer (PO) and CMS RO for further instructions.*

TAG	Regulation	Interpretive Guidelines
X053	(1) Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.	In nearly all cases, the transplant program must conduct and document the psychosocial evaluation conducted on a prospective transplant candidate before his/her placement on the waitlist. However, conducting a psychosocial evaluation is not always possible, for example, in emergency situations or when the patient is very young. The psychosocial evaluation is not complete until the selection committee has heard and considered the findings prior to transplant candidate placement on the waitlist. While the transplant program has flexibility in the specific psychosocial evaluation tool(s) to be used, the psychosocial evaluation is expected to be completed and to be focused on the individual's suitability for transplantation. It is expected that a psychosocial evaluation of this nature would be conducted by transplant program qualified professional healthcare personnel (e.g., Masters of Social Work (MSW), Licensed Clinical Social Worker (LCSW), psychiatrist or psychologist) and would address 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 • Mental health history, including substance and alcohol use or abuse and how it may impact the success or failure of organ transplantation. The psychosocial evaluation must be age-appropriate. Similar to psychosocial evaluations in other areas, in cases of young pediatric transplant candidates, the evaluation would include interviews with the parents/guardians. <u>Survey Procedures</u> Review the written patient selection policy to verify that it contains requirements for transplant candidates to receive a psychosocial evaluation by qualified professional healthcare personnel (e.g., MSW, LCSW, psychiatrist or psychologist) in all situations in which it is possible to do so prior to placement on the waiting list. The transplant program policy must include: • The length of time for which the psychosocial evaluation is deemed to be current, • 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 manner and method of communicating the psychosocial evaluation findings into the selection process.

TAG	Regulation	Interpretive Guidelines
X053 (cont'd)	Blank	Verify in transplant recipient medical records that the psychosocial evaluation was completed by a person authorized under the program's policy before the candidate is placed on the UNet^{SM} and transplant program's waiting lists. (UNet^{SM} is the secure Internet-based transplant database operated by the contractor for the OPTN/UNOS for the nation's transplant programs and OPOs to register transplant candidates and LDs on the waiting list and for transplantation and living donation.) In each case, if a referral was made for further psychosocial evaluation before it could be determined whether an individual was to be placed on the UNet^{SM} waiting list, verify that additional evaluation was completed as required by the transplant program's policies and procedures for follow-up and referral. It is expected that in nearly all cases, a psychosocial evaluation is possible and should be conducted as part of the determination of whether or not someone would be a suitable transplant candidate. There are rare or emergency situations when a psychosocial evaluation cannot be completed prior to transplantation due to the transplant candidate's medical condition and the absence of family or a transplant candidate representative that can provide information/insight into the psychosocial history of the transplant candidate. In such cases, verify that documentation is included in the transplant candidate's medical record that describes the reason a psychosocial evaluation was waived or unable to be completed. Examples of these exceptional or emergent circumstances may include untreatable encephalopathy, massive liver trauma, and acute (fulminant) liver failure (e.g., acetaminophen overdose, mushroom poisoning).
X054	(2) Before a transplant center 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.	Survey Procedures: Review the transplant program's patient selection policy to verify that the program requires documentation of the transplant candidate's blood type in the medical record before placing a transplant candidate on the waiting list. Review a sample of the medical records of transplant candidates currently on the program's waiting list to confirm that the program is following its policy. Determine the date each transplant candidate was activated on the UNet^{SM} waiting list, and confirm in the medical record that the blood type of the transplant candidate was determined prior to the activation date.

TAG	Regulation	Interpretive Guidelines
X055	(3) When a patient is placed on a center'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.	The selection criteria used for determination of when a potential transplant candidate is placed on the waiting list or is selected to receive a transplant must be documented in the transplant candidate's medical record. The program must document the actual diagnosis and the selection criteria that the transplant candidate meets. If the transplant candidate does not meet the criteria but was placed on the waiting list, the reasons for the exception and listing despite not meeting the selection criteria would also need to be documented. The program's policy must reflect the decision of the multidisciplinary team. Documentation of the selection criteria used may be in narrative or checklist form, as long as it is verified by the signature of at least one member of the multidisciplinary team. Ensure that the policy defines the selection criteria determination time-frames for re-evaluation to make sure the candidate's condition continues to meet the transplant program selection criteria. <u>Survey Procedures</u> Review a sample of medical records of transplant candidates on the transplant program's waiting list to determine if there is documentation of the specific selection criteria that were used to place the transplant candidate on the waiting list. Confirm that the criteria used are consistent with the program's policy. During the review of the transplant candidate's medical records, confirm that it is still appropriate for the individual to receive a transplant (i.e., the selection criteria continue to be met, and that any re-evaluation(s) required by the program's selection criteria policies/procedures have been conducted). Consider the date of the documented selection criteria and the date of the transplant or potential transplant to determine if the selection criteria continue to be met. Cite a deficiency if the selection criteria used to place a transplant candidate on the waiting list are not documented in the medical record, or if the selection criteria used do not follow the program's written patient selection criteria. Cite a deficiency if there is evidence that an exception has been made that is inconsistent with the program's transplant candidate selection policies. The policy must describe the complete process for making, justifying and documenting exceptions. In these cases, documentation in the medical record must indicate that those circumstances applied and/or the specified conditions were met.

TAG	***Regulation***	***Interpretive Guidelines***
X056	*(4) A transplant center 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.*	*Survey Procedures* *Review the materials that describe the selection criteria. The transplant program is required to distribute such materials upon request.*

TAG	Regulation	Interpretive Guidelines
X058	(b) Standard: Living Donor Selection. The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must: (1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,	For a program that performs LD transplants, verify that the transplant program's policy requires that prior to donation, the potential LD receives a medical and psychosocial evaluation that is completely independent of the transplant candidate's evaluation. An independent evaluation requires that the transplant candidate (and any other individual(s) with an interest in the transplant candidate's transplant) may not be present during the potential LD's psychosocial and medical evaluation. The potential LD and transplant recipient evaluations must be filed in each respective individual's medical record and cannot be dually documented in both transplant candidate and LD medical records. The transplant program policy for LD selection must include, but is not limited to: 1. The length of time for which the psychosocial evaluation is deemed to be current, 2. The type of qualified professional healthcare personnel (e.g., MSW, LCSW, psychiatrist or psychologist) who may complete these evaluations, 3. The follow-up and referral procedures if a transplant candidate requires such activities, and 4. The manner and method of incorporating the psychosocial evaluation findings into the selection process. In the event of a paired-exchange or LD/transplant recipient swap process, the transplant program accepting the LD organ for their transplant candidate must review the pre-transplant evaluation for the potential LD. The program must document review and approval of the medical and psychosocial evaluation prior to donation. <u>Survey Procedures</u> Review the sample of LD medical records to verify that the psychosocial and medical evaluations were completed independently from the evaluations of the transplant recipient; within the time frame established by the program's policy; prior to the donation; and performed by the person(s) identified in the transplant program's policy as the professional healthcare personnel (e.g., MSW, LCSW, psychiatrist or psychologist) qualified to conduct such evaluations. The medical evaluation is expected to address not only the potential LD's medical suitability for donation, but also any of the potential LD's health issues that would be affected by the donation. (For example, if the potential LD were taking any medications treating an existing condition that needed to be stopped preoperatively, there must be documentation describing a plan to address the existing condition.)

TAG	Regulation	Interpretive Guidelines
X058 (cont'd)	Blank	The medical and psychosocial evaluations are expected to be completed prior to donation and to be focused on the individual's suitability for donation. It is expected that a psychosocial evaluation of this nature would address the following: • Social, personal, housing, vocational, financial, and environmental supports; • Coping abilities and strategies; • Understanding of the risks of donation; and • Mental health history, including substance and alcohol use or abuse and how it may impact the donor following the donation. For information only: The OPTN requires all transplant program members to include specific medical and psychosocial elements in their respective LD evaluations. The OPTN website contains information about the specific LD evaluation and tools it requires.
X059	(2) Document in the living donor's medical records the living donor's suitability for donation, and	The program's policy must describe the decision making process of the multidisciplinary team and how the team will document the LD's suitability for donation. The selection criteria used for the determination must be documented in the potential LD's medical record (i.e., the actual diagnosis or criteria indicating that the potential LD meets the program's criteria or is suitable as a potential LD). If the potential LD does not meet the criteria but is determined to be suitable for donation because an exception was made, the exception would also need to be documented in the medical record. Survey Procedures Review the sample of LD medical records to verify that each LD's suitability for donation is documented. At a minimum, the surveyor will verify that there was a discussion by the multi-disciplinary team (which would include the Independent Living Donor Advocate (ILDA)) of the relevant findings of the medical and psychosocial evaluations and the impact of those findings on the LD's suitability for donation. See tag X060 for further description on reviews for paired-LD exchanges.

TAG	Regulation	Interpretive Guidelines
X060	(3) Document that the living donor has given informed consent, as required under §482.102.	The medical record must provide evidence that the potential LD has given informed consent. "Informed consent" means the individual participates in his or her healthcare decision-making through a process which: 1. Provides information about the decision and procedures, alternatives, risks, relevant uncertainties, benefits and other pertinent information; 2. Must be provided to the individual in a manner suitable for comprehension; 3. Includes an assessment by the informing practitioner that the person understands and can articulate this understanding; and 4. Provides voluntary (without coercion) consent by the LD. <u>Survey Procedures</u> Review the sample of LD medical records to verify that the informed consent process (meeting the requirements of 42 CFR §482.102(b), X159-X168) is complete and is documented in the medical record. The surveyor must review the documentation in the medical record that describes the completed informed consent process, and review all dated and witnessed forms signed by the LD.
X071	**§482.92 Condition of Participation: Organ Recovery and Receipt.** Transplant centers 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 center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.	If the program's protocol or policy is determined to be inadequate after review but the program is performing the applicable duties under the condition, then cite the failure to meet policy requirements under the relevant standard. Effective on July 16, 2012, the regulation at 42 CFR §482.92(a) was amended to remove the requirement to review and compare blood type and other vital data before deceased organ recovery takes place for hospitals that recover their own organs (formerly at X072). The requirements for validation of donor-recipient blood type and other vital data for organ receipt, and LD organ transplantation processes were renumbered as subsections (a) and (b) and are still required and continue to remain in effect. (See 77 Fed. Reg. 29034, 5/16/12).

TAG	Regulation	Interpretive Guidelines
X073	(a) Standard: Organ Receipt. After an organ arrives at a transplant center, 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 beneficiary.	The verification required by this standard is intended to identify the correct donor organ with the intended recipient. The verification is required to occur after the organ arrives in the transplant operating room and prior to transplant. The transplant recipient's medical record (electronic or written) must include: 1. Written evidence that the verification occurred (i.e., notations of the donor and recipient blood type (ABO), other vital data (OVD) and UNOS/OPTN ID). The verification would also include any other donor/recipient compatibility elements that the transplant program has identified in its own protocols; and 2. Signatures that are dated and timed of both required individuals performing the ABO, OVD and UNOS/OPTN ID verification to include: a. Transplanting surgeon; b. Another licensed heath care professional. The professionals serving as "Another licensed healthcare professional" must be identified in the transplant program's policies and procedures. <u>Note:</u> The verification must be documented in the medical record and requires signatures of both the transplanting surgeon and another licensed healthcare professional. <u>Note:</u> If one or both individuals verified the organ and the recipient visually, prior to transplantation (i.e., the operation was already underway), this should be clearly documented with date(s) and time(s) of the verification occurring during the operation. Individual(s) who visually verified the donor organ with the recipient prior to transplant must follow-up with a note and corresponding signature(s) attesting to the fact that the verifications were made visually prior to transplant, and per hospital policy. 3. Dates and times of organ receipt in the operating room, organ verification and first anastomosis. Verification must occur prior to transplantation. In cases where the recipient surgery is started prior to donor organ arrival it is permissible for the program to document the implantation or the first anastomosis time, provided the verification always occurs after the donor organ arrives in the operating room. 4. Documentation that the verification occurred in the recipient operating room with both the organ and the intended recipient present. <u>Note</u>: The verification is done onsite in the transplant operating room at the time of the procedure and it cannot be completed via phone or performed remotely. If the organ was procured in the recipient hospital, verification is still required in the recipient operating room with both the organ and the intended recipient present. Verification prior to transplant and verification prior to organ recovery are two different and separate verification processes.

