DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-19-11-Transplant

DATE: **March 29, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Transplant Program Survey Activity Transition

Memorandum Summary

- All survey activity for approval and re-approval of Medicare transplant programs was transitioned back to the State Survey Agencies (SAs) as of January 1, 2019. These surveys were conducted by a federal contractor from 2013 until September, 2018.
- The SAs also assumed responsibility for communications between the approved transplant programs and the Centers for Medicare & Medicaid Services (CMS), to include recommendations to the CMS Regional Offices (ROs) regarding denials/approvals of new applicants, re-approval of approved programs, and/or termination of approvals.
- Funds were added to the State Agency budgets for FY 2019 for the additional survey activity.

Discussion

Effective January 1, 2019, all survey activities for transplant programs reverted back to the State SAs to be consistent with all other certified provider and supplier programs where the surveys are conducted by the State Agencies. From 2013 through September, 2018 these surveys were conducted by a federal contractor. This memorandum provides guidance to the SAs on the survey activities and expectations for the transplant programs. These activities include:

1. **Initial Approvals**:

It is recommended that each SA post on its website a list of the materials and information that must be provided to the SA by any transplant program requesting initial Medicare approval. A list of those items has been provided as Attachment A to this memorandum. If the SA does not post the information on its website, a list of the materials and information should be provided to the applicant upon notification of its request for approval. The applicant should be reminded by the SA that it is necessary for the hospital in which the transplant program is located (transplant programs must be located within a hospital that has a Medicare provider agreement (§482.68)), to submit a revised CMS-855A to its Medicare Administrative Contractor (MAC) indicating the addition of a practice location. The SA should confirm receipt of all necessary documents with the applicant and inform the applicant that the initial survey will be scheduled upon notification from the MAC that the revised CMS-855 has been approved.

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal – **Date:**

SUBJECT: State Operations Manual (SOM), Appendix X, Interpretive Guidelines for Organ Transplant Programs

I. SUMMARY OF CHANGES: CMS has established a new appendix in the State Operations Manual that outlines the interpretive guidelines 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.**

Transplant Program "X" TAGS and Abbreviated Identifiers

X001	**§482.68**	**Special Requirements for Transplant Centers**
X002	**§482.72**	**Condition: OPTN Membership**
X011	**§482.74 (a)**	**Condition: Notification to CMS**
X012	482.74 (a)(1)	Change in key staff members
X014	482.74 (a)(2)	Notified of termination of agreement with OPO
X015	482.74 (a)(3	Notified of inactivation
X021	**§482.76(a)**	**Condition: Pediatric Transplants**
X022	482.76 (b)(1-2)	Adult majority approved before pediatric program
X023	482.76 (c)(1-3)	Pediatric majority approved before adult program
X024	482.76 (d)(1)	PedHeart-OBRA97 – jointly operated
X025	482.76 (d)(2)	PedHeart-OBRA97 – unified program
X026	482.76 (d)(3)	PedHeart-OBRA97 – qualified svcs
X031	**§482.80**	**Condition: Data Submit/Experience/Outcomes, Initial Approval**
X032	482.80 (a)	Standard: Data submission, init approval
X033	482.80 (b)	Standard: Clinical experience (volume) init approval
X035	482.80(c)(1-4)	Outcomes: patient/graft survival init approval
X036	482.80 (c)(5)	Kidney transplant volume – new program, initial approval
X041	**§482.82**	**Condition: Data Submit/Experience/Outcomes, Re-Approval**
X042	482.82 (a)	Standard: Data submission, re-Approval
X043	482.82 (b)	Standard: Clinical experience (volume), re-approval
X045	482.82 (c)(1-4)	Outcomes: patient/graft survival, re-approval
X051	**§482.90**	**Condition: Patient and Living Donor Selection**
X052	482.90 (a)	Standard: Patient selection criteria non-discriminatory
X053	482.90 (a)(1)	Psychosocial evaluation for transplant candidate
X054	482.90 (a)(2)	Candidate's blood type documented
X055	482.90 (a)(3)	Patient selection criteria documented
X056	482.90 (a)(4)	Provide selection criteria to patient/dialysis facility
X058	482.90 (b)	Standard: Living donor selection
X058	482.90 (b)(1)	Psychosocial evaluation for living donor
X059	482.90 (b)(2)	Suitability for donation documented
X060	482.90 (b)(3)	Informed consent documented
X071	**§482.92**	**Condition: Organ Recovery and Receipt**
X073	482.92 (a)	Standard: Organ receipt
X074	482.92 (b)	Standard: Living donor transplantation
X081	**§482.94**	**Condition: Patient & Living Donor Mgmt**
X082	482.94 (a)(1-2)	Standard: Patient and living donor car
X083	482.94 (b)	Standard: Waiting list management
X084	482.94 (b)(1)	Update patient clinical information
X085	482.94 (b)(2)	Removal from waiting list
X086	482,94 (b)(3)	Notification of removal to OPTN
X087	482.94 (c)	Standard: Patient records
X088	482.94 (c)(1)	Patient informed of waiting list status
X089	482.94 (c)(2)	Patient notification of removal from waiting list
X090	482.94 (c)(3)(i)	Multi-disciplinary care planning – transplant period
X091	482.94 (c)(3)(ii)	Multi-disciplinary discharge planning
X092	482.94 (d)	Standard: Social services
X093	482.94 (d)(1-2)	Qualified social worker
X094	482.94 (e)	3Standard: Nutritional services
X099	**§482.96**	**Condition: Quality Assessment and Performance Improvement (QAPI)**
X100	482.96 (a)	Standard: Components of QAPI program
X101	482.96 (a)(1)	QAPI – actions/tracking to improve & sustain performance
X102	482.96(b)(1)	Standard: Adverse events
X103	482.96 (b)(2)	Analysis/Documentation of adverse events
X104	482.96 (b)(2)	Effect changes to prevent repeat incidents

Transplant Program "X" TAGS and Abbreviated Identifiers

X109	**§482.98**	**Condition: Human Resources**
X110	482.98 (a)	Standard: Director of transplant center
X111	482.98 (a)	Director's responsibilities
X112	482.98 (a)(1)	Adequate training of nursing staff
X113	482.98 (a)(2)	Tissue typing/organ procurement services available
X114	482.98 (a)(3)	Surgery performed by qualified transplant surgeon
X115	482.98 (b)	Standard: Transplant surgeon and physician
X116	482.98 (b)(1)	Transplant surgeon's responsibilities
X117	482.98 (b)(2)	Transplant physician's responsibilities
X118	482.98 (c)	Standard: Clinical transplant coordinator
X119	482.98 (c)(1)	Transplant Coordinator is licensed RN or clinician
X120	482.98 (c)(2)	Transplant coordinator responsibilities
X121	482.98 (d)	Standard: Independent living donor advocate or advocate team
X122	482.98 (d)(1)	Advocate/team not involved in transplantation
X123	482.98 (d)(2)	Advocate/team knowledge and understanding
X124	482.98 (d)(3)	Advocate/team responsibilities
X125	482.98 (e)	Standard: Transplant team
X126	482.98 (f)	Standard: Resource commitment
X139	**§482.100**	**Condition: Organ Procurement**
X149	**§482.102**	**Condition: Patient and Living Donor Rights**
X150	482.102 (a)	Standard: Informed consent for transplant patients
X151	482.102 (a)(1)	Patient informed - evaluation process
X152	482.102 (a)(2)	Patient informed - surgical procedure
X153	482.102 (a)(3)	Patient informed - alternative treatments
X154	482.102 (a)(4)	Patient informed - medical and psychosocial risks
X155	482.102 (a)(5)	Patient informed - nat'l and center's outcomes
X156	482.102 (a)(6)	Patient informed - donor risk factors
X157	482.102 (a)(7)	Patient informed - right to refuse transplant
X158	482.102 (a)(8)	Patient informed of immunosuppressive drug payment factors
X159	482.102 (b)	Standard: Informed consent for living donors
X160	482.102 (b)(1)	Donor informed that communication is confidential
X161	482.102 (b)(2)	Donor informed - evaluation process
X162	482.102 (b)(3)	Donor informed - surgical procedure
X163	482.102 (b)(4)	Donor informed - alternative treatment for recipients
X164	482.102 (b)(5)	Donor informed - medical and psychosocial risks
X165	482.102 (b)(6)	Donor informed - nat'l and center's outcomes
X166	482.102 (b)(7)	Donor informed - possible non-coverage
X167	482.102 (b)(8)	Donor informed - right to opt out
X168	482.102 (b)(9)	Donor informed - risk of recipient drug non-payment
X169	482.102 (c)	Standard: Notification to patients
X170	482.102 (c)(1)	Notify patients of single transplant surgeon
X171	482.102 (c)(2)	Notify patients of Medicare termination
X172	482.102 (c)(3)	Notify patients of voluntary inactivation
X184	**§482.104**	**Condition: Addt'l Requirements for Kidney Transplant Programs**
X185	482.104 (a)	Standard: End stage renal disease (ESRD) services
X186	82.104 (a)(1)	Ongoing communication with dialysis facility
X187	482.104 (b)	Standard: Dialysis services
X188	482.104 (c)	Standard: Participation in ESRD network activities

TAG	Regulation	Interpretive Guidelines June 13, 2008	Interpretive Guidelines March 29, 2019
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.*	**Note**: This tag should also be cited as "not met" if any Condition below is found out of compliance. Please note that these requirements became effective on June 28, 2007, and under no circumstances should the transplant program be required to provide medical records or other documentation pre-dating June 28, 2007.	***Guideline §482.68*** *As noted by their definitions in §482.70, pancreas and intestine programs are approved as a part of their associated "parent" approval (kidney and liver, respectively) and therefore these programs are reviewed as a component of the survey of the associated parent transplant program.* *If any Condition of Participation is found to be out of compliance, then this Condition must also be cited as being out of compliance.*
	(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.	Note: 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 located in a Medicare-approved kidney-program. To become a Medicare-approved heart/lung program, the hospital must also have a Medicare-approved heart and a Medicare-approved lung program. An intestinal/multi-visceral program must be located in an approved liver program.	
	(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.	In some states a Federal Contractor surveys transplant programs; in other states, the State Survey Agency (SA) conducts the surveys. Federal Contractor Surveyors' observation of a transplant program's non-compliance with the Hospital Conditions of Participation (CoP) must be referred to the applicable SA and CMS Project Officer for appropriate action. If SA surveyors identify any issues of non-compliance with the general hospital CoPs, the observations must be referred to the state SA unit responsible for hospital surveys. However, surveyors may initiate a hospital complaint investigation while onsite for the transplant survey (after receiving approval from CMS, and following the procedures of Chapter 5 of the SOM), or the identified issues may be reviewed by the SA at a later time as a complaint investigation.	
	General Requirements for Transplant Centers		
X002	***§482.72 Condition of Participation: OPTN Membership.*** *A transplant center must*	The most recent CMS Transplant Program Quarterly Report (TPQR) must confirm current OPTN membership. Surveyors may provide a copy of the TPQR to a transplant program during the onsite survey, so that the program has the	***Guideline §482.72*** *The hospital in which the organ transplant program(s) is a part of must be a member of the Organ Procurement and*

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	be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary pursuant to §121.4 of this title. *No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.*	opportunity to address any issues that it has with the information provided in the TPQR. As an OPTN member, the transplant hospital's membership status may fall into one of several possible categories (for example, full member, conditional approval, probation, and member not in good standing). If the transplant hospital has either of the following membership statuses listed: 1) "Withdrawal of OPTN Membership" or 2) "Not an OPTN Member," cite a condition-level deficiency. All other membership statuses should not be cited as a deficiency. If the TPQR indicates that a given transplant program is <u>not</u> approved by the OPTN for that organ-type or has terminated its membership, but the hospital is still approved for one or more programs, do not cite the deficiency here. Transplant programs that are not approved by 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. In addition, the OPTN has not reviewed the qualifications of personnel providing services. In these cases, review the Condition of Participation regarding Patient and Living Donor Management (X081, X083), Human Resources (X109, X115, X125), and Organ Procurement (X139) and the requirements at 42 CFR §488.61(e), and cite the appropriate deficiencies.	*Transplantation Network (OPTN) prior to Medicare approval and for as long as it is approved. In the event that the Secretary issues formal notice of his approval of a recommendation for the exclusion of a program from the OPTN, the associated Medicare approval will be terminated pursuant to non-compliance with 42 CFR 482.72.*
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:*	"Significant change" for purposes of this section, means any event that is likely to have considerable impact on the program's operations (such as the availability of the program for transplant, the number of transplants done, and the outcomes for patients). See Tags X012 through X015 for additional detail in each of the key areas. For purposes of this section, notifying CMS "immediately" means within 7 business days of when the transplant program becomes aware of the change (either that the change has occurred or will occur).	***<u>Guideline §482.74</u>*** *For purpose of this condition and its relative tags at X-012, X-014 and X-015, "immediately" means within seven business days of when the transplant program becomes aware that either a change will occur or has occurred.*

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X012	*§482.74(a)(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 (except intestinal and/or multivisceral programs) must have a designated primary surgeon and designated primary 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 at any time the program deviates from the OPTN policy. Prior to going onsite, review the most recent TPQR and note the designated 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, unless the facility can provide evidence that CMS was notified of the change. In the cited deficiency, document the date the designation of the physician or surgeon actually changed for the transplant program. If the program notified CMS regarding a change in the designated 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 designate to the OPTN a primary transplant surgeon and primary transplant physician. Inform the transplant program that they must immediately send a letter notifying CMS of the change, even though the citation has been recorded.	
X013	*(2) A decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with §482.82;*	**Note: This section does not apply to surveys for initial approval under §482.80.** During the course of the survey process (interviews, review of medical records, waiting list, transplant list, etc.) note any extended period of time when there were "significant changes" occurring at the transplant program which would have a direct effect on the transplant program's ability to conduct transplants or the outcomes of those transplants to such an extent that a reasonable person could conclude that the change would result in the program being out of compliance with the clinical experience (volume) or outcome requirements under §482.82. See examples of significant	

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		events below. Confirm that CMS was notified of any such event based on the information listed in the TPQR. A deficiency recorded for this Tag should identify that the provider failed to notify CMS within 7 business days. The surveyor should inform the transplant program that they must immediately send a letter notifying CMS of the events. Clinical Experience Examples: For programs subject to clinical experience (volume) requirements (i.e., adult heart-only, adult lung-only, adult kidney-only, adult liver, and adult intestinal and/or multivisceral), examples of significant events include (but are not limited to): 1. The transplant program loses a significant number or type of personnel including the primary surgeon or primary physician, which decreases the ability of the program to perform transplants for any period exceeding 3 months; and could result in the clinical experience requirement (an average of 10 per year) not being met. 2. The program loses access to hospital resources or facilities (e.g., lab services, damages to the physical plant or infrastructure) to such an extent that the loss seriously limits or prevents transplants from being performed for any period exceeding 3 months; and could result in the clinical experience requirement (an average of 10 per year) not being met. 3. Cases in which a transplant program's team transferred to another hospital. It would be expected that recruitment of another transplant team would take a significant amount of time; or 4. A program seeking reapproval that has conducted 5 transplants in Year 1 and Year 2. The likelihood of performing 25 transplants in Year 3 is low. Outcomes Examples: For programs subject to outcome requirements, requirements, examples of significant events include (but are not limited to): 1. Changes in patient selection criteria, patient care practices or protocols that had the unintended	

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		result of lowering patient or graft survival rates for a period exceeding 30 days that could result in the transplant program not meeting the outcome requirements. 2. The program (a) loses access for more than 30 days to hospital resources or facilities (e.g., lab services, damages to the physical plant or infrastructure) that affect the program's outcomes, and (b) the loss could lead a reasonable person to conclude that compliance with the outcomes under 482.82 may be jeopardized. Examples include but are not limited to the level of staffing or staffing coverage patterns, changes to the patient care practices, or immunosuppressant drug protocol. Some examples of circumstances where notifications to CMS is not expected include: 1. A patient's death, as opposed to a pattern of deaths that is significantly higher than historical rates. Please note that programs may be required to report this type of event to other governing bodies; or 2. A program that has 8 transplants in year 1 of the re-approval period.	
X014	*§482.74(a)(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*	Review the transplant hospital's current Organ Procurement Organization (OPO) agreement to verify that it has been in effect consistently. Confirm that this is the OPO listed for the transplant hospital on the most recent TPQR Report. A deficiency recorded for this tag should identify that the provider failed to notify CMS in a timely manner. The surveyor should also inform the transplant program that they must also send a letter notifying CMS of the change in OPO.	*Guideline §482.74(a)(2)* *Outside an approved waiver process, a hospital may not terminate its agreement with its designated OPO. Via a waiver request submitted to CMS, a hospital may request to work with an OPO in another OPO Donation Service Area. Should the waiver be granted, a hospital may then terminate the agreement with its designated OPO. See also 42 CFR 486.308. The transplant program must notify the applicable State Survey Agency (SA) of its hospital's intention to seek a waiver of its designated OPO. The hospital must submit the actual request for an OPO waiver to the Center for Medicare within CMS Central Office in Baltimore. Once the waiver is granted or denied, the hospital must provide a copy of the decisional document to the SA.*
X015	*§482.74(a)(3) Inactivation of the transplant center.* *§482.74(b) Upon receiving*	Transplant programs will be required to notify CMS when the program is either: 1) unable to receive organ allocation offers for transplant	*Guideline §482.74(a)(3)*

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	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.*	candidates for a period of 15 days or more, or 2) when no transplants have been performed for 90 days or more for heart, kidney, and liver programs and 6 months or more for pancreas, intestine/multivisceral, heart/lung and lung programs. CMS will send surveyors the TPQR report. This transmittal will provide any notifications CMS has received regarding transplant program inactivity. To verify that CMS was notified when appropriate, review the list of organ transplants for the last three years or since June 28, 2007, whichever date is most recent. Note any periods (that include dates after June 28, 2007) where there were no transplants for more than a 90-day period for heart, kidney, and liver programs and a 6 month period for pancreas, intestine/multivisceral, heart/lung, and lung programs. Review the transplant program's list of received/declined organs during the corresponding time period. If organs were declined, determine the reason(s) why and confirm that the reasons were unrelated to the transplant program's operational status or ability to perform organ transplants (such as the available organs were considered not to be viable options for the transplant candidates, or the transplant candidates were not available for transplants). The sole purpose of this aspect of the survey process is to assess periods of inactivity, not to judge the transplant program's turndown policy or practice. If necessary, interview the Director of the transplant program to verify whether the heart, kidney, or liver programs were inactive for more than 90 days, or for more than 6 months for pancreas intestine/multivisceral, heart/lung or lung programs. Compare the time periods with information from the TPQR to confirm that CMS was notified as required. If the transplant program was available to provide services but no transplants were performed due to organ unavailability (or in rare cases when a transplant recipient may not be available), do <u>not</u> consider this to be an inactive period.	*Upon notification of a program's plan for inactivation, CMS may request additional information from the program pertaining to the reason for the inactivation and the communications that have occurred to notify and assist the patients on the program's waitlist in association with the inactivation period.* *Per §488.61(e) Transplant Center Inactivity, "A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months." Program inactivity does not preclude a program from survey for compliance with the Conditions of Participation during the inactivation period. If a program's inactivity period exceeds 12 months, it must reactivate, voluntarily withdraw from Medicare participation, or be subject to termination of its Medicare approval.*
X021	***§482.76*** ***Condition of Participation: Pediatric Transplants.*** *A transplant center that seeks Medicare approval to provide transplantation services to*	Determine if the transplant program is applying for or approved for both an adult and a pediatric transplant program for the same organ type by reviewing the CMS TPQR. Transplant programs that serve both adult (age 18 and	***<u>Guideline §482.76(a)</u>*** *Upon application to the Medicare program, a transplant program must specify whether it requests approval as an adult or pediatric program.*

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	pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at §488.61 of this chapter. (a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at §482.72 through §482.74 and §482.80 through §482.104 with respect to its pediatric patients.	over) and pediatric (under age 18) patients may choose to apply for separate approval as an adult and pediatric program, 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 50% or more of its transplants in a 12-month period to pediatric patients must apply as a pediatric program. A program that provides 50% or more of its transplants in a 12- month period must apply as an adult program.	
X022	***§482.76 (b) A center that performs 50 percent or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.*** *(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants. (2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform adult transplants.*	This section applies only if both the adult and pediatric transplant programs are Medicare-approved as separate program types, or are seeking separate Medicare approval. In reviewing a pediatric transplant program determine: 1) whether or not there is a corresponding adult program for this organ type; and 2) based on the TPQR data, whether or not the adult program performed 50% or more of all transplants over the previous 12 months. If the answer to both of these is "yes," then the adult program must be separately approved for Medicare participation before (or simultaneously with) its pediatric program can be approved. Example: Consider a pediatric kidney-only program at a transplant hospital that performed 8 transplants on pediatric patients within the last 12 months. The adult kidney-only program is also seeking Medicare approval and performed 16 transplants in the previous 12 months. First, determine the total number of transplants performed for both the adult and pediatric programs. In this example, the total is 24, and the adult program is the majority program performing 66% of the transplants (16/24). In this example, if the adult program is approved (or will be approved following the survey), then the pediatric program can be approved. On the other hand, if the adult program cannot be approved, then the pediatric program cannot be approved, even if the	***Guideline §§482.76 (b)(1)-(2)*** *A pediatric transplant program is permitted to perform adult transplants under its pediatric Medicare approval. But, if the pediatric program performs 50% or more of its total volume of transplants, in a 12 month period, on adults, the program must decide whether to seek an additional adult program approval or revise their single designation to an adult designation.* *If the program elects to maintain its pediatric approval and to seek an additional adult program approval, there may be an impact in the event of a termination of one of the programs. Termination of the pediatric program will trigger a review of the adult program. Termination of the adult program will result in the automatic termination of the pediatric program.*

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		pediatric program meets the other Medicare Conditions of Participation. If the transplant program performs an equal number of adult and pediatric transplants so that each program performs exactly 50.0% of the transplants, then the adult and pediatric programs can be Medicare-approved if they meet the Medicare requirements. Cite this tag at the Condition-level if the adult program for a given organ type performs the majority of the transplants and can not be Medicare-approved (or loses its Medicare approval), and as a result, the corresponding pediatric transplant program may not be approved. 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.	
X023	***§482.76 (c) A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.*** *(1) Loss of Medicare approval to perform pediatric transplant, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants.* *(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform pediatric transplants.* *(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a*	This section is the reverse of Tag X022. This section applies only if both the adult and pediatric transplant programs are Medicare-approved as separate program types, or are seeking separate Medicare approval. In reviewing adult transplant programs, determine 1) whether or not there is a corresponding pediatric program for this organ type; and 2) whether or not the pediatric program performed more than 50% of all transplants over the previous 12 months based on information provided in the TPQR. If the answer to both of these is "yes," then the pediatric program must be separately approved for Medicare participation before (or simultaneously with) approval for the adult program. Example: Consider an adult heart/lung transplant program at a hospital that performed 1 transplant on an adult patient within the last 12 months, based on data from the TPQR report. The transplant hospital has also applied for Medicare approval of its pediatric heart/lung program. The pediatric program is also being surveyed during this visit. The pediatric heart/lung program performed 3 transplants in the previous 12 months based on the TPQR. Determine the total number of transplants performed for both the adult and pediatric programs. In this example, the total is 4, and the pediatric program is the majority program performing 75% of the transplants (i.e., 3 of the 4	*Guideline §§482.76(c)(1),(2) and (3)* *An adult transplant program is permitted to perform pediatric transplants under its Medicare approval. However, if the number of pediatric transplants performed exceeds 50% of the total volume of transplants performed under the adult approval within a 12 month period, the program is required to seek separate pediatric approval. The pediatric transplant program would now represent the majority of transplants performed and therefore must maintain its Medicare approval in order for the adult program to continue to perform adult transplants,* *If the pediatric program becomes the majority population served, loss of this approval would also mean a loss of the programs ability to perform adult transplants.* *If the approval for the adult program is lost, the pediatric program may continue to perform transplants, but could be subject to a program review.*

