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Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-08-25

DATE: **June 13, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy - Organ Transplant Program Interpretive Guidelines

Memorandum Summary

- **Organ Transplant Interpretive Guidelines Update:** Attached is an advance copy of the Organ Transplant Interpretive Guidelines. These Interpretive Guidelines will also be published in a new Appendix X of the State Operations Manual (SOM).

The Organ Transplant Interpretive Guidelines represent the most recent surveyor guidance for conducting surveys of organ transplant programs and should replace all previously-released versions

Attachment A is an advance copy of the final Organ Transplant Interpretive Guidelines that will ultimately be published in the standard portrait format used in the State Operations Manual. The Appendix X in the SOM may differ slightly from this advance copy which is formatted as a 3-column side-by-side version. The Interpretive Guidelines have been modified to clarify certain areas and incorporqate feedback from previously-released versions.

The Interpretive Guidelines have changes and revisions in several areas. One area we would like to highlight is the identification of the multidisciplinary team and the written evidence of the activities of that team. There are four sections within the Conditions of Participation that address these requirements (Tags X082, X090, X091, X0125). These tags are summarized below:

- X082: Standard: Patient and Living Donor Care requires a transplant program to identify a multidisciplinary team that is coordinated by a physician for each transplant patient and living donor that provides care throughout transplantation or donation phases.

- X090: Requires that there is a multidisciplinary patient care planning during the transplant period.

- X091: Requires that there is a multidisciplinary patient care planning during the

discharge planning period; and

- X125: Standard: Transplant Team requires that there is a transplant team, that the responsibilities of the team members are identified and that it is composed of individuals with the appropriate qualifications, training and experience in the areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

When surveying transplant programs for compliance with these four areas, please keep the following in mind:

- The transplant program is required in the Conditions of Participation to have written policies and procedures that address care management for transplant patients and living donors. The program should be following these policies and procedures.

- The CoPs do not specify the format that multidisciplinary care planning must take. For example, transplant programs may choose to have formal meetings to coordinate their efforts through a Multidisciplinary Patient Care Form in the medical record, or to verbally communicate with the different disciplines and to have some written evidence of this communication. Please note that if a transplant program chooses to have regularly-scheduled meetings, we do not require a certain frequency for these meetings (e.g., daily).

- The written evidence that a transplant program is conducting multidisciplinary care planning may also vary. Some transplant programs may have formal attendance records or meeting notes. Other programs may chart in the patient's medical record on a single form so that all disciplines can easily review the identified medical concerns and plan for treatment. A third program may use progress notes to convey the communication that has occurred between the various disciplines and there is a comprehensive discharge plan that provides evidence that all disciplines were been involved. Surveyors should use the information gained through interviews and other methods to determine where this written evidence can be found and how to evaluate the evidence presented.

- If a multidisciplinary tam does not exist or is incomplete, then Tags X082 and X125 would be cited for deficiencies. If there is a complete multidisciplinary team identified, but the surveyor is unable to find any written evidence of its multidisciplinary patient care planning, then Tag X090 or X091 would be cited.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

If you have additional questions or concerns, please contact Karen Tritz at 410-786-8021 or via email at Karen.Tritz@cms.hhs.gov.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment

Attachment A: Organ Transplant Surveys, Interpretive Guidelines

TAG	Regulation	Interpretive Guidelines
X001	**§482.68 – Special Requirements for Transplant Centers**. A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §482.72 through §482.104 in order to be granted approval from CMS to provide transplant services.	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.
	(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 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.	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 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.
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).
X012	(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center's "primary transplant surgeon" or "primary transplant physician;"	Though the transplant program may have multiple transplant surgeons and/or physicians, OPTN requires that each program (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 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. <u>Clinical Experience Examples:</u> <u>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):</u> 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. <u>Outcomes Examples:</u> <u>For programs subject to outcome requirements, requirements, examples of significant events include (but are not limited to):</u> 1. Changes in patient selection criteria, patient care practices or protocols that had the unintended 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	(3) 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.
X015	(4) Inactivation of the transplant center.	Transplant programs will be required to notify CMS when the program is either:

		1) unable to receive organ allocation offers for transplant 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.
X021	**§482.76 Condition of Participation: Pediatric Transplants.** A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at §488.61 of this chapter. (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.	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 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	(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	<u>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.</u>

	transplants in order to be approved to perform pediatric transplants.	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 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	(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.	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 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	(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.
X025	(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. 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	(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

		program indicate problems in providing the specialized facilities, services and personnel required by pediatric heart transplant patients under the jointly-operated program.
	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.
X032	(a) Standard: Data Submission. No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.	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 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	(b) Standard: Clinical Experience. To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12-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 can not 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 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." <u>Note about #2, #3, and #4 Above:</u> 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 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).	
X035	(3) 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 or expected graft survival rate; and (ii) All three of the following thresholds are crossed over: (A) The one-sided p-value is less than 0.05, (B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and (C) The number of observed events divided by the number of expected events is greater than 1.5.	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.
X036	(5) A kidney transplant center that is not Medicare-approved on the effective date of this rule (June 28, 2007) is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.	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	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.

	to be re-approved.	
X042	(a) Standard: Data Submission No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. 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.	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 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	(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 re-approval period.	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 can not 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 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.	
X045	(3) 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 1.5.	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.
	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 must use written donor selection criteria in determining the suitability of candidates for donation.	
X052	(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.
X053	(1) Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.	Review the written patient selection policy to verify that it contains a requirement for a prospective transplant 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 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	(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	(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 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	(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.

X057	(b) Standard: Living Donor Selection. The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:	
X058	(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,	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 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.
X059	(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 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	(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.
X071	**§482.92 Condition of Participation: Organ Recovery and Receipt.** Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.	
X072	(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.	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 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 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 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	(b) Standard: Organ Receipt. After an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient.	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^{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 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 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	(c) Standard: Living Donor Transplantation. If a center performs living donor transplants, the transplanting surgeon and another licensed health care professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).	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. 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.
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.	
X082	(a) Standard: Patient and Living Donor Care. The transplant center's patient and donor management policies must ensure that: (1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and	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 care

		plan 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. The multidisciplinary team must include representatives from the following disciplines: • Medicine (Transplant surgeon or Transplant physician) • Nursing • Social services • Clinical Transplant Coordinator

	(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.	• 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 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. <u>For living donor patients, review the following:</u> 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 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: • 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	(b) Standard: Waiting List Management.	

	Transplant centers must keep their waiting lists up to date on an ongoing basis, including:	
X084	(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.
X085	(2) Removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a center's waiting list; and	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.
X086	(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.	Request a list of the patients removed from the 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.
X087	(c) Standard: Patient Records. Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.	
X088	(1) For each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of: (i) The patient's placement on the center's waiting list; (ii) The center's decision not to place the patient on its waiting list; or (iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.	For individuals placed on the waiting list after June 28, 2007, 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. For individuals not placed on the waiting list, but evaluated for placement after June 28, 2007, 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 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	(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.
X090	(3) In the case of patients admitted for organ transplants, transplant centers must maintain written records of: (i) Multidisciplinary patient care planning during the transplant period; and	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.
X091	(ii) Multidisciplinary discharge planning for post-transplant care.	Review written evidence by the transplant program to 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.

X092	(d) Standard: Social Services. The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families.	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; 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	A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and (1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) Is working as a social worker in a transplant center as of June 28, 2007 (effective date of this final rule) and has served for at least 2 years as a	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

	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.	evidence of a back and forth dialogue concerning issues 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.
X094	(e) Standard: Nutritional Services. Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.	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 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	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

	services, including services provided under contract or arrangement.	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 • 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.
X100	(a) Standard: Components of a QAPI Program. The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights.	Examples of objective 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.
X101	The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.	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 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.
X102	(b) Standard: Adverse Events. A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.	**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

	(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.	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 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	(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) • *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	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.	
X110	(a) Standard: Director of a Transplant Center. The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with §482.98(b).	The transplant program must designate a Director and describe the qualifications that he or she must possess. At a minimum, the Director must be a qualified transplant surgeon or a qualified transplant physician. 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 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.