X073 (cont'd)	*Blank*	*Survey Procedures* *Review the transplant program's policies and procedures and a sample of medical records to verify documentation of the donor ABO, OVD and UNOS/OPTN ID compatibility with the intended recipient, i.e., there is documentation verifying that these match or are an intended mismatch. Verify the documentation was attested to or completed by the transplant surgeon and another licensed healthcare professional as defined by the transplant program's policy, with signatures, dates and times, in the recipient operating room, prior to implantation/anastomosis.* *If multiple organs from the same donor are being implanted into the same recipient, CMS does not require that there is a separate form for each organ. However, presuming that the organs are being implanted at separate times and by separate teams, additional documentation would be required. The transplanting surgeon for each organ and another licensed healthcare professional must complete the verification prior to implantation of that organ. In addition to compatibility, this comparison will verify that the donor organ is being transplanted into the intended recipient.* *Visual verification confirming compatibility of the ABO, OVD and UNOS/OPTN ID between the donor organ and the recipient is permitted. All of the required information must be documented by the person attesting that the verification occurred, dated and signed. After the transplant case is complete, the transplanting surgeon and the other licensed healthcare professional must sign, date and time that attestation. If the person documenting the attestation is the other licensed healthcare professional, they must document their own verification of this data as well as the verbal verification by the transplanting surgeon. The other licensed healthcare professional's documentation must reflect the explicit time and date the verifications occurred. The transplanting surgeon must then attest to the accuracy of this documentation following the operation.* *This is a separate procedure from the verification required to be performed in the LD operating room under tag X074. If the same surgeon recovering the donor organ is going to perform the transplant surgery, the ABO, OVD and UNOS/OPTN ID must be verified by the transplanting surgeon and another licensed healthcare professional again once the organ is in the transplant operating room, and prior to transplantation.* *Note: OPTN policy requires that the verification takes place after receipt of the organ and prior to first anastomosis. This comparison will verify that the proper organ will be transplanted. The UNet^{SM} system performs a compatibility review of specific vital medical factors (e.g., ABO compatibility, HLA antigens, serology status/acceptance, age, size, etc.) as part of the computerized matching process of donors for a potential recipient. The transplant program is not required to repeat this full compatibility review, but must verify that the organ being recovered is for the potential recipient that has been identified on the UNet^{SM} match list. The transplant program is not*

TAG	***Regulation***	***Interpretive Guidelines***
X073 (cont'd)	*Blank*	*precluded from beginning the recipient's operation prior to arrival of the organ at the transplant program. If the operation has begun and the surgeon is awaiting arrival of the donated organ, the transplant surgeon remains responsible for verifying the ABO, OVD and UNOS/OPTN ID. It is not required that the surgeon would stop the operation to enter the documentation for this verification (given the time-sensitive nature of some transplant surgeries).*

TAG	Regulation	Interpretive Guidelines
X074	(b) Standard: Living Donor Transplantation. If a center 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 beneficiary's organ(s).	The verification required by this standard is intended to identify the correct donor organ with the intended recipient prior to donor incision. This requirement applies to programs that perform LD transplants (either directly or under contract or by agreement). The LD medical record (electronic or written) must include: 1. Written evidence that the verification occurred, i.e., notation of the donor and recipient blood type ABO, OVD and UNOS/OPTN ID. The verification must also include any other donor/recipient compatibility elements that the transplant program has identified in its own protocol; and 2. Signatures that are dated and timed of both required individuals performing the ABO, OVD and UNOS/OPTN ID verification, to include: a. Transplanting or recovery surgeon (a LD recovery surgeon is not required to be the transplant surgeon, i.e., a LD kidney may be recovered by a general surgeon, a urologist, etc.); and b. Another licensed healthcare professional. The professionals serving as "another licensed healthcare professional" must be identified in the transplant program's policies and procedures; 3. Documentation that the verification occurred after patient arrival to the LD operating room and prior to anesthesia. Verification must be completed onsite at the time of the procedure and cannot be done in preparation for, or prior to the patient's arrival in the operating room, or via phone or remotely. 4. Documentation that the verification took place after the donor arrival in the operating room and prior to anesthesia administration. The verification should occur before the removal of the recipient's organ(s), if applicable. The phrase "if applicable" refers to the fact that a) in some cases, the recipient's native organ(s) are not explanted and may remain in the body even though it is being replaced by the donor's organ; or b) the recipient's organ (usually a kidney) may be removed well in advance of transplantation of the LD's organ, based on medical necessity. Verification prior to LD organ recovery under tag X074 and verification after organ receipt under tag X073 are two different and separate verification processes. If the same surgeon recovering the donor organ is going to perform the transplant, the same surgeon will conduct two different verifications. The ABO, OVD and UNOS/OPTN ID must be verified by the transplanting surgeon and another licensed healthcare professional again once the organ is in the transplant operating room, and prior to implantation or first anastomosis for transplantation. See section 482.92(b) above at tag X073.

TAG	Regulation	Interpretive Guidelines
X074 (cont'd)	*Blank*	*Survey Procedures* *Review the transplant program's policies and procedures (specific to LD transplants) and a sample of medical records to verify the inclusion of language that the recovery surgeon or transplanting surgeon and another licensed healthcare professional complete verification of the donor and recipient ABO, OVD and UNOS/OPTN ID. The verification must occur after LD arrival to the LD operating room and prior to anesthesia administration.* *Note: This comparison will verify that the correct organ is being recovered from the LD for transplantation into the intended recipient. The UNet℠ system performs a compatibility review of specific vital medical factors (e.g., ABO compatibility, HLA antigens, serology status/acceptance, age, size, etc.) as part of the computerized matching process of donors for a potential recipient. The transplant program is not required to repeat this full compatibility review, but must verify that the organ being recovered is for the potential recipient that has been identified on the UNet℠ match list, and must verify that the donor's and potential recipient's blood types are compatible or an intended mismatch.*
X081	***§482.94 Condition of Participation: Patient and Living Donor Management.*** *Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.*	*If the program does not have a policy for patient and LD management and is not performing duties required for patient and LD management, cite this tag at the Condition level and all applicable standards.* *Transplant Candidate/Recipient Care Phases:* • *Pre-Transplant/Evaluation (from the first presentation for evaluation of a potential recipient and placement on the program's waiting list until the time the transplant candidate enters the OR for the transplant surgery.)* • *Transplant Inpatient Stay (from the time the transplant recipient enters the OR for the transplant surgery until the patient is discharged following the inpatient surgery stay.)* • *Discharge (from the point the transplant recipient is awake and alert following surgery until actual discharge.)* • *Post-Transplant: (pertaining to QAPI)* *Living Donor Care Phases:* • *Pre-Donation (from first presentation by the potential donor until the time they enter the OR for the donation surgery.)* • *Donor Inpatient Stay (from the time the donor enters the OR for the donation surgery until donor discharge from the inpatient surgery stay.* • *Discharge Planning (from the time when the donor is alert and awake following surgery until discharge.)* • *Post-Donation (pertaining to QAPI) (from the time of discharge until the care is transferred to donor's primary physician.)*

TAG	Regulation	Interpretive Guidelines
X082	(a) Standard: Patient and Living Donor Care. The transplant center'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 center 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.	The regulation does not prescribe the specific clinical management policies and procedures that must be used by a transplant program. Programs may have different clinical management policies for transplant candidates/recipients in different situations (for example, policies may need to differ for those transplant candidates/recipients who live a significant distance from the transplant program). Surveyors must assess whether or not the transplant program has developed patient and donor management policies and that it is following its own policies and procedures. The policies should describe what actions should occur in each phase of treatment, the staff responsible for these tasks, clinical actions, and how interventions are documented. The multidisciplinary team for transplant must include, at a minimum, representatives from the following disciplines: • Surgical (Transplant surgeon) • Medical (Transplant physician) • Nursing • Clinical Transplant Coordinator • Social Services • Nutritional Services • Pharmacology (Pharmacology deficiencies should be cited respectively at X082, X090, X091 and X125 based on their relevant phase and clinical issue.) • Financial Coordination See Tag X125 for an outline of the roles and responsibilities of the disciplines that must be represented on the multidisciplinary team for transplant candidates/recipients. The post-transplant discharge plan should address, at a minimum, the following areas: • 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-specific nutrition plan, as applicable; • A plan for addressing relevant psychosocial issues (for example, available supports, adaptation to stress of transplant, etc.);

TAG	Regulation	Interpretive Guidelines
X082 (cont'd)	Blank	• 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 transplant recipient's schedule for taking medication and the process to obtain the medication; • Assistance required to access local medical care, equipment or support; and • Financial coordination Transplant recipients require regular post-operation follow-up visits to the transplant program for a period of time to monitor the transplant recipient's recovery and to ensure that the recipient is not showing signs of rejection of the newly transplanted organ. The policies and procedures of an outpatient transplant clinic and interviews with post-transplant recipients about their outpatient experiences are not included within the scope of this survey. If issues are identified with outpatient services, these should be referred to the RO or CO for follow-up as needed. There are two areas where surveyors are expected to interface with the outpatient clinic: • To identify and interview post-transplant recipients about their experience as an inpatient at that transplant program; and • In cases where the discharge plan or discharge instructions in the medical record are not clear, then the surveyor may review the policies or transplant recipient education materials of the outpatient clinic so that the surveyor can assess the discharge plan and instructions that are given to transplant recipients. If the transplant recipient's local physician is responsible for his/her post-operative care, the transplant program is responsible for documenting coordination with that local physician to ensure continuity of care. <u>Transplant Recipient Survey Procedures</u> Review the transplant program's written clinical management policies for the pre-transplant evaluation, transplant and discharge phases of transplantation, including the routine follow-up visit schedules. The policies and procedures must detail the composition, roles, and documentation required of each member of the multidisciplinary team. Review a sample of transplant recipients' medical records to evaluate regulatory compliance throughout all phases of the transplant process: evaluation (to include time on the wait list), transplant and discharge planning.

TAG	Regulation	Interpretive Guidelines
X082 (cont'd)	Blank	*Verify that the medical record, viewed as a whole, indicates that the members of the multi-disciplinary team performed the responsibilities described in the transplant program's own policies and procedures. All members of the transplant team should have, at a minimum, documentation in the medical record that meets the requirements specified in the program's policies and procedures for all of the phases, including pre-transplant/evaluation, transplant and discharge planning. Verify that the documentation of the multidisciplinary care plan shows coordination by a physician, including any interventions, directions to staff, etc.* *If a discharge plan was written and required follow-up is documented, review the post-transplant records to see that all tasks have been completed. If that is not the case, the deficiency should be cited under discharge planning.* *If the multidisciplinary team does not conduct actual meetings for transplant recipient care planning, the surveyor should evaluate the evidence (e.g., medical records, interviews) that the multidisciplinary team members conducted joint discussions, issue identification, and joint planning efforts throughout the evaluation (to include time on the wait list), transplant and discharge processes. It is not necessary for all members of the team to be involved in all aspects of clinical care so long as the medical record, viewed as a whole, has documentation that each member of the team performed the duties and responsibilities accorded to him or her by the transplant regulations and by the program's own policies and procedures.* *The LD multidisciplinary team, at a minimum, must include representatives from the following disciplines:* • *Surgical (Organ recovery surgeon or transplant surgeon)* • *Medical (Organ-specific physician)* • *Nursing* • *Clinical Transplant Coordinator* • *Social Services* • *ILDA (Do not cite ILDA deficiencies at this tag. Cite these under the section of 42 CFR §482.98 that pertains to ILDA (tags X121-X124)* • *Nutritional Services* • *Pharmacology (Pharmacology deficiencies should be cited respectively at X082 and X125, based on their relevant phase and clinical issue.)* • *Financial Coordination*

TAG	Regulation	Interpretive Guidelines
X082 (cont'd)	Blank	Note: Nutrition and pharmacology services may be phased out if no specific needs are identified and documented by one or both disciplines during the donor evaluation, or if not specifically warranted in future phases of donation. It is not necessary for of all the members of the team to be involved in all aspects of clinical care, so long as the medical record, viewed as a whole, has documentation that each member of team performed the duties and responsibilities according to the regulation and the program's own policies and procedures. At a minimum, the discharge plan (initiated at donor admission for donation and formalized post-donation) for LDs should address the following areas: • 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 for questions; • The clinical signs and symptoms, specifically indicative of a potential complication from donation, that would necessitate a call to the doctor; • A LD-specific nutrition plan (as applicable); • A LD-specific psychosocial plan (as applicable, to include post-donation adjustment); • 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 donor's schedule for taking medication, and the process to obtain the medication; and • Assistance required to access local medical care, equipment, or support. LD Survey Procedures If there is a LD program, review the clinical management policies and procedures for LD evaluation, inpatient, and discharge planning phases and verify that the LD's clinical management is directed by a multidisciplinary team coordinated by a physician (which may include the organ recovery or transplant surgeon). The policies and procedures should include the schedule for routine follow-up visits. The program must determine the relevant timeframe for the evaluation of donor suitability, and time-frames and indicators for re-assessment if donation is pending. Post-donation patients may require follow-up visits (per the program policy) to the transplant program to ensure they are recovering from the donation and not experiencing any medical issues related to donation.

TAG	Regulation	Interpretive Guidelines
X082 (cont'd)	Blank	The policies and procedures of an outpatient transplant clinic and interviews with post-LDs about their outpatient experiences are not included in the scope of this survey. If issues are identified in outpatient services, these may be referred to the RO or SA for follow-up as needed. There are two areas where surveyors are expected to interface with the outpatient clinic: • To interview post-donation patients about their experience as an inpatient at that transplant program; and • If the discharge plan or LD's discharge instructions in the medical record are not clear, then the surveyor may review the policies and procedures and patient education materials at the outpatient clinic so that the surveyor can assess the discharge plan and instructions. Review a sample of LD medical records to evaluate the compliance and quality of LDs' care throughout all phases of the donation, including: evaluation, the donation process, and discharge planning. Verify that the medical record, viewed as a whole, indicates that the members of the multidisciplinary team performed the responsibilities required of them by the transplant regulations and the transplant program's own policies and procedures. Documented evidence of this performance may be accomplished in various ways by the multi-disciplinary team members. Verify that the documentation of the multidisciplinary care plan shows coordination by a physician including any interventions, direction to staff, etc.
X083	(b) Standard: Waiting List Management. Transplant centers must keep their waiting lists up to date on an ongoing basis, including:	Transplant programs are required to keep their waiting lists up to date to ensure that all active waitlist patients are ready for organ offers and transplantation based on their current clinical presentation. Programs' policies and procedures must include, at least: • Timeframes for waitlist updates, • Methods for updating a patient's clinical status, and • A description of information provided to transplant candidates on the waiting list regarding the candidates' responsibility to notify the program about changes in their medical and psychosocial status. The policies and procedures must specify the medical and psychosocial conditions requiring notification to the program and the methods for notification.