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	pediatric transplant center	transplants). If the pediatric program is the predominant program, (i.e., performing more than 50% of transplants of an organ type on pediatric patients), then the pediatric program must be approved for Medicare participation before, or simultaneously with, approval of an adult program for that organ type. If the transplant program performs an equal number of adult and pediatric transplants so that each program performs exactly 50.0% of the transplants, both the adult and pediatric programs must be Medicare-approved. Cite this tag at the Condition-level if the pediatric program for a given organ type performs the majority of the transplants and the pediatric program cannot be Medicare-approved (or loses its Medicare approval), and as a result, the corresponding adult transplant program may not be approved. 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.	
X024	***§482.76 (d) Instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub.L.100-203), as follows:*** *(1) The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare- approved;*	Prior to going onsite, review the TPQR report to determine whether the pediatric heart program is seeking alternate approval under this section. The TPQR Report 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 pediatric program. Review the joint operating agreement between hospital with the 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: A. A commitment by the transplant hospital and the associated facility to jointly operate the pediatric heart transplant program; and, B. Confirmation that the associated facility is Medicare-approved to perform heart transplants.	***Guideline §482.76 (d)(1)*** *In order for a pediatric heart transplant program to be approved under the OBRA of 1987 criteria rather than the Conditions of Participation, there must be evidence that it is being operated jointly by the hospital in which it's located and another Medicare hospital. Joint operation means that services and staff from both hospitals are required to accomplish the transplants performed at the pediatric hospital. See standards and guidance at §482.76(d)(2) and §482.76(d)(3) below. This joint operation may occur pursuant to a structured affiliation between the two hospitals or pursuant to a written agreement.*

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X025	***§482.76(d)(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and***	Surveyors will likely need to visit both sites to verify that the program that is 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, patient protocols, oversight of the program, and/or patient selection criteria. Review the post-June 28, 2007, medical records of a sample of pediatric heart transplant patients, and a sample of post- June 28, 2007, medical records of heart transplant patients 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. 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 patients 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 within the two programs; • different processes for analyzing and reviewing adverse events; • different patient and/or living donor informed consent protocols; and different patient selection criteria or different processes for granting exceptions to those criteria. The key question for surveyors in assessing differences is "Are these differences the result of the specialized services or needs for pediatric patients if other operations are unified among the two programs?" If the response is "yes," then this would not be considered a deficiency. Listed below are examples of differences that may exist between two programs that a reasonable person would assess as being specific to the needs of pediatric patients, and would not be considered evidence that the program is not operating in a unified manner.	*Guideline §482.76(d)(2)* *The surgeons who perform the heart transplants at the pediatric hospital are credentialed for cardiac surgery at both the pediatric Medicare-approved hospital and the other approved hospital. The surgeons may be employed full time by the other Medicare-approved facility.* *The pediatric heart transplant program must be able to provide evidence that the QAPI programs for both hospitals are shared and would include review, analysis and recommendations for the pediatric transplants. The other Medicare-approved facility reviews data as regards the pediatric surgical services and the pediatric hospital reviews the data concerning evaluation, pre and post-operative care. Both QAPI programs would review and evaluate the need for any changes in the collaboration between the two entities.*

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		Example 1: The review of medical records indicates that there is a designated transplant coordinator (with expertise in pediatric patients) that does not work with the adult patients from the associated heart transplant program. This is permissible and would not be considered out of compliance since this is an example of specialized services for pediatric patients, if other operations are unified between the two programs. Example 2: A transplant program informed consent practices for the pediatric heart program may be different than the adult heart program. One set of materials could be provided to pediatric patients (presented at a level understood by children) with more detailed information provided to parents/guardians. The adult program may not follow this same procedure. This is permissible. An example of a program operating in a non-unified manner would include a program that has two separate quality assessment and performance improvement (QAPI) programs that each monitor their own program and the QAPI reports and activities are not shared with one another and/or discussed.	
X026	***§482.76 (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.***	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 patients. This description may include but is not limited to: A. what specialized facilities (e.g., equipment, patient areas) will be provided for pediatric heart transplant patients; B. what special services are available to provide for pediatric heart transplant patients (e.g., a designated transplant coordinator for pediatric patients, or a pediatric psychologist); and C. what are the unique qualifications and competencies that the transplant personnel must have to care for pediatric heart transplant patients, 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 most recent survey of the associated heart transplant program to see if any deficiencies cited for that	***Guideline §482.76(d)(3)*** *Facilities include (for example): surgical suites; recovery rooms; inpatient rooms.* *Services include (for example): laboratory services; radiology.* *Personnel include (for example): all required members of the Multidisciplinary Team; pre-operative and post-operative medical and nursing services.*

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		program indicate problems in providing the specialized facilities, services and personnel required by pediatric heart transplant patients under the jointly-operated program.	
	§482.78 Condition of participation: Emergency preparedness for transplant centers. *A transplant center must be included in the emergency preparedness planning and the emergency preparedness program as set forth in §482.15 for the hospital in which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in §482.15.*		***Interpretive Guidelines for §482.78*** *A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness program, as required under §482.15(g)(1).* *Transplant centers would still be required to have their own emergency preparedness policies and procedures as required under §482.78(a), as well as participate in mutually-agreed upon protocols that address the transplant center, hospital, and OPO's duties and responsibilities during an emergency.* ****Refer to State Operations Manual Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types for guidance and* ***42 C.F.R. 482.78 Emergency preparedness for transplant centers.********
	Transplant Center Data Submission, Clinical Experience, and Outcome Requirements		
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 the regulation 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.	***Guideline §482.80*** *The Standards of this Condition are evaluated by the surveyor off-site, prior to the survey. The determination of compliance or non-compliance will be communicated to the program at the time of the survey entrance conference. Since this finding is based upon data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data, during the survey, to change the compliance determination.*
X032	***§482.80 (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*	Review the most recent TPQR for the program. Verify that 95% of the required forms have been submitted to the OPTN consistent with the required timeframe. No onsite verification is required. Cite a deficiency if the submission percentage recorded on the TPQR is less than 95%. If a program was not required to submit any forms during the time period assessed in the TPQR, the number of forms	***Guideline §482.80 (a)*** *The determination of compliance or non-compliance with this Standard is made prior to the on-site survey. The determination is shared with the program at the time of the survey entrance conference. Since this finding is based upon data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data, during the survey, to change the compliance determination.*

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	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.	due will be listed as 0, and the percentage compliance will be listed as 0%. This is not considered a deficiency; the TPQR will note "Meets compliance, no OPTN forms were due." Note: For initial approval, the time frame used to assess compliance with this section is the calendar quarter prior to the onsite survey.	
X033	***§482.80 (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" for purpose of this section means the program is first approved under these Conditions of Participation. Review the most recent TPQR for the number of transplants performed over the previous 12-month period. The following types of programs are subject to a clinical experience requirement of 10 transplants performed over a 12-month period for initial approval: • Adult Heart-Only • Adult Lung-Only • Adult Liver • Adult Intestinal and/or Multivisceral • Adult Kidney-Only (See note below.) Note for adult kidney-only programs: If the program was Medicare-approved as of June 28, 2007, then the program must meet the clinical experience requirements of 10 transplants over the previous 12-month period. For programs that are not Medicare-approved as of that date, the program must perform at least 3 transplants within the 12 months prior to approval. See Tag X036 for additional information. Transplants performed on pediatric patients cannot be used to meet the adult clinical experience (i.e., volume) requirements. A program's inactivity does not create an exemption from this regulatory requirement. Cite a deficiency if a program has performed fewer than 10 transplants over a 12-month period unless: 1. The transplant program can provide more recent data that shows that the transplant program performed 10 transplants over a 12-month period, or 2. There were adult kidney/pancreas transplants	*Guideline §482.80(b)* *Generally means in all instances except where specifically exempted by the regulations.* *The following types of programs are subject to a clinical experience requirement of having performed generally 10 transplants over a 12-month period for initial approval:* *• Adult Heart-Only* *• Adult Lung-Only* *• Adult Liver* *• Adult Intestinal and/or Multivisceral* *For purposes of the clinical experience requirement, multi-organ transplantation will be included as separate transplants for each organ. For example, a combined liver-kidney transplant will account for one liver transplant and one kidney transplant.*

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		performed by the same transplant team(s) s that routinely perform kidney transplants at the same hospital, that, when added to the number of adult kidney-only transplants, would total 10 or more and show compliance with this standard. For example, if there were 14 adult kidney/pancreas transplants performed, and 8 kidney-only adult transplants performed by the same team at the same transplant hospital, the deficiency would not be cited, because the kidney-only program would be considered to have performed 22 transplants. 3. An adult heart-only program may include the number of adult heart/lung transplants performed by the same transplant team(s) who routinely performs heart-only or lung-only transplants at the same hospital, for the purpose of compliance with this standard. 4. An adult lung-only program may include the number of adult heart/lung transplants performed by the same team(s) who routinely perform heart-only or lung- only transplants at the same hospital, for the purpose of compliance with this standard. The surveyor should determine whether or not a transplant team that performs the multi-organ transplant can be considered "the same team" that performs the single organ transplant. Performance of the multi-organ transplant by the same surgeon(s) that perform the single-organ transplant can be considered as persuasive evidence in most cases, but there may be circumstances in which there are other substantial differences in the support teams and other key personnel involved in the transplantation process (e.g., physicians, clinical transplant coordinators, nurses, etc.), in which the determination could be that it is not "the same team." Note about #2, #3, and #4 Above: The exceptions described above allow the clinical experience gained in a multi-organ transplant (generally, a more complex surgery) to be counted in the clinical experience requirements for a single-organ transplant (which would generally be less complex), provided that the same transplant team(s) performs both the single and multi-organ transplants. The adult kidney-only, adult heart-only, and adult-lung programs were singled out for these exceptions because they have both clinical experience requirements and related	

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		multi- organ transplant programs (i.e., kidney/pancreas, and heart/lung). Note: Consistent with OPTN policy, multi-organ transplants not covered under the combination types above would be counted as one for each organ type. For example, a liver/kidney transplant would be counted for both liver and kidney.	
X034	(c) Standard: Outcome Requirements. (2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center- specific report (CSR).	*Blank*	
X035	***§482.80(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:* *(i)A center's observed patient*	Review the TPQR. The report will indicate whether the program meets any outcome requirements that may apply. If the TPQR indicates that the outcome requirements have not been met, cite a deficiency. The TPQR information already considers whether a program is required to meet outcome requirements, and the methodology that SRTR uses to calculate the CSR for each program-type. The program types subject to this requirement include: • Adult Kidney-Only • Adult Heart-Only • Adult Lung-Only (Includes ages 12 and over.) • Adult Liver • Pediatric Kidney-Only (Includes only 1-year graft survival) • Pediatric Heart-Only • Pediatric Lung-Only (Includes ages 12 and over.) • Pediatric Liver Note: The methodology of the SRTR Center Specific Report (CSR) for lung programs calculates one risk-adjusted report that includes transplant recipients ages 12 and over and another non-risk adjusted pediatric report for those under age 12. The regulation (482.80(c)) states that for lung programs, CMS will review adult and pediatric outcomes together. Therefore, this single risk-adjusted report (covering ages 12 and over) will be used to assess compliance for both the adult and pediatric lung programs.	***Guideline §§482.80(c) and (d)(1)-(4)*** *The program types subject to this requirement and not exempted include:* • *Adult Kidney-Only* • *Adult Heart-Only* • *Adult Lung-Only* • *Adult Liver-Only* • *Pediatric Kidney-Only (Includes only 1-year graft survival)* • *Pediatric Heart-Only* • *Pediatric Lung-Only* • *Pediatric Liver-Only*

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	survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and *(ii)All three of the following thresholds are crossed over:* *(A) The one-sided p-value is less than 0.05,* *(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and* *(C) The number of observed events divided by the number of expected events is greater than 1.85.* *(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 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*		

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	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 transplant 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 transplant center.*		
X036	***§482.80(d) (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.***	See Tag X033.	
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.*	Note: Paragraph (d) of this section refers to those programs that are exempt from clinical experience and/or outcome requirements. Since the items listed in paragraph (d) are not surveyed, they are not part of these guidelines. A description of these exceptions can be found in the regulation text.	
X042	*§**482.82 (a) Standard: Data Submission*** *No later than 90 days after the due date established by the OPTN, a transplant center*	Review the most recent TPQR. Verify that 95% of the required forms have been submitted to the OPTN, consistent with the required timeframe. No onsite verification is required. Cite a deficiency if the	***Guideline §482.82(a)*** *CMS receives required data submission reports directly from the OPTN and therefore no additional information or adjustments may be accepted by CMS during an onsite survey.*

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	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.	submission percentage on the TPQR is less than 95%. Note: The timeframe used to assess compliance with this section includes calendar quarters following the initial approval through the most recent calendar quarter before the survey considering re-approval.	
X043	***§482.82 (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.*	Review the most recent TPQR for the average number of transplants performed during the re-approval period. Transplant programs subject to clinical experience requirements must perform an average of 10 transplants per year. This means that a transplant program is not out of compliance with this requirement if they perform 30 transplants over the three-year re-approval period regardless of whether 10 transplants are performed in each calendar year. The TPQR information already considers whether a program is required to meet clinical experience requirements. If the TPQR indicates that this requirement has not been met, cite a deficiency. Note: The timeframe for the re-approval period is from the previous approval of the program to the current survey. The following types of programs are subject to clinical experience requirements to be considered for re-approval: • Adult Kidney-Only • Adult Heart-Only • Adult Lung-Only • Adult Liver • Adult Intestinal and/or Multivisceral Transplants performed on pediatric patients cannot be used to meet the adult clinical experience (i.e., volume) requirements. A program's inactivity does not create an exemption from this regulatory requirement. If the program has clinical experience requirements and the average number of transplants performed is less than 10	*Guideline §482.82(b)* *Generally means in every instance except where specifically exempted by regulation.* *The transplant programs listed below do not have any exemptions and must perform an average of 10 transplants per year.* • *Adult Heart-Only* • *Adult Lung-Only* • *Adult Liver-Only* • *Adult Intestinal and/or Multivisceral* • *Adult Kidney-Only* *For purposes of the clinical experience requirement, volume for multi-organ transplantation will be included for each respective organ type. For example, a combined liver-kidney transplant will account for one liver transplant and one kidney transplant.*

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		per year (based on the information from the TPQR), cite the finding unless: 1. The transplant program can provide more recent data that shows that the transplant performed an average of 10 transplants per year during the re-approval period; or 2. An adult kidney-only transplant program demonstrates that a sufficient number of adult kidney/pancreas transplants were performed by the same transplant team(s) who are at the same hospital to bring the adult kidney-only program into compliance with this standard; or 3. An adult heart-only program may include the number of adult heart/lung transplants performed by the same transplant team(s) that routinely perform heart-only or lung-only transplants at the same hospital, for the purpose of compliance with this standard. 4. An adult lung-only program may include the number of adult heart/lung transplants performed by the same transplant team(s) that routinely perform heart-only or lung-only transplants at the same hospital, for the purpose of compliance with this standard. Note about #2, #3, and #4 Above: The exceptions described above allow the clinical experience gained in a multi-organ transplant (generally, a more complex surgery) to be counted in the clinical experience requirements for a single-organ transplant (which would generally be less complex), provided that the same transplant team performs both single and multi-organ transplants. The adult kidney-only, adult heart-only, and adult-lung programs were singled out for these exceptions because they have both clinical experience requirements and related multi- organ transplant programs (i.e., kidney/pancreas, and heart/lung).	
X044	**(c) Standard: Outcome Requirements.** (2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center- specific report.	*Blank*	

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X045	***§482.82(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:* *(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 1.85.* *(D) Exceptions* *(1) A heart-lung transplant center is not required to*	Review the TPQR. The report will indicate whether the program meets any outcome requirements that may apply. If the TPQR indicates that the outcome requirements have not been met, cite a deficiency. Note: The TPQR information already considers whether a program is required to meet outcome requirements, and the methodology that SRTR uses to calculate the CSR for each program-type. The program types subject to outcome requirements include: • Adult Kidney-Only; • Adult Heart-Only; • Adult Lung-Only (Include ages 12 and over.); • Adult Liver; • Pediatric Kidney-Only (Includes only 1-year graft survival); • Pediatric Heart-Only; • Pediatric Lung-Only (Include ages 12 and over.); and • Pediatric Liver. Note: The methodology of the SRTR Center Specific Report (CSR) for lung programs calculates one risk-adjusted report that includes transplant recipients ages 12 and over and another non-risk adjusted pediatric report for those under age 12. The regulation (482.82(c)) also states that for lung programs, CMS will review adult and pediatric outcomes together. Therefore, this single risk-adjusted report (covering ages 12 and over) will be used to assess compliance for both the adult and pediatric lung programs.	*Guideline §482.82(c)* *The program types subject to outcome requirements and are not exempted include:* • *Adult Kidney-Only* • *Adult Heart-Only* • *Adult Lung-Only* • *Adult Liver-Only* • *Pediatric Kidney-Only (Includes only 1-year graft survival)* • *Pediatric Heart-Only* • *Pediatric Lung-Only* • *Pediatric Liver-Only*

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	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 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 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.*		
	Transplant Center Process Requirements		
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*	*Blank*	***Guideline §482.90*** *Transplant programs are required to develop their own hospital-approved selection criteria to determine suitability for organ transplantation and living donation. There must be evidence that the written selection criteria are followed for the selection of transplant candidates to be placed on the transplant waitlist and, if applicable, potential living donors. Any changes to the hospital-approved, written selection criteria are approved according to the hospital policy approval process. The selection criteria (medical, psychosocial, financial, etc.) must clearly define all the factors that are considered in*

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	must use written donor selection criteria in determining the suitability of candidates for donation.		*determining suitability for transplantation or living donation. These criteria may not exclude groups or individuals without documentation supporting the exclusionary foundation(s).*
X052	***§482.90(a) Standard: Patient Selection.*** *Patient selection criteria must ensure fair and non-discriminatory distribution of organs.*	Review the transplant program's written transplant patient selection criteria. The selection criteria (medical, psychosocial, financial, etc.) must clearly define the characteristics of the patients for whom the program will and will not provide transplant services. These criteria may not exclude groups of individuals based on factors such as race, ethnicity, religion, national origin, gender, or sexual orientation. Please note, there are factors that some transplant programs can and do use in their patient selection criteria including age, ability to pay, ability to adhere to immunosuppression regimen, presence of an active infection, etc. Consideration of these types of factors is permissible. Review the complete list of the transplants performed by the program within the last 3 years or June 28, 2007, whichever is most recent. The list should include, at a minimum: name, address, country of primary residence, resident alien or non- resident alien status, race, and gender. Compare the transplant program's patient selection criteria and the list of transplants performed for the last 3 years for any patterns that suggest the program's selection criteria are not being followed. Include questions in the interview process of transplant program staff to verify that the transplant program's policy is being followed. If patterns of discriminatory distribution of organs by the program are identified, contact the appropriate CMS Regional Office for further instruction. Such patterns may indicate that the national organ allocation (OPTN) policy is not being followed appropriately. Each organ allocation is reviewed by the OPTN. It is outside the scope of this survey to determine whether a specific organ that became available should have been matched with a specific transplant recipient on a transplant program's waiting list, or whether another person on the waiting list should have received the organ.	***Guideline §482.90(a)*** *The patient selection criteria must be followed consistently in a fair and non-discriminatory manner for all potential transplant candidates and living donors. For candidates that are placed on a transplant program's waiting list outside of the patient selection criteria, documented evidence must be present to support the exception.* *Discrimination can mean exclusion of those who meet the transplant program's hospital approved selection criteria and should be included on the waitlist as well as inclusion on the waitlist of those who do not meet the hospital approved selection criteria*
X053	***§482.90(a)(1) Prior to placement on the center's***	Review the written patient selection policy to verify that it contains a requirement for a prospective transplant	***Guideline §482.90(a)(1)***

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	waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.	candidate to receive a psychosocial evaluation by a qualified healthcare professional PRIOR TO PLACEMENT ON THE WAITING LIST. The policy is expected to (1) indicate the length of time in which the psychosocial evaluation is deemed to be current, (2) identify the qualified healthcare professionals who may complete these evaluations (it is expected that these professionals would have knowledge of transplantation), and (3) include the follow-up and referral procedures if a transplant candidate requires such activities. While the transplant program has flexibility in the specific psychosocial tool to be used, the psychosocial evaluation is expected to be completed and to be focused on the individual's suitability for transplantation. It is expected that a psychosocial evaluation of this nature would be conducted by transplant program personnel and would address the following: 1) social, personal, housing, vocational, financial, and environmental supports; 2) coping abilities and strategies; 3) understanding of the risks and benefits of transplantation; 4) ability to adhere to a therapeutic regimen; and 5) mental health history, including substance or alcohol use or abuse and how it may impact the success or failure of organ transplantation. The psychosocial evaluation is expected to be age-appropriate. Similar to psychosocial evaluations in other areas, in cases of young pediatric patients, the evaluation would include interviews with the parents/guardians. Verify in the sample of post-June 28, 2007, transplant recipient medical records that the psychosocial evaluation was completed by a person authorized under the program's policy before that potential recipient was placed on the UNET and transplant program's waiting lists. UNET is the secure Internet-based transplant database operated by the contractor for the OPTN (UNOS) for the nation's transplant programs and Organ Procurement Organizations to register patients and donors on the waiting list and for transplantation. In each case, if a referral was made for further psychosocial evaluation before it could be determined whether an individual was to be placed on the UNET waiting list, verify that additional evaluation was completed as required by the transplant program's policies and procedures for follow-up	*An evaluation of each candidate's psychosocial status must be conducted in all situations in which it is possible to do so in order to determine suitability for transplantation and/or identify resources that potentially will be needed for the safe care and discharge of the patient post-discharge. The transplant program must conduct and document the psychosocial evaluation performed on a potential recipient before their placement on the waitlist. The only exception for not completing the psychosocial evaluation prior to placement on the waitlist would be an emergent situation where the need for transplant is imminent or the patient is very young. Justification for not conducting a psychosocial evaluation prior to a potential recipient's placement on the waitlist must be documented in the medical record.* *While the transplant program has flexibility in the selection of a specific psychosocial evaluation tool(s) to be used, it is expected that the psychosocial evaluation would be conducted by transplant program personnel who have the professional qualifications to administer psychosocial evaluations, make resultant assessments and make recommendations to the multidisciplinary team. Evaluations should include, at a minimum, the following:* • *Social, personal, housing, vocational, financial, and environmental supports;* • *Coping abilities and strategies;* • *Understanding of the risks and benefits of transplantation;* • *Ability to adhere to a therapeutic regimen; and* • *Ongoing psychological issues that may impact the success or failure of organ transplantation.*

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		and referral. It is expected that in nearly all cases, a psychosocial evaluation is possible and should be conducted as part of the determination of whether or not someone would be a suitable transplant candidate. There are rare or emergency situations when a psychosocial evaluation cannot be completed prior to transplantation due to the patient's medical condition and with the absence of family or others that can provide information/insight into the psychosocial history of the patient. In such cases, verify that documentation is included in the transplant patient's medical record that describes the reason a psychosocial evaluation was waived or unable to be completed, due to the need for emergency intervention or exceptional circumstances and that no family or others were available to address the psychosocial history of the patient. Examples of these exceptional or emergent circumstances may include untreatable encephalopathy, massive liver trauma, and acute (fulminant) liver failure (e.g., Tylenol overdose, mushroom poisoning).	
X054	***§482.90(a)(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.***	Review the transplant program patient selection policy to verify that the program requires documentation of the transplant candidate's blood type in the medical record before placing a patient on the waiting list. Review the post-June 28, 2007, medical records of a sample of patients 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 waiting list, and confirm in the medical record that the blood type of the patient was determined prior to this date.	
X055	***§482.90(a)(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.***	Review the post-June 28, 2007, medical records of a sample of patients on the transplant program's list to determine if there is documentation of the specific selection criteria that were used to place the patient on the waiting list. Confirm that the criteria used are consistent with the program's policy. During the review of transplant patient'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). Cite a deficiency if the selection criteria used to place a patient on the waiting list are not documented in the	*Guideline §482.90(a)(3)* *The potential recipient medical record must contain documentation that the multidisciplinary team considered all evaluations in the context of the hospital-approved selection criteria. If the potential recipient does not meet the hospital-approved selection criteria, but was placed on the waiting list anyway, the exception justification for listing must be clearly documented in the potential recipient's medical record.*