X111	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	(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

		coordinators to provide care to transplant patients, and the areas outlined in the regulation under tags X081, X082, X118 and X120. Approach this task by looking at outcomes – do the training programs exist, does pertinent staff participate and complete the training? Absence of these outcomes is evidence of failure to ensure adequate training. Procedures: Review a sample of personnel records for transplant nurses (i.e., those providing direct care to transplant recipients and/or donors) to verify that these individuals have the appropriate licensure and qualifications. The qualifications and licensure requirements for clinical transplant coordinators are reviewed under Tag X119. To evaluate continuing education, review training records of the transplant nurses and clinical transplant coordinators (based on the sample size listed in the survey protocol) for evidence of: 1. Initial approval (or, if specified by the program's own policies, certification) by the transplant program documenting the competency of the transplant nurses and clinical transplant coordinators to work with transplant patients and living donors; and 2. Successful completion of an orientation program that provides an opportunity to raise questions, (for example didactic, hands-on learning, direct observation) including : • Clinical assessment of transplant patients;

		• Clinical assessment of living donors (if applicable); • Monitoring for signs and symptoms of organ rejection, and transplant-related infection; • Monitoring for signs and symptoms of complications following living donation (if applicable); • Providing patient education related to signs and symptoms of organ rejection and complications following living organ donation; • Providing donor education related to complications following living organ donation; • Monitoring of immunosuppressive therapy; and • Providing patient education about immunosuppressive therapy. 3. Participation in continuing education programs in the care of transplant patients and living donors. Review evidence that the continuing education program is: • held at regular intervals based on training dates; and • attended by nursing staff and clinical transplant coordinators as evidenced by training attendance records. Interview a sample of nursing staff hired within the past three (3) months, to verify that those nursing staff that are new to transplantation had adequate training including instructional, on-the job training, and close supervision. <u>For transplant programs that use traveling nurses, contract nurses or float pool nurses</u>: Most traveling, contract, or float pool nurses do not have specific training and/or experience in the care of transplant patients and living donors.

		These nurses may provide certain types of care to transplant recipients and living donors provided that there is clear evidence in the program's policies and procedures, medical records, and interviews of the following: 1) that the float pool nurses practiced within the scope of basic nursing care for which they have had training and experience; 2) that a nurse with adequate training and experience in transplantation provided close supervision/consultation to the float pool nurse so that there was ample opportunity to discuss a patient's condition and how it may correlate with the pre- or post-transplant care (e.g., the implications of certain lab values). An experienced transplant nurse would be able to provide additional information and judgment as to why certain events might be occurring in the context of transplantation, and whether or not follow-up intervention would be warranted; and 3) that a transplant nurse experienced with the specific organ(s) type that is providing the direct care to the patient in situations in which such training and expertise is required. At a minimum, this would include pre- and post-transplant education regarding the transplantation process, pre- and post-donation education, the medication regimen and side effects, and administering immunosuppressive medications.
X113	(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.
X114	(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).	Review a sample of transplant recipients' medical records for documented presence of a qualified transplant surgeon during the transplant surgery.
X115	(b) Standard: Transplant Surgeon and Physician. The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate 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 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	(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.
X117	(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.
X118	(c) Standard: Clinical Transplant Coordinator. The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation 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 Transplant Recipient • 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. <u>Living Donor</u> • 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	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).
X120	The clinical transplant coordinator's	Review multidisciplinary care plan notes, and progress notes

	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.	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) 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[sm] 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	(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	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

	independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.	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. 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, confirm that in all instances, the independent living donor advocate operated independently from the transplant team.