TAG	Regulation	Interpretive Guidelines
X084	(1) Updating of waiting list patients' clinical information;	The program must have policies and procedures in place for on-going assessments and evaluations required for patients to remain on their waiting lists. The program should consider seeing patients on the waitlist at least annually. Transplant programs will likely have different policies and procedures for updating clinical information. In addition, OPTN has certain requirements for updating clinical information based on the patient's characteristics. The surveyors should assess whether or not the program is following its policies and procedures. <u>Survey Procedures</u> Review the transplant program's policies and procedures for updating both the waiting list and the pre-transplant clinical information for waiting list patients. The policies and procedures must include the timeframe within which these updates must be completed, what type of information is updated, who is designated to update the clinical information, and how often the clinical information for waiting list patients is reviewed. Review a sample of transplant candidate medical records currently on the program's waiting list (these may be inpatient or outpatient records) to ensure that the clinical information in the medical record corresponds to the transplant program's waiting list information identified in UNet^{SM}. During interviews with transplant program staff, request information about the process and frequency with which the transplant program reviews and updates the clinical information of waiting list patients, both in the patient's medical record and on the transplant program's waiting list. Request a demonstration of updating both the UNet^{SM} and transplant program's waiting list (if different from the list of patients on UNet^{SM}).

TAG	Regulation	Interpretive Guidelines
X085	(2) Removing patients from the center'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 center's waiting list; and	Note: • The program is not required to notify the patient's family in the event of removal for death. • Some transplant recipients may remain on the waiting list due to a need to be re-transplanted due to rejection or malfunction of the previously transplanted organ. It should be documented for the patient who currently has a transplanted organ whether the patient is listed for re-transplant due to graft loss or is listed for multiple organs. Survey Procedures Select a sample of transplant candidates on the current waiting list and confirm through their medical records that, based on their clinical status, they should still be on the waiting list (that is, the medical records do not show documentation of changes that would exclude them from the program's selection criteria). Additionally, the transplant candidates on the waiting list must not have already received a transplant (except as described above) and must still be living.
X086	(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.	The sample of transplant recipients removed from the waitlist within 24 hours should not be initially requested or reviewed unless a complaint is submitted on this matter or issues are identified onsite that require further investigation. The OPTN provides CMS with information on removal from the waitlist and if issues are reported from OPTN, those will be included in the TPQR. Cite a deficiency according to the TPQR report, if noncompliance is identified during a survey. If potential non-compliance is identified onsite related to this area during a complaint investigation or interview, the sample may be pulled for review. CMS has aligned this requirement to coincide with the OPTN requirement of removal within one (1) day and is not using the exact 24 hour calculation to avoid confusion for providers. Survey Procedures Review a sample of medical records of the patients removed from the waiting list by the transplant program over the past 12-months, including the date and time they were removed. Compare documentation in the medical record that identifies the date the transplant program determined that the individual should no longer be on the waiting list. Review the date the OPTN was notified to verify that no more than 1 day had elapsed between these two dates.

TAG	***Regulation***	***Interpretive Guidelines***
X087	*(c) Standard: Patient Records. Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.*	*Transplant programs must maintain medical records for all individuals evaluated by the program for transplantation or living donation. A record must be maintained, even if the evaluation is limited to review of a referral and medical information from another provider or facility and a determination is made that the individual is not a candidate for transplant or living donation. Review of medical information indicates the beginning of an evaluation for transplant, and therefore accurate and current records must be kept and may be requested by CMS for survey review purposes.* *If the patient is not accepted by the program for its waitlist, the program should counsel the patient on the decision and any circumstances that would enable reconsideration, and this must be reflected in the medical record. For patients that are evaluated but not selected, the program must document the selection criteria used for not placing the patient on the waitlist.* *If the transplant candidate or potential living donor has begun but not completed an evaluation, there is not a required timeline for when that transplant candidate or potential living donor must complete their clinical workup.*

TAG	Regulation	Interpretive Guidelines
X088	(1) For each patient who receives an evaluation for placement on a center's waiting list, the center 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 center's waiting list; (ii) The center's decision not to place the patient on its waiting list; or (iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.	For transplant candidates placed on the waiting list, documentation in the medical records should verify that the transplant candidate was informed of his/her status on the waiting list. In the case of kidney transplant candidates on dialysis, the dialysis facility must also be informed of the transplant candidate's waiting list status. The notification of change of waiting list status for acuity changes to transplant candidates must be based on program policies and procedures, (for example, LAS, MELD or PELD score changes). For transplant candidates placed on the waiting list that are changed from active to inactive status, transplant candidate notification must be documented in the medical record as this affects their ability to receive a transplant. For transplant candidates evaluated but not selected for the waitlist, the transplant program must document in the medical record the rationale for the decision and that the transplant program discussed with the transplant candidate any changes that the transplant candidate could make to meet the program's selection criteria (for example, smoking cessation, changes to alcohol consumption, weight changes, etc.). In the case of a kidney transplant candidate, the dialysis facility must also be informed of the transplant candidate's waiting list status. For transplant candidates evaluated, but for whom the program was unable to make a determination, the transplant program must inform the transplant candidate of the specific additional testing or documentation needed to make a determination, and the expected timeframe for completing the determination. In the case of a kidney transplant candidate, this information must also be conveyed to the transplant candidate's dialysis facility. <u>Survey Procedures</u> Review a sample of wait list medical records to verify these patient discussions have occurred and are documented.

TAG	Regulation	Interpretive Guidelines
X089	(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center 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.	Transplant candidates that are removed from the OPTN waitlist for reasons other than death or transplantation must be removed within 10-business days. Notification and detail of the reason for this removal must be provided to the transplant candidate within 10-business days. Survey Procedures Request a list of transplant candidates removed from the waiting list during the past 12-months for reasons other than death or transplantation (do not include those placed on "inactive" status on the waitlist – these transplant candidates are generally listed as a "Status 7"). Verify notification of removal from the waiting list no later than 10 business days after the date the transplant candidate was removed. The notification must be by letter, but it should provide an opportunity for the transplant candidate to have further discussion (either by telephone or face-to-face) with the transplant program.
X090	(3) In the case of patients admitted for organ transplants, transplant centers must maintain written records of: (i) Multidisciplinary patient care planning during the transplant period; and	Refer to Tags X082 and X125 for guidance as to the components of the multidisciplinary transplant recipient's care planning process, and personnel participating in the multidisciplinary team. Survey Procedures Review written evidence by the transplant program to confirm that a multidisciplinary care planning effort by each member of the team occurred while the transplant recipient was in the hospital. This evidence may take a variety of forms, with examples including, but not limited to, a completed multidisciplinary care plan in the medical record, progress notes in the medical record that provide evidence of a joint care planning effort, or notes from multidisciplinary team rounding which document the disciplines attending the rounds, discussion items/plan of care, etc.

TAG	Regulation	Interpretive Guidelines
X091	(ii) Multidisciplinary discharge planning for post-transplant care.	Refer to Tags X082 and X125 for a discussion of the components of the multidisciplinary discharge planning process, and the personnel participating in the multidisciplinary discharge planning. Survey Procedures Review a sample of medical records to confirm that a multidisciplinary discharge planning effort by all team members occurred for discharge planning. Confirm that the discharge planning documentation is up to date by all multidisciplinary members as the transplant recipient's/ LD's clinical care requires prior to discharge. Review the medical record to identify any recipient or LD changes that have occurred during the length of stay that are not addressed or updated in the final discharge plan documentation.
X092	(d) Standard: Social Services. The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families.	Social services by qualified social workers that the transplant program must make available to transplant recipients, LDs and families include, but are not limited to, social work assessment, care planning, intervention, reassessment, and discharge planning related to the following: • Acknowledgement of the risks and benefits of transplantation and/or LD as appropriate; • The transplant candidate/recipient's and potential LD/LD's ability to adhere to therapeutic regimens; • The transplant candidate/recipient's and potential LD's/LD's mental and psychosocial health history, including substance and alcohol use and how it may impact the success or failure of organ transplantation or the transplant recipients and LD's mental health post-transplant; • The transplant candidate/recipient's and potential LD's/LD's (if applicable) coping abilities and strategies; • The transplant candidate/recipient's and potential LD's/LD's financial capabilities and resources, including who will pay for post-discharge medical care for the LD, if necessary; and • Availability of adequate social, personal, housing and environmental support. Survey Procedures Review a sample of post-transplant recipient and post-LD medical records to verify that the social work consultation and/or progress notes reflect the social worker's participation in the initial assessment, care planning, intervention, reassessment, and discharge planning as reflected by documentation in all phases. It is reasonable to expect different levels of intervention and services based on the needs of the transplant candidate/recipient or potential LD/LD. Cite a deficiency if there is evidence in the medical record that (1) social services were not provided; or (2) the medical record reflects that social service issues were identified, but not addressed.

TAG	Regulation	Interpretive Guidelines
X093	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	The MSW is ultimately responsible for the care of transplant recipients and LDs. Consultative relationships between a Non-MSW and an MSW must be confirmed by evidence of dialogue concerning issues related to transplantation and LD as appropriate, and social work standards of practice. Examples of evidence of an ongoing consultative relationship may include, but are not limited to: • Documentation of collaboration on transplant and living donation cases (as appropriate); • Documentation of substantive discussion of transplant and living donation (as appropriate) cases, including social work methods or practices that would provide assistance to the potential transplant candidate/transplant recipient and the LD (as appropriate); • Participation of the MSW social worker in multidisciplinary meetings along with the non-MSW social worker; • Documentation of the discussion of resources available for transplant candidate/transplant recipients and LDs (as appropriate); • Supervisory/subordinate relationships; and/or • Personnel evaluations or continuing education provided by the MSW to the non-MSW social worker.
X093 (cont'd)	(2) Is working as a social worker in a transplant center as of June 28, 2007 (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.	A qualified, transplant-trained, Masters of Social Work (MSW) is required to supervise any social work interns or students and have ultimate responsibility for the transplant recipients'/LD evaluation or any social work interaction with transplant recipients and LDs. Any subsequent interactions the student has with the transplant recipients and LDs must be reviewed and co-signed by the MSW, who remains ultimately responsible for those evaluations and interactions. <u>Survey Procedures</u> Review the personnel records of social workers who provide services to the transplant program to ensure that all individuals are qualified and licensed (if required) in the state in which the transplant program is located. The regulation does not require advanced social work licensure, such as a Licensed Clinical Social Worker, which typically requires a MSW degree as well as an extended period of supervised clinical work (e.g., 3 years, 3000 hours, etc.). Review the policy if applicable for SW student/interns training to verify the program meets this standard.

TAG	Regulation	Interpretive Guidelines
X094	(e) Standard: Nutritional Services. Transplant centers 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.	Transplant candidates/transplant recipients and potential LD/LDs, depending upon their health and nutritional status, may require various levels of nutritional assessment and intervention. Nutritional assessments and diet counseling services must be provided by a qualified dietician during all phases of the transplantation and donation processes. At a minimum, there must be documentation of the appropriate level of assessment and intervention necessary to ensure that the nutritional needs for all the transplant candidates/transplant recipients and LD/LDs are adequately addressed. The nutritional assessments and diet counseling may be phased out for LDs based on clinical need, provided that programs develop a policy which delineates how the dietician is notified of changes in condition and need for re-evaluation. Any follow-up for referrals for further assessment or intervention are the responsibility of the qualified dietitian. For example, if no interventions are recommended by the dietician for the LD, the dietician's participation in the care of that patient may be phased out if the program has a process for triggering re-evaluation generated by clinical changes. The multidisciplinary team must note any further clinical needs identified after phase-out and notify the dietician if there is a need for further intervention. Nutritional services may include, but are not limited to: • Dietetic consultation; • Nutritional assessment and nutritional interventions; • Nutritional education; and • Physician consultation for total parenteral nutrition (TPN), peripheral parenteral nutrition (PPN), or enteral feeding. <u>Survey Procedures</u> Verify that the transplant program's current policies and procedures for nutritional services outline how the transplant program will determine the level of nutritional assessment, dietetic counseling, or nutritional intervention warranted. Review a sample of transplant recipient and LD medical records for multidisciplinary team notes to ensure that the multidisciplinary team discussed any identified nutritional needs of the individual throughout the transplantation or donation process. Identify any instances of conditions that warranted further nutritional services based on the transplant program's criteria (diabetes, for example) and verify that nutritional services were provided, as indicated. Review the personnel records of dietitian(s) who serve on the transplant program's multidisciplinary team to ensure there is documentation of his/her registration with the Commission on Dietetic Registration. If there are state licensure requirements, the dietitian must be currently licensed in that state.