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		medical record, or if the selection criteria used do not follow the program's written patient selection criteria. 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. Note if the program's policies identify any exceptions to the selection criteria that are allowed. The policy must describe the complete process for making, justifying and documenting exceptions. Cite a deficiency if there is evidence that an exception has been made that is inconsistent with the program's patient selection policies.	
X056	***§482.90(a)(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.***	Request and review any materials which the transplant program distributes upon request to explain the program's selection criteria and process. Ensure these materials are at a reading level easily understood by the patient population served by the transplant program. During interviews with transplant program staff, include questions to determine how the program ensures that patients and dialysis facilities are provided a copy of the selection criteria upon request. During interviews with transplant patients, include questions regarding whether they requested a copy of the patient selection criteria from the program and what information they received.	***Guideline 482.90(a)(4)*** *Interviews with transplant patients and dialysis facilities should confirm the receipt of the written selection criteria upon request.*
X057	(b) Standard: Living Donor Selection. The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:	*Blank*	
X058	***§482.90(b) Standard: Living Donor Selection.*** ***The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:***	For a center that performs living donor transplants, verify that the transplant program's policy requires that prior to donation, the prospective living donor receives a medical and psychosocial evaluation that is completely independent of the recipient evaluation. An independent evaluation requires that the transplant recipient (or other individuals vested in the recipient's transplant) may not be present	***Guideline §482.90(b)(1)*** *Each prospective living donor must receive a medical and psychosocial assessment prior to donation to ensure that any risks to the donor are identified and to assist in the determination of appropriateness for donation. It is expected that a psychosocial evaluation for living donors would address the following:*

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	(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,	during the donor's psychosocial and medical evaluation. The donor and recipient evaluations must be filed in respective individual medical records and must not be dually documented in both medical records. The transplant program's policy is expected to: (1) indicate the length of time in which the medical and psychosocial evaluations are deemed to be current; (2) identify the type of qualified healthcare professional(s) who may complete these evaluations; and (3) include the follow-up and referral procedures if a living donor requires such activities. Review the post-June 28, 2007, sample of living donor medical records to verify that the psychosocial and medical evaluations were completed independently from the evaluations of the transplant recipient; were done within the time frame established by the program's policy; completed prior to the donation; and performed by the person(s) identified in the transplant program's policy as qualified to conduct such evaluations. The medical evaluation is expected to address not only the living donor's medical suitability for donation, but also any of the donor's health issues that would be affected by the donation. For example, if the donor were taking any medications treating an existing condition and this medication regimen would have to be stopped or altered for any period of time following the donation. While the transplant program has flexibility in the specific psychosocial tool to be used, the psychosocial evaluation is expected to be completed and to be focused on the individual's suitability for donation. It is expected that a psychosocial evaluation of this nature would address the following: 1) social, personal, housing, vocational, financial, and environmental supports; 2) coping abilities and strategies; 3) understanding of the risks of donation; 4) ability to adhere to a therapeutic regimen; and 5) mental health history, including substance or alcohol use or abuse and how it may impact the donor following the donation.	• *Social, personal, housing, vocational, financial, and environmental supports;* • *Coping abilities and strategies;* • *Understanding of the risks and benefits of donation;* • *Ability to adhere to a therapeutic regimen; and* • *Mental health history, including substance and alcohol use or abuse and how it may impact the success or failure of organ transplantation.*
X059	***§482.90(b)(2) Document in the living donor's medical records the living donor's suitability for donation, and***	Review the sample of living donor medical records to verify that each donor'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) of the relevant findings of the medical and psychosocial	***Guideline §482.90(b)(2)*** *The potential living donor medical record must contain documentation that the multidisciplinary team considered all evaluations and made a determination as to donation suitability. If the potential donor is deemed as not suitable for donation by the team, no donation may occur.*

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		evaluations and the impact of those findings on the donor's suitability for donation. If the multidisciplinary team has a meeting to discuss the donor's suitability for donation, this would comply with the requirements of the regulation. If there is not an actual meeting by the multidisciplinary team, then there must be evidence in the medical record and/or other documentation that there is a formal process for all members of the multidisciplinary team to raise concerns and discuss any issues that they may have regarding the donor's suitability. This process must be managed such that 1) there is clear written evidence that multidisciplinary team members have reviewed, discussed, and are aware of one another's concerns about the donor's suitability, and 2) there is a process for the members of the multidisciplinary team to register their agreement/disagreement regarding the donor's suitability.	
X060	***§482.90(b)(3) Document that the living donor has given informed consent, as required under §482.102.***	Review the sample of living donor medical records to verify that the informed consent process (meeting the requirements of §482.102(b), (X159)) is complete and is documented in the medical record. The medical record should provide evidence that the living donor has provided consent and that it is informed consent. "Informed consent" generally means the individual participates in his or her health care decision-making through a process which: a) provides information about the decision and procedures, alternatives, risks, relevant uncertainties, benefits and other pertinent information; b) is provided to the individual in a manner suitable for comprehension; c) includes an assessment by the informing practitioner that the person understands and can articulate this understanding; and d) that there is voluntary consent by the living donor. The surveyor should review the documentation in the medical record that describes the completed informed consent process, and review all dated and witnessed forms signed by the living donor.	*Guideline §482.90(b)(3)* *"Informed consent" means the individual participates in his or her health care decision-making through a process which:* *a) provides the living donor with information about the decision to donate and the procedures, alternatives, risks, benefits and other pertinent information;* *b) is provided to the living donor in a manner suitable for comprehension;* *c) includes documentation by the hospital that the living donor understood and can articulate his/her understanding of the information above; and* *d) ensures voluntary consent by the living donor.*
X071	***§482.92 Condition of Participation: Organ Recovery and Receipt.*** *Transplant centers must have written protocols for validation of donor-recipient*	*Blank*	

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	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 beneficiary.		
X072	§482.92(a) Standard: Organ Recovery. When the identity of an intended transplant recipient is known and the transplant center sends a team to recover the organ(s), the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place. **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).	This standard **only** applies when the transplant program sends its own team to recover the organ(s) for a patient at that transplant program. Review the transplant program written policies and procedures to verify that the program's organ recovery team must obtain, review, and compare the deceased donor's blood type and donor identification with the intended recipient's blood type ONSITE (at the donor's hospital), PRIOR TO ORGAN RECOVERY TAKING PLACE. Note: This comparison will verify that the proper organ is being recovered. The UNetSM 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 UNetSM match list, and must verify that the donor's and potential recipient's blood type are compatible. Request a list of the instances over the past 3 years (but not prior to June 28, 2007) when the transplant program dispatched its own team to recover an organ that was then transplanted at that program. Review the transplant program's documentation for a sample of the transplant patients who received an organ recovered by the transplant program's team during that time. Confirm that the blood type and donor identification were verified onsite prior to organ recovery. The location of this documentation may vary by transplant program (e.g., progress notes, organ recovery sheet). Interview one of the transplant program team members that participated on an organ recovery team that recovered an organ that was subsequently transplanted at that program. Confirm that the team member is aware of the policy for	

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		validation and complies with this policy. Note: There may be teams from the OPO which go to recover an organ; these recoveries **should not** be included in this sample. This would also include instances when an individual may be on-call with an OPO, but is not recovering an organ for a patient at his/her own transplant program.	
X073	***§482.92(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.*	Review the transplant program's policies and procedures to verify a requirement that when an organ arrives at the transplant program, a transplant surgeon and another licensed healthcare professional must verify that the donor's blood type and donor identifying information are compatible with the intended recipient prior to transplantation at the transplant program. Note: This comparison will verify that the proper organ will be transplanted. 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 type is compatible. The transplant program is not precluded from beginning the recipient's operation prior to arrival of the organ at the transplant program (see additional information below for verification responsibilities). The transplant program's policy must specifically identify who qualifies as "another licensed healthcare professional" to verify the compatibility of blood type and donor identifying information. Review the sample of post-June 28, 2007, transplant recipient medical records to verify that the transplanting surgeon and the other licensed healthcare professional, as defined by the transplant program's policy, have attested that the donor's blood type and donor identifying information were compared at the transplant program and found to be compatible with the intended recipient. The documentation outlining the donor's blood type and donor identifying information must arrive with the organ at the transplant program. If the documentation is missing or incomplete, the transplanting surgeon and other licensed	***Guideline §482.92(a)*** *The verification occurs once the organ arrives in the operating room, prior to transplantation. The second person verifying the blood type (and other data) may be any licensed health care professional who is in the operating room at the time of the verification. The transplant program should identify in its protocols which categories of health care professional(s) may do the second verification. If the transplant surgeon is already scrubbed and gloved, he/she may do a visual verification and sign that verification in the medical record at the end of the surgery. The time of `the visual verification should be entered into the recipient's record by the second person at the time it is done and should state that the verification was visual by the transplant surgeon. The second person will sign their verification at that time. After the case is concluded, the surgeon confirms his visual verification in the record by either co-signing the verification entry by the second person or writing a separate progress note which chronicles the verification (including times).* *The reference to "other vital data" is considered to be the OPTN Identification Number.*

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		health must follow-up to ensure adequate verification. Even though a transplant program's own team may recover the organ (as described in Tag X072) and verifies the blood type and donor ID prior to organ recovery, the transplant program is still responsible for verifying the blood type and donor identification as described under this section after the organ has arrived at the transplant program prior to transplantation. If the operation has begun and the surgeon is awaiting arrival of the donated organ, the transplant surgeon remains responsible for verifying the blood type and donor identification. It is not required that the surgeon would stop the operation for this verification (given the time-sensitive nature of some transplant surgeries). He or she would be permitted to verify this information visually, with explicit timed documentation of the visual verification of the data by the other health care professional. The transplant surgeon must then attest to the accuracy of this documentation following the operation. Include questions during the interviews to ensure that transplant program staff are aware of and following the procedures.	
X074	***§482.92(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).*	Review the transplant program's policies and procedures (specific to living donor transplants) and verify the inclusion of language that the transplant surgeon and another licensed healthcare professional verify that the donor's blood type and identifying information are compatible with the intended recipient, prior to organ recovery. Note: This comparison will verify that the proper organ is being recovered. 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, and must verify that the donor's and potential recipient's blood type is compatible. The policies and procedures must also define who qualifies as "another licensed healthcare professional" who may verify the compatibility of the living donor's blood type and donor identifying information with the transplant recipient.	***Guideline §482.92(b)*** *See above discussion at X073 regarding surgeon and other health care professional verification.* *Verification that the living donor blood type and other vital data are compatible with the intended recipient must occur onsite, after the donor arrival in the operating room but prior to the induction of general anesthesia.* *The verification must be completed by the transplanting surgeon and another licensed healthcare professional. The program should identify in its protocols which categories of health care professional(s) may do the second verification.* *Verification by the transplant surgeon and another licensed healthcare professional must be documented. The documentation must include signatures and corresponding date and time of the verification. To ensure that verification is completed immediately before the removal of the donor organ(s), documentation must include the time of donor arrival into the operating room, time of organ verification and time general anesthesia was started.* *Verification of correct organ for the correct recipient and*

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		Review the post-June 28, 2007, medical records of a sample of living donors to confirm that the transplanting surgeon and one other "licensed healthcare professional" verify that the donor's blood type and donor identifying information were compatible with the intended recipient, PRIOR TO REMOVAL of the donor organ (s). This verification must also take place before the removal of the recipient's organ(s), if applicable. The phrase "if applicable" refers to the fact that 1) in some cases the recipient's organ may remain in the body even though it is being replaced by the donor's organ; or 2) the recipient's organ (usually a kidney) may be removed well in advance of transplantation of the living donor's organ, based on medical necessity. Include questions during personnel interviews to ensure that transplant program staff are aware of and following this procedure.	*verification that the blood type and other vital data are compatible with the potential recipient must occur immediately before the removal of the living donor organ(s).* *If the donor organ recovery surgeon is also the transplanting surgeon, verification prior to removal of the living donor organ(s) and verification prior to transplantation must occur separately.*
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.*	*Blank*	***Guideline §482.94*** *Transplantation and Living Donor Care Phases are generally defined as:* *Transplantation Care Phases:* • *Transplant Phase: Begins when the potential transplant candidate is evaluated for transplantation and continues through completion of the transplantation surgery.* • *Discharge Phase: Begins at the transplant candidate admission to the hospital and continues through to his/her discharge from the inpatient stay.* *Living Donor Care Phases:* • *Evaluation Phase: Begins from first presentation by the potential donor until the time he/she enters the OR for the donation surgery.* • *Donation Phase: Begins from the time the potential donor enters the OR for the donation surgery until the donor is discharged from the inpatient surgery stay.* • *Discharge Phase: Begins at admission to the hospital and continues through the donor's discharge from the inpatient stay.* *Some transplant programs perform living donor services under arrangement with other hospitals. In these cases, the transplant program retains all responsibility for compliance with management of the living donor. The transplant program must communicate the donor management activities that are required as a part of the living donor organ recovery to the hospital under the arrangement and ensure that the activities are completed appropriately.*

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X082	***§482.94(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.*	For transplant patients: Review the transplant program's written clinical management policies for the transplant and discharge phases of transplantation including the routine follow-up visit schedules. Policies should detail the composition, role, and required documentation done by the multidisciplinary team. 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 patients in different situations (for example, those patients who live a significant distance from the transplant program). Assess whether or not the transplant program is following its own policies and procedures. Review a sample of medical records of transplant patients to evaluate the quality of patient care throughout all phases of transplant and discharge planning and verify that the medical record, viewed as a whole, indicates that the members of the multi-disciplinary team performed the responsibilities accorded to them by the regulations and by the transplant program's own policies and procedures. Nutrition and pharmacology must be represented on the transplant team, but may participate in discussions on an as-needed basis. Verify that the documentation of the multidisciplinary careplan shows coordination by a physician including any interventions, directions to staff, etc. If the multidisciplinary team does not conduct actual meetings for patient 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 transplantation and discharge process. 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 documents 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. In interviews with the transplant patient, or the patient's representative, assess whether or not the patient received information about and believes he or she understood the plan for his or her care. In addition, assess whether or not he or she had the opportunity to discuss issues and was seen by various members of the multidisciplinary team.	***Guideline §482.94(a)*** *In those instances where it is determined that the transplant recipient or living donor is not receiving or did not receive the services needed as identified by assessment, consultation and the multidisciplinary plan of care, the resulting deficiency should be cited at this regulatory cite.*

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		The multidisciplinary team must include representatives from the following disciplines: • Medicine (Transplant surgeon or Transplant physician) • Nursing • Social services • Clinical Transplant Coordinator • Nutrition (various levels of assessment/intervention are permissible based on the patient's needs and status) • Pharmacology (various levels of assessment/intervention are permissible based on the patient's needs and status) See Tag X125 for the requirements outlining the disciplines that must be represented on the multidisciplinary team. Discharge planning begins with placement on the transplant program's waiting list and intensifies as discharge becomes imminent. At a minimum, the post-transplant discharge plan should address the following areas: • Follow-up appointments; • Contact numbers of transplant program staff that should 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 patient-specific nutrition plan, as applicable; • A plan for addressing relevant psychosocial issues (for example, available supports, adaptation to stress of transplant, etc.); • Activity restrictions and limitations (for example, driving after taking pain medication); • Need for coordination of other health services (for example, physical, or occupational therapies, home care, etc.); • Medication and administration, including patient's schedule for taking medication and the process to obtain the medication; and • Assistance required to access local medical care, equipment or support. Most post-transplant patients require regular follow-up visits to the transplant program for a period of time to monitor the patient's recovery and to ensure that individual is not showing signs of rejection of the newly-transplanted organ. There are two areas where surveyors are expected to interface with the outpatient clinic: 1) to identify and interview post-transplant patients about their experience as	

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		an inpatient at that transplant program; and 2) in cases where the discharge plan or discharge instructions in the medical record is not clear, then the surveyor may review the policies or patient education materials of the outpatient clinic so that the surveyor fully understands the discharge plan and instructions that are given to patients. The policies and procedures of an outpatient transplant clinic and interviews with post-transplant patients 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 Regional Office or State Agency for follow-up as needed. For post-transplant patients where a local physician is following up on his/her care, the transplant program is responsible for coordinating with that local physician to ensure continuity of care; however, the policies or procedures of that local physician are not included within the scope of this survey. If a post-transplant patient is re-admitted to the hospital for a non-transplant related-event, the transplant program is not required to, nor precluded from, reconvening the transplant team. For living donor patients, review the following: If there is a living donor program, review the clinical management policies and procedures for living donor evaluation, donation, and discharge phases and verify that the living donor'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 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 living donors in different situations (for example, those patients who live a significant distance from the transplant program). Assess whether or not the transplant program is following its own policies and procedures. Review the post-June 28, 2007, medical records of a sample of living donors to evaluate the quality of living donor's care throughout all phases of the donation	

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		including: evaluation, the donation process, and discharge planning and verify that the medical record, viewed as a whole, indicates that the members of the multidisciplinary team performed the responsibilities accorded to 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 and may include notes in the medical record by 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. In interviews with the living donor, assess whether or not the donor received information about and believes he or she understood the plan for his or her care. In addition, assess whether or not he or she had the opportunity to discuss issues and was seen by various members of the multidisciplinary team. At a minimum, the multidisciplinary team must include representatives from the following disciplines: • Medicine (Organ recovery surgeon or transplant physician) • Nursing • Clinical Transplant Coordinator • Social Services • Living Donor Advocate / Living Donor Advocate Team • Nutrition (various levels of assessment/intervention with a given donor are permissible) • Pharmacology (various levels of assessment/intervention with a given donor are permissible) See Tag X125 for the requirements outlining the disciplines that must be represented on the multidisciplinary team. Note: Nutrition and pharmacology services may be phased-out if no specific needs are identified during the donor evaluation, or if not specifically warranted in future phases of donation. It is not necessary for 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, documents that each member of team performed the duties and responsibilities accorded to him or her by the regulation and the program's own policies and procedures. At a minimum, the discharge plan (initiated at donor evaluation and formalized post-donation) for living donors should address the following areas:	

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		• 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 should be contacted for questions; • The clinical signs and symptoms, specifically indicative of a potential complication from donation, that would necessitate a call to the doctor; • A patient-specific nutrition plan (as applicable); • A patient-specific psychosocial plan (as applicable, to include post-donation adjustment); • Activity restrictions and limitations (for example, driving after taking pain medication); • Need for 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. Post-donation patients may require follow-up visits to the transplant program to ensure that the patient is recovering from the donation and is not experiencing any adverse reactions. There are two areas where surveyors are expected to interface with the outpatient clinic: 1) to interview post- donation patients about their experience *as an inpatient* at that transplant program; and 2) if the discharge plan or patient's discharge instructions in the medical record is not clear, then the surveyor may review the policies or patient education materials at the outpatient clinic so that the surveyor fully understands the discharge plan and instructions. The policies and procedures of an outpatient transplant clinic and interviews with post-transplant patients 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 Regional Office or State Agency for follow-up as needed.	
X083	***§482.94(b) Standard: Waiting List Management.*** *Transplant centers must keep their waiting lists up to date on an ongoing basis, including:*	*Blank*	

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X084	***§482.94(b)(1) Updating of waiting list patients' clinical information;***	Review the transplant program's policies and procedures on updating both the waiting list and the pre-transplant clinical information for waiting list patients. The policies and procedures should include the timeframe within which these updates must be completed, what type of information is updated, who is designated to update the clinical information, and how often the clinical information for waiting list patients is reviewed. Please note that different types of organ programs will likely have different policies and procedures for updating clinical information. In addition OPTN has certain requirements for updating clinical information based on the patient's characteristics. Differences in policies/procedures are permitted. The surveyors should assess whether or not the program is following its policies/procedures. During interviews with transplant program staff, request information about the process and frequency with which the transplant program reviews and updates the clinical information of waiting list patients, both in the patient's medical record and on the transplant program's waiting list. Using the transplant program's policy of providing UNet access to certain personnel, ask one of these designees for a demonstration of updating both the UNET and transplant program's waiting list (if different from the list of patients on UNET). Review the post-June 28, 2007, medical records for a sample of transplant candidates currently on the program's waiting list (these may be inpatient or outpatient records) to ensure that the clinical information in the medical record corresponds to the transplant program's waiting list information identified in UNet.	*Guideline §482.94(b)(1)* *Timely updates to clinical information for patients on the waiting list affects: (1) organ allocation priority based on medical urgency and (2) a candidate's ability to receive a transplant. Transplant programs must update the waiting list with accurate, recent and timely clinical information to ensure that a candidate is able to receive a transplant should an organ become available. Transplant programs should determine how often waiting list patients should be evaluated and provided ongoing assessment.*
X085	***§482.94(b)(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***	Select a sample of transplant candidates on the current waiting list and confirm via 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 and must still be living (Note that some transplant patients may need to be re-transplanted due to rejection or malfunction of the previously transplanted organ.) Determine if the program is following its policies and procedures to update the waiting list.	*Guideline §482.94(b)(2)* *There may be instances where a recently transplanted recipient is placed back on the wait list. In these instances, documentation must include the original date of removal and the date of the new placement on the list.*
X086	***§482.94(b)(3) Notifying the***	Request a list of the patients removed from the waiting list	*Guideline §482.94(b)(3)*

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	OPTN no later than 24 hours after a patient's removal from the center's waiting list.	by the transplant program over the past 12 months (but not before June 28, 2007) including the date and time they were removed. Review the medical records of a sample of patients removed from the waiting list after June 28, 2007, to compare the time an individual was removed from the program's waiting list and the time the OPTN was notified to verify that no more than 24 hours elapsed between these two times. Some transplant programs may not maintain their own separate waiting list. In these cases, review documentation in the medical record that identifies the date and time the transplant program determined that the individual should no longer be on the waiting list. Review the time OPTN was notified to verify that no more than 24 hours elapsed between these two times. Interview responsible staff about this process to determine how timeliness is ensured.	*For the purpose of this Standard, the 24 hour period to notify the OPTN of a patient's removal begins at the time of the patient's death; transplantation; the patient's decision to be removed from the list; or notification of death or transplantation from an outside source (family or another transplant hospital if the patient was listed with more than one transplant program).* *The OPTN is considered to have been automatically notified once the patient is removed from the waitlist in UNET by the transplant program. No additional notification is required by the transplant program to the OPTN.*
X087	***§482.94(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.*	*Blank*	
X088	***§482.94(c)(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*	<u>For individuals placed on the waiting list after June 28, 2007</u>, the documentation in the medical records should verify that the patient was informed of his or her status on the waiting list. In the case of a kidney patient, the patient's usual dialysis facility must also be informed of the patient's waiting list status. <u>For individuals not placed on the waiting list, but evaluated for placement after June 28, 2007</u>, the transplant program must document in the medical record the rationale for the decision and that the transplant program discussed with the individual any changes that he or she 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 patient, the patient's	

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	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.*	usual dialysis facility must also be informed of the patient's waiting list status. For individuals evaluated after June 28, 2007, for whom the program was unable to make a determination, the transplant program must inform the individual 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 potential kidney transplant patient, this information must also be conveyed to the patient's usual dialysis facility. These discussions must be documented in the medical record.	
X089	***§482.94(c)(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant 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.***	Request a list of patients removed from the waiting list during the past 12 months (but not before June 28, 2007) for reasons other than death or transplantation (do not include those placed on "inactive" status on the waitlist – these patients are generally listed as a "Status 7"). Review the medical records of a sample of these patients. Verify patient notification of removal from the waiting list no later than 10 days after the date the patient was removed. The notification may be either by letter or telephone message, but it should provide opportunity for the patient to have further discussion (either by telephone or face-to-face) with the transplant program.	***Guideline §482.94(c)(2)*** *Transplant programs determine the most appropriate method for communication with the patient and the dialysis facility. The communication must be evidenced by documentation in the medical record.*
X090	***§482.94(c)(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*	Review written evidence by the transplant program to confirm that a multidisciplinary care planning effort occurred while the individual was in the hospital (for transplants that occurred after June 28, 2007). This evidence may take a variety of forms. Examples could include (but are not limited to) a completed multidisciplinary care plan in a medical record, progress notes in the medical record that provide evidence of a joint care planning effort, or notes from multidisciplinary team meetings, etc. During interviews, surveyors should talk with members of the multidisciplinary team about how multidisciplinary care planning occurs where evidence of this planning would be located. Refer to Tag X082 and X125 for guidance as to the components of the multidisciplinary patient care planning process, and personnel participating in the multidisciplinary team.	***Guideline §482.94(c)(3)*** *A multidisciplinary care plan includes ongoing assessments to identify any new patient needs and/or to determine if any currently identified patient's needs have changed. A multidisciplinary team must be identified for each patient at the time the evaluation for wait listing begins. This multidisciplinary team participates in the patient care planning from evaluation through transplantation. At the time of the initial evaluation, each member of the team participates in the evaluation of the patient. It may not be necessary for all team disciplines to see the patient again until transplant is imminent unless there are identified needs.* *Following the transplant, each discipline must, as appropriate:* *1) reassess the recipient following the surgery;* *2) see the recipient as often as indicated by identified issues; and* *3) see the recipient prior to discharge.*
X091	***§482.94(c)(ii)***	Review written evidence by the transplant program to	***Guideline §482.94(c)(ii)***