X122	(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.	"Routine basis" is defined as scheduled participation with any activities (on an ongoing or occasional basis) that involve any transplant recipients regardless of organ type, for example, 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.
X123	(2) The independent living donor advocate or living donor advocate team must demonstrate: (i) Knowledge of living organ donation,	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,

	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.	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. 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; • 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. <u>Demonstrating knowledge of informed consent means the following:</u> • 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	(3) The independent living donor advocate or living donor advocate team is responsible for: (i) Representing and advising the donor; (ii) Protecting and promoting the interests of the donor; and (iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.	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. 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.
X125	(e) Standard: Transplant Team. The transplant center must identify a multidisciplinary 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 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	(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: Organ Procurement.** The transplant center must ensure that the	Review the hospital's written agreement with the designated OPO.

	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.
X149	**§482.102 Condition of Participation: Patient and Living Donor Rights.** In addition to meeting the condition of participation "Patients rights" requirements at §482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.	
X150	(a) Standard: Informed Consent for Transplant Patients. Transplant centers must implement written transplant patient informed consent policies that inform each patient of:	For each of the subparagraphs identified in the standard (1) through (8), the transplant program's polices 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 process is complete. The informed consent process is expected to involve multiple discussions with the prospective transplant recipient at different points in time (e.g., prior to being placed on the waiting list, prior to surgery). The medical record and interviews must validate that timely and appropriate discussions were held. Transplant 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	(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.

X152	(2) The surgical procedure;	Discussions with the transplant candidate about the surgical procedure should occur on several occasions prior to the surgery. Prior to placement of the transplant candidate on the 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.
X153	(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^{sm} waiting list. The discussions of alternative treatments should be reviewed again with the patient subsequent to any significant changes in the patient's medical condition or other alternative treatments that become available.
X154	(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.
X155	(5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and 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^{sm} 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 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	(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;	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).
X157	(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.
X158	(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.	
X159	<u>(b) Standard: Informed consent for living donors.</u> Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:	For each of the subparagraphs identified in the standard (1) through (9), the transplant program's polices and procedures should address: 1) who is responsible for discussing informed consent process with the donor; 2) where in the medical record informed consent 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 <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 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.
X160	(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.	The requirements at 45 CFR parts 160 and 164 establish standards for the security, privacy, and authorized release of personal health information. 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).
X161	(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. j. 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; k. suitability for donation; l. results of laboratory and donor -specific diagnostic testing; m. relevance of any psychosocial issues related to donation; and n. 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.
X162	(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 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.
X163	(4) The availability of alternative treatments for the transplant recipient;	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.
X164	(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.
X165	(6) The national and transplant center-specific outcomes for recipients, and the national and center-specific outcomes for living donors, as data are available;	Discussions regarding the transplant program's outcomes must be done prior to the prospective donor's consent for donation. If more than six (6) months has elapsed between consent for donation and the scheduled timeframe for the organ donation surgery, discussions to update the data 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.
X166	(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, 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	(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	(9) the fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for	

	under Medicare Part B.	
X169	(c) Standard: Notification to patients. Transplant centers must notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.	The transplant program's policies and procedures must clearly delineate how the program notifies the 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	(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.
X171	(2) At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must: (i) Inform patients on the center's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list; and (ii) Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.	
X172	(3) As soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance	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

	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.	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.
X184	**§482.104 Condition of Participation: Additional Requirements for Kidney Transplant Centers.**	
X185	(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	A kidney transplant center must have written policies and procedures for ongoing	The kidney or kidney/pancreas transplant program must have ongoing communication with all dialysis facilities associated

	communications with dialysis patients' local dialysis facilities.	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; 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 of patients who have special stipulations

		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	(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	(c) Standard: Participation in network activities.	Review information provided by CMS that will indicate whether the transplant program is fulfilling its

	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.	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 SOW can be found on the CMS website at http://www.cms.hhs.gov/ESRDNetworkOrganizations.