TAG	Regulation	Interpretive Guidelines
X099	**§482.96 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)** Transplant centers 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	**Five Aspects of Transplant Quality Assessment and Performance Improvement (QAPI) Programs** **Aspect 1: Design and Scope** An effective transplant QAPI program is ongoing and comprehensive, dealing with the full range of services offered by the transplant program, including patient safety, clinical care, quality of life, and those services provided under contract or arrangement. The program is data-driven, reflects the complexity of transplant services, and addresses all systems of care and management practices relevant to transplantation. The program is therefore multi-disciplinary and covers all phases of transplantation and donation in a continuous cycle of review and improvement. Transplant QAPI is connected or integrated with the hospital quality program and includes processes to identify high risk, high (or very low) volume, and problem prone areas. The program includes methods for conducting analyses, implementing corrective actions, evaluating improvements, and assessing whether improvements are sustained. Transplant programs have a written QAPI program that is implemented and includes active multi-disciplinary participation, methodologies to fulfill hospital and federal requirements, process and outcome objective measures, established frequencies for review of performance, identification of transplant-specific adverse events, structured investigation processes, and mechanisms for reporting between transplant and hospital programs. **Aspect 2: Governance and Leadership** The hospital leadership and governing body must be clearly engaged in QAPI oversight. The governing body ensures that the QAPI program is implemented, ongoing, comprehensive, effective, and that adequate resources are applied to conduct QAPI efforts and operate in a continuous manner. The governing body sets clear expectations for quality and safety. The transplant program administration, in conjunction with the hospital leadership and the governing body, develops a culture of quality assessment and performance improvement utilizing input from transplant program staff, transplant recipients, living donors, and their families or representatives. Hospital leadership and transplant administration ensure that written policies are developed to sustain QAPI by setting expectations for safety, quality care, and patient rights for transplant recipients and living donors. They create an atmosphere where staff are comfortable identifying and reporting quality problems as well as opportunities for improvement. QAPI education is part of the accountable culture. The transplant program must identify members of the multidisciplinary QAPI team and specify their roles and responsibilities. This includes designated staff to be accountable for QAPI; developing leadership and hospital-wide training on QAPI; and ensuring that staff time, equipment, and technical training are provided as needed. Transplant QAPI reports are provided to the hospital leadership and the governing body and are used to assess, improve and sustain quality of care and performance, reduce risk of harm to patients and utilize lessons learned.

TAG	Regulation	Interpretive Guidelines
X099 (cont'd)	Blank	***Aspect 3: Feedback, Data Systems and Monitoring*** *The transplant program must have systems in place to monitor care and services in all phases and settings of transplant and living donation, drawing from multiple sources. Feedback systems include input from staff, transplant recipients, living donors and families or representatives as well as bidirectional communication between hospital and transplant quality programs. Process and outcome indicators reflecting the complexity of services within the program are defined, measured, analyzed and tracked. Applicable benchmarks or targets are established by the program to measure performance. The program includes effective surveillance to identify and respond to adverse events, additionally tracking and monitoring implemented improvement activities to prevent reoccurrence.* ***Aspect 4: Systematic Analysis and Systemic Action*** *The transplant QAPI program uses a methodical approach to determine when in-depth analysis is needed to fully understand improvement opportunities, causes, and implications of change for care and services delivered. Transplant programs must develop policies and procedures and demonstrate proficiency in conducting a thorough analysis. The transplant QAPI program must analyze collected data. Analyses must include, but are not be limited to, analysis of data related to proactively defined quality indicators and the ongoing use of systemic methods to assess and analyze adverse events. Transplant adverse events must be identified, tracked, investigated, analyzed, and the results used to prevent recurrence. There must be evidence that the transplant QAPI program develops system-based interventions to improve quality of care and performance on an ongoing basis to reduce risk of harm to patients. Systemic actions look comprehensively across all involved systems to prevent future negative events and promote sustained improvement. The transplant QAPI program uses an identifiable structure, policies and procedures to address investigation of root causes of transplant quality issues and document actions taken toward correction and sustaining change.* *Note: As defined in CMS regulations at 42 CFR 482.70, an "adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof." Examples of adverse events include (but are not limited to) graft failure, serious medical complications or death, donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintended transmission of infectious disease to a beneficiary.*

X099 (cont'd)	*Blank*	***Aspect 5: Performance Improvements*** *The transplant QAPI program must define, implement, and evaluate performance improvement interventions with the objective of improving quality of care. Performance improvements are concentrated efforts that involve systematic gathering of information to identify issues or problems, and subsequent development of interventions to prevent recurrences. Once implemented, the interventions are later evaluated for success or continued need for improvement. Evidence of evaluation and sustained improvement is communicated to all stakeholders. The bi-directional reporting of these activities between staff, the transplant program, and hospital leaders, promotes a culture of continuous learning and improvement. The transplant program conducts activities to examine and improve care or services in areas that the transplant program identifies as needing attention (high risk, high (or very low) volume and problem prone areas). Areas that need attention will vary depending on the organ type. Documentation of transplant performance improvement interventions should reflect utilization of the program's defined performance improvement model or methodology.* *Additional, General Considerations* ***Written:*** *There must be a written transplant QAPI program, whose plan clearly defines the QAPI program purpose, structure, and operations. The QAPI program must either include or reference the program's patient safety plan to identify, prioritize, and address adverse events. Programs may maintain a separate adverse event or "patient safety" plan or they may incorporate the identification and management of adverse events into one unified QAPI program. The transplant QAPI program must include its structure including how it is organized and integrated into the organizational (hospital-wide) QAPI program, and must also identify the program leadership and management. The QAPI program must also have written specifications for data collection, analysis and use.* ***Comprehensive:*** *A comprehensive transplant QAPI program includes proactively-identified, transplant-specific indicators across all phases of transplant, transplant services (including those provided under contract or arrangement), for the transplant candidate/recipient and potential LD/LD. This includes off-site departments and remote locations (other inpatient campuses) providing care to the transplant candidate/recipient and potential LDs/LDs.* *Since the transplant QAPI program is distinct from the hospital's QAPI program, there must be clear evidence that information and findings from the transplant QAPI program are communicated to the hospital's QAPI program and that the transplant program incorporates appropriate hospital-wide QAPI activities. The hospital governing body must be aware of priority areas of the transplant QAPI program, including findings from thorough analyses in order to appropriately resource the QAPI program and individual projects.*

X099 (cont'd)	*Blank*	*The scope of the transplant survey does not include a full assessment of the hospital QAPI program, but it does include tracing transplant identified issues to the hospital QAPI program and leadership attention. The hospital QAPI program must have documentation of these issues and support activities to improve services that are provided potential transplant candidate/transplant recipients.* ***Data-driven:*** *The program must clearly specify:* • *The data to measure various aspects of quality of care and patient safety;* • *The frequency of data collection and how the data will be collected, analyzed and used;* • *Proactively-defined indicators for systematic data collection in regular intervals;* • *A comprehensive system to identify adverse events, and after identifying an adverse event, collect additional qualitative and/or quantitative information in preparation for root cause analyses; and* • *How the program utilizes data analysis to drive continuous improvement.* ***Survey Procedure*** *Review transplant program QAPI policy and documents to ensure the presence of the following:* • *Multidisciplinary team participation, with individuals identifiable by title, role, and responsibilities;* • *QAPI methods for developing objective measures, consisting of outcome and process measures for all phases of transplantation and living donation.* • *Demonstration of how quality-related data is collected, analyzed, and utilized;* • *Established frequencies for review of program performance, and reporting to the QAPI Committee and to the hospital-wide QAPI program;* • *Designation of an individual who will be responsible for monitoring the transplant program's QAPI program (i.e., QAPI coordinator);* • *Evidence of performance improvement initiatives including identifying high-risk, high (or very low)volume and problem-prone areas in need of improvement, and tracking and implementing recommendations for improvement;*

TAG	***Regulation***	***Interpretive Guidelines***
		• *Evidence of ongoing compliance with changes implemented as a result of QAPI activities;*

TAG	Regulation	Interpretive Guidelines
X099 (Cont'd)	Blank	• Specific issues relevant to each of the disciplines represented in the multidisciplinary team (e.g., surgical, nursing, social services, dietary, and pharmacy), as warranted; and, • Participation of the transplant program's personnel (director, transplant surgeon(s), transplant physician(s), clinical transplant coordinator(s), and nursing personnel). Examples of their participation include being a member of QAPI committee/sub-committees and project improvement teams, presenting topics to the QAPI committee, authoring reports or updates for the QAPI committee about the program's status. • An internal communication structure to ensure that information is communicated up through the organization and back to front line staff. • An Adverse Event Policy, see section §482.96 (b). **Comprehensive Program Content** A comprehensive QAPI program is expected to include the following: • Individual members identifiable by title, role, and responsibilities; • Objective measures consisting of outcome and process measures for all phases of transplantation and living donation for which quality-related data will be collected and analyzed (including the measures described in §482.80 and §482.82); • Data-driven: The program must clearly specify: ◦ The data to measure various aspects of quality of care and patient safety; ◦ The frequency of data collection and how the data will be collected, analyzed and used; ◦ Proactively-defined indicators for systematic data collection in regular intervals; ◦ A comprehensive system to identify adverse events, and after identifying an adverse event, collect additional qualitative and/or quantitative information in preparation for root cause analyses; and ◦ How the program utilizes data analysis to drive continuous improvement. • Established frequencies for review of program performance, and reporting to the QAPI Committee and to the hospital-wide QAPI program;

		• *Evidence of performance improvement initiatives including identifying high risk, problem prone areas in need of improvement, and of tracking and implementing recommendations for improvement;*
X099 (Cont'd)	*Blank*	• *Evidence of ongoing compliance with changes implemented as a result of recommendations by the QAPI Committee; and* • *Broad representation of staff and transplant program issues relevant for the disciplines represented in the multidisciplinary team (e.g., surgery, nursing, social services). This means that the QAPI program would not solely be focused on a single discipline (e.g., surgery) but would include performance measures relevant for other disciplines.* • *Method by which key findings and recommendations are reported to transplant QAPI program members, to the hospital-wide QAPI program, and to individuals determined by the QAPI program as instrumental to act on important analyses, findings, and recommendations and sustained improvements;* • *The program must conduct an appropriate, thorough analysis of any adverse event and utilize the analysis to effect changes in policies and practices to prevent repeat incidents. There must be a documented process/policy for identification, reporting, analysis and prevention of adverse events, including written definition of transplant-specific adverse events as an "untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof" including all phases of transplant and donation (pre-transplant, transplant, post-transplant; pre-donation, donation and post-donation). The program must conduct an appropriate, thorough analysis of any adverse event and utilize the analysis to effect changes in policies and practices to prevent repeat incidents.*
X100	*(a) Standard: Components of a QAPI Program. The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation*	*Objective measures are defined data elements that are selected to reflect program activities and outcomes. "Objective" means being able to be reviewed in an unbiased manner, strictly identified by a numerator and denominator. The measures selected should be sufficiently defined for program staff so that all members understand their meaning. Activities or processes must relate to the core transplant processes across all phases of transplant and living donation as mandated by CMS, the OPTN and all other applicable standards and regulations and as described in the program's policies and procedures. Outcome measures must relate to the intended and unintended effects resulting from the care provided. The objective measures must be defined, collected and analyzed and result in recommendations that are communicated to the transplant program decision-makers.*