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	Multidisciplinary discharge planning for post-transplant care.	confirm that a multidisciplinary discharge planning effort occurred for discharge planning (after June 28, 2007). This evidence may take a variety of forms. Examples could include (but are not limited to) a completed comprehensive discharge plan in the medical record that includes the various disciplines involved in providing care. During interviews, surveyors should talk with members of the multidisciplinary team about how discharge planning occurs and where evidence of this planning would be located. Refer to Tag X082 and X125 for a discussion of the components of the multidisciplinary discharge planning process, and the personnel participating in the multidisciplinary discharge planning.	*Discharge planning begins on admission. Each member of the dedicated multidisciplinary team must be involved in assessing the needs of the patient in preparation for discharge from the hospital. Areas of assessment for discharge planning include medical, psychosocial and financial.* *The recipient's medical record must contain documentation that the dedicated multidisciplinary team participated in the development of the discharge plan to address the individual needs of the recipient.* *Components of a multidisciplinary discharge plan may include, but are not limited to:* • *A description of the recommended follow-up appointments and the practitioners expected to perform the follow-ups (such as the transplant program, a local physician, or both);* • *Contact numbers of transplant program staff that can be contacted for questions;* • *The clinical signs and symptoms indicative of a potential complication from transplantation that would necessitate a call to the doctor;* • *A transplant recipient/living donor specific nutrition plan, as applicable;* • *A plan for addressing psychosocial issues (for example available supports, adaptation to stress of transplant, etc.);* • *Activity restrictions and limitations (for example driving after taking pain medication);* • *Need for coordination of other health services (for example physical or occupational therapies, home care, etc.) and assistance in securing these health services;* • *Medication and administration, including the transplant recipient's schedule for taking medication and the process to obtain the medication; and* • *Any assistance required to access local medical care, equipment or support.*
X092	***§482.94(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…*	Review the medical records after June 28, 2007, of a sample of post-transplant patients and living donors 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. It is reasonable to expect different levels of intervention and services based on the needs of the transplant patient or living donor. Examples of social services include: 1) Acknowledgement of the risks and benefits of transplantation and/or living donation as appropriate;	***Guideline §482.94(d)*** *Making social services available means that if a social service need for a recipient/donor/family is identified at any point from evaluation through discharge, the program must provide a qualified social worker to address the need/issue and documentation in the medical record should confirm the social worker intervention.*

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		2) Assessment of patients' ability to adhere to therapeutic regimens; 3) Assessment of patient's mental health history, including degree of substance and alcohol use and how it may impact the success or failure of organ transplantation or the donor's mental health post- transplant. 4) Assessment of patient's and living donor's (if applicable) coping abilities and strategies 5) Assessment of patient's financial capabilities and resources, including who will pay for post-discharge medical care for the donor, if necessary; and 6) Provision of adequate social, personal, housing and environmental support. Interview a sample of transplant recipients and living donors, (if no patients are in-house, interview patients coming in for follow-up visits) regarding the assistance/counseling provided to them and their families by the transplant program's social worker. Specifically, inquire as to whether the patient's needs were identified promptly and addressed in a timely manner. This area should be cited if (1) the social services are not available at all; or (2) if there is evidence in the medical record that social service needs were clearly present and the program did not actively let the individual know that services were available to address the expressed needs. For example, if the individual expressed concern about availability of financial supports or housing when he/she leaves the hospital, and no one that followed up or told the patient that he/she could receive assistance from a social worker to help address some of these concerns. Exercise care to ensure that the patient voluntarily consents to be interviewed.	
X093	*§482.94(d)(cont'd)* ***...A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices;*** *and* *(1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the*	Review the personnel records of social work personnel who provide services to the transplant program after June 28, 2007, to ensure that all individuals are qualified and licensed (if required) in the State in which the transplant program is located. Note the regulation does not require advanced social work licensure, such as a Licensed Clinical Social Worker which typically requires a Master of Social Work (MSW) as well as an extended period of supervised clinical work (e.g., 3 years, 3000 hours, etc.). Consultative relationships (between the Non-MSW and MSW-prepared social workers) should be confirmed by evidence of a back and forth dialogue concerning issues	*Guideline §§482.94(d)(cont'd) and (d)(1)-(2)* *Non-MSW employees functioning as a transplant program social worker prior to the June 28, 2007, which is the effective date of the final rule, "Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants" (72 FR 15198, Mar. 30, 2007), must have a consultative relationship with an MSW who meets the requirements of §482.94(d)(1). The purpose of the consultative relationship is for the MSW to advise, support and often guide a social worker in their position. A consultative relationship generally would include:* • *Meetings between the MSW and the non-MSW on a routine or re-occurring basis; and*

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	Council on Social Work Education; or *(2) Is working as a social worker in a transplant center as of effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.*	related to transplantation and living donation as appropriate, and/or social work standards of practice (e.g., case-specific transplant issues, accessing community resources, cultural competence in social work practice). Examples of evidence of an ongoing consultative relationship may include (but are not limited to): A. Documentation of collaboration on transplant and living donation cases (as appropriate) (for example, sharing responsibilities for a particular case); B. Documentation of substantive discussion of transplant and living donation (as appropriate) cases including social work methods or practices that would provide assistance to the transplant patient and the living donor (as appropriate); C. Participation of the MSW-prepared social worker in multidisciplinary meetings along with the non-MSW social worker; D. Documentation of the discussion of resources available for transplant patients and living donors (as appropriate); E. Supervisory/subordinate relationships; and/or F. Personnel evaluations or continuing education provided by the MSW to the non-MSW social worker. Interview both the MSW and non-MSW social worker to determine the nature and extent of the consultative relationship. It is acceptable for the MSW social worker to be physically located in another part of the hospital, provided that there is evidence of the relationship between the two staff, as described above.	• *Evidence that the MSW is available and responsive for ad hoc consultation with the non-MSW employee.*
X094	***§482.94(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.*	Verify that the transplant program's current policies and procedures for nutritional services outline how the transplant program will determine when a complete nutritional assessment, dietetic counseling, or nutritional intervention is warranted. For transplant patients and living donors, depending upon their health, nutritional status and the type of organ transplant they are receiving, various levels of nutritional assessment and interventions may be warranted at different points in the transplantation or donation phases. It is expected that, at a minimum, the multidisciplinary team would discuss and determine the appropriate level of assessment and intervention to ensure that the nutritional needs for all transplant recipients and living donors are	***Guideline §482.94(e)*** *Transplant programs must have a process in place to ensure that a qualified dietician is available to provide nutritional assessments or diet counseling to all transplant patients and living donors that require such services. Nutritional services include consultation, assessment, intervention(s) and education. If a need is identified by any member of the multidisciplinary team, and a request is made for nutritional services, but the requested services are not provided due to the lack of nutritional staff available in the hospital, a deficiency would be cited.*

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		adequately addressed. As necessary, any follow-up for referrals for further assessment or intervention are the responsibility of the qualified dietitian. Review the post June 28, 2007, multidisciplinary team notes in the medical records of a sample of the transplant patients and living donors to ensure that the multidisciplinary team discussed any identified nutritional needs of the individual throughout the transplantation or donation process. For example, if the medical record indicates that the individual developed diabetes post-transplant, it is expected that the dietitian would provide diet counseling and intervention in managing this condition. In the review of a sample of post-June 28, 2007, medical records for transplant patients and living donors, note any instances of conditions that warrant further nutritional services based on the transplant program's criteria (diabetes, for example) and verify that nutritional services were provided, as indicated. Nutritional Services may include: 1) dietetic consultation; 2) nutritional assessment and nutritional interventions; 3) nutritional education; and 4) physician consultation for total parenteral nutrition (TPN), peripheral parenteral nutrition (PPN), or enteral feeding. Review the personnel records of dietitian(s) who serve on the transplant program's multidisciplinary team to ensure documentation of registration with the Commission on Dietetic Registration. If there are state licensure requirements, the dietitian must be currently licensed in that state.	
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.*	Based on the requirement that the participating hospital's QAPI program cover all areas of the hospital (42 CFR §482.21), the transplant program's QAPI program must be incorporated into the hospital's overall QAPI program. If the transplant program's QAPI program is separate from the hospital's QAPI program, there must be clear evidence that information and findings from the transplant program's QAPI program are communicated to the hospital's QAPI program. The transplant program's portion of the QAPI program must: • Specifically address the individual components of the transplant program; and	*Guideline §482.96* *The transplant center develops its transplant program-specific quality assessment and performance improvement (QAPI) program either individually or collaboratively with the transplant hospital QAPI program and functions as a component of the associated hospital QAPI program required at 42 CFR §482.21. There should be evidence of communication between the two entities to ensure that both entities are actively involved in QAPI activities which address the specific requirements of the transplant CoPs. If the transplant program has a separate QAPI program, it must provide evidence that it is interrelated with the hospital QAPI plan.* *A comprehensive transplant QAPI program evaluates and monitors performance of transplantation services across every*

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		• Include the participation of the transplant program's key personnel (Director, primary transplant surgeon, primary transplant physician, clinical transplant coordinator, and nursing personnel). Examples of their participation include participation in QAPI committee meetings, presenting topics to the QAPI committee, authoring reports or updates for the QAPI committee about the program's status. The transplant program's QAPI program must be written and comprehensive. A comprehensive QAPI program is expected to include the following: a. Individual members identifiable by name, title, role, and responsibilities; b. QAPI methods of operating and decision- making (e.g., by committee, sub-committee, other); c. Objective measures by which the quality- related data will be collected and analyzed (including the measures described in §482.80 and §482.82); d. Established frequencies for review of program performance, and reporting to the QAPI Committee and to the hospital-wide QAPI program; e. Method by which key findings and recommendations are reported to QAPI transplant members, to the hospital-wide QAPI, and to individuals determined by the QAPI program as instrumental to action on important analyses, findings, and recommendations; f. Designation of an individual who will be responsible for monitoring the transplant program's QAPI program (i.e., QAPI coordinator); g. Evidence of tracking and implementing recommendations for improvement; h. Evidence of ongoing compliance with changes implemented as a result of recommendations by the QAPI Committee; and i. Broad representation of transplant program issues relevant for the disciplines represented in the multidisciplinary team (e.g., surgical, nursing, social services). This means that the QAPI would not solely be focused on a single discipline (e.g., the surgeon) and would include performance measures relevant for other disciplines. Note: If a given discipline is not specifically addressed, do not cite as a deficiency as long as: (1) the overall intent is still met that the QAPI program is comprehensive; and (2) there is no evidence in the survey that would identify this area as problematic.	*aspect of the program from the evaluation of a potential recipient/donor candidate through his/her discharge from the hospital. A comprehensive QAPI program approach embraces a broad, multidisciplinary, system-wide perspective. It encompasses all aspects of clinical care and all relevant hospital services and includes input from a broad representation of staff at all levels, including individuals with authority to make decisions about the transplant program's policies, practices and resources. It continuously monitors, evaluates and improves all organ transplantation services for transplant candidates, transplant recipients, potential living donors across all phases of transplantation and living donation, including transplant services provided under contract or arrangement.* *A data-driven transplant QAPI program continually uses data to guide quality assessment and performance improvement activities with respect to all transplantation services. The program proactively, systematically and at regular specified intervals:* • *Identifies, implements, assesses and re-assesses the data to be collected for each measure and other information needed to monitor and evaluate performance of transplantation services in all areas;* • *Collects, records and reviews the data for accuracy;* • *Analyzes the data and uses the data/analyses to assess the program's performance; and* • *Uses the results of its analyses to monitor, evaluate and improve the quality and safety of all transplantation/donation services on an ongoing basis.*

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X100	***§482.96(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 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 beneficiary matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights….*	Examples of objective measures may include (but are not limited to): • Review of survival outcomes and fluctuations in outcomes over a designated period of time; • Frequency of the use of exceptions in the patient/donor selection process; • Blood type compatibility errors over a designated period of time; • Consistency between the OPTN waiting list and transplant program's waiting list as measured by periodic comparisons for accuracy; • Number of patient rights and patient/family complaints (received, investigated, confirmed, satisfactory disposition); • Number of complaints related to consent practices; • Percentage of organs refused over a given period of time; • Percentage of organ rejection over a given period of time; • Number of post-transplant or post-living-donation infections and other complications; • Measurements of the effectiveness of patient/donor/family education. Confirm that the QAPI program uses objective measures for review that render a comprehensive evaluation of the performance of the transplant program, including services provided under contract or arrangement.	*Guideline §482.96(a)* *This standard requires transplant QAPI programs to identify, implement, assess and re-assess objective measures to evaluate and improve both their transplantation outcomes as well as the quality, safety and performance of their transplantation activities, across all phases of transplant and living donation.* *Transplantation and living donor care - including but not limited to the potential areas for measurement listed in this standard – involve multiple phases, activities and potential outcomes, each with various aspects that may be amenable to objective measurement. Objective measures can mean that a transplant program will select some measures for routine monitoring on an ongoing basis; others will be identified and implemented in order to address, evaluate and monitor a particular problem or opportunity for improvement. Each transplant QAPI program should identify and implement multiple objective measures that are relevant and meaningful for evaluating its own performance with regard to both transplantation activities and outcomes to:* • *Collect and analyze data to assess its baseline performance and to track performance on the selected measures over time; and* • *Use the information gained to evaluate and improve performance and to ensure that improvements are sustained over time.* *Measuring an outcome means measuring the health status of a patient resulting from health care. For example, the SRTR reports contain a number of objective outcome measures useful for performance monitoring and improvement (such as patient and graft survival), but additional patient outcomes not reported by the SRTR may also be important for a program to measure (for example, rates of specific intra- and post-operative complications for transplant recipients and living donors).* *In addition to measuring relevant outcomes, other types of clinical quality measures are needed to evaluate transplantation activities. Each program must critically examine its own services and performance to determine which activities (and which aspects of the activity) within each phase of transplantation or donation should be evaluated and monitored using objective measures.*
X101	***§482.96(a)(cont'd)*** ***…The transplant center must take actions that result in***	Review the transplant program's post June 28, 2007, QAPI committee meeting minutes, QAPI reports, and consultation reports, if applicable. Verify that problem areas are	*Guideline §482.96(a)(cont'd)* *The transplant program must use what it learns from monitoring the objective measures described under Tag X100*

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	performance improvements and track performance to ensure that improvements are sustained.	promptly identified and that appropriate follow-up actions are taken when problems are identified by the QAPI program, and that long-term corrective measures are implemented to ensure continuous compliance. Review the extent to which key findings are (a) made; (b) communicated to the hospital's QAPI and determined by the transplant program's QAPI as instrumental for taking action to implement program improvement; and (c) 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 and outcomes.	*to identify and implement actions to improve its performance.* *The program should review the available evidence, if any, for particular performance improvement strategies and implement activities that are most likely to be effective in addressing the specific factors that are contributing to the program's performance. If successful, performance will need to be monitored over time to verify that improvements are sustained. If not, the program will need to re-evaluate, determine an appropriate alternative course of action, and track performance.*
X102	***§482.96(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 Definition 482.70-** "Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant programs, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient." Note: Transplant programs are not required to report adverse events to CMS. Review the program's current written policy and procedures for identifying, reporting, investigating and analyzing adverse events. The policies should address: 1. Procedure for reporting an adverse event by transplant program personnel, the hierarchy of reporting, and for conducting analysis based on the reports; 2. The required timeframe for reporting, investigating and analyzing adverse events. 3. The corrective action process after the completion of the analysis and the timeframes for the action; 4. Use of analysis of reported adverse events in prevention; 5. External reporting of events to OPTN, ESRD Network, and States, etc. as required and applicable. 6. Reporting to, or inclusion of, Institutional Review Board (IRB)/Western Institutional Review Board (WIRB) if the	***Guideline §482.96(b)(1)*** *An adverse event is defined at 42 CFR §482.70 as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof."* *The facility policies should include:* • *A clear definition of what the transplant program considers an adverse event incorporating the CMS regulatory definition;* • *The procedures for internal reporting of adverse events in all phases of transplant recipient or living donor care within the hospital;* • *The process(es) used for analyzing adverse events in the transplant program;* • *The process for developing, evaluating and tracking actions to prevent recurrence; and* • *The required timeframe for reporting, investigating and analyzing adverse events.* *The policies should also address any external adverse event reporting obligations, such as:* • *External reporting of events to the OPTN, ESRD Network, etc. as required and applicable;* • *Reporting to other federal or state agencies as required by law (e.g., for suspected medical device-related deaths or serious injury, transmission of an infectious disease, etc.); and* • *Reporting to the OPO if a transplant recipient infection is related to an infectious disease present in a transplanted organ to ensure that other recipients who received organs from the same donor can be notified.*

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		adverse event occurred within the context of an approved study; 7. For suspected medical device-related deaths or serious injury, reporting to the Food and Drug Administration (FDA) and the device manufacturer as required by federal law. 8. Reporting to the OPTN if the adverse event caused, or may have caused, transmission of an infectious disease, and reporting to the Centers for Disease Control (CDC), if CDC requires such reporting to them. 9. Reporting to the OPO if the adverse event was related to an infectious disease present in a recovered organ from a deceased donor that could have been transmitted to other recipients who received organs from that same donor, or an otherwise compromised organ that was not detected either through the donor screening or organ transport processes.	
X103	***§482.96(b)(2) The transplant center must conduct a thorough analysis of and document any adverse event....***	Request the program's log of reported adverse events over the past 12 months (but not prior to June 28, 2007). Verify that the program followed its policies on investigation, reporting, and analysis. During the review of post-June 28, 2007, medical records and interviews, note any indication of an adverse event(s). Also review incident/ adverse event reports, and any tracking mechanism for adverse events (if applicable). Verify that the events were reported, investigated and analyzed thoroughly. A "thorough analysis" is expected to include (but are not limited to): a. 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 patient was affected; b. A review of whether or not similar events have occurred in the past; and c. An analysis of related systems and processes that contributed to the event's occurrence. Examples of systemic factors that may contribute to adverse events include: • Human Factors (for example, communication procedures, staff training, scheduling) • Environment(for example, location of needed equipment, systems for organizing/labeling medication) • Equipment (for example, technology that does not warn of pending error)	*Guideline §482.96(b)(2)* *A thorough analysis is a planned, systematic investigative process that considers all of the phases of transplantation/living donation in identifying the causes of and factors contributing to an adverse event. The scope and depth of analysis, as well as the extent of multi-disciplinary involvement, may be scaled in proportion to the scope and severity of the harm experienced and/or the risk of harm involved.* *A thorough analysis would include, but is not limited to:* • *A description of the key facts of the event in enough detail so that one can clearly understand the facts and chronology of what occurred, the severity of the event, and how the potential recipient or potential living donor was affected;* • *A review of whether similar events have occurred in the past;* • *All of the information needed to identify factors that may have caused or contributed to the outcome, directly or indirectly;* • *Analysis of the information to identify actual and potential vulnerabilities and opportunities to reduce risks and improve care;* • *Use of the results of the analysis to design improvement actions to address the factors that caused or contributed to the event's occurrence, including factors and processes; and* • *Specific plan for implementing, evaluating and monitoring improvement actions (timeframes, responsible parties, measurement strategy to assess effectiveness, etc.).*

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		• Policies (for examples polices that may exist but are unclear, or where no policies exist) • Procedures (for example, there are no procedures for verification of blood type) • Organizational (for example, the transplant program may not be monitoring adherence to or reinforcing care protocols)	
X104	***§482.96(b)(2)(cont'd)*** ***...and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.***	Using the program's log of adverse events described above (X103) and the corresponding analysis of those adverse events conducted by the transplant program, look for evidence that the transplant program's policies and procedures and/or practices were changed to prevent repeat incidences (as indicated). Examples of this evidence could include (but are not limited to) policy changes, protocols that outline a specific care practice for transplant patients or living donors, staff directives, and in-service training. It is expected that changes would be permanent so that the adverse event is not repeated, and that the transplant program would monitor that the change had been fully implemented by the program (e.g., assessing staff understanding of changes, reviewing medical records to ensure that staff were following the new care protocols, etc.).	
X109	***§482.98 Condition of Participation: Human Resources.*** *The transplant 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.*	*Blank*	
X110	***§482.98(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*	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. Review the personnel record of the designated Director to verify compliance with board certification and licensure requirements as required in the state of practice. "General supervision" means overseeing the performance	***Guideline §482.98(a)*** *The designated director of a transplant center must be either a transplant surgeon credentialed in the hospital for transplant surgeries or a qualified physician. Qualified physician means a physician that is credentialed in the hospital to provide transplant medical services for the specific organ program type.* *Serving as the director on a less than full time basis means*

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	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)... .	of the transplant program's operations and maintaining responsibility for these operations. The Director of a Transplant Center is permitted to delegate day-to-day operations to an Administrator.	*that the director may continue his/her clinical responsibilities in addition to his/her role in general supervision of the program.* *See Tags X-111 through X-114 for the responsibilities of the director of a transplant center.*
X111	***§482.98(a)(cont'd) ... The director is responsible for planning, organizing, 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:***	Interview the Director of the transplant program to determine the extent of his/her involvement in the planning and oversight of the program in such areas as: development of policies and procedures, staffing, budgeting process, interaction with the general hospital, strategic planning, quality improvement, frequency of meetings with staff. 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.	
X112	***§482.98(a)(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.***	We consider it implicit in any concept of "adequate training" that there would be: (a) a thorough orientation to the program's policies and procedures; (b) structured continuing education for nursing staff and clinical transplant coordinators; and (c) an evaluation of staff training needs. Adequate training also 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. The surveyor should assess whether or not the training program(s) (or any competency assessments) address the topics needed for transplant nurses and clinical transplant	*Guideline §482.98(a)(1)* *Care of transplant patients and living donors is unique and complex, requiring clarification of roles and responsibilities and appropriate training for nursing staff and clinical transplant coordinators. The director of the transplant center is responsible for coordination with the hospital's Nursing Department to determine the appropriate depth and type of orientation and training that will be provided to nursing staff that care for the transplant patients.* *Evidence of coordination should include:* *1. The transplant director has participated in the development of training and orientation plans for nurses who work or will work with transplant recipients and living donors;* *2. The transplant director offers ongoing training opportunities for nursing staff; and* *3. The transplant director provides feedback to the Nursing Department on the clinical competency of those nursing staff working with transplant recipients or living donors.*
X113	***§482.98(a)(2) Ensuring that tissue typing and organ procurement services are available.***	Verify that tissue typing services are available either in-house or by contract. Verify that organ procurement services are available as evidenced by the agreement with the OPO. During medical record reviews and interviews, be alert to any evidence that tissue typing and organ procurement services were not or are not available for any periods after June 28, 2007.	

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X114	***§482.98(a)(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).***	Review a sample of transplant recipients' medical records for documented presence of a qualified transplant surgeon during the transplant surgery.	***Guideline §482.98(a)(3)*** *A transplant surgeon must be credentialed by the hospital in which the transplant program is located to perform transplant surgeries.* *If a fellow or a resident participates in a surgery, the attending transplant surgeon must remain in the operating room or be physically present in the operating suite.*
X115	***§482.98(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 training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.*	Review the most recent CMS TPQR for the primary transplant surgeon and transplant physician that has been identified to the OPTN. Confirm that these individuals are the current surgeon and physician designated as having primary responsibility for the transplant program. "Immediately available" means that the transplant surgeon and transplant physician must be available to provide transplantation services within a time frame that ensures there is no compromise to the viability of the organ or the health of the organ transplant recipient. Recognizing that it is not practical for the primary transplant surgeon and primary physician to be available 24 hours per day 7 days a week, the responsibility for being immediately available may be delegated to other qualified transplant surgeons and physicians. Review the program's policies to ensure that proper delegation procedures are in place to formally transfer the primary surgeon's and primary physician's responsibilities to alternative qualified surgeons/physicians, if necessary. For example, a formal on- call schedule can be evidence of delegation. The on-call transplant surgeon or 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. To verify that transplant surgeons and physicians 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. During interviews with the transplant team members, note any instances where a transplant was delayed or aborted due to the unavailability of a transplant surgeon or transplant physician. The primary transplant surgeon and primary transplant physician must be approved by the OPTN. In addition, review the personnel records of the primary transplant surgeon and primary transplant physician to confirm the	

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		following: 1. Are currently licensed in their state of practice; 2. Meet the hospital's credentialing and privileging requirements; and 3. Have either current Board Certification, or approval from OPTN of foreign equivalency.	
X116	***§482.98(b)(1) The transplant surgeon is responsible for providing surgical services related to transplantation.***	Review a sample of transplant recipients' medical records for evidence that the transplant surgeon performs or supervises all surgical services related to transplantation which could include surgical procedures, monitoring immunosuppression regimen during the post-operative period, etc.	***Guideline §482.98(b)(1)*** *The transplant surgeon determines when consultation from other surgical specialists is indicated and ensures all indicated services are provided.*
X117	***§482.98(b)(2) The transplant physician is responsible for providing and coordinating transplantation care.***	For each transplant patient, there must be a designated transplant physician. Review a sample of post-June 28, 2007, 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.	***Guideline §482.98(b)(2)*** *Transplant programs may operate differently in regard to the provision of care for transplant recipients. In most cases, the transplant physician is the primary provider of non-surgical transplant services associated with pre-surgical medical issues as well as post transplant non-surgical services. In this role, the transplant physician has the primary responsibility for ensuring that all non-surgical services required by the recipient are provided. However, in some cases, the transplant surgeon may also serve in this role which may also be acceptable.*
X118	***§482.98(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 and the donor evaluation, donation, and discharge phases of donation… .*	Identify the designated clinical transplant coordinator(s) for the program. Review the transplant program policies on the role of the Coordinator in all phases of transplantation and donation. Please note that the transplant coordinator may have a more active role during some phases of care than others; for example, the transplant coordinator typically does not have an active role during the donation and transplantation procedures <u>Transplant Recipient</u> • Consider the *pre-transplant phase* to be from the evaluating a potential recipient and placing the individual on the program's waiting list to the pre-surgery preparation. • Consider the *transplant phase* to be from pre-surgery preparation until the patient is awake and alert following surgery. • Consider the *discharge phase* to be from the point the patient is awake and alert following surgery through post-transplant clinical management and post-discharge follow-up.	

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		Living Donor • Consider the *donor evaluation phase* to be from first presentation by the potential donor until the pre-surgery preparation for the donation. • Consider the *donation phase* to be from pre-surgery preparation until the donor is awake and alert following surgery. • Consider the *discharge phase* to be from the point the donor is alert and awake following surgery through discharge from post-donation clinical management and follow-up.	
X119	*§482.98(c)(cont'd)* ***... 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... .***	Review the personnel files of the Clinical Transplant Coordinator(s); confirm that he or she is a registered nurse or a licensed clinician in the State, and has knowledge and experience with transplantation and, if applicable, living donation issues. In addition to a registered nurse, a licensed clinician may include a physician assistant, nurse practitioner, a clinical registered nurse specialist, licensed vocational nurse (LVN), or licensed practical nurse (LPN).	*Guideline§482.98(c)* *Clinicians other than nurses may also serve in the role of the clinical coordinator. The expectations of the coordinator, as defined by the individual transplant program, will determine the particular professional clinical background required for the coordinator. However, regardless of the clinical background of the coordinator, the most critical factor of this Standard is the requirement for experience and knowledge. Clinical coordinators must have experience working with transplant patients or living donors in any setting.*
X120	*§482.98(c)(cont'd)* ***... The clinical transplant coordinator's responsibilities must include, but are not limited to, the following:*** *(1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and* *(2) Acting as a liaison between a kidney transplant center and dialysis facilities, as applicable.*	Review multidisciplinary care plan notes, and progress notes in the patient and living donor post-June 28, 2007, medical records to ensure that the transplant coordinator(s) fulfills the responsibilities of coordinating the clinical care of transplant patients and living donors by: 1) addressing elements identified in the pre-transplant or pre-donation assessment and care plan, peri-operative and post-operative; 2) educating patients, living donors, and families about treatment options and post-operative care or therapies as necessary; 3) monitoring patients' and living donors' medical, surgical and psychosocial status; and 4) providing feedback to other team members. 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. Look for evidence that the clinical transplant coordinator(s)	*Guideline §§482.98(c)(cont'd) and (c)(1)-(2)* *Clinical transplant coordinators are important links between transplant recipients/living donors and the transplant program and dialysis facilities, as applicable. A transplant coordinator is often the patient's primary contact for communication and direction on transplantation or donation related activities. This communication involves patients, families, medical team, organ procurement organizations, donor hospitals, and all other members of the transplant team.* *The primary purpose of the coordinator is to ensure that all the multidisciplinary needs of the patients are met in all phases of transplantation or donation.* *The coordinator is also the primary contact with the ESRD facility in the case of kidney transplant patients. Evidence of the collaboration between the coordinator and the ESRD includes wait list changes; laboratory results; and changes in medical condition.*

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		carried out these responsibilities at all phases of transplantation and donation (as described in X118.) Some examples could include discussing post-transplant organ function with the surgeon or physician, participating in the development of patient care protocols, monitoring routine nursing care, coordinating on-call 24/7 transplant coverage, updating UNet℠ information for patients on the waiting list, participating in multi-disciplinary care teams, developing a discharge plan for the transplant patient or living donor, or providing staff education. Generally transplant patients 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. Expect to see evidence that the clinical transplant coordinator is involved and assisting with any follow-up conducted by the transplant program. Increasingly, (over time) post-discharge care may be handled by a local physician, look for evidence that the clinical transplant coordinator ensured coordination with the local physician to appropriately transition follow-up activities. There are no minimum standards for follow-up with living donors. Be aware that post-donation follow-up activities are sometimes handled by a local physician, look for evidence of the coordinator's role in 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 and intervention, as indicated by the care plan.	
X121	***§482.98(d) Standard: Independent Living Donor Advocate or Living Donor Advocate Team.*** *The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective*	The transplant program's policies and procedures must require designation of an independent living donor advocate or living donor advocate team, and outline the qualifications and training (both initial and ongoing) required for living donor advocates or the living donor advocate team. If it is an advocate team, identify the composition of the team. By "independent" we mean that the individual(s) should function independently from the transplant team to avoid conflicts of interest. It does not mean that the individual must be employed by or supervised by someone outside of the hospital or outside the transplant program.	***Guideline §482.98 (d)*** *Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) prior to the initiation of the evaluation and continuing to and through the discharge phase.*

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	living donors.	The surveyor must be able to confirm that the independent living donor advocate or advocate team can operate independently of the transplant team and in a manner that puts the best interests of the living donor first. In doing so, the surveyor should evaluate the following factors: 1) Position within the Hospital: What position does the advocate (advocate team) have within the hospital? Is he or she located outside the transplant program? If not, does the position allow the advocate to provide independent representation to the donor (e.g., a donor coordinator)? 2) Job Description: Does the job description of the living donor advocate outline clear expectations that the role of this position is to represent and advise the donor; and to promote his/her interests. This individual must be focused on ensuring that the rights of living donors and prospective living donors are protected and that the donor's decision is informed and is free from coercion. 3) Policies and Procedures that Support Independent Functioning: Does the program's policies and procedures make it clear to all staff within the transplant program that the living donor advocate(s) functions independently from the transplant team, and that the donor's interests and rights will be put ahead of the wishes of the transplant team, if there is a conflict? 4) Supervisory Chain of Authority: What is the independent living donor advocate's supervisory chain of authority? To whom does he/she report? Is the supervisor someone whom a reasonable person would determine does not have a vested interest in the transplant taking place? 5) Complaints and Grievances: Does the independent living donor advocate have the ability to file a complaint/grievance with a third party if the donor advocate believes that the rights of the living donor are not being properly protected? The responses to the factors listed above should be considered *as a whole* before determining whether or not the independent living donor advocate can and does operate independently from the transplant team and that the donor's interests are properly protected. Verify in a sample of post-June 28, 2007, living donor medical records that an independent living donor advocate or team is identified for each living donor. In the review of medical records and policies and procedures and in the responses to interview questions,	

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		confirm that in all instances, the independent living donor advocate operated independently from the transplant team.	
X122	***§482.98(d)(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, on-call, waiting list management, organ allocation decisions, direct transplant patient care, and clinical transplant coordination, etc. It is not considered to be a "routine basis" if there is unscheduled, occasional participation on a contingency basis, for example, if the donor advocate was asked to cover for the on-call transplant coordinator when someone unexpectedly called out sick. It is expected that the living donor advocate (or advocate team) will be able to provide information (and/or facilitate information sharing with) to the living donor about transplantation and donation. Therefore, this section does not require that the individual conduct his or her donor advocate activities entirely outside the operation of the transplant program.	*Guideline §482.98(d)(1)* *Because of the conflict of interest which would be created for an advocate to perform any transplant activities, even on an infrequent basis, the ILDA or ILDAT must not be associated with the transplant program in any capacity even on a temporary or intermittent basis.*
X123	***§482.98(d)(2) The independent living donor advocate or living donor advocate team must demonstrate:*** *(i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and* *(ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.*	Review the medical record documentation of a sample of living donors to verify that the independent living donor advocate (or advocate team) demonstrates knowledge and understanding of living organ donation, transplantation, medical ethics and informed consent, as described in more detail below. Transplant programs have flexibility in determining how they will inform the living donor of the various components of the informed consent process and who will provide the information. However, if transplant program staff other than the Living Donor Advocate are providing the information to the donor, the living donor advocate (or advocate team) would continue to have a role in attending these informational sessions with the donor and creating opportunities for the living donor to discuss issues, ask additional questions, or request follow-up information. If information is provided directly by the Living Donor Advocate, the discussions between the donor advocate/team and the living donor should occur in a setting that is apart from the transplant recipient and other transplant program staff involved with the recipient. The donor advocate (or advocate team) must ensure that the living donor has received the information he or she needs to make an informed decision.	*Guideline §482.98(d)(2)* *The advocate/team must be able to provide evidence of successful training which addressed the topics listed in the standard.* *Interviews with living donors confirm that the advocate/team provided information concerning:* • *The organ donation process;* • *The requirements of the informed consent process;* • *The immediate and long-term expectations following donation;* • *The immediate and long-term risks of donation;* • *The expected outcomes for the recipient;* • *The potential financial responsibilities related to donation; and* • *Any alternative treatment(s) for the potential transplant recipient, if available.* *The living donor medical record should fully chronicle the interactions between the advocate or advocate team and donor candidate including the assessed level of understanding by the donor candidate during interactions.*

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		The documentation in the medical records post-June 28, 2007, should provide evidence that the living donor advocate (or advocate team) discussed with the donor the topics described below, confirmed donor understanding, and addressed any donor 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 donor's decision to donate and the future medical care and social support of the donor); • Any family or external pressures that impact the prospective living donor's decision about whether to donate; • The donor's current medical history and its implications for the suitability of the donor, possible long-term clinical implications of the organ donation; • The living organ donation process (e.g., 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 issues including future access to Medicare and private health insurance, and information about who will pay for necessary post-donation care and follow-up); • Various options for the recipient other than an organ donation from a living donor; and • The required areas of informed consent for the living donor (See Tag X159 through X168) and an assessment of donor understanding. In review of the post-June 28, 2007, medical records for living donors and transplant recipients, note any instances where medical ethics or informed consent may have been breached. In any such instance, interview the advocate (or team) to determine whether the advocate (or team) has knowledge of the pertinent medical ethics or informed consent terms. An example of such a breach would be if confidential information about the donor was shared with the transplant recipient. For any such breach, also review tags X057, X082, X124 and X160. <u>Demonstrating knowledge of medical ethics means the following</u>: • Holding the donor's welfare of primary importance; • Respecting the decisions and autonomy of the donor in his/her decision to donate and the care he/she receives;	

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		• Understanding the donation process, acknowledging current and future risks for the living donor, and identifying the methods/ process to ensure that the donor has the opportunity to ask questions and receive additional information about those risks; • Maintaining confidentiality of the communication between the donor 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 living donor during the informed consent process to be able to accurately assess the donor's understanding; • Evaluating donor's understanding through discussion; and • As needed, identifying areas where additional information or clarification is warranted to improve donor understanding; and if necessary, involve other transplant program or hospital staff. In reviewing documentation for a sample of post-June 28, 2007, living donor medical records, verify that there were opportunities provided that would ensure that the donor had the opportunity to ask questions and note any answers given to these questions. The medical record documentation/ notes should demonstrate the quality and thoroughness of the advocate (or advocate team) and donor interactions. Interview the living donor advocate or living donor advocate team to discuss the level of involvement between the advocate(s) and living donor and verify that the advocate(s) has knowledge of living donation and informed consent issues.	
X124	***§482.98(d)(3) The independent living donor advocate or living donor advocate team is responsible for:*** *(i) Representing and advising the donor;* *(ii) Protecting and promoting*	Review a sample of post-June 28, 2007, living donor medical records, advocate (or advocate team) notes, and multidisciplinary care plan notes. This documentation should provide evidence that the advocate (or advocate team) discussed with the donor the entire donation experience and risks, responded to donor questions or concerns, used techniques to evaluate the donor's understanding, and respected the donor's final decision.	***Guideline §482.98(d)(3)*** *The ILDA or ILDAT are primarily the representatives of the donor candidate. There may be instances where the advocate/team advises the potential donor candidate where to seek additional information, encourages the candidate to ask pertinent questions, encourages the candidate to have additional discussions with the family or advises the donor candidate to delay the decision to donate at any point without*

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	the interests of the donor; and *(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.*	The living donor advocate or team must also take steps to ensure that the donor has received the information outlined in the informed consent process, that the donor has had the opportunity to ask questions regarding the donation, and that the donor's decision is free from coercion. There must be a summary notation in the notes to verify that the donor was presented with the possible complications of donation and the donor is choosing freely to proceed with the donation. Interview donors if applicable and available (either recovering post-donation, or being seen for follow-up care in an outpatient clinic) for this tag. Discuss with the donors their interactions with the living donor advocate (or team). Please note, as is general surveyor practice, exercise care in interviewing donors to ensure that the individual voluntarily consents to the interview. Verify their account with the medical record account.	*reprisal if they choose. However, the advocate/team does not advise as to a decision on donation.* *All discussions and meetings between the potential donor candidate and the advocate/team must center upon the needs, interests and choices of the potential donor. These discussions must not address the needs of the potential recipient. If at any point in the process the donor changes his/her mind and decides not to donate, the advocate must support and intercede on behalf of the donor candidate if indicated.*
X125	***§482.98(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 that describe the membership of the multidisciplinary team and the responsibilities of each team member. Review a sample of personnel files for multidisciplinary team members unless reviewed under previous Tags. Verify that the team members have the appropriate qualifications and training, and are appropriately credentialed and licensed as required in the State of practice. For transplant surgeons and transplant physicians the qualifications include: 1. Are currently licensed in their state of practice; 2. Meet the hospital's credentialing and privileging requirements; and 3. Have either current Board Certification, or approval from OPTN of foreign equivalency. In general, review of other items in the personnel file (e.g., evaluations, initial employment questionnaire, 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 a comprehensive and ongoing training	***Guideline §482.98(e)*** *While it is desirable that each multidisciplinary team include a pharmacist member, there may be other disciplines on the team who may also be qualified to provide pharmacology services. Examples of individuals other than a pharmacist who are also qualified to provide pharmacology services on the team, are a physician, advanced nurse practitioner, or physician assistant.*

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		program. The training should include areas such as: new technology, changes in the field of transplant patient and living donor care, transplant specific training sessions, updates and sharing best practices learned during relevant conference attendance, and individual training opportunities according to the transplant program and overall hospital policies. Interview multidisciplinary team members to confirm that their activities for the transplant patient or living donor conform to the responsibilities outlined in their written policies. Review post-June 28, 2007 medical records of a sample of transplant patients to confirm documentation of each team member's appropriate implementation of his or her respective responsibilities. Review medical records of a sample of living donors to confirm documentation of each team member's appropriate implementation of his or her respective responsibilities. Evidence of the multidisciplinary team's performance can be assessed through a variety of ways: for example review of the documentation in the medical records, review of multidisciplinary team notes taken by an individual, and interviews of transplant team members about their meeting schedule and participation. Daily documentation of multidisciplinary team meetings is not required by this section	
X126	***§482.98(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.*	If the required services are provided in-house, ensure that the services are available 24-hours per day, 7 days per week. If any service is provided by contract, review the contract to ensure that services are available 24 hours per day, 7 days per week. Tissue typing services are not required to be available 24-hours a day. Review a sample of post-June 28, 2007, medical records for transplant patients and if applicable, living donors, to confirm the provision of these services in a timely manner and the furnishing of these services by qualified professionals. Note any instances when the required service(s) were not available upon request or according to a patient's or living donor's care plan.	
X139	***§482.100 Condition of Participation:***	Review the hospital's written agreement with the designated OPO.	***Guideline §482.100*** *The hospital in which the transplant program is located must*

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	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.*	The written agreement must identify the specific responsibilities of the hospital and the OPO and how they commit to work collaboratively. <u>Common responsibilities for the transplant hospital are expected to include (but are not limited to):</u> 1. Providing current personnel contact information to the OPO, and notification of changes in key personnel; 2. Reporting inactivation and reactivation of transplantation services to the OPO; 3. Describing the method of communication with the OPO regarding organ acceptance or declinations; 4. Notifying the OPO of adverse events that would indicate that the donor may have had a transmissible disease which could impact the morbidity or mortality of recipients of other organs or tissues from the same donor; 5. Updating the UNet^{SM} data system in a timely manner with information about patient status and determinations regarding organ offers; 6. Providing a surgical recovery team to recover organs from donors, as appropriate, and transmitting licensure and/or credentialing information for the recovering surgeons to the OPO; and 7. Outlining a process for identifying and resolving issues, complaints, and concerns. <u>Common responsibilities for the OPO are expected to include (but are not limited to):</u> 1. Determining the medical suitability of the donor; 2. Describing the method and timeliness of communication with the transplant hospital; 3. Notifying the transplant program of policy and procedure changes by the OPO that may affect organ recovery, placement, packaging, labeling, perfusion, and transport; 4. Ensuring the proper composition and credentialing of the organ recovery team; 5. Ensuring that proper documentation is provided to the transplant program about the recovered organ(s) which includes the blood type and other identifying information; and 6. Outlining a process for identifying and resolving issues, complaints and concerns.	*have a written agreement with their designated OPO for cooperation with the OPO in the recovery of donor organs. The agreement must meet the requirements of §482.45.*
X149	***§482.102 Condition of Participation: Patient and Living Donor Rights.*** *In addition to meeting the condition of participation*	*Blank*	

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	"Patient's rights" requirements at §482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.		
X150	***§482.102(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 identified in the standard (1) through (8), the transplant program's policies and procedures should delineate: 1) who is responsible for discussing the informed consent process with the patient; 2) where the discussions concerning the informed consent process are documented in the medical record; 3) the methods used by the program to ensure and document patient understanding; and 4) when the discussion will take place. Request a copy of all educational materials provided to patients as part of the informed consent process. Confirm that the educational materials are written at a reading level easily understood by the patient population served by the transplant program. Interview a sample of available post-transplant patients (either inpatient or patients coming in for follow-up clinic visits), to verify that the transplant program obtained fully informed consent in all of the areas under subparagraphs (1) through (8) of the standard. Pre-transplant patients (or their representatives) may also be interviewed. Interviews may also be conducted with the patient's parents, significant others, friends, or legal representatives that have close knowledge of the patient's transplant experience. Confirm that the informed consent process described by the interviewed patients conforms to the documentation of informed consent in the medical records of those patients. If no inpatients are available and no patients are available in the clinic, interviews should be conducted with post-transplant patients via telephone. A signed informed consent <u>form</u> and/or hospital surgical informed consent form should not be considered evidence that the informed consent <u>process</u> is complete. The informed consent process is expected to involve multiple discussions with the prospective transplant recipient at	***<u>Guideline §482.102(a)</u>*** *As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide a potential transplant recipient with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose all available information to a potential recipient who makes the voluntary choice to accept or refuse treatment. The transplant physician must ensure each potential recipient that is considered for organ transplantation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to them.* *The signed hospital surgical consent form alone is not considered evidence that the informed consent process for transplant patients was completed to include the requirements of §§482.102(a)(1)-(8).*

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		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 patients must be given an opportunity to ask questions and the level of patient understanding must be assessed. Note: A properly executed informed consent form that is signed and documented in the medical record for surgery and other treatments is still required under the hospital Conditions of Participation.	
X151	***§482.102(a)(1) The evaluation process;***	The evaluation process begins at the time an individual is identified as a potential transplant candidate and continues until the time the individual is placed on the waiting list. During the evaluation time period, the following topics, at a minimum, should be discussed with the patient. a) results of the physical evaluation; b) patient selection criteria and suitability for transplant; c) results of laboratory and transplant-specific diagnostic testing; d) relevance of any psychosocial issues to the success of the transplant; e) financial responsibilities resulting from the transplant; and f) necessity of following a strict medical regimen post-transplant.	***Guideline §482.10(a)(1)*** *A part of the informed consent process is ensuring the candidate understands what the evaluation process entails prior to its initiation. Prior to a potential recipient making a decision to undergo an evaluation for transplantation, they must understand all that is involved in the evaluation process, which includes what the potential recipient and transplant program responsibilities will be; all possible decisions regarding wait listing and transplantation that could be reached as a result of the evaluations; and what factors could result in their removal from the waiting list.*
X152	***§482.102(a)(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 waiting list, the transplant program must, at a minimum, provide an overview of the surgical procedure and potential risks. A detailed discussion of the surgical procedure and anesthesia risks, the risks involved with the use of blood or blood products, the expected post-surgical course; and the benefits/risks of transplant surgery relative to other alternatives should occur prior to transplantation surgery.	***Guideline §482.102(a)(2)*** *Discussions by the transplant surgeon with the potential recipient would include:* • *What is the surgical procedure to be performed?* • *What are the risks of the surgery?* • *How is the surgery expected to improve the potential recipient's health or quality of life?* • *How long will the potential recipient be hospitalized?* • *What is the expected recovery period?* • *When may normal daily activities be resumed?*
X153	***§482.102(a)(3) Alternative treatments;***	The options for alternative treatments will vary by organ type and by the patient's specific medical condition. For example, kidney transplant candidates have some dialysis options. The discussion of these alternative treatments should occur before or simultaneously with placement on the UNet℠ waiting list. The discussions of alternative treatments should be reviewed again with the patient subsequent to	***Guideline §482.102(a)(3)*** *Each potential recipient's options for treatment will vary based on organ type and individual medical condition(s). It is expected that discussions related to alternative treatments occur prior to a candidate undergoing an evaluation for transplantation.* *The discussions of alternative treatments should be reviewed any time the candidate has significant changes in their medical*

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		any significant changes in the patient's medical condition or other alternative treatments that become available.	*condition and as other alternative treatments become available with advancements made in the science of disease management and treatment.*
X154	***§482.102(a)(4) Potential medical or psychosocial risks;***	Discussions regarding potential medical or psychosocial risks should occur early in the evaluation process and with any major material change in the patient's medical or psychosocial condition. Discussion of potential medical risks should include, at a minimum: a) wound infection, b) pneumonia, c) blood clot formation, d) organ rejection, failure, or re-transplant; e)lifetime immunosuppressant therapy; f) arrhythmias and cardiovascular collapse, g) multi-organ failure, and h) death. Discussion of potential psychosocial risks should include, at a minimum: depression, Post Traumatic Stress Disorder (PTSD), generalized anxiety, anxiety regarding dependence on others, and feelings of guilt. A transplant candidate must also be informed that future health problems related to the transplantation may not be covered by his or her insurance carrier, and if applicable, alternative financial resources should be discussed and explored. The candidate must be informed of the possibility that attempts to obtain medical, disability, and life insurance in the future may be jeopardized and that denial of coverage is a possibility.	*Guideline §482.102(a)(4)* *There are general risks applicable to all organ transplant types and there are risks specific to each organ type. The transplant program must address both categories of risk with the potential recipient prior to his/her decision to proceed with the evaluation process.*
X155	***§482.102(a)(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 graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;***	Discussions with the transplant candidate regarding transplant programs' outcomes should, at a minimum, occur prior to the date of placement on the UNet℠ waiting list. Following the initial discussion, if more than six (6) months has elapsed between placement on the waiting list and selection for transplant, discussions should be held again with the patient prior to any surgical procedure. This section does not require transplant programs to notify patients every 6 months with the updated information, but should communicate any updated information to the patients when follow-up discussions occur prior to surgery. The prospective transplant recipient must be informed, in understandable language of: 1. The program's current 1-year post-transplant patient survival rate and 1-year post-transplant graft survival rate. 2. How these rates compare to the national averages. 3. Whether the latest reported outcome measures in the SRTR Center Specific Report comply with Medicare's	*Guideline §482.102(a)(5)* *Prior to undergoing an evaluation, the transplant program informs the potential recipient of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program's performance. The potential recipient should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website. This information allows the patient to make an informed decision about listing with the program.*