	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.	*Examples of objective outcome measures include, but are not limited to:* • *Survival rate (graft and patient) over a designated period of time, including sub-group analyses;* • *Number of blood type compatibility errors over a designated period of time;* • *Number of post-transplant or post-living-donation infections and other complications;* • *Delayed graft function;* • *Percentage of organ rejection over a given period of time; and,* • *Measurements of the effectiveness of the transplant candidate/recipient and potential LD/LD and family education.* *Examples of objective process measures include, but are not limited to:* • *Frequency of the use of criteria exceptions in the patient/donor selection process;* • *The extent to which OPTN rules for removal from the wait list are adhered to;* • *Number of the transplant candidate/recipient and potential LD/LD or family complaints that were received, investigated, and resolved;* • *Number of complaints related to consent practices;* • *Returns to the OR in a specified period; and,* • *Extent of adherence to patient evaluation steps.* *<u>Survey Procedures</u>* *Confirm that the QAPI program uses objective measures for a comprehensive evaluation of the performance of the transplant program, including services provided under contract or arrangement. Measures should cover all components of the program and all transplant and LD phases.* • *Review the indicators to verify that they are appropriate to local organizational needs and include adverse events, collecting data in accordance with a clear plan, analyzing that data to produce actionable information, and then acting to address areas of prioritized concern.*
X101	*The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.*	*A transplant program must provide evidence of implemented performance improvement initiatives, documentation of improvement activities, and verification of sustained improvement. The number and scope of activities must reflect the complexity of the specific program.* *<u>Survey Procedures</u>* *Review the transplant program's QAPI documents including committee meeting minutes, reports, and policies and procedures. Verify that actual or potential transplant-specific high risk, high (or very low) volume and problem prone areas are promptly identified, and appropriate follow-up actions are taken and tracked for performance over time. The impact of corrective actions*

		should be both short and long-term, and implemented to ensure continuous improvement which is sustainable. *Review the extent to which key findings are communicated to the hospital's QAPI program and acted upon to improve the program.* *Note: This tag should be viewed within the context of the overall Standard outlined in Tag X100. Specifically, the actions and tracking of performance must relate to the objective measures that evaluate the program's performance with regard to transplantation activities/processes and outcomes.*
X102	*(b) Standard: Adverse Events. A transplant center 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.*	*Adverse event is defined at §**482.70 as*** *"an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof."* *Examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient." Additional examples include, but are not limited to, medication error contributing to graft loss or delayed function; surgical site infection or other hospital acquired infection; and unplanned return to the operating room for surgical complications.* *The phrase 'or the risk thereof' contained in the definition indicates that an adverse event does not require harm, death or serious injury to have occurred; but carries the risk of serious harm or death if the event occurs. Some examples of adverse events with the risk for serious harm or death include, but are not limited to: falls; medication errors; miss-labeled laboratory results/specimens; blood transfusion errors; allergic reactions; un-timely reporting of critical lab values; discharge planning that fails to address key medication and appointment instructions; or lack of proper ABO and other vital data verification.* *Organizations utilize various terminologies to describe these occurrences, such as incidents, serious preventable events, serious safety events, never events, and sentinel events. Regardless of the definition or terminology utilized by the transplant program, transplant policies must address methods for identification, reporting, and analysis that will be utilized for ANY event that meets the CMS adverse event definition, and develop action towards preventing adverse events.*
X102 (cont'd)	*Blank*	*Transplant programs may adhere to the hospital adverse event policies rather than have a separate transplant adverse event policy. Regardless, it is important for the activities of the transplant program to be outlined and defined. There should be a distinction between hospital adverse events and transplant adverse events so that the transplant program analyzes their*

		transplant adverse events and takes actions to prevent recurrence. *Adverse events in all phases of transplant recipient or LD care must be reported to the hospital per hospital policies and procedures (which would include any event reporting system that was established by the hospital).* *<u>Survey Procedure</u>* *Review the transplant program QAPI written policies and procedures for identifying, reporting, investigating, and correcting adverse events. Additionally, look for evidence that trends are identified and addressed to ensure that change is implemented, monitored and sustained. See also the descriptions near the end of tag X001 for more information regarding "written" and "comprehensive" policies and procedures.* *The policies should include:* • *Clear definition of what the program considers an adverse event, at a minimum, incorporating CMS' regulatory definition.* • *The procedure for reporting any adverse event.* • *The process or method that will be used for analyzing an adverse event, regardless of the severity or harm associated with the event.* • *The required timeframe for reporting, investigating and analyzing adverse events.* • *External reporting of events to OPTN, ESRD Network and SA, etc. as required and applicable.* • *Reporting to, or inclusion of, Institutional Review Board (IRB)/Western Institutional Review Board (WIRB) if the adverse event occurred within the context of an approved study.* • *Reporting to other federal agencies as required by federal law (i.e. for suspected medical device-related deaths or serious injury, transmission of an infectious disease, etc.).* • *Reporting to the OPO if an infection in a transplant recipient is related to an infectious disease present in their recovered organ so that other recipients who received organs from the same donor can be notified.* *<u>Note</u>: Transplant programs are not required to report adverse events to CMS.*
X103	*(2) The transplant center must conduct a thorough analysis of and*	*The program must have and follow clear processes to identify, document, track, report internally, and analyze adverse events, to conduct an analysis of every adverse event, and to develop and implement actions to prevent recurrence.* *A "thorough analysis" is a planned systematic investigative process that seeks to identify the causes of an event (such as root causes and contributing causes). 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 involved. Adverse events that*

		resulted in, or had the potential to result in death, graft loss or other very serious harm warrant use of a more elaborate and in-depth thorough analysis process (including multi-disciplinary, root cause analysis for every patient death or graft loss). Less elaborate and time-intensive methods that nonetheless allow for the collection and analysis of essential facts about systems factors (event details, staff, equipment, policy, environmental concerns and procedures) may be sufficient to thoroughly analyze adverse events that resulted in, or had the potential to result in less serious harm. *A thorough analysis includes:* • *Determination of human and other factors most directly associated with the event;* • *Analysis of direct processes and systems related to the event (including policies);* • *Analysis of underlying / secondary systems and processes (including policies);* • *An inquiry into all areas appropriate to the event;* • *An identification of risk points and their potential contributions to the type of event;* • *A determination of potential improvements that will likely decrease future events.* *Transplant programs should clearly define the methods that will be utilized to conduct a "thorough analysis" for any adverse event (e.g., death, harm, no harm, or process deviation events) that may affect a transplant candidate/recipient and potential LD or LD.* *A thorough analysis must address all phases of transplantation or living donation, include information obtained from personnel associated with the event, include a multi-disciplinary review through involvement of individuals knowledgeable about key factors that may contribute to such events, include input from decision makers that can implement recommended changes, and be documented in such a manner that permits trending related to adverse events and evaluation of the effectiveness of corrective actions.*
X103 (cont'd)	*Blank*	*<u>Survey Process</u>* *Request evidence that the program has effectively identified, tracked and analyzed all adverse events over the past 12-months. This time period may be expanded (but not reduced) as needed to a time not to exceed 36 months prior to the survey date (unless a longer time is needed to address an event that is the subject of a complaint investigation). Verify that the program followed its policies, and the CMS regulation, on identifying, investigating, reporting, and analyzing adverse events.* *During the review of medical records and interviews, note any indication of an adverse event(s). Also review incident/adverse event reports, and any tracking mechanism for incident/adverse events (if applicable). Verify that the*

		events were identified, documented, reported internally in the hospital investigated, and analyzed according to transplant program policies and procedures and in accordance with CMS regulations. *A "thorough analysis" is expected to include (but is not limited to):* 1. *A description of the key facts of the event in enough detail so that one can clearly understand what occurred, the severity of the event, and how the transplant candidate/recipient and potential LD/LD was affected;* 2. *A review of whether or not similar events have occurred in the past; and* 3. *An analysis of related systems and processes that contributed to the event's occurrence.* *If an adverse event affecting a transplant candidate/recipient and potential LD/LD was identified and included in causal analysis that was conducted by the hospital, then the transplant surveyor may review the hospital assessment and analysis as part of the transplant survey.*
X104	*…and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.*	*The transplant program must utilize its "thorough analysis" to make changes to prevent repeat incidents. Changes must be implemented, monitored and sustained to prevent recurrence.* *Survey Procedures* *Using available evidence (such as a log of adverse events) and the corresponding analysis of those adverse events conducted by the transplant program, look for evidence that the transplant program's policies and procedures were changed to prevent repeat incidences.* *Examples of this evidence could include (but are not limited to) policy changes, protocols that outline a specific care practice for the transplant candidate/recipient and potential LDs/LDs, staff directives, and in-service training (e.g., assessing staff understanding of changes, including information in new hire orientation/job descriptions, reviewing medical records to ensure that staff were following the new care protocols, etc.).* *Seek evidence that the program has monitored the change(s) to ensure that they had been fully implemented and sustained over time (e.g., assessing staff understanding of changes, information about new hire orientation/job descriptions or personnel or training changes, revised or new protocols, information in medical records that indicate whether staff were following new care protocols, etc.).*
X109	***§482.98 Condition of Participation: Human Resources.*** *The transplant*	*In surveying the standards at tags X110 through X126, surveyors will evaluate whether or not 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.* *Survey Procedures*

	center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.	*Each program must have written job descriptions and training requirements for each multidisciplinary team member.*
X110	*(a) Standard: Director of a Transplant Center.* *The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with §482.98(b).*	*The transplant program must designate a Director and describe the qualifications that he or she must possess. At a minimum, the Director must be a qualified transplant surgeon or a qualified transplant physician.* *"General supervision" means overseeing the performance of the transplant program's operations and maintaining responsibility for these operations. The Director of a transplant program is permitted to delegate day-to-day operations to an Administrator.* *Refer to tag X115 for surgeon and physician requirements.* *<u>Survey Procedures</u>* *Review the personnel record of the designated Director to verify documentation of compliance with board certification and licensure requirements as required in the state of practice.*
X111	*The director is responsible for planning, organizing,*	*While the Director of the transplant program is ultimately responsible for the transplant program's operations, as described in Tag X110 above, he or she may delegate day-to-day operations to an Administrator.*

	conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:	
X112	*(1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.*	*CMS considers it implicit in any concept of "adequate training" that there would be:* *1. A thorough orientation to the program's policies and procedures;* *2. Structured continuing education for nursing staff and clinical transplant coordinators; and* *3. Ongoing evaluation of staff training needs.* *"Adequate training" means that the scope and intensity of training is responsive to individuals' needs for different levels of training. For example, new employees who do not have previous transplant experience are expected to need more training (i.e., instructional, on-the job training, and close supervision) than personnel with transplant experience. The Director may accomplish this by coordinating with a training program operated by the hospital.* *To evaluate continuing education, review training records of the transplant nurses and clinical transplant coordinators (based on the sample size listed in the survey protocol) for evidence of:* *1. Initial training assessment of staff upon hire by the transplant program, including documentation of evaluation of competency of the transplant nurses and clinical transplant coordinators to work with transplant candidates/transplant recipients and potential LDs/LDs.* *2. Successful completion of an orientation program that provides an opportunity to raise questions (for example, didactic, hands-on learning, direct observation), including:* *• Clinical assessment of transplant candidate/transplant recipients;* *• Clinical assessment of potential LDs/LDs (if applicable);* *• Monitoring for signs and symptoms of organ rejection, and transplant-related infection;* *• Monitoring for signs and symptoms of complications following living donation (if applicable);* *• Providing patient education related to signs and symptoms of organ rejection and complications following living organ donation;* *• Providing donor education related to complications following*

		living organ donation; • *Providing patient education about immunosuppressive therapy; and* • *Monitoring of immunosuppressive therapy.* 3. *Participation in continuing education programs in the care of transplant candidates/transplant recipients and potential LDs/LDs. Review evidence that the continuing education program is:* • *Held at regular intervals based on training dates; and* • *Attended by nursing staff and clinical transplant coordinators as evidenced by training attendance records.*
X112 (cont'd)	*Blank*	*For transplant programs that use traveling nurses, contract nurses, or float pool nurses: Traveling, contract, or float pool nurses are expected to have specific training and/or experience in the care of transplant candidates/transplant recipients and potential LDs/LDs. If these nurses do not have this training, their performance may need to be monitored.* *Traveling nurses, contract nurses and float pool nurses can provide certain types of care to transplant candidates/transplant recipients and potential LDs/LDs provided that there is clear evidence in the program's policies and procedures, medical records, and interviews of the following:* 1. *The traveling/contract/float pool nurses practice within the scope of basic nursing care for which they have had training and experience;* 2. *A nurse with adequate training and experience in transplantation provides close supervision/consultation to the traveling/contract/float pool nurse so that there is ample opportunity to discuss a patient's condition and how it may correlate with the pre- or post-transplant care (e.g., the implications of certain lab values). An experienced transplant nurse would be able to provide additional information and judgment as to why certain events might be occurring in the context of transplantation, and whether or not follow-up intervention would be warranted; and* 3. *A transplant nurse experienced with the specific organ(s) type is providing the direct care to the patient in situations in which such training and expertise is required. At a minimum, this would include pre- and post-transplant education regarding the transplantation process, pre- and post-donation education, explaining medication regimen and side effects, and administering immunosuppressive therapy.* *<u>Survey Procedures</u>* *The surveyor will assess whether or not the training program(s) (and/or any competency assessments) address the topics needed for transplant nurses and Clinical Transplant Coordinators (CTCs) to provide care to transplant candidate/transplant recipients, and the areas outlined in the regulation under*

		tags X081, X082, X118 and X120. *Review a sample of training records for evidence of training programs, pertinent staff participation and completion of trainings. Absence of these training records is evidence of failure to ensure adequate training.* *Review a sample of personnel records for transplant nurses (i.e., those providing direct care to potential transplant candidates/transplant recipients and/or potential LDs/ LDs) to verify that there is documentation that these individuals have the appropriate licensure and qualifications for the state in which the transplant program is located.* *Verify completion of updated transplant-specific training as required by the regulation for all staff, including those employed prior to June 28, 2007.* *The qualifications and licensure requirements for Clinical Transplant Coordinators (CTCs) are reviewed under Tag X119.*
X113	*(2) Ensuring that tissue typing and organ procurement services are available.*	*<u>Survey Procedures</u>* *The organ procurement organization (OPO) agreement with the transplant program and the OPO should only be reviewed if there are issues identified during the survey. During medical record reviews and interviews, be alert for any evidence that tissue typing and organ procurement services were not or are not available. If there is evidence that the services may not be available, review the OPO and transplant program agreement. Cite if there is evidence that these services are not available.*
X114	*(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).*	*"Direct supervision" means that the transplant surgeon who is supervising the transplantation surgery is physically present in the operating room at all times during the surgery, from verification through closure.* *<u>Survey Procedures</u>* *Review a sample of transplant recipients' medical records for documentation that a qualified transplant surgeon was present during the transplant surgery.*
X115	*(b) Standard: Transplant Surgeon and Physician.* *The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate*	*<u>Survey Procedures</u>* *Review the most recent CMS TPQR for the primary transplant surgeon and primary transplant physician that have been identified to the OPTN. Confirm that these individuals are the current surgeon and physician designated as having primary responsibility for the transplant program. If the program has not designated a primary transplant surgeon and a primary transplant physician to the OPTN, cite this here. If the program has not notified CMS of a change in these key personnel, see tag X012.* *Recognizing that it is not practical for the primary transplant surgeon and primary transplant physician to be available 24 hours per day, 7 days a week, the responsibility for being immediately available may be delegated to other*