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		outcome requirements. For additional information the patient could be provided the SRTR and OPTN websites at www.ustransplant.org and www.optn.org respectively. When requested, the transplant center should provide assistance in the interpretation of the appropriate reports for the patient.	
X156	***§482.102(a)(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immune-deficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;***	Before a donor is identified and the transplant candidate is put on a waiting list, these discussions should involve a general discussion of the implications of the transplant. These discussions should include the possibility of graft failure and/or other health risks related to the health status of the organ donor including: a) the medical and social history and age of the donor, b) the condition of the organ(s), and c) the risk of contracting HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), cancer or malaria if the donor is infected, but the infection is not detectable at the time of donation. After an organ offer is made for a patient, the transplant program must discuss with the patient the possible risks associated with transplantation of that specific organ. The discussion of risks should include any issues that could affect the success of the organ transplant (the condition of the organ), and any issues that could potentially place the health of the patient at risk (for example, known high-risk behaviors in the donor's background).	***Guideline §482.102(a)(6)*** *During the pre-evaluation period, the program informs the potential recipient of the general risks as listed in this regulation. At the time an organ is offered, the potential recipient must be informed of any risk factors specific to the organ recovered or to be recovered.* *The transplant program should utilize the PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation to identify those instances where the potential recipient must be informed as to increased risk with a particular organ condition. 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	***§482.102(a)(7) His or her right to refuse transplantation; and***	Documentation in the medical record confirms that the prospective 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.	***Guideline §482.102(a)(7)*** *The transplant program must inform all transplant candidates of their right to withdraw consent for transplantation any time during the process.*
X158	***§482.102(a)(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.***	*Blank*	
X159	***§482.102(b) Standard: Informed consent for living donors.*** *Transplant centers must implement written living donor informed consent*	For each of the subparagraphs identified in the standard (1) through (9), the transplant program's policies and procedures should address: 1) who is responsible for discussing informed consent process with the donor; 2) where in the medical record informed consent	***Guideline §482.102(b)*** *As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide patients with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose appropriate information to a patient which allows them to*

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	policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:	discussions are documented; 3) the process for assessing donor understanding; and 4) the appropriate point of the donation process to hold these discussions. Request a copy of all educational materials provided to donors as part of the informed consent process. Confirm that educational materials are written at a reading level that is easily understood by the donor population served by the transplant program. Interview a sample of available post-operative donors (either inpatient or coming in for follow-up clinic visits) to ensure that the transplant program provided to the donor the information outlined in the areas under (1) through (9) of this standard. Post-donation patients should be selected for interviews if possible because the informed consent process will be completed. However, if no post-donation patients are available, prospective donors may be interviewed about those portions of the informed consent process that have already been completed considering where a potential donor may be in the pre-donation evaluation. Review the corresponding medical records of the donors who are interviewed to ensure that the informed consent process as described by the donor corresponds to the documentation of informed consent in the medical record. If no donors are available on the floor, no donors are available in the clinic, and no prospective donors are available, interviews may be done with post-donation donor patients via telephone. A signed informed consent form and/or hospital surgical informed consent form should not be considered evidence that the informed consent process is complete. The informed consent process is expected to involve multiple discussions with the prospective donor at different points in time (e.g., while being evaluated as a potential donor candidate, prior to surgery). Living donors must be given an opportunity to ask questions and the level of understanding must be assessed. Note: A properly executed informed consent form that is signed and documented in the medical record for surgery or treatment for the patient is still required under the hospital Conditions of Participation.	*make the voluntary choice to accept or refuse treatment. The physician must ensure each patient that is considered for organ donation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to the recipient.* *Transplant programs must develop and implement informed consent policies for living donors that delineate the information to be shared and the responsibilities of any transplant staff member that will consult with the patient.* *The signed informed consent form and/or hospital surgical informed consent form alone is not considered evidence that the informed consent process for the prospective living donor is complete. Transplant programs must provide documentation that ensures the living donor candidate was informed of subparagraphs (1) through (8) of this standard.*
X160	***§482.102(b)(1) The fact that communication between the***	The requirements at 45 CFR parts 160 and 164 establish standards for the security, privacy, and authorized release	***Guideline §482.102(b)(1)*** *Requirements in 45 CFR part 160 and subparts A and E of part*

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	donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.	of personal health information. Verify through interviews with the living donor and the review of a sample of post-June 28, 2007, living donor medical records that donors were given information about the types of personal health information that will be collected and that this information and any communication between a donor and the donor advocate, and a donor and the transplant program will remain confidential, subject to the authorized release of this information under certain circumstances (such as when the individual provides consent)	*164 relate to the privacy of individually identifiable health information and prevention from fraud and abuse related to the provision of or payment for health care for the purpose of protecting the privacy of health information.* *Requirements in subpart C of 45 CFR part 164 relate to the security standards for the protection of electronic protected health information, notification procedures in the case of breach of unsecured protected health information, and the privacy, uses, and disclosure of individually identifiable health information.* *Accordingly, any information shared between the living donor candidate and the transplant program may not be shared with the potential recipient and/or their families except as permitted by 45 CFR parts 160 and 164.*
X161	***§482.102(b)(2) The evaluation process;***	The evaluation process begins when an individual is identified as a potential living donor and continues until donation occurs or he or she is no longer a donor candidate. During the evaluation process, the following topics, at a minimum should be discussed with the prospective living donor. a. results of the physical evaluation including a discussion of how any current health issues or medication regimen could be effected by the donation or could affect recovery from the donation; b. suitability for donation; c. results of laboratory and donor -specific diagnostic testing; d. relevance of any psychosocial issues related to donation; and e. financial responsibilities resulting from the living donation as well as post-donation expenses, including the potential for out-of- pocket costs if the donor has complications from the surgery, needs medication following discharge, or is expected to undergo follow- up testing or a physical examination so that the center can report the donor's status to the OPTN. The prospective donor must be advised that the transplant center cannot require him or her to pay for post-donation testing or examination for follow-up purposes. See Tag X166.	***Guideline §482.102(b)(2)*** *The informed consent process ensures that the donor understands what the evaluation process entails prior to its initiation. Prior to a donor candidate making a decision to undergo an evaluation for donation, they must understand what the process demands, patient and transplant program responsibilities, what determination(s) can be made as the result of an evaluation, and what factors could determine their non-candidacy for donation.* *The evaluation process is ongoing, beginning at the time an individual is identified as a possible candidate for donation and continues until donation. Routine re-assessments, as determined by the program's protocols must be conducted to ensure continued suitability for donation.*
X162	***§482.102(b)(3) The surgical procedure, including post-operative treatment;***	Discussions with a prospective living donor about the surgical procedure should occur on several occasions. Prior to consent for donation, discussions should, at a minimum, provide the potential donor with an overview of the surgical	***Guideline §482.102(b)(3)*** *Discussions by the transplant surgeon with the potential donor candidate would include:* • *What is the surgical procedure to be performed?*

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		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: 1. risks associated with the surgery; 2. risks and effects of general anesthesia; 3. possible need for blood transfusion and the risks involved with use of blood or blood products; 4. expected post-surgical course and discomforts (e.g. possible need for artificial ventilation, pain, bleeding, and infection); and 5. termination of the surgery with any indication that he/she is at risk of significant complications or death during the surgery.	• *What are the risks of the surgery?* • *How is the surgery expected to improve the potential recipient's health or quality of life?* • *How long will the potential recipient be hospitalized?* • *What is the expected recovery period?* • *When may normal daily activities be resumed?*
X163	***§482.102(b)(4) The availability of alternative treatments for the transplant beneficiary;***	Prior to consent for donation, the donor must be informed of the alternate treatment regimen(s) available to the transplant candidate in lieu of receiving a donated organ. This discussion must be documented in the donor evaluation notes or progress notes. The options for alternative treatments will vary by organ type and by the patient's specific medical condition. For example, kidney transplant candidates have some dialysis options.	***Guideline §482.102(b)(4)*** *A potential donor must be made aware of all alternative treatments that are available for the potential recipient which may include the possibility of a deceased donor transplant.*
X164	***§482.102(b)(5) The potential medical or psychosocial risks to the donor;***	Discussions regarding potential medical or psychosocial risks to the potential donor should occur early in the evaluation process prior to the consent for donation and with any change in the donor's medical or psychosocial condition. Discussion of the potential medical risks should include, at a minimum: a) wound infection, b) pneumonia, c) blood clot formation, d) arrhythmias and cardiovascular collapse, e) organ failure of the remaining organ (or part of the organ), f) potential need for organ transplant later on in life, and g) death. Discussion of the potential psychosocial risks should include, at a minimum: depression, Post Traumatic Stress Disorder (PTSD), generalized anxiety, anxiety regarding dependence on others while recovering from the donation, and possible feelings of guilt.	***Guideline §482.102(b)(5)*** *There are general risks applicable to all organ transplants and there are risks specific to each organ type. The transplant program must address both categories of risk with the potential donor prior to his/her decision to proceed with the evaluation process.* *The informed consent discussion should include information regarding the fact that long term medical implications of organ donation have not been fully identified.*
X165	***§482.102(b)(6) The national and transplant center-specific***	Discussions regarding the transplant program's outcomes must be done prior to the prospective donor's consent for	***Guideline §482.102(b)(6)*** *Prior to undergoing an evaluation, the transplant program*

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	outcomes for beneficiaries, and the national and center-specific outcomes for living donors, as data are available;	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 should be held with the prospective donor. The prospective donor should be informed, in understandable language of: 1. The program's current 1-year post-transplant patient survival rate and 1-year post-transplant graft survival rate, and available data on outcomes for living donors. 2. How these rates compare to the national averages. 3. Whether the latest reported outcome measures in the SRTR Center Specific Report comply with Medicare's outcome requirements 4. The center's outcomes for living donors, including rate and type of complications (pre-discharge and long-term) and donor deaths. 5. National outcomes for living donors, as available. 6. The types of outcomes for living donors that are not calculated due to insufficient national data (such as long-term outcomes for living donors), as appropriate. For additional information the patient should be provided with the SRTR and OPTN websites at www.ustransplant.org and www.optn.org respectively. Upon request, the transplant center should provide assistance in the interpretation of the appropriate reports.	*informs the potential donor of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program performance. The potential recipient should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website.* *There are currently no national or center specific outcomes for living donors calculated by the SRTR.*
X166	***§482.102(b)(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected;***	Documentation must confirm that, a prospective donor was informed that the donation procedure and future health problems related to the donation may not be covered by his or her insurance carrier or, if covered, may affect his or her maximum lifetime benefits under the insurance. Alternative financial resources must be discussed with the living donor and documented. The donor must also be informed that attempts to obtain medical, disability, and life insurance in the future may also be jeopardized and there is the possibility of denial of coverage.	
X167	***§482.102(b)(8) The donor's right to opt out of donation at any time during the donation process; and***	Interviews and documentation in the medical record must verify that the donor was advised of, and understood his or her right to withdraw consent for living donation at any time during the process.	
X168	***§482.102(b)(9) The fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant***	*Blank*	

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	beneficiary's ability to have his or her immune-suppressive drugs paid for under Medicare Part B.		
X169	***§482.102(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 potential transplant patients of the customary availability of key personnel for transplants, and other transplantation services, and how the patients will be informed of changes to this customary availability. Review a sample of the post-June 28, 2007, medical records of patients on the waiting list, and verify that in each case, the patient 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 donor transplants in cases where living donor transplants may be an option at other transplant programs). Note: A transplant program may not have continuous availability if the program is served by a single transplant surgeon, which is permissible if waiting list patients are notified and acknowledge understanding of this fact.	
X170	**§482.102(c)(1) A transplant center served by a 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.	A transplant program served by a single transplant surgeon or transplant physician must have written policies and procedures in place to inform the patients on the program's waiting list regarding: (a) the potential unavailability of the transplant surgeon or physician; and (b) 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 policy will designate who will inform the waiting list patients, and how the record of this notification will be documented. Review a sample of post-June 28, 2007, medical records for patients on the waiting list to verify that a) full and accurate information was provided to the patient regarding the possible unavailability of key personnel or support services; and b) the patient acknowledges understanding the possible unavailability. This documentation should identify that the patient was made aware of potential unavailability prior to placement on the transplant program's waiting list.	***Guideline §482.102(c)(1)*** *The absence of a transplant surgeon or physician may impact a transplant candidate's ability to receive a transplant if an organ becomes available. Transplant programs must disclose the possibility of such an event as well as whether the program has a process to provide an alternate transplant surgeon or transplant physician in such an event prior to the potential recipient undergoing evaluation. Any changes that occur following the informed consent process must also be shared with each candidate on the waiting list.*

TAG	Regulation	Interpretive Guidelines June 13, 2008	Interpretive Guidelines March 29, 2019
X171	***§482.102(c)(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; 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.*	*Blank*	
X172	***§482.102(c)(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.***	The transplant program must have policies that describe how patients will be informed if a program becomes voluntarily inactive (a 60-day or greater period for heart, kidney, pancreas and liver programs and a 90-day or greater period for intestine, heart/lung and lung programs.) 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 post-June 28, 2007, 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 center, as directed by the Secretary.	*Guideline §482.102(c)(3)* *A transplant program may choose to inactivate for reasons including: the inability to meet clinical experience (volume) requirements; temporarily lacking medical or surgical coverage; and a significant change in operations that require a temporary cessation of transplant activity.* *Transplant programs that intent to become inactive must notify the patient group that will be affected by the inactivity. If the determination is made to inactivate a transplant program or a component of a transplant program, all potential recipients on the waiting list would be unable to receive an organ offer during the time period of inactivity. As such, transplant programs must notify all affected patients of the upcoming inactivation. It must also inform the potential recipients of the expected time period of inactivation, if known, and options for waitlisted patients to transfer to another facility.* *Waiting list patients should receive notification of the program's voluntary inactivation at least 30 days prior to the planned inactivation date. Transplant programs determine the method of communication with the potential recipients and the program must be able to document the communication.* *If a transplant candidate elects to be transferred to another transplant program, the inactivating transplant program must facilitate communication and help with the exchange of*

TAG	Regulation	Interpretive Guidelines June 13, 2008	Interpretive Guidelines March 29, 2019
			information. The transplant program should coordinate with the receiving facility to place the patient on their waiting list.
X184	§482.104 Condition of Participation: Additional Requirements for Kidney Transplant Centers.		
X185	***§482.104(a) Standard: 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… .*	In addition to the medical and surgical services required for all transplant patients, 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 within the physical location of the participating hospital. To verify that these are furnished directly, interview transplant personnel such as nursing and/or medical staff.	
X186	***§482.104(a)(cont'd)… 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 patients on the transplant program's waiting list. The transplant program must have written policies that describe the method and frequency of communication with the dialysis centers as well as types of information that must be shared. Communications should be documented and should indicate the method of communication whether via electronic communications, written communications, or phone calls. Interview the clinical transplant coordinator to determine if there is ongoing communication with the respective dialysis facilities. In a sample of post-June 28, 2007, medical records for patients either on the waiting list or receiving dialysis post-transplant, request the documentation of communications with local dialysis facility(ies). This documentation may be in transplant outpatient progress notes and/or specialty notes. Confirm through documentation in the post-June 28, 2007, medical records that there is ongoing communication with the patients' local dialysis facility regarding significant issues such as: a. Changes of key personnel in the transplant program;	***Guideline §482.104(a)(cont'd)*** *Transplant programs must have policies in place on how information is shared with dialysis facilities for patients currently receiving dialysis. Transplant programs must have bi-directional communication with the dialysis facility about any waiting list status changes or changes in patient condition. The communications usually include laboratory values and change in inpatient status. There will be communication periodically between the two entities, however, the frequency is determined by patient status changes and the policies of the transplant program.*

TAG	Regulation	Interpretive Guidelines June 13, 2008	Interpretive Guidelines March 29, 2019
		b. Changes to key policies in the transplant program; c. Changes in a patient's health status, such as infections, increase in the severity of heart disease or other conditions that could affect suitability for transplant, or death; d. The status o for transplantation, such as a cardiac workup or weight loss; and e. Changes in the center's transplant patient selection criteria. Note: 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 state survey agency as a potential complaint about an End State Renal Disease (ESRD) facility.	
X187	*§482.104(b) Standard: Dialysis services.* ***Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement.***	The inpatient dialysis services may 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 dialysis facility must have an appropriate agreement with the participating hospital for the provision of inpatient dialysis. During interviews with transplant program staff, determine if appropriate inpatient dialysis services are available. 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 state survey agency.	
X188	*§482.104(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.***	Review information provided by CMS that will indicate whether the transplant program is fulfilling its responsibilities to cooperate with the ESRD Network related to the Network's statement of work (SOW), including the submission of appropriate forms. 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	*Guideline §482.104(c)* *The most current ESRD Network statement of work includes the direction and goals that are set by the Network and completed through partnership with other stakeholders, such as a transplant programs. Transplant programs are expected to cooperate, and participate if necessary, in fulfilling the goals set by the Networks.* *The most current Statement of Work can be found on the CMS website for ESRD Networks at: https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/* *Information on the geographic areas of Networks and the SOW can be found on the CMS Website*

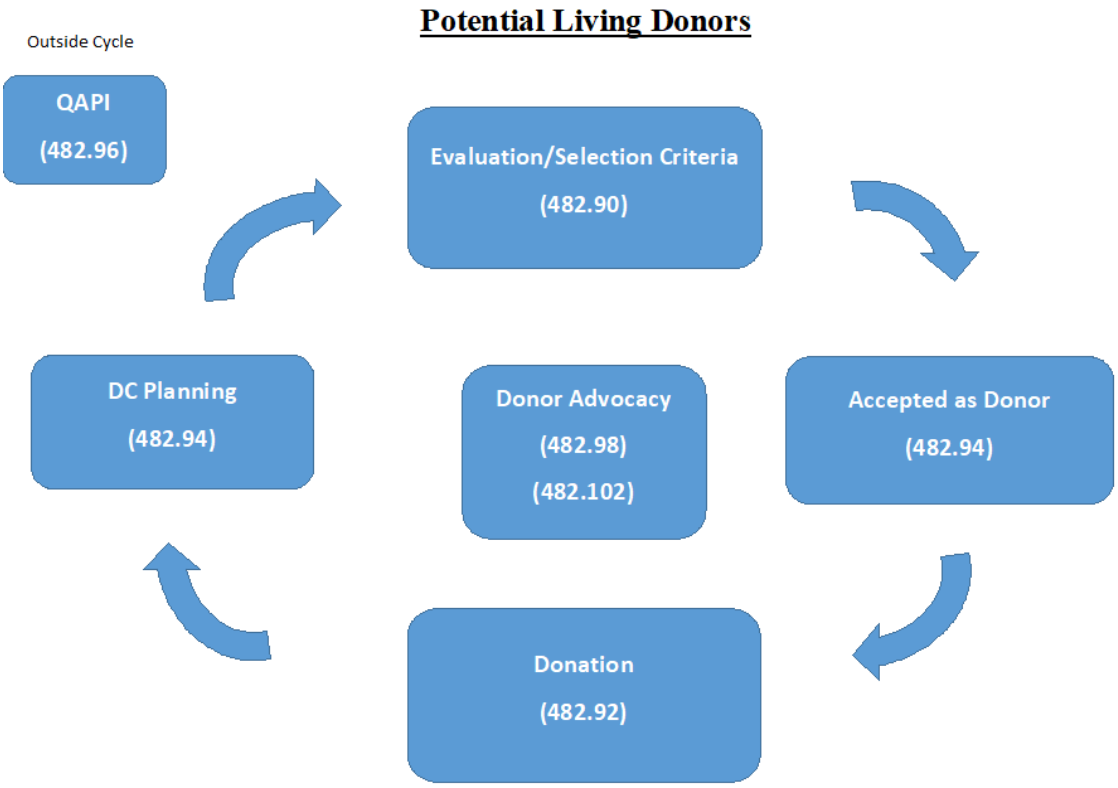
TAG	Regulation	Interpretive Guidelines June 13, 2008	Interpretive Guidelines March 29, 2019
		SOW can be found on the CMS website at http://www.cms.hhs.gov/ESRDNetworkOrganizations.	*(http://www.cms.hhs.gov/ESRDNetworkOrganizations).*

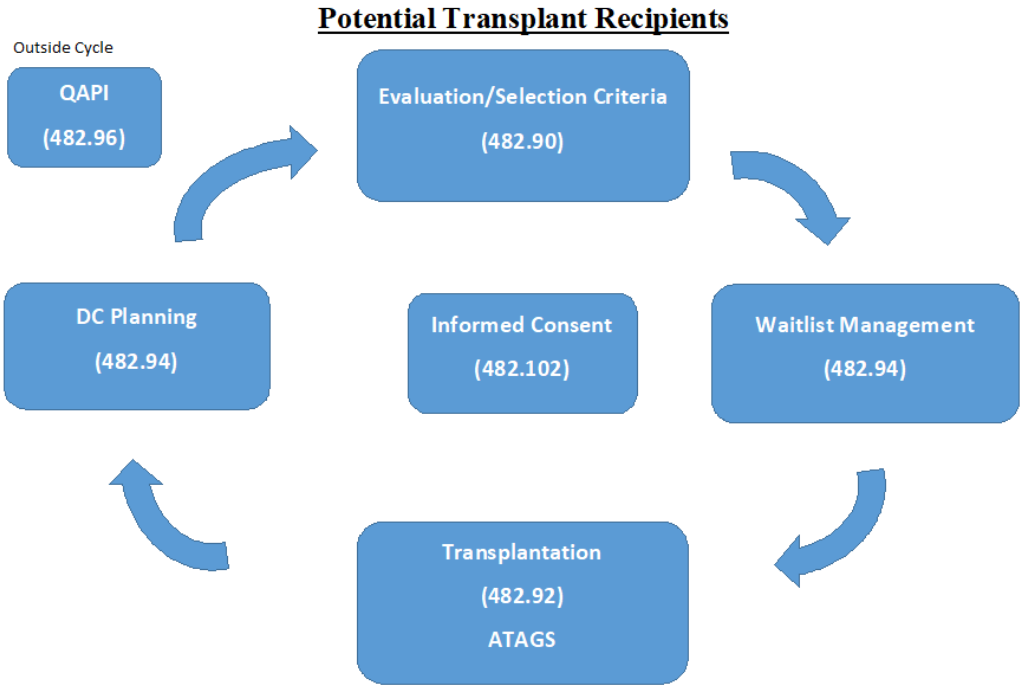
List of Items Requested by Surveyors at Start of Survey June 2016	Lists Requested During Entrance Conference March 29, 2019
Lists of Transplant Candidates, Recipients and Living Donors (by organ type)	
1. The transplant program's complete **current active waiting list** including the following information: patient name, date of listing, MRN, wait list status, age, race, gender, address, country of primary residence, resident alien or non-resident alien status and total number of individuals on the waiting list;	1. Each transplant program's complete current active waiting list including the following information: name, date of listing, wait list status, medical record number, age (at time of transplant), race and gender of each patient;
2. List and number of all patients **removed from the waiting list** including the reason for the removal within the past 12 months. (Removed due to death or transplant). Please include patient name, MRN, date of removal and reason for removal;	
3. List and number of persons **removed from the transplant program's waiting list** over the last 12 months **for reasons *other than* death or transplant**. Please include patient name, MRN, date of removal and reason for removal;	2. List of all patients (to include their medical record number) removed from the waiting list within the past 12 months of each program for reasons other than death or transplant;
4. List and number of persons **evaluated for transplant that *were not* placed on the waiting list** within the past 12 months. Please include patient name, decision date, decision reason and MRN. Do not include persons that are currently in the evaluation process;	3. List of all persons evaluated within the last 12 months by each transplant program who were not placed on the waiting list. (Do not include persons that are currently in the evaluation process). The list should include patient name and medical record number.
5. List and number of the **transplants performed** within the past three years including patient name, date of transplant, MRN, organ(s) transplanted, age, race, gender, address, country of primary residence, resident alien or non-resident alien status, and the date of death or graft failure if applicable;	4. List of all of the transplants performed within the last 18 months (including patient name, medical record number, age (at time of transplant), and date of transplant);
6. List and number of **living donors** to include all types: (Paired Exchange, Regional, Altruistic, Adult to Pediatric and Pediatric to Adult). Include the patient name, MRN or UNOS number, organ(s) donated and the date of donation within the past three years.	5. If applicable, list of all of the living donors who were evaluated during the past 12 months denoting those potential donors who proceeded to donation. Include name, medical record number, the organ(s) donated and date of donation within the designated time period;
List of Meeting Schedules, Scheduled Follow-up Visits and Current Transplant Inpatient Census	
7. List and number of transplant patients and living donors that are currently an inpatient and the location of patient (unit, and floor);	6. List of all of the transplant recipients and living donors who are currently inpatient(s) and the location of the patient(s) within the hospital;
8. List and number of post-transplant patients and post-donation individuals that are scheduled for follow-up visits during the survey timeframe;	
9. A schedule of any multidisciplinary team meetings that will be held during the survey; Include team rounding schedule;	
10. A schedule of any selection committee meetings that will be held during the survey;	
11. A schedule of any QAPI committee meetings that will be held during the survey;	
List of Offers	
12. List and number of the organs that the transplant program received offers for within the past 3 years, and declined, and the reason for the declination/UNOS	

List of Items Requested by Surveyors at Start of Survey June 2016	Lists Requested During Entrance Conference March 29, 2019
decline code;	
Program Administration/Contracts	
Administrative/Contracts	Request Program Administration Materials
13. An organizational chart of the transplant program which includes the chain of command and how the transplant program fits within the overall hospital structure;	1. Request an organizational chart of the transplant program, which includes the chains of command and how the transplant program fits within the overall hospital structure;
	3. Inform the administrator that policies, procedures, personnel, and QAPI manuals will be requested, as needed, for review.
14. Any contracts with external parties that the hospital or transplant program have for services relevant to transplantation including but not limited to: Anesthesiology, Blood banking, Dialysis Services (inpatient or outpatient), Histocompatibility (HLA) or Immunology Laboratory, Infectious Disease, Internal Medicine, Living Donor (including Paired Exchange, Regional, Altruistic, Adult to Pediatric, or Pediatric to Adult donors), Nursing, Pathology, Radiology, Nutritional/Dietary Services or Surgery.	
Personnel	
15. List of all transplant associated professional personnel, their titles, primary organ transplant program affiliations and any other transplant program affiliations; (X082, X090, X091, X125)	
16. The curricula, training plan, and/or training schedule for personnel, (agenda, dates, evidence of attendance);	
17. On-call schedule for transplant surgeons and transplant physicians for the past 30 days; (Include Transplant Surgeon's distance & time from home to program.)	
Policies and Procedures	
18. Patient selection criteria (transplant recipient and living donor); provide the criteria that your program uses to select patients for transplant and living donation; (X051-60)	
19. Organ Receipt policy for ABO and Other Vital Data Verification (include associated forms); (X071, X073)	
20. Living Donor Recovery for ABO and Other Vital Data Verification (include associated forms); (X074)	
21. Transplant Recipient Patient Management Policies for Pre-Transplant, Transplant and Discharge Planning Phases (X082, X090, X091, X125)	
22. Living Donor Patient Management for Pre-Donation, Donation and Discharge Planning Phases (X082, X125)	
23. Waitlist Management Policy (including patient notifications); (X081-94)	
24. Informed Consent Policy for Recipients (include associated forms); (X149-158)	

List of Items Requested by Surveyors at Start of Survey June 2016	Lists Requested During Entrance Conference March 29, 2019
25. Informed Consent Policy for Living Donors (include associated forms); (X060, X124, X149, X159-168)	
26. Ongoing communication with patients and dialysis centers (Informing patient and dialysis center of patient's listing status); (X120, X186)	
27. Procedure for informing patients on the waitlist of the availability of a transplant team that could impact the patients' ability to receive a transplant should an organ become available; (X169)	
28. If a transplant program served by a single transplant surgeon or physician the potential unavailability of the transplant surgeon or physician. (X170)	
Education Information	
29. A copy of the written material that is distributed to potential transplant recipients and living donors to explain the selection criteria;	
30. Any written educational materials used pre and post-transplant for transplant recipients; (X126, X150-158, X159-172)	
31. Any written educational materials used pre and post-transplant for living donors; (X060, X126, X159-171)	
QAPI	
32. The written copy of the Transplant programs Quality Assessment and Performance Improvement (QAPI) plan;	
33. The written copy of the Hospital's Quality Assessment and Performance Improvement (QAPI) plan;	
34. Any QAPI reports, records and minutes of QAPI committee meetings, or consultation reports about the QAPI program;	
35. Policy/Protocol on complaints, adverse events and other occurrences or variance reporting issues;	
36. Log of any reported adverse events for the past 24 months and documentation of the investigation, analysis of events and any follow-up action taken.	2. Request a log of any and all reported adverse events for the past 12 months (extend to 24 months if no reports found in the 12 month log). This list will be used to select the patient sample for adverse events.

Attachment F: Survey Schematic





Attachment H: GLOSSARY
Resource for Surveyors

ABO Blood Type. Categorical classification of blood based on differences in molecules (carbohydrates and proteins) on red blood cell surfaces. Blood types are: A, B, AB, and O.

Acute Rejection. The graft is recognized as foreign, and the host produces an immunological assault on the graft tissues. Acute rejections most commonly occur within the first year.

Advisory Committee on Organ Transplantation (ACOT). Formed by the United States Department of Health and Human Services (HHS) in the autumn of 2000, the ACOT was convened to strengthen the scientific, medical, and public oversight by HHS over transplantation policy. In particular, ACOT provides independent review and advice to HHS concerning organ donation, patient welfare, and organ allocation policies.

Allocation Policies. Rules or policies, generally based on medical criteria, established by the OPTN to guide and regulate organ allocation and distribution in the United States.

Alternative Treatments for Transplant Candidates (Examples):

Heart: Venticular Access Device, artificial heart

Lung: artificial lung, stem cell therapy, lung volume reduction

Liver: Hepatocyte Transplantation, partial liver transplant

Kidney: Dialysis, Peritoneal Dialysis

Pancreas: Pancreatic Islet Cell Transplantation, medication regimen

Intestine: Segmental reversal of the small bowel, medication regimen

Antibody. A protein made by the body's immune system in response to a foreign substance. Exposure to foreign cells from a previous transplant, blood transfusion, or pregnancy may cause a transplant recipient to make antibodies that can react against subsequently transplanted cells, tissues, or organs.

Antigen. A foreign molecule or substance with the capacity to trigger an immune response. Special antigens on the surface of each cell indicate to the immune system whether that cell is foreign or native to an individual.

Anti-rejection Drugs (immunosuppressive drugs). These drugs are taken to prevent the body from rejecting a new graft.

Candidate. An individual who is registered on the organ transplant waiting list.

Crossmatch. A test to detect preformed antibodies in a potential recipient's blood against antigens on the surface of a potential donor's cells. A positive crossmatch means that the recipient has antibodies against the donor's cells. With a few exceptions, a positive crossmatch makes successful transplantation between that donor and recipient pair impossible.

Delayed Graft Function (DGF). This occurs when a transplanted organ is unable to function properly after the transplantation. Often, DGF occurs with kidney transplants, as kidneys may take up to three or four weeks to function properly. Until proper functioning occurs, kidney transplant recipients will need to receive dialysis.

Donor. An individual who supplies tissues or organs for transplantation.

End-Stage Liver Disease (ESLD). Irreversible liver failure that requires transplantation as hepatic replacement therapy.

End-Stage Organ Failure. The permanent need for organ replacement therapy. The option of transplantation exists for the failure of kidney, liver, heart, lung, pancreas, and intestine.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

Graft. In the context of transplantation, a graft is an organ or tissue transplanted from one individual to another of the same species (e.g., human to human).

Graft Survival. Continued functioning of a transplanted organ, usually expressed as a measure of time since transplantation.

Health Resources and Services Administration (HRSA). The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, is the primary federal agency for improving health care to people who are geographically isolated, economically or medically vulnerable.

HRSA programs help those in need of high quality primary health care, people living with HIV/AIDS, pregnant women, and mothers. HRSA also supports the training of health professionals, the distribution of providers to areas where they are needed most and improvements in health care delivery.

HRSA oversees organ, bone marrow and cord blood donation. It compensates individuals harmed by vaccination, and maintains databases that protect against health care malpractice, waste, fraud and abuse.

Since 1943 the agencies that were HRSA precursors have worked to improve the health of needy people. HRSA was created in 1982, when the Health Resources Administration and the Health Services Administration were merged.

Hepatitis C Virus (HCV). A form of hepatitis caused by the hepatitis C virus (HCV), previously known as non-A, non-B hepatitis.

Histocompatibility Antigens. See **Human Leukocyte Antigen System (HLA System)**.

Human Leukocyte Antigen System (HLA System). Human leukocyte antigens (HLA), also known as histocompatibility antigens, are molecules found on all nucleated cells in the body. Histocompatibility antigens help the immune system recognize whether a cell is foreign to the body. These antigens are inherited from one's parents. Human leukocyte antigens are used to determine the compatibility of kidneys and pancreata for transplantation from one individual to

another. The major groups of HLA antigens are HLA-A, HLA-B, and HLA-DR. The values shown are based on the six HLA antigens (two each for the A, B, and DR loci) reported for both donors and recipients. Tables reporting the level of HLA mismatch indicate the number of HLA antigens found in the donor that are not shared by the recipients. In general, a smaller number of HLA mismatches yields better compatibility between donor organ and recipient.

Immunogenicity. The capacity of an antigen to stimulate an immune response.

Immunosuppression. The suppression of the immune response, usually with medications, to prevent the rejection of a transplanted organ or tissue. Medications commonly used to suppress the immune system after transplantation include corticosteroids, calcineurin inhibitors, antimetabolites, polyclonal antibodies, monoclonal antibodies, and TOR inhibitors, among others. A recipient's immunosuppressive regimen may include several different drugs, and it may vary depending on whether it is being used for induction, maintenance, or to treat a rejection episode.

Induction Therapy: The administration of a brief course of high-dose immunosuppression in the early period following transplantation. Induction therapy precedes and overlaps with less intense long-term maintenance immunosuppression.

Living Donor. A living person who donates for transplantation an organ such as a kidney or a segment of the lung, liver, pancreas, or intestine. Living donors may be blood relatives, emotionally related individuals, or altruistic strangers.

Living Donor Paired Donation. The practice of two kidney recipients trading donors to avoid the problem of blood type incompatibility between recipient and intended donor.

Living Related Donor. When a blood-related family member donates an organ, which can include a kidney or part of a lung, liver, or pancreas, to another family member or relative. Examples include parent to child and sibling to sibling.

Living Unrelated Donor. A person who is not closely related by blood donates an organ to another person; this can include a kidney or part of a lung, liver, intestine, or pancreas. Examples of this include husband to wife or friend to friend. Stranger-to-stranger living donations and transplants have become increasingly common within the past few years.

Lung Allocation Score (LAS). A measure used since 2005 to rank candidates for lung transplantations on the waiting list since 2005. A patient's LAS is calculated from estimates of survival probability while on the lung transplant waiting list and following transplantation.

Match. The compatibility of an organ between a donor and a recipient. The greater the compatibility of the match, the more likely the transplantation will be successful.

Median Time to Transplant. See **Time to Transplant (TT)**.

Median Waiting Time. See **Waiting Time (WT)**.

MELD Score. See **Model for End-Stage Liver Disease (MELD) Scoring System.**

Mismatch. See **Human Leukocyte Antigen System (HLA System)**.

Model for End-Stage Liver Disease (MELD) Scoring System. A measure of illness severity used in the allocation of livers to adults, established in February 2002. The MELD system uses three laboratory values (bilirubin, creatinine, and INR) to calculate a score, on a scale of 6 to 40, that is predictive of the risk of death within three months on the liver waiting list. Livers are allocated to wait-listed patients with chronic liver disease on the basis of this score. See also **Pediatric End-Stage Liver Disease (PELD) Scoring System**.

Morbidity. A disease condition or the occurrence or rate of a disease among a population.

Multiple Listing. The act of being wait-listed at more than one transplant center.

National Organ Transplant Act (NOTA). The National Organ Transplant Act of 1984 (Public Law 98-507), approved October 19, 1984 created the Organ Procurement and Transplantation Network (OPTN) and Organ Procurement Organizations (OPOs), among other provisions;also required the establishment of a registry that includes such information respecting patients and transplant procedures as the Secretary of Health and Human Services (HHS) deems necessary to an ongoing evulation of the scientific and clinical status of organ transplantation. The Scientific Registry of Transplant Recipients (SRTR) has served this purpose since 1987.

Organ Procurement and Transplantation Network (OPTN). Established under §372 of the Public Health Services Act. Under a contract from the Health Resources and Services Administration (HRSA) and with oversight from the Division of Transplantation (DoT), the OPTN operates the national network for organ procurement and allocation and works to promote organ donation. Through its policies, the OPTN works to ensure that all patients have a fair chance at receiving the organ they need, regardless of age, sex, race, lifestyle, religion, or financial or social status. The current OPTN contractor is the United Network for Organ Sharing (UNOS), based in Richmond, Virginia.

Organs: Parts of the body made up of cells and tissues that have certain purposes and perform certain functions for the body. Organs covered by Medicare that can be transplanted include hearts, lungs, livers, kidneys, intestines, and pancreata.

Pediatric End-Stage Liver Disease (PELD) Scoring System. A measure of illness severity used in the allocation of livers to pediatric candidates, established in February 2002. The PELD system uses three laboratory values (albumin, bilirubin, and INR), a presence of growth failure (at least two standard deviations below average height or weight), and an indicator of whether the patient is less than 1 year of age to calculate a score predictive of the risk of death within three months on the liver waiting list for candidates under the age of 18 years. The range of PELD scores is greater than that of the model for end-stage liver disease (MELD) scores, ranging from less than zero to greater than 40. See also **Model for End-Stage Liver Disease (MELD) Scoring System**.

Preservation: The process of keeping organs viable between procurement and transplantation.

Rejection: A medical condition that occurs when a recipient's immune system attacks a transplanted organ, tissue, or cell. Immunosuppressive drugs help prevent rejection.

Retransplantation: The process of receiving another transplant due to rejection or failure of a transplanted organ.

Scientific Registry of Transplant Recipients (SRTR): **The SRTR** supports the ongoing evaluation of solid organ transplantation in the United States. SRTR designs and carries out data analyses and maintains two websites to disseminate organ transplant information.

This site is srtr.transplant.hrsa.gov. Here you will find the OPTN/SRTR Annual Data Report, which publishes organ transplant statistics and is produced each year by SRTR staff and staff of the national Organ Procurement and Transplantation Network (OPTN).

Both sites aim to inform transplant programs, organ procurement organizations, policy makers, transplant professionals, transplant recipients, organ donors and donor families, and the general public about the current state of solid organ transplantation in the US.

SRTR also helps facilitate transplant research by providing access to data for qualified researchers interested in studying various aspects of solid organ transplantation. Data in the SRTR are collected by the OPTN from hospitals and OPOs and contains current and past information about the full continuum of transplant activiety related to organ donation and waitlist candidates, transplant recipients, and survival statistics. The SRTR is administered by the Chronic Disease Research Group of the Minneapolis Medical Research Foundation, with oversight and funding from the Health Resources and Services Administration.

Tissue Type: An individual's combination of human leukocyte antigens. Matching for tissue type is used in kidney and pancreas transplantation. The tissue type for each patient on the waiting list is entered into a central computer maintained by the OPTN.

UNet: UNet is a centralized computer network, maintained by UNOS, which links all organ procurement organizations (OPOs) and transplant centers. Transplant professionals can access this computer network 24 hours a day, seven days a week.

United Network for Organ Sharing (UNOS). Located in Richmond, Virginia, UNOS is a private, nonprofit membership organization that coordinates the nation's transplant system under the OPTN federal contract. UNOS assists the transplant community and the patients it serves by maintaining the national organ transplant waiting list, coordinating the matching and distribution of donated organs, increasing public awareness of the need for donated organs, serving as a forum to create and define organ-sharing policies that maximize the use of donated organs, producing professional education tools, and providing extensive information about organ transplantation to patients and the public.

Ventricular Assist Device (VAD). A mechanical pump that is implanted into a patient with heart failure to maintain blood circulation; it is used as a bridge to heart transplantation.

Waiting List (Active, Inactive, Removal). After evaluation by a team of transplant professionals, a patient is added to the national waiting list by the transplant center. Lists are specific to both geographic area and organ type: kidney, pancreas, kidney-pancreas, liver, intestine, heart, lung, and heart-lung. Each time a donor organ becomes available, a computer generates a list of potential recipients based on factors that may include genetic similarity, organ size, medical urgency, and time on the waiting list. Through this process, a new list that best matches a waiting patient to a donated organ is generated each time an organ becomes available.

- Active—An “active” patient does not have any contraindications to transplantation at the current time and is actively awaiting transplantation.
- Inactive—Patients can be placed on inactive status if they temporarily are not appropriate candidates for transplantation (e.g., because of an active infection).
- Removal—A patient can be removed from the waiting list in the following ways: voluntarily, by becoming too ill to withstand or benefit from transplantation, by achieving a spontaneous recovery of organ function, by receiving a transplant, or by dying.

Commonly Used Acronyms and Abbreviations*

ARF: Acute Renal Failure
LOS: Length of Stay
QAPI: Quality assessment and performance improvement
SCD: Standard criteria donor
LRD: Live donor
ECD: Expanded criteria donor
PRA: Panel reactive antibodies
DGF: Delayed graft functions
PFO: Patent Foramen Ovale
BSI: Blood stream infection
DVT: Deep vein thrombosis
PE: Pulmonary embolism or Physical exam
VAP: Ventilator associated pneumonia
UTI: Urinary track infection
BMI: Body mass index
CIT: Cold Ischemic Time
CHF: Congestive Heart Failure
SRTR: Scientific Registry of Transplants Recipients
MELD: Model for End-Stage Liver Disease
LAS: Liver Allocation Score

THE STANDARD TRANSPLANT PROGRAM SURVEY PROTOCOL

Overview & Key Concepts

This survey protocol provides a standardized framework for surveyors to fully evaluate compliance with all transplant program Conditions of Participation (CoPs). Surveyors will utilize a tracer methodology for patient observation, clinical record reviews, and interviews during initial and re-approval transplant program surveys. For complaint investigations, surveyors should follow instructions found in Chapter 5 of the SOM. Hospitals may have more than one transplant program, and each program must be surveyed and approved individually, with the exception of pancreas and intestine which are surveyed as a part of their affiliated organ program

Program Types and Consideration of Adult versus Pediatric Program Types

Transplant program types including:

1. Adult Heart-only (AHO)
2. Adult Lung-only (ALO)
3. Adult Kidney-only (AKO)
4. Adult Pancreas-only (APO) is surveyed with an approved AKO program
5. Adult Liver (ALI)
6. Adult Intestine/Multivisceral (AIM) program is surveyed with an approved ALI program
7. Pediatric Heart-only (PHO)
8. Pediatric Lung-only (PLO)
9. Pediatric Kidney-only (PKO)
10. Pediatric Pancreas (PPO) is surveyed with an approved pediatric kidney program
11. Pediatric Liver (PLI)
12. Pediatric Intestine/Multivisceral (PIM) is surveyed with an approved PLI program

Survey Team Size and Composition

The survey team size and composition are determined by the number of transplant programs to be surveyed and the type of surveys to be completed (full survey, revisit, or complaint investigation). Below are the general team size and composition parameters.

A. In planning for team assignments, the following minimum team staffing should be considered according to the number of thoracic, abdominal and pediatric programs seeking approval or requiring re-approval. There should never be less than two (2) surveyors on any initial or re-approval transplant program survey.
B. If one or more adult thoracic programs will be surveyed simultaneously, a minimum team of two surveyors must be assigned to survey the programs.
C. If one or more adult abdominal programs will be surveyed, a minimum team of two surveyors must be assigned to survey the program(s).

These survey teams cannot be combined, shared, or intertwined between the two sets of programs. Basically, thoracic and abdominal programs operate separately within the hospital structure. But operationally within the hospital, it can be expected that surveyors will more than likely encounter shared or at least collaborative services between heart and lung programs and between kidney and liver programs which can enhance the use of time on a survey.

When pediatric only programs are to be surveyed, minimum survey team staffing should be considered according to the number of thoracic or abdominal programs seeking approval or requiring re-approval. Additionally, if one or more pediatric thoracic programs will be surveyed, a minimum team of two surveyors must be assigned to survey that/those program(s). If one or more pediatric abdominal programs will be surveyed, a minimum team of two surveyors must be assigned to survey that/those program(s). These survey teams cannot be combined, shared, or intertwined between the two sets of programs.

If there is one or more pediatric thoracic program(s) to be surveyed in additional to one or more adult thoracic program(s), a minimum of one additional surveyor should added to the team in order to focus on the pediatric aspect. If there is one or more pediatric abdominal program(s) to be surveyed in addition to one or more adult abdominal program(s), a minimum of one additional surveyor should be added to the team to focus on the pediatric aspect.

See Table below:

Program Type	Minimum Number of Surveyors
Adult-Only or Pediatric-Only Thoracic Program(s) (Heart, Lung, Heart/Lung)	2
Adult-Only or Pediatric-Only Abdominal Program(s) (Kidney, Liver, Pancreas, Multi-visceral/Intestinal)	2
Pediatric Program in Addition to Adult-Only (Thoracic or Abdominal)	1 Additional Pediatric Record

Survey Protocol Tasks

The Components of the Standard Transplant Program Survey Protocol	
TASK #	**Task**
1	Pre-survey: Off-site Preparation
2	Entrance Activities
3	Sample Selection
4	Tracer for Selected Patients and Living Donors including Observations of Care, Interviews and Medical Record Review
5	Administrative Review
6	Personnel Record Review (If Indicated)
7	Pre-exit
8	Exit Conference
9	Post Survey Activities

TASK 1 - PRE-SURVEY: OFF-SITE PREPARATION

Prior to the survey, determine the number and types of transplant programs at the transplant

hospital to be surveyed to determine survey team composition. Review each program using the information below:

1. Any prior survey and certification issues, e.g. previous complaints that indicate further investigation or follow-up;
2. CMS Transplant Program Quarterly Report (TPQR) to determine:
    a. Is the program listed as a member of the OPTN, and what is the status of that membership; (X002)
    b. Has the program submitted the required 95 percent of data on all transplants to the OPTN; (X032)
    c. Does the program remove individuals from the waiting list in a timely manner (i.e., within 1 day); (X086)
    d. If applicable, has the program completed the number of transplants required to meet the clinical experience requirements (adult kidney, adult liver, adult heart, adult lung, adult intestinal/multivisceral); (X043)
    e. If applicable, has the program met the outcome requirements (adult kidney, pediatric kidney, adult liver, pediatric liver, adult heart, pediatric heart, adult lung & pediatric lung); (X045)
    f. Has the program exceeded a 12 month inactivation period; (X172)
    g. Was any inactivation reported to CMS within seven (7) days; (X172)

Note that the information reviewed for 2(a)-(g) above, is preparatory only. Any deficiencies in this regard do not require further on-site surveyor investigation, but should be communicated with the program administrator at the time of the entrance conference.

TASK 2 - ENTRANCE ACTIVITIES

All transplant program surveys must include these entrance activities:

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

Activities conducted during the entrance conference include the following:

- Introduction of surveyors;
- Explain that the purpose of the survey is to determine the program's compliance with the Medicare CoPs for each transplant program being surveyed (list the programs).
- Discuss the projected survey schedule for the survey including the projected time and date for the exit conference.
- Confirm that the primary transplant surgeon and primary transplant physician are consistent with the information contained on the TPQR; (if information is not consistent, the surveyor must confirm that the OPTN was notified of the change.) Inform the program of any deficiencies which will be cited for outcome requirements, clinical experience or data reporting to the OPTN.

- Determine whether living donor transplants are performed at the transplant center.
- Determine whether the hospital uses any contracted services that also serve that transplant program.
- As applicable, determine whether adult transplants are performed under a pediatric program or pediatric transplants are performed under an adult program (to enable sample selection).
- Explain that interviews may be conducted with transplant program staff and patients as indicated.
  Request that surveyors be granted access to medical records as indicated. Identify the areas in the hospital or on the hospital campus where transplant services including inpatient transplant care and outpatient care, are provided.