	training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.	*qualified transplant surgeons and transplant physicians.* *Review the program's policies to ensure that proper delegation procedures are in place to formally transfer the primary transplant surgeons and primary transplant physician's responsibilities to alternative qualified surgeons and physicians, if necessary. For example, the on-call schedule can be evidence of delegation.* *To verify that the primary transplant surgeon and primary transplant physician are immediately available, review the on-call schedule for the past month and compare the surgeons' and physicians' names to their place of residence in their personnel files to ensure that the response time is possible.* *The on-call transplant surgeon and transplant physician must be reachable by cell phone and/or pager, and must be able to be physically present on the unit within 60 minutes of notification to provide transplantation services.*
X116	*(1) The transplant surgeon is responsible for providing surgical services related to transplantation.*	*Survey Procedures* *Review a sample of transplant recipients' medical records for evidence that the transplant surgeon performs or directly supervises all surgical services related to transplantation, which could include surgical procedures, monitoring immunosuppression regimen during the post-operative period, etc.*
X117	*(2) The transplant physician is responsible for providing and coordinating transplantation care.*	*For each transplant candidate/transplant recipient, there must be a designated transplant physician responsible for providing and coordinating transplantation care.* *Survey Procedures* *Review a sample of transplant recipient medical records to confirm that the transplant physician coordinated with the transplant surgeon and the multidisciplinary team and provided non-surgical components of transplantation care.*
X118	*(c) Standard: Clinical Transplant Coordinator.* *The transplant center 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*	*Identify the designated CTC(s) for the transplant program.* *Survey Procedures* *Review the program policies and procedures on the role of the CTC in all phases of transplantation and donation.* *Note: There must be policies and procedures in place for CTC communication throughout the phases. The CTC may have a more active role during some phases of care than others; for example, a Nurse Practitioner may be functioning as the inpatient coordinator during the donation and transplantation procedures and there may be separate coordinators for the other phases.*

	and the donor evaluation, donation, and discharge phases of donation.	
X119	*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.*	*Survey Procedures* *Review the personnel files of the CTC(s); confirm that there is documentation that he or she is a registered nurse or a licensed clinician in the state in which they practice. Review their training and years of experience with transplantation, time with preceptor for transplant or any certifications with the American Board for Transplant Certification (ABTC) and, if applicable, living donation experience. In addition to a registered nurse, a licensed clinician may include a physician assistant, nurse practitioner, a clinical registered nurse specialist.*
X120	*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 center and dialysis facilities, as applicable.*	*The CTC must be involved in, and ensure the coordination of the clinical aspects of any pre-transplant/donation and follow-up conducted by the transplant program for transplant candidates/transplant recipients and potential LDs/LDs. Transplant candidates/transplant recipients will require intensive follow-up for some period of time following the transplant depending on the type of transplant involved. This follow-up can include in-person visits, lab work, phone calls, etc. which may be performed either by the transplant program or by another entity that is charged with following the patient post-transplantation. There must be evidence that the CTC is involved in and ensures the coordination of the clinical aspects of any follow-up conducted by the transplant program. Increasingly, after the first 6 months, post-discharge care may be handled by a local physician. There must be evidence that the CTC ensured coordination of the clinical aspects of care throughout discharge planning, especially in instances where the care of the patient would be shared with the transplant recipient's local physician, to appropriately transition follow-up activities.* *There are no minimum standards for follow-up with LDs. Post-donation follow-up activities are sometimes handled by a local physician; there must be evidence of the coordinator's role in ensuring the effective transition of follow-up care. After the first 6 months, the frequency and intensity of involvement by the clinical transplant coordinator may decrease; however there must still be evidence of ongoing communication, intervention and coordination, as indicated by the care plan.*
X120 (cont'd)	*Blank*	*In the case of a kidney transplant program, the clinical transplant coordinator is responsible for communications with the dialysis facility. These*

		communications must be documented and must indicate the method of communication, whether via electronic communications, written communications, or phone calls. *<u>Survey Procedures</u>* *Review multidisciplinary care plan notes and progress notes in the transplant candidate/transplant recipient and potential LD/LD medical records to ensure that the CTC(s) fulfills the responsibilities of coordinating the clinical care of transplant candidates/transplant recipients and potential LDs/LDs by:* • *Addressing elements identified in the pre-transplant or pre-donation assessment and care plan; and in the peri-operative and post-operative care plans;* • *Educating patients, LDs, and families about treatment options and post-operative care or therapies as necessary;* • *Monitoring patients' and LDs' medical, surgical and psychosocial status and ensuring the provision and coordination of needed care; and* • *Providing feedback to other team members.* *Look for evidence that the CTC(s) carried out these responsibilities in all phases of transplantation and donation (as described in tag X082).*
X121	*(d) Standard: Independent Living Donor Advocate or Living Donor Advocate Team.*	*The transplant program's policies and procedures must require designation of an ILDA or independent LD advocate team (IDLA team) and outline the qualifications and training (both initial and ongoing) required for members of the ILDA/IDLA team. If there is an ILDA team, there must be identification of the composition of the team.* *"Independent" means that the ILDA individual(s) function independently from the transplant team to avoid conflicts of interest. It does not mean that the individual must be employed or supervised by someone outside of the hospital/program.* *The transplant program must be able to confirm that the ILDA or team operates independently of the recipient transplant team and in a manner that puts the best interests of the potential LD/LD first. In doing so, the surveyor will evaluate the following factors:*
X121 (cont'd)	*The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent*	1. *The position must allow the ILDA/team to provide independent representation to the potential LD/LD.* 2. *The job description of the ILDA/team must outline clear expectations that their position is to represent and advise the donor; and to promote his/her interests. This ILDA/team 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.* 3. *Policies and procedures make it clear to all staff within the transplant program that the ILDA(s)/team functions independently from the recipient transplant team, and that the potential LD/LD interests and*

	living donor advocate team to ensure protection of the rights of living donors and prospective living donors.	*rights will be put ahead of the wishes of the recipient transplant team, if there is a conflict.* *4. The ILDA supervisor ensures that the ILDA/team does not have a vested interest in the transplant taking place.* *5. The ILDA/team has the ability to file a complaint/grievance with a third party if the ILDA/team believes that the rights of the potential LD/LD are not being properly protected.* *The responses to the factors listed above should be considered as a whole before determining whether or not the ILDA/team can and does operate independently from the recipient transplant team and that the donor's interests are properly protected.* *<u>Survey Procedures</u>* *Verify in a sample of potential LD/LD medical records that an ILDA/team is identified for each potential LD/LD.* *In the review of medical records and policies and procedures, confirm that in all instances, the ILDA/team operated independently from the recipient transplant team.*
X122	*(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.*	*"Routine basis" is defined as scheduled participation with any activities (on an ongoing or occasional basis) that involve any transplant recipients, regardless of organ type (for example, regular on-call duties, waiting list management, organ allocation decisions, direct transplant candidate/transplant recipient care, and clinical transplant coordination, etc.). The ILDA/team may occasionally participate on a contingency basis, for example, if the ILDA was asked to cover for the on-call transplant coordinator when someone unexpectedly called out sick.* *<u>Survey Procedures</u>* *Review a sample of LD medical records and program schedules to verify the ILDA/team for the LD is not involved in transplant activities on a routine basis. This does not require that the ILDA/team conduct their ILDA activities entirely outside the operation of the transplant program, only that they are not routinely involved in transplant activities.* *Cite at this tag if there is evidence that the ILDA/team is involved in transplant activities on a regular basis.*
X123	*(2) The independent living donor advocate or living donor advocate team must demonstrate:* *(i) Knowledge of*	*Transplant programs have flexibility in determining how they will inform the potential LD/LD of the various components of the informed consent process and who will provide the information. However, if transplant program staff other than the ILDA/team is providing the information to the potential LD/LD, the ILDA/team would continue to have a role in attending these informational sessions with the potential LD/LD and creating opportunities for the potential LD/LD to discuss issues, ask additional questions, or request follow-up information. If information is provided directly by the ILDA/team, the*

	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.*	*discussions between the ILDA/team and the potential LD/LD must occur in a setting that is apart from the transplant candidate/transplant recipient and other transplant program staff involved with the recipient. The ILDA/team must ensure that the potential LD/LD has received the information he or she needs to make an informed decision.* *The documentation in the medical records must provide evidence that the ILDA/team discussed with the potential LD/LD the topics described below, confirmed potential LD/LD understanding, and addressed any potential LD/LD questions or follow-up requests for information in the following areas:* • *Emotional/psychological aspects of living donation (for example, discussion of the psychosocial assessment, family support of the potential LD's/LD's decision to donate and the future medical care and social support of the donor);* • *Any family or external pressures that impact the potential LD's/LD's decision about whether to donate;* • *The potential LD's/LD's current medical history and its implications for the suitability of the potential LD/LD, and possible long-term clinical implications of the organ donation;* • *The living organ donation process (i.e., donor evaluation, donation surgery, and post-donation recovery; potential complications; and general recovery from the surgery);* • *Financial aspects of living donation (for example, discussion of health insurance and other insurance issues including future access to insurance, and information about who will pay for necessary post-donation care and follow-up);* • *Various options for the transplant recipient other than an organ donation from a LD; and* • *The required areas of informed consent for the potential LD/LD (See Tags X159 through X168) and an assessment of potential LD/LD understanding.*
X123 (cont'd)	*Blank*	*Demonstrating knowledge of medical ethics means the following:* • *Ensuring the potential LD's/LD's welfare is of primary importance;* • *Respecting the decisions and autonomy of the potential LD/LD in his/her decision to donate and the care the potential LD/LD receives;* • *Understanding the donation process, acknowledging current and future risks for the potential LD/LD, and identifying the methods/ process to ensure that the potential LD/LD has the opportunity to ask questions and receive additional information about those risks;* • *Maintaining confidentiality of the communication between the potential LD/LD and the transplant program;* • *Setting and maintaining standards of competence and integrity; and* • *Ensuring that one's knowledge and skills concerning living donation and transplantation issues are up-to-date.*

		Demonstrating knowledge of informed consent means the following: • *Understanding the content that will be discussed with the potential LD/LD during the informed consent process to be able to accurately assess the potential LD's/LD's understanding;* • *Evaluating potential LD's/LD's understanding through discussion; and* • *As needed, identifying areas where additional information or clarification is warranted to improve potential LD/LD understanding; and if necessary, involving other transplant program or hospital staff.* *Survey Procedures* *Review a sample of potential LD/LD medical records to verify that the ILDA/team demonstrates knowledge and understanding of LD, transplantation, medical ethics and informed consent, as described in more detail above.* *Review a sample of potential LD/LD medical records to verify that there were opportunities provided that would ensure that the potential LD/LD had the opportunity to ask questions and note any answers given to these questions.* *In review of the medical records for potential LDs/LDs and transplant candidates/transplant recipients, note any instances where medical ethics or informed consent may have been breached. Determine whether the ILDA/team has knowledge of the pertinent medical ethics and informed consent terms. An example of such a breach would be if confidential information about the potential LD/LD was shared with the transplant recipient. For any such breach, also review tags X057, X082, X124 and X160.* *The medical record documentation/notes must demonstrate that the ILDA/team complies with these standards in all of their interactions with the potential LD/LD.*
X124	*(3) The independent living donor advocate or living donor advocate team is responsible for:* *(i) Representing and advising the donor;* *(ii) Protecting and promoting the interests of the donor; and*	*The ILDA/team must take steps to ensure that the potential LD/LD has received the information outlined in the informed consent process, has had the opportunity to ask questions regarding the donation, and the decision to donate is free from coercion. There must be a summary notation in the medical record to verify that the potential LD/LD was presented with the possible complications of donation and is choosing freely to proceed with the donation.* *The program must describe how the ILDA/team communicates with the potential LD/LD and multidisciplinary team (donor selection committee, multidisciplinary team meetings, and individual assessments) throughout the three phases of donation in the policies and procedures.*

	(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.	*Survey Procedures* *Review a sample of potential LD/LD medical records, ILDA/team notes and multidisciplinary care plan notes. The medical record documentation by the ILDA/team must provide evidence that the ILDA/team discussed with the potential LD/LD the entire donation experience and risks, responded to questions or concerns, evaluated the potential LD's/LD's understanding, and respected their final decision.*
X125	*(e) Standard: Transplant Team. The transplant center 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.*	*The transplant program must have written policies and procedures that describe the membership of the multidisciplinary team and the specific roles and responsibilities of each team member. Each program must have written descriptions of the roles and responsibilities and training requirements for each multidisciplinary team member.* *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 LD.* *Survey Procedures* *Review the program's description of the responsibilities of each member of the multidisciplinary team, and a sample of personnel files for multidisciplinary team members. Verify that the multidisciplinary team includes members from medicine, nursing, nutrition, social services, transplant coordination, and pharmacology. Verify that there is documentation that each team member has the appropriate qualifications, training, experience and credentials (e.g., license, certification, etc.).* *Review of other items in the personnel file (e.g., evaluations, initial employment questionnaire, job descriptions, CPR certification, etc.) would only occur when there are issues identified in the survey process that raise questions about the qualifications, training, or experience of transplant program staff.* *Review the training records of the multidisciplinary team members and the upcoming training schedules to ensure that the professional staff are provided with and have participated in comprehensive and ongoing transplant-specific training. The training should include areas such as: new technology, changes in the field of potential transplant candidate/transplant recipient and potential LD/LD care, other transplant-specific training sessions, updates and sharing best practices learned during relevant conference attendance, and other individual training opportunities required by the transplant program and overall hospital policies.* *Review a sample of the medical records of potential transplant candidate/transplant recipients and potential LDs/LDs to confirm documentation of each team member's appropriate implementation of his or*

		her respective responsibilities. *Cite the lack of pharmacist involvement as a multidisciplinary team member under this tag and any applicable transplant phases and discharge planning tags in X090 or X091.* *Daily documentation of multidisciplinary team meetings is not required by this section.*
X126	*f) Standard: Resource Commitment. The transplant center 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.*	*Whether the required services are provided in-house or under contract or arrangement, the transplant program must ensure that the services are available 24-hours per day, 7 days per week.* *Tissue typing services are not required to be available 24-hours a day.* *<u>Transplant Programs Receiving LD Services Under Contract or Arrangement from a Program Located in Another Hospital</u>* *Some transplant programs provide transplant services for organ recipients, but do not provide living donor services or recover organs from living donors intending to donate to their patients. Such programs may enter into various types of arrangements with transplant programs in other hospitals that do provide living donor services/organ recovery from living donors. Under such an arrangement, the transplant program caring for the recipient receives the living donor's organ from the hospital that provides the living donor services. CMS is aware of several types of arrangements in which a transplant program does not directly provide services for a LD but, under contract or arrangement with another transplant program, receives donor organs from a separate hospital that does not provide services to the organ recipient. The guidance in this section covers all of these types of arrangements. For example, there may be an ongoing arrangement between two transplant programs, such as pediatric and adult programs, or a transplant program that contracts with another program for the medical and psychosocial evaluations of the LD. 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 LD. If the services for a LD are provided by a transplant program located at another hospital, then those services are considered to be services of the recipient transplant program that are being provided under contract or arrangement by the LD transplant program. (42 C.F.R. §482.12(e) outlines the Medicare requirements for a contracted service in a hospital). A transplant program must also comply with all Hospital CoPs (42 CFR §482.1 through §482.57). As such, the transplant program providing services to the transplant recipient is responsible to ensure that the program serving the LD is Medicare-approved.*

		1. *A recipient's transplant program that has its LD services provided by one or more programs under contract or arrangement on either an ongoing or episodic basis must have written evidence of a contract or agreement with the LD 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 LDs and recipients.*
X126 (cont'd)	*Blank*	2. *A recipient's transplant program must have a copy of the Medicare approval letter for the transplant program providing LD care with which it has a contract or agreement and have documented evidence that the CMS website was reviewed prior to accepting the LD organ to ensure that the program is a Medicare-approved program.* 3. *A recipient's transplant program must retain copies of the medical records to include the LD evaluation and workup up to the point of admission to the hospital for the donation for any LDs 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:* • *There is a complete medical and psychosocial evaluation in the medical record performed by qualified professional healthcare personnel (e.g., MSW, LCSW, psychiatrist or psychologist) which determines that the individual is a suitable LD.* • *An ILDA has met and worked with the LD candidate and has been included in the discussions of the potential donor's suitability.* • *There is a fully-documented informed consent process in the LD's medical record that meets the CoPs.* • *CMS requires the recipient transplant programs to perform due diligence to ensure that the requirements described above are met prior to accepting a LD organ. It is permissible for a transplant recipient's program to use another hospital's policies and procedures for any given LD as long as the minimum standards described above are met.* • *This is not an exhaustive list of the requirements that apply to LD services. The identification of this subset does not mean that the other CoPs for LDs are waived. This subset of CoPs is outlined because the recipient's transplant program must verify that these requirements have been met prior to the donation.*

		Survey Procedures *Review a sample of medical records for transplant candidate/transplant recipients and potential LDs/LDs, to confirm the provision of these services in a timely manner and the furnishing of these services by qualified professionals. Identify any instances when the required service(s) were not available upon request or as needed according to the care plan for any transplant candidates/transplant recipients and potential LD's/LD's. If the care required by this standard is needed by any transplant candidate/transplant recipient and potential LD/LD and is not available, cite it under this tag.*
X139	***§482.100 Condition of Participation: Organ Procurement.*** *The transplant center 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.*	*Surveyors are not required to review the OPO agreement with the hospital. If during the survey there is concern with the OPO agreement, such as evidence of improper use of organs, problems with obtaining organs, problems with referral of organ offers or organ allocation, review the following below and contact your contract PO and CMS CO.* *The written agreement must identify the specific responsibilities of the hospital and the OPO and how they commit to work collaboratively.* *Common responsibilities for the transplant hospital should include (but are not limited to):* • *Providing current personnel contact information to the OPO, and notification of changes in key personnel;* • *Reporting inactivation and reactivation of transplantation services to the OPO;* • *Describing the method of communication with the OPO regarding organ acceptance or declinations;* • *Notifying the OPO of adverse events, as applicable;* • *Updating the UNet^{SM} data system in a timely manner with information about transplant candidate/transplant recipients, potential LD/LD status, and determinations regarding organ offers;* • *Providing a surgical recovery team to recover donor organs as appropriate, and transmitting licensure and/or credentialing information for the recovering surgeons to the OPO; and* • *Outlining a process for identifying and resolving issues, complaints, and concerns.* *Common responsibilities for the OPO are expected to include (but are not limited to):* • *Determining the medical suitability of the potential donor;* • *Describing the method and timeliness of communication with the transplant hospital;* • *Notifying the transplant program of policy and procedure changes by the OPO that may affect organ recovery, placement, packaging, labeling,*

		perfusion, and transport; • *Ensuring the proper composition and credentialing of the organ recovery team;* • *Ensuring that proper documentation is provided to the transplant program about the recovered organ(s), which includes the blood type and other identifying information; and* • *Outlining a process for identifying and resolving issues, complaints and concerns.* *Survey Procedures* *Review the hospital's written agreement with the designated OPO (if warranted).*
X149	***§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 center must protect and promote each transplant patient's and living donor's rights.*	*Blank*
X150	*(a) Standard: Informed Consent for Transplant Patients.* *Transplant centers must implement written transplant patient informed consent policies that inform each patient of:*	*For each of the subparagraphs (1) through (8) identified in this standard, the transplant program's policies and procedures must delineate:* • *When the discussions will take place;* • *Who is responsible for discussing the informed consent process with the transplant candidate/transplant recipient;* • *Where in the medical record informed consent discussions and the actual informed consent are documented; and* • *The methods used by the program to ensure and document transplant candidates'/transplant recipients' understanding.* *A transplant candidate's/recipient's signed informed consent form and/or hospital surgical informed consent form should not be considered evidence that the informed consent process was complete. The informed consent process is expected to involve multiple discussions with the transplant*

		candidate/transplant recipient at different points in time (e.g., prior to being placed on the waiting list, prior to surgery). The medical record and interviews must validate that timely and appropriate discussions were held. Transplant candidates/recipients must be given an opportunity to ask questions and the level of transplant candidates'/recipients' understanding must be assessed. *Note: The informed consent requirements in this regulation are in addition to the requirements for a properly executed informed consent form under the hospital CoPs. The hospital CoPs require that a surgical informed consent form is signed and documented in the medical record for surgery and other medical treatments.* *Survey Procedures* *Review a sample of the transplant recipients' medical records to confirm that the informed consent process includes all of the content this standard requires (see below in tags X151 to X158).* *Request a copy of all educational materials provided to transplant candidates/recipients as part of the informed consent process. Confirm that the educational materials are written at a reading level easily understood by the transplant candidates/recipients (i.e., transplant population) served by the transplant program.*
X151	*(1) The evaluation process;*	*The evaluation process begins at the time an individual is identified as a transplant candidate and continues until the time the individual receives the transplant.* *During the evaluation time period, the following topics, at a minimum, should be discussed with the transplant candidate.* • *Results of the physical evaluation;* • *Transplant candidate selection criteria and suitability for transplant;* • *Results of laboratory and transplant-specific diagnostic testing;* • *Relevance of any psychosocial issues to the success of the transplant;* • *Financial responsibilities resulting from the transplant; and* • *Necessity of following a strict medical regimen post-transplant.*
X152	*(2) The surgical procedure;*	*Discussions with the transplant candidate about the surgical procedure should occur on several occasions prior to the surgery. Prior to placement of the transplant candidate on the UNet℠ waiting list, the transplant program must, at a minimum, provide an overview of the surgical procedure and potential risks.* *Prior to transplant surgery, a detailed discussion of the surgical procedure, anesthesia risks, risks involved with the use of blood or blood products, expected post-surgical course and possible complications; and benefits/risks of transplant surgery relative to other alternatives should occur.*

X153	*(3) Alternative treatments;*	*The options for alternative treatments will vary by organ type and by the transplant candidate's specific medical condition. For example, kidney transplant candidates have dialysis options.* *The discussion of these alternative treatments should occur before placement on the UNet[SM] waiting list. The discussions of alternative treatments should be reviewed again with the transplant candidate subsequent to any significant changes in the transplant candidate's medical condition or other alternative treatments that become available.*
X154	*(4) Potential medical or psychosocial risks;*	*Discussions regarding potential medical and psychosocial risks should occur early in the evaluation process, on several occasions prior to the surgery and with any change in the patient's medical or psychosocial condition.* *Prior to transplant surgery, a detailed discussion of the surgical procedure, anesthesia risks, risks involved with the use of blood or blood products, expected post-surgical course and possible complications; and benefits/risks of transplant surgery relative to other alternatives should occur.* *Discussion of potential medical risks should include, at a minimum:* • *Wound infection,* • *Pneumonia,* • *Blood clot formation,* • *Organ rejection, failure, or re-transplant;* • *Lifetime immunosuppressant therapy and potential complications thereof;* • *Arrhythmias and cardiovascular collapse,* • *Multi-organ failure and* • *Death.* *Discussion of potential psychosocial risks should include, at a minimum:* • *Depression,* • *Post-Traumatic Stress Disorder (PTSD),* • *Generalized anxiety, issues of dependence, and feelings of guilt.*
X155	*(5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and*	*Discussions with the transplant candidate regarding transplant programs' outcomes should, at a minimum, occur prior to the date of placement on the UNet[SM] waiting list.* *The program should have a policy and procedures for when, how and by whom the potential transplant recipient/transplant recipient will be informed of the SRTR data. Verification of the actual SRTR data (identified by the report date) provided or discussed with the transplant candidate must be documented in the medical record.* *Following the initial discussion, if more than six (6) months has elapsed between placement on the waiting list and selection for transplant, discussions*

	graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;	*should be held again with the transplant candidate prior to any surgical procedure. This section does not require transplant programs to notify transplant candidates every 6 months with the updated information, but the program must communicate any updated information to transplant candidates when follow-up discussions occur prior to surgery, or if the program is out of compliance with Medicare outcome requirements.* *The transplant candidate must be informed of:* • *The program's current 1-year post-patient survival and graft survival rate.* • *How these rates compare to the national averages.* • *Whether the latest reported outcome measures in the SRTR PSR comply with Medicare's outcome requirements.* • *The program's outcomes for LDs, including rate and type of complications (pre-discharge and long-term) and LD deaths.* • *National outcomes for LDs, as available.* *This information must be provided in a manner that is most appropriate for the transplant candidate's level of understanding allowing them to make an informed decision about their care.* *For additional information, the transplant candidate could be provided the SRTR (http://www.srtr.org/) and OPTN (http://optn.transplant.hrsa.gov/) websites, respectively. When requested, the transplant program must provide assistance in the interpretation of the appropriate reports for the transplant candidate.*
X156	*(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immune-deficiency virus and other infectious diseases*	*Before the transplant candidate is put on a waiting list, there must be a general discussion of the implications of the transplant. These discussions must include the possibility of graft failure and/or other health risks related to the health status of the deceased donor, including risks related to the:* • *Medical and social history and age of the donor,* • *Condition of the organ(s), and* • *Risk of contracting cancer, or HIV, hepatitis B virus (HBV), hepatitis C virus (HCV) or malaria if the infection is not detectable at the time of donation.* *After an organ offer is made to a transplant candidate, the transplant program must discuss with the transplant candidate the possible risks associated with transplantation of that specific organ. The discussion of risks should include any issues that could affect the success of the organ transplant (e.g., the condition of the organ), and any issues that could potentially place the health of the transplant candidate at risk (e.g., known high-risk behaviors in the deceased donor's or potential LD's background). This discussion should be documented prior to the transplant and again when the organ is determined suitable for a transplant candidate. The program should follow the PHS*