Request that the program create the following lists described below. The surveyor should observe the development of these lists.

Lists Requested During Entrance Conference:

1. Each transplant program's complete current active waiting list including the following information: name, date of listing, wait list status, medical record number, age (at time of transplant), race and gender of each patient;
2. List of all patients (to include their medical record number) removed from the waiting list within the past 12 months of each program for reasons other than death or transplant;
3. List of all persons evaluated within the last 12 months by each transplant program who were not placed on the waiting list. (Do not include persons that are currently in the evaluation process). The list should include patient name and medical record number.
4. List of all of the transplants performed within the last 18 months (including patient name, medical record number, age (at time of transplant), and date of transplant);
5. If applicable, list of all of the living donors who were evaluated during the past 12 months denoting those potential donors who proceeded to donation. Include name, medical record number, the organ(s) donated and date of donation within the designated time period;
6. List of all of the transplant recipients and living donors who are currently inpatient(s) and the location of the patient(s) within the hospital;

Request Program Administration Materials

1. Request an organizational chart of the transplant program, which includes the chains of command and how the transplant program fits within the overall hospital structure;
2. Request a log of any and all reported adverse events for the past 12 months (extend to 24 months if no reports found in the 12 month log). This list will be used to select the patient sample for adverse events.
3. Inform the administrator that policies, procedures, personnel, and QAPI manuals will be requested, as needed, for review.

TASK 3 – SAMPLE SELECTION

Refer to the lists requested during the entrance conference (1-6) above and the adverse event log requested during the entrance conference to accomplish the patient sample selection. The goal is

to choose, within the sample, a representation of the overall transplant program services and patients.

Seven categories that must be included in the patient sample; the chart below reflects the minimum number of patients that must be selected randomly for each area.

Patients Transplanted <6 months ago	Patients Transplanted 7-18 months ago	Patients on Current Waitlist	Patient Adverse Events	Patients Removed from Waitlist	Patients Removed from the waiting list within the past 12 months for reasons other than death or transplant	Patients Evaluated but not Waitlisted	Living Donors (if applicable)
2	2	2	2	2	2	2	2

If a program performs both adult and pediatric transplants under one approval, there must be at least one patient from each age group selected for each category.

If there were no patients transplanted within the last six months, add two additional patients to the Patients on Current Waitlist category sample.

Select waitlist patients based upon the time they have been on the waitlist. Review a patient who has been on the list three years or more and a patient who has been on the list less than 3 years.

TASK 4 – TRACER FOR PATIENT AND LIVING DONORS

Once the patient sample has been selected, the surveyors will then trace the patient experience from evaluation through discharge planning for those receiving transplants. For those patients who are currently on the waitlist, the surveyor will trace their experience from evaluation until the most current stage in the phases of transplant.

During the tracer activities, the surveyor will spend no more than two hours reviewing each medical record to get an overview of the patient experience and identify those multidisciplinary team members that must be interviewed based upon findings from the medical record review. During the record review, the surveyor should verify that the plan established for the patient to achieve successful transplantation was individualized for the needs of the particular patient.

I. Patient Experience- Evaluation:

Each patient experience should begin with an evaluation regardless of whether they are or are not ultimately placed on the waitlist. This evaluation must include multidisciplinary involvement to identify all the patient characteristics and attributes to determine suitability for transplant.

Multidisciplinary involvement means that each member of the patient care team (designated by the facility) must complete an evaluation of the potential recipient. The evaluation process may appear differently based on the individualized needs of the patient during the evaluation. When reviewing the medical record, identify the members of the multidisciplinary team that have been involved in the care of the patient, identify recommendations, and review for follow-up on these recommendations. Please note that there are specifics in the evaluation that must occur such as medical evaluation, psychological evaluation, and the informed consent process.

Completion of the informed consent process may be documented in a single document or throughout the record. The surveyor must confirm, through medical record documentation, that the facility ensured that the patient has made an informed decision to proceed with the process of transplantation. The process includes informing the candidate of medical and psychosocial risks, the right to refuse transplantation, donor risk factors, alternative treatments, potential costs outside insurance, the surgical procedure, and the transplant program's patient outcomes. A surgical consent for the actual transplantation surgery does not confirm the informed consent process.

II. Patient Experience- Patient Selection

(Waitlist Sample) The medical record must include the rationale for the decision to place the patient on the waitlist. This rationale should be consistent with the written criteria of the facility. If not, the record must include rationale for waitlisting outside the criteria.

(Evaluated but not Listed Sample) In instances where a patient was evaluated but not placed on the waiting list, there should be documentation of the reason for not placing the patient on the waitlist and whether the patient was informed of the decision not to place him/her on the wait list based on the evaluation. If there is evidence that the potential candidate meets the wait list criteria but was not listed, there must be documentation by the facility as to why they were not placed on the waitlist.

III. Patient Experience- Waitlist Management

(Waitlist and Transplant Recipient Sample) For those patients who were placed on the transplant waitlist, there should be evidence of periodic follow up during their time on the wait list. There are no set requirements for the frequency of the periodic follow-up or any requirement that the follow-up must be conducted by the transplant program. However, based on the identified needs of the patient and the policy of the transplant program the transplant program would see the patients periodically or maintain on-going communication with the patient's community health care providers.

While the patient is on the waitlist, under 42 C.F.R. § 482.94(a)(1) there should be evidence that any recommendations made by a multidisciplinary team member are being followed up by the team member and that any referrals to multidisciplinary team member are promptly addressed.

Please note that the length of time on the waitlist may vary for each individual.

IV. Patient Experience- Transplantation

(Transplant Recipient Sample) For those patients who received a transplant, the medical record

must include evidence that prior to the transplant: an ABO verification occurred (blood type and other vital Data (OVD)); there is evidence that the facility discussed any potential risks associated with the organ being offered and whether the patient agrees to accept the organ; and there is a documented surgical consent for the transplant procedure. It is expected that all members of the multidisciplinary team will continually assess the patient and provide any recommendations which would facilitate discharge. Recommendations may or may not require ongoing involvement with the team member based upon the individual patient's needs and any complications which may prolong the hospital stay.

V. Patient Experience- Living Donation

(Living Donor Sample) The record must include documentation of the evaluation process conducted with the living donor. The evaluation includes a final recommendation and justification as to whether the living donor/ is suitable for donation. The donor is notified as to suitability and rationale for the decision.

The medical record must include evidence that the Independent Living Donor Advocate (ILDA)/TEAM was made available to the living donor, to include the name and contact information of the ILDA. Every living donor must be assigned and have an interview with the ILDA or ILDA team prior to the initiation of the evaluation and throughout the donation phase.

VI. Patient Experience- Patient Care

Once the medical record has been reviewed for each sampled patient, the survey should move to the clinical areas where inpatient and outpatient care is provided. During the time the surveyor spends in the clinical areas, all available inpatient and outpatients receiving transplant care on the unit or in the clinic are interviewed. If an interviewed patient was part of the original sample, then compare the information received from the patient with the information received in his/her medical record. . If an interviewed patient is not part of the original sample, the medical record must be reviewed and the information compared to the information provided by the patient regarding his/her patient experience.

General observations should be made during the time the surveyor spends in the clinical areas. Any concerns, whether related to specifically transplant CoPs or hospital CoPs, should be investigated further as warranted. Interviews with transplant staff in general should be conducted pursuant to medical record findings, patient interview findings, or specific observations.

Interviews with both patients and staff should be conducted one-on-one with the surveyor when possible. It is acceptable for surveyors to conduct telephone interviews with key personnel in the event that they are unavailable during the survey.

TASK 5 – Quality Assurance and Improvement

Review of Quality Assessment and Performance

Review the medical records for the adverse events sample. The surveyor should examine the record for events leading up to the event. In addition, the QAPI materials associated with the adverse event should be reviewed for each sampled event. Review the QAPI materials to look for the analysis of the event, actions taken following the event, and safeguards to prevent future

occurrence. Review the data the program is tracking associated with the adverse event to ensure there is no recurrence. If the program has effectively addressed all the activities outlined above, the surveyor concludes from the sample review that the program does do QAPI activities reactively. However the QAPI director must be interviewed to determine the proactive activities of the QAPI program and the integration of the transplant program QAPI and the hospital QAPI program.

TASK 6 – PERSONNEL RECORD REVIEW

If concerns regarding staff education, qualifications, and training for staff providing transplant care are identified during observations or interviews, the surveyor may request applicable personnel records. For staff new to transplant, or who appear unfamiliar with the care of transplant patients, the surveyor validates the presence of orientation education and/or additional training to ensure that the staff are prepared to care for patients undergoing transplants.

TASK 7 - PRE-EXIT CONFERENCE

Survey Team Discussion Meeting

Each team member will review and share the evidence he/she has gathered with the other team members. The team should determine any non-compliance and document any such findings including making photocopies of medical records or other documents needed to support the non-compliance. Make all copies prior to the exit conference.

TASK 8 – EXIT CONFERENCE

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

During the conference:

- Identify each deficiency found and restate those deficiencies being cited on information in the TPQR;
- Provide an opportunity for the transplant program to present additional information that may not have been presented during the survey (except for deficiencies cited from the TPQR review);
- Outline the next steps
    - The hospital administration will receive a written form (the CMS-2567 Statement of Deficiencies and Plan of Correction) from the State Survey Agency that describes the survey findings and cited noncompliance deficiencies. Findings for all programs that were surveyed together will be included on one CMS-2567. Each deficiency will be identified by the applicable program. Following receipt of the CMS-2567 (generally within 10 days of the exit conference), the transplant program must submit a plan of correction within 10 days of receipt of the CMS-2567 for each individually cited deficiency.

- Explain that all findings are preliminary and subject to administrative review.

Although it is CMS' general policy to conduct an exit conference, be aware of situations that would justify refusal to continue an exit conference. For example, if the hospital administrator

or transplant program administrator is represented by counsel, surveyors may refuse to continue the conference if the lawyer tries to turn it into an evidentiary hearing.

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

TASK 9 - POST SURVEY ACTIVITIES

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

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

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

ALTERNATE SURVEY PROTOCOL: PEDIATRIC HEART PROGRAM

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

Under §482.76(d), instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant 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).

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

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

TASK 1 – PRE-SURVEY PREPARATION OFF-SITE

None required:

TASK 2 – ENTRANCE ACTIVITIES

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

Requested Items for Review:

Lists of Transplant Candidates and Patients:

Log of the transplants performed including name and date of transplant for both the pediatric heart transplant program and the associated heart transplant program within the past three years;

Program Administration: Policies, Procedures, Personnel, and QAPI

1. A copy of the joint operating agreement between the pediatric heart transplant program and the associated heart transplant program that is jointly operating this program;
2. An organizational chart of the pediatric heart transplant program and the associated program;
3. Credentials for cardiac transplant surgeons and physicians and confirmation they are permitted to practice at both facilities; and
4. Log of any reported adverse events (by the pediatric heart transplant program and the associated program) and corresponding documentation of the investigation and analysis of those events for the past 12 months.

TASK 2 – SAMPLE SELECTION

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

Pediatric Heart Transplant Recipients Sample Selection

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

TASK 3 – REVIEW OF TRANSPLANT PATIENT MEDICAL RECORDS

Task 2 describes the number of transplant patient medical records that must be selected for review both in the pediatric heart transplant program and the associated program. Surveyors will focus the review of medical records on the following sections:

1. Evaluations: psychosocial and medical;
2. Patient selection criteria;
3. Informed consent documentation;
4. Blood type, ABO and UNOS ID verification;
5. Operative reports;
6. Progress Notes for patient care, staff activities, informed consent discussions, etc.;
7. Multidisciplinary care plan and patient teaching tools for involvement of all key personnel;

8. Discharge planning; and
9. Follow-up (outpatient) chart or section of record.

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

TASK 4 – STAFF INTERVIEW

Follow standard protocol for interviews.

TASK 5 – PERSONNEL RECORD REVIEW

Follow standard protocol for personnel file review.

TASK 6 – ADMINISTRATIVE REVIEW

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

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

TASK 7 – PRE-EXIT CONFERENCE

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

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

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

TASK 8 – EXIT CONFERENCE

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

TASK 9 – POST SURVEY ACTIVITIES

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

State Operations Manual
Appendix X - Interpretive Guidelines for Organ Transplant Programs

Table of Contents
(Rev.)

Transmittals for Appendix X
Attachment A: Organ Transplant Surveys, Interpretive Guidelines:

Abbreviations:

CMS Certification Number	*CCN*
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*
Hepatitis C Virus	*HCV*
Human Leukocyte Antigen	*HLA*
Independent Living Donor Advocate	*ILDA*
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*
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*

Definitions and Clarifications

Transplantation/Donation Phases—

Transplant Recipient Phases:

- *Transplant Phase: Begins when the potential candidate is evaluated for transplantation and continues through the completion of the transplantation surgery.*
- *Discharge Phase: Begins at admission to the hospital and continues through the discharge from inpatient stay.*

Living Donor Care Phases:

- *Evaluation Phase: Begins with the first presentation by the potential donor to the transplant program and continues until the time the donor enters the OR for the donation surgery.*
- *Donation Phase: Begins from the time the donor enters the OR for the donation surgery until the donor is discharged from the inpatient surgery stay.*
- *Discharge Phase: Begins with the donor's admission to the hospital and continues through the donor's discharge from the inpatient stay.*

Transplant Program Survey Tools

Medical Record Checklist

The **TPQR** has been reviewed for the Choose an item. and there are no issues identified at this time.
1. Transplant program is a member of OPTN
2. Status of Membership: _____
3. Data Submission shows at least 95% of forms have been submitted
4. Program has **volume** requirements applicable to: (adult kidney, adult liver, adult heart, adult lung, adult intestinal/multivisceral)
a. Program has met the required volume requirements
5. Program has **outcome** requirements applicable to: (adult kidney, pediatric kidney, adult liver, pediatric liver, adult heart, pediatric heart, adult & pediatric lung)
a. Program has met the required outcome requirements
b. How many out of the last 5 reports did not meet the outcome requirements? Choose an item.
c. Does the current report plus one other report within the last 2 years NOT meet outcome requirements?
d. If program *does not* meet outcome requirements, is the deficiency at the **condition or standard** level?
6. Has the program had any periods of inactivity?
a. If yes, were the periods of inactivity reported immediately?

The **TPQR** has been reviewed for the Choose an item. and there are no issues identified at this time.
7. Program has a primary surgeon and primary physician listed?
8. Has the program provided any notifications to CMS regarding:
a. Changes in primary surgeon/physician
9. Waitlist Removal – Has the program removed patients within 1 day?
10. Is the program also seeking approval for the opposite age group (adult or pediatric) – based on TPQR?
11. If yes, which age group is the majority program (receives 50% or more of the transplants of this type)? ☐ **ADULT** ☐ **PEDIATRIC**
Note: The majority program must be able to be approved before the related program can be approved.
a. Is the program a pediatric heart transplant program that is seeking alternate approval by operating jointly with another Medicare-approved heart transplant program? b. If yes, refer to the CMS *Alternate Survey Protocol for Approval of Pediatric Heart Transplant Programs*.

Waitlist Sample
Identifier **Patient Name** **Med Record #**
LISTING DATE: (See UNet Candidate History) **STATUS CHANGES** noted in UNet? **(X186)**
PSYCHOSOCIAL EVALUATION: Did the patient have a psychosocial evaluation *prior* to listing***?*** **(X053)**
What was the evaluation Date?
If **NO psychosocial evaluation was done prior to listing** was it an *emergent* listing?
Did the Psychosocial, H&P or any other exam or interview identify **SPECIAL NEEDS or RECOMMENDATIONS for follow-up, referral re-evaluation or further testing prior to listing or transplant?**
Were issues **addressed *prior to listing****?*
Were issues **addressed *prior to transplant****?*
WHY were issues not addressed prior to listing or transplant: (***Get documentation*** *supporting the issues identified and an explanation of* **WHY** there was no follow-up or resolution prior to listing or transplant **Re-interview** responsible staff if necessary to support your deficiency)

SELECTION CRITERIA: (X051, X055) *Does the program have written selection criteria* to determine patient's suitability for transplant? **Are the selection criteria that the transplant program used to determine this patient was suitable or not for a transplant *documented in the medical record*?**	
Date of Committee Meeting Decision:	
Does the program have written *expanded selection criteria* or exceptions to their standard criteria in which they may consider for suitability?	
In determining suitability or unsuitability to list for transplant, *did this patient meet the programs' written selection criteria*?	
Notification to the Patient **NOTIFICATION to the *Patient*** of *Listing*. **NOTIFICATION to the *Patient*** of *Status Change(s)*.	
If the Patient was on dialysis **NOTIFICATION to *Dialysis Center***: of the patient's listing if on dialysis. **(X088**) **NOTIFICATION to *Dialysis Center***: of the patients of Status Change(s) if on dialysis. **(X088**)	
NOTES:	
Staff Interview /Date:	**Staff's Title**

Removed From the Wait List **Ask for a copy of the** (*Candidate Removal History*) **to be printed from UNet**	
Identifier **Patient Name** **Med Record #**	
Date Added to UNET:	**Date Removed from UNET:**
Reason Removed	**Time Removed from UNET:**
(If this patient was removed from the transplant program's waitlist for any reason *other than death or transplant,* the record should *not* be included in this sample.) **Date & time of transplant** as documented in the medical record *or* the d**ate & time** the transplant program was notified of the patient's **death:**	
OPTN Notified: Was the OPTN notified, no later than 24 hours after the patients' removal from the transplant program's waitlist? The 24 hour time period should begin after the patient receives a transplant, the documentation of the candidate being removed for any other reason, or the transplant center receives notification that the patient died **(X083, X085, X086)**	
Please Note the date and time removed to be sure that it was within the 24 hour period following the documented decision to remove the candidate from the waitlist	
NOTES:	
Staff Interview Name:	**Staff Title**
Date:	**Time:**

Patients Evaluated for Transplant during the Past 12 Months and Not Placed on the Waitlist	
Identifier **Patient Name** **Med Record #**	
Patient Notification: Is there documentation that the patient was notified of the reason they were not placed on the waiting list. (should be in the medical record) (**X083, X087, X088**)	
If Dialysis Patient: Is there documentation that the patient's dialysis facility was notified that the patient was not placed on the Waiting List. (**X083, X087, X088**)	
Decision based on Selection Criteria?	
NOTES/Findings:	
Staff Interview	**Staff's Title**
Date:	**Time:**

Transplant Recipient
Identifier **Patient Name**

Med Record # The transplant patient's UNet Candidate Removal History will provide an accurate date of listing and removal and status changes.	
Date Added to UNet:	**Listed before CoPs:**
Date Removed:	**Time Removed:**
Reason Removed:	**Status Change Date:**
Dialysis: Was this patient on dialysis?	**Date Notified:**
Notified Patient of Listing (X088)	**Date Notified:**
Notification of Status Change	**Date Notified:**
Psychosocial Evaluation Date: *prior to listing?* (X053)	
If no Psychosocial was this an *emergent* listing **If yes, please describe**:	
Did the **Psychosocial Evaluation** reveal ***special needs*** or ***recommendations*** for follow-up, referral or re-evaluation? Were the **special needs** or **recommendations addressed prior to listing or transplant?**	
Date Informed Consent Completed:	
Evaluation process (X151)	**National/Center Outcomes (SRTR) (X155)**

Potential Medical Risks	**Drug Payment Factors related to Medicare Part-B (X158)**
Psychosocial risks (X154)	**Alternative treatments (X153)**
Right to REFUSE (X157)	**Donor Risk Factors (X156)**
Surgical procedure (X152)	**No significant program changes noted**

Multidisciplinary (Multi-D) Team Involvement
Review medical records and selection meeting minutes. Documentation should support that all Multidisciplinary team members were involved in the patient's care. * It is not necessary for 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, documents that each member of team performed the duties and responsibilities accorded to him or her by the regulation and the program's own policies. (X090, X091, X125)

Transplant Admit Date:	Transplant Date:	**Transplant Discharge Date:**

Multi-D Team Member	**Transplant Phase**	**D/C/P Phase**
Dietician		
Pharmacist		
Social Worker		
Surgeon/Physician		
Nurse		

Education/Teaching post-transplant: Was post-transplant education/teaching provided for the patient prior to discharge? Look for some acknowledgement of understanding. **(**X126, X150**)**

Organ Receipt ABO & Other Vital Data (OVD) Verification (X073**)**

Time Pt In OR:	**Date Surgeon Signed:**

Time of Organ Arrival:	**Date 2nd LHCP Signed:**
Visual Verification:	**Time Surgeon Signed:**
Time of Anastomosis:	**Time 2nd LHCP Signed:**
ABO Verified by Surgeon:	**ABO Verified by 2nd LHCP:**
OVD Verified by Surgeon:	**OVD Verified by 2nd LHCP:**
NOTES:	
Staff Interview Name	**Staff Title**
Date:	**Time:**

Living Donor

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Identifier

Living Donor's Name

Med Record #

ABO and Other Vital Data (OVD) compatibility verification for the living donor surgery (Recovery of the Living Donor Organ) X071, X074

Date of Surgery:	**Date** and Time **Surgeon Signed:**
Time Prior to Anesthesia:	**Date and Time 2nd LHCP Signed:**
ABO Verified by Surgeon:	**ABO Verified by 2nd LHCP:**
OVD Verified by Surgeon:	**OVD Verified by 2nd LHCP:**

Psychosocial Evaluation; did the living donor have a psychosocial evaluation *prior to living donation*? **(X058)**

Medical Evaluation; did the living donor have a medical evaluation *prior to living donation* ?(**X058)**

Patient Specific Issues; were there any special needs or triggers identified during the evaluation, donation, post donation or discharge-planning phase that required follow-up or referral? Examples may include but not limited to: Weight fluctuations or actual BMI not within the program's established living donor selection criteria, significant medication changes, substance abuse, additional diagnoses, need for further testing prior to or after living donation, etc.

If so, what were the special needs or triggers identified and were they resolved?

Education provided pre & post donation; How? Request education materials given to the patient. Look for some acknowledgement of understanding. **(X126, X159)**
Selection Criteria; Does the transplant program have written donor selection criteria for determining the suitability of candidates for living donation **(X051)**
Did the **transplant program's decision** to select this patient for living donation meet the program's own living donor selection criteria? (**X051**)
Is the Living Donor's **suitability for donation** documented in the medical record? **(X059)**
Living Donor Advocate: Did this living donor have a living donor advocate?
Was a **Living Donor Advocate** available to the living donor throughout all phases of living donation to ensure and protect the donor's rights? **(X121, X124)**
Informed Consent: Review Policy Look for documentation that informed consent was explained to the patient prior to donation and some type of acknowledgement of understanding. Living Donors must be re-informed every 6 months and/or prior to surgery IF there have been any significant changes with the program, e.g. SRTR data. Any patients who were evaluated prior to 06/28/07, and donated after the CoPs were implemented, still should have been informed of the elements of informed consent prior to their surgery with the exception of the Evaluation Process, which they would have already completed. Review policy; (X159, X060) (Elements of informed consent may be explained in the Education Materials)
Date Informed Consent Completed:

Confidential communication, (X160)	**National/center outcomes (X165)**

Evaluation process (X161)	**Possible Insurance non-coverage (X166)**
Potential Medical Risks Surgical procedure (X162)	**Living Donor's right to opt out (X167)**
Alternative treatments for transplant recipients (X163)	**Risk of non-payment for drugs under Medicare Part-B for the transplant recipient (X168)**
Potential medical & psychosocial risks (X164)	

Does the program have a **policy** regarding Living Donor Follow-Up (After Living Donation)? (X082)

Follow-up: Follow-up is/was scheduled per program policy.

Multidisciplinary (Multi-D) Team Involvement: Look for involvement from all members of Multi-D team in the **PRE-DONATION**, **DONATION** and **DISCHARGE PLANNING** phases of living donation. **(X125, X082)**

Donor Admit Date:	Donor Surgery Date:	**Donor Discharge Date:**

Multi-D Team Member	**Pre-Donation**	**Donation**	**Discharge Planning**
Dietician			
Pharmacist			
Social Worker			
Surgeon/Physician			
Nurse			

Living Donor Advocate			

NOTES:

Staff Interview Name	**Staff Title**
Date:	**Time:**