	if the disease cannot be detected in an infected donor;	*Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation. Once the potential recipient has been provided with necessary donor information related to risk(s) associated with transplantation of the specific organ, the patient should be given the option to refuse an increased risk organ for any reason and continue to be listed on the waitlist. The PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation is available at: http://www.publichealthreports.org/issueopen.cfm?articleID=2975*
X157	*(7) His or her right to refuse transplantation; and*	*Documentation in the medical record confirms that the transplant candidate was advised of the right to withdraw his or her consent for transplantation at any time during the process, and that he or she understands this right. This pertains to individuals that want to withdraw consent and be removed from the list.*
X158	*(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.*	*This regulation text in this section is to be provided to all transplant candidates during the evaluation phase even if the program is a Medicare-approved facility.* *This information should be provided to the transplant candidate after an organ offer is made to the transplant candidate and prior to the transplant candidate accepting the organ offer for transplant.*
X159	*(b) Standard: Informed consent for living donors. Transplant centers 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 centers must ensure that*	*For each of the subparagraphs (1) through (9) identified in this standard of the condition, the transplant program's policies and procedures must address:* *1. When the discussions will take place;* *2. Who is responsible for discussing the informed consent process with the potential LD;* *3. Where in the medical record the informed consent discussions are documented; and* *4. The methods used by the program to ensure and document potential LD understanding.* *This informed consent process is expected to involve multiple discussions with the potential LD at different points in time (e.g., while being evaluated as a potential LD and prior to surgery). The signed informed consent form and/or hospital surgical informed consent form should not be considered evidence that the informed consent process was complete without documentation that the nine elements were explained to the potential LD. Potential LDs must be given an opportunity to ask questions and their level of understanding must be*

	the prospective living donor is fully informed about the following:	*assessed.* *Note: A properly executed informed consent form that is signed and documented in the medical record for surgery or treatment for the potential LD is required under the hospital CoPs.* *Survey Procedures* *Review the medical records of the potential LDs to ensure there is documentation that the informed consent process corresponds to the requirements described above.* *Request a copy of all educational materials provided to potential LDs as part of the informed consent process. Confirm that educational materials are written at a reading level that is easily understood by the potential LD population served by the transplant program.*
X160	*(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.*	*The requirements at 45 CFR parts 160 and 164 establish standards for the security, privacy, and authorized release of personal health information.* *Survey Procedures* *Review a sample of potential LD medical records to verify that they were given information about the types of personal health information that will be collected and that this information and any communication between a potential LD and the ILDA/team, and a potential LD and the transplant program will remain confidential, subject to the authorized release of this information under certain circumstances (such as when the potential LD provides consent).*
X161	*(2) The evaluation process;*	*The evaluation process begins at the time an individual is identified as a LD candidate and continues until donation occurs or the potential LD is no longer a LD candidate.* *During the evaluation process, at a minimum, the following topics must be discussed with the potential LD.* • *Results of the physical evaluation, including a discussion of how any current health issues or medication regimen could be affected by the donation or could affect recovery from the donation;* • *Suitability for donation;* • *Results of laboratory and potential LD-specific diagnostic testing;* • *Relevance of any psychosocial issues related to donation; and* • *Financial responsibilities resulting from the living donation as well as post-donation expenses, including the potential for out-of-pocket costs if the potential LD has complications from the surgery, needs medication following discharge, and for follow-up testing or a physical examination so that the program can report the potential LD's status to the OPTN.* • *The potential LD must be advised that the transplant program cannot*

		require him or her to pay for post-donation testing or examination for follow-up purposes. (See Tag X166).
X162	*(3) The surgical procedure, including post-operative treatment;*	*Discussions with a potential LD about the surgical procedure must occur on several occasions prior to surgery. Prior to consent for donation, discussions should, at a minimum, provide the potential LD with an overview of the surgical procedure and potential risks and complications. A more detailed discussion of the surgical procedure should occur prior to the organ recovery surgery.* *At a minimum, the more detailed discussion of the surgical procedure occurring prior to the surgery should include:* • *Risks associated with the surgery;* • *Risks and effects of general anesthesia;* • *Possible need for blood transfusion and the risks involved with use of blood or blood products;* • *Expected post-surgical course and discomforts (e.g. possible need for artificial ventilation, pain, bleeding, and infection); and* • *Termination of the surgery with any indication that the LD is at risk of significant complications or death during the surgery.* • *If a kidney transplant, the risks of living with one kidney after donation.*
X163	*(4) The availability of alternative treatments for the transplant beneficiary;*	*Prior to consent for donation, the potential LD must be informed of the alternative treatment regimen(s) available to the recipient in lieu of receiving an organ from a live donor. This discussion must be documented in the potential LD evaluation notes or progress notes.* *The options for alternative treatments will vary by organ type and by the potential transplant recipient's specific medical condition. For example, kidney transplant candidates have dialysis options.*
X164	*(5) The potential medical or psychosocial risks to the donor;*	*Discussions regarding potential medical or psychosocial risks to the potential LD should occur early in the evaluation process prior to the consent for donation and with any change in the potential LD's medical or psychosocial condition.* *Discussion of the potential medical risks must include, at a minimum:* • *Wound infection,* • *Pneumonia,* • *Blood clot formation,* • *Arrhythmias and cardiovascular collapse,* • *Organ failure of the remaining organ (or part of the organ),* • *Potential need for organ transplant later on in life, and* • *Death.* *Discussion of the potential psychosocial risks must include, at a minimum:* • *Depression,*

		• *Post-Traumatic Stress Disorder (PTSD), and* • *Generalized anxiety, anxiety regarding dependence on others while recovering from the donation, and feelings of guilt.*
X165	*(6) The national and transplant center-specific outcomes for beneficiaries, and the national and center-specific outcomes for living donors, as data are available;*	*Discussions regarding the transplant program's outcomes must be done prior to the potential LD's consent for donation. If more than six (6) months has elapsed between consent for donation and the scheduled timeframe for the organ donation surgery, discussions to update the data must be held with the potential LD.* *The program must have a policy and procedures for when, how and by whom the potential LD will be informed of the SRTR data. Verification of the actual SRTR data (identified by the report date) provided or discussed with the potential LD must be documented in the medical record.* *The potential LD must be informed of the following, in understandable language:* • *The program's current 1-year post- survival and graft survival rate.* • *How these rates compare to the national averages.* • *Whether the latest reported outcome measures in the SRTR Program Specific Report comply with Medicare's outcome requirements.* • *The program's outcomes for LDs, including rate and type of complications (pre-discharge and long-term) and LD deaths.* • *National outcomes for LDs, as available.* • *The types of outcomes for LDs that are not calculated due to insufficient national data (such as long-term outcomes for LDs), as appropriate.* *This information must be provided in a manner that is most appropriate for the potential LD's level of understanding allowing them to make an informed decision about their care.* *For additional information the patient should be provided with the SRTR (http://www.srtr.org/) and OPTN (http://optn.transplant.hrsa.gov/) websites, respectively. Upon request, the transplant program should provide assistance in the interpretation of the appropriate reports.*
X166	*(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,*	*Documentation must confirm that a potential LD was informed that the donation procedure and future health problems related to the donation may not be covered by the donor's insurance. The potential LD must be informed that the donor's ability to obtain medical, disability, and life insurance in the future may also be jeopardized and there is the possibility of denial of coverage.*

	disability, or life insurance may be affected;	
X167	*(8) The donor's right to opt out of donation at any time during the donation process; and*	*Documentation in the medical record must verify that the potential LD was advised of, and understood his or her right to withdraw consent for living donation at any time during the process.*
X168	*(9) the fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant beneficiary's ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.*	*This regulation text must be provided to all potential LDs during the evaluation phase even if the program is a Medicare- approved facility.* *This information should be provided to the potential LD prior to acceptance as a LD.*
X169	*(c) Standard: Notification to patients. Transplant centers must notify patients placed on the center's waiting list of information about the center 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.*	*The transplant program's policies and procedures must clearly delineate how the program notifies the transplant candidate of the availability of key personnel for transplants, and other transplantation services, and how the transplant candidates will be informed of changes to this availability.* *<u>Note</u>: A transplant program may not have continuous availability if the program is served by a single transplant surgeon. This is permissible if transplant candidates are notified and acknowledge understanding of this fact. Transplant candidates must be notified if the program is not accepting organ offers or if the transplant candidate's ability to receive an organ offer is in any way affected. In essence, the transplant surgeon must be available or the transplant candidate must be notified.* *<u>Survey Procedures</u>* *Review a sample of the medical records of transplant candidates on the waiting list, and verify that in each case, the transplant candidate was informed about any aspect of program operations that could impact his or her ability to receive a transplant at that location (e.g., availability of key transplant personnel, only performing deceased organ transplants in cases where LD transplants may be an option at other transplant programs).*
X170	*(1) A transplant center served by a*	*A transplant program served by a single transplant surgeon or transplant physician must have written policies and procedures in place to inform the*

	single transplant surgeon or physician must inform patients placed on the center'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.*	*transplant candidates on the transplant program's waiting list regarding:* • *The potential unavailability of the transplant surgeon or physician; and* • *Whether or not the transplant program has the ability to provide an alternate qualified transplant surgeon or qualified transplant physician that meets the transplant program's credentialing policies.* • *The policies/procedures must also designate who will inform the waiting list transplant candidates, and how the record of this notification will be documented.* *<u>Survey Procedures</u>* *Review a sample of medical records of patients on the waiting list to verify that:* • *There is evidence that documentation was provided to the transplant candidates regarding the possible unavailability of key personnel;* • *The transplant candidates acknowledged understanding of the possible unavailability; and* • *The transplant candidates were made aware of potential unavailability prior to placement on the transplant program's waiting list.*
X171	*(2) At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must:* *(i) Inform patients on the center's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list;*	*This section is not reviewed onsite by CMS surveyors, unless it is the subject of a complaint investigation and CMS determines that onsite fact-finding is advisable.*

	and *(ii) Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.*	
X172	*(3) As soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center'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 center without loss of time accrued on the waiting list.*	*Transplant programs must have policies and procedures that describe how the patient is informed of program inactivity.* *<u>Survey Procedures</u>* *Review the TPQR to determine whether the transplant program became inactive for any period since the last date of review. If the inactivity was voluntary, the surveyor will review a sample of medical records for patients who were on the waiting list at that time. Confirm in the medical record that the patient was notified of the inactivation promptly once the inactivation was planned; and if applicable, assistance was provided to transfer to the waiting list of another Medicare-approved transplant program.*
X184	***§482.104 Condition of Participation: Additional Requirements for Kidney Transplant Centers.***	*Blank*
X185	*(a) Standard:*	*In addition to the medical and surgical services required for all transplant*

	End stage renal disease (ESRD) services. Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients.	*candidate/transplant recipients, ESRD patients may require additional services to support their potential need for dialysis services either in anticipation of transplantation or post-transplantation. This would include the availability of medical and surgical services to create and support vascular access and to provide interdialytic care.* *The term "directly furnished" is defined as services being provided within the physical location of the participating hospital. Verify that these are furnished directly.*
X186	*A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.*	*The kidney or kidney/pancreas transplant program must have ongoing communication with all dialysis facilities associated with transplant candidates on the transplant program's waiting list.* *<u>Survey Procedures</u>* *The transplant program must have written policies and procedures that describe the method and frequency of communication with the dialysis programs as well as types of information that must be shared.* *Communications should be documented and indicate the method of communication whether via electronic communications, written communications, or phone calls.* *Confirm through documentation that there is ongoing communication with the transplant candidates' local dialysis facility regarding significant issues such as:* • *Changes of key personnel in the transplant program;* • *Changes to key policies and procedures in the transplant program;* • *Changes in a transplant candidate's health status, such as infections, increase in the severity of heart disease or other conditions that could affect suitability for transplant, or death;* • *The status of transplant candidates who have special stipulations for transplantation, such as a cardiac workup or weight loss; and* • *Changes in the program's transplant candidate selection criteria.* *<u>Note</u>: Instances where the evidence indicates the transplant program has attempted to communicate with a dialysis facility, but the dialysis facility has been unresponsive should be referred to the applicable SA, RO and CO as a potential complaint about an ESRD facility.*
X187	*(b) Standard: Dialysis services. Kidney transplant centers must*	*The inpatient dialysis services must be furnished in either an acute dialysis center or a chronic dialysis facility (classified as either an "independent" or "hospital-based" facility for ownership purposes) located within the participating hospital, or performed in the inpatient care room. The chronic*

	furnish inpatient dialysis services directly or under arrangement.	*dialysis facility must have an agreement with the participating hospital for the provision of inpatient dialysis.* *Survey Procedures* *Verify that ESRD services are available for the care of ESRD patients.* *Survey of dialysis services is not included as a part of this survey. During the transplant program survey, the surveyor determines that inpatient dialysis services are available. Refer any concerns about the dialysis facility to the applicable RO.*
X188	*(c) Standard: Participation in network activities. Kidney transplant centers must cooperate with the ESRD Network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.*	*Each transplant program must have a relationship with its respective ESRD Network. ESRD Networks are mandated by statute, and Networks are responsible for developing criteria and standards relating to the quality and appropriateness of ESRD patient care, including the care of patients undergoing or preparing for transplantation. Information on the geographic areas of Networks and the SOW can be found on the CMS Website (http://www.cms.hhs.gov/ESRDNetworkOrganizations).* *Survey Procedures* *Review documentation of program participation with the ESRD Network related activities.*