DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-09-09

DATE: **October 24, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy - Organ Transplant Program State Operations Manual (SOM) and Survey Protocol

Memorandum Summary

Organ Transplant State Operations Manual and Survey Protocol: Attached is an advance copy of changes to Chapters 2 and 3 of the SOM and the Survey Protocol which will be included in Appendix X of the SOM.

The Centers for Medicare & Medicaid Services (CMS) is revising the SOM to include provisions related to the survey of Organ Transplant Programs and represent the most recent surveyor guidance for conducting surveys of organ transplant programs. This guidance should replace all previously-released versions including Survey and Certification Letter 08-17. CMS has also developed an Organ Transplant Survey Protocol which surveyors should follow in reviewing organ transplant programs

Attachment A is an advance copy of the SOM which include changes to Chapter 2 and 3. Please note that this document makes a substantive change to the policy outlined in Survey and Certification Letter 08-17. Surveyors will no longer be reviewing the most recent 2 years of patient and graft survival data from the program to determine whether or not programs should be cited at the Standard-level or Condition-level. Surveyors must base their decision on the number of reports from the Scientific Registry of Transplant Recipients that were also out of compliance.

In Chapter 2 of the SOM, we have added sections, §2060 through §2067. These sections will provide guidance specific for the survey and approval of organ transplant programs, for example, the transplant program application process, the specific procedures for surveying organ transplant programs, and data we receive from other sources which is also part of the survey process.

In Chapter 3 of the SOM, we have added a sub-section under Section §3010B that identifies special procedures for findings of immediate jeopardy when the transplant survey is conducted by CMS' Contractor. We have also added a new section §3012.3 which outlines the termination procedures for organ transplant programs that have Condition-level deficiencies for surveys conducted by the State and CMS Contractor.

Attachment B is an advance copy of the final Survey protocol that will ultimately be published in the standard format used in the SOM in Appendix X.

The final version of these documents, when published in the online SOM, may differ slightly from this advance copy.

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: ADVANCE COPY STATE OPERATIONS MANUAL

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal **Date:**

SUBJECT: Update for Publication 100-07 - amendments to the State Operations Manual (SOM) to add requirements for organ transplant programs.

SUMMARY OF CHANGES: We have added new sections to the SOM to outline the requirements for organ transplant programs. Specifically, we have made changes to Chapter 2, and Chapter 3, and have added a new Appendix.

In Chapter 2, we have added sections, §2060 through §2067. These sections will provide guidance specific for the survey and approval of organ transplant programs, for example, the transplant program application process, the specific procedures for surveying organ transplant programs, and data we receive from other sources that is part of the survey process.

In Chapter 3, we have added a sub-section under Section §3010B that identifies special procedures for findings of immediate jeopardy when the transplant survey is conducted by CMS' Contractor. We have also added a new section §3012.3 which outlines the termination procedures for organ transplant programs that have Condition-level deficiencies for surveys conducted by the State and CMS Contractor.

Finally, we have established a new appendix in the State Operations Manual that outlines the survey protocol and the Interpretive Guidelines for survey of organ transplant programs.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	2/Table of Contents
N	2/2060/Organ Transplant Programs
N	2/2060/2060A/Citations
N	2/2060/2060B/Definitions
N	2/2060/2060C/Regulatory Background
N	2/2061/Organ Transplant Program Application Process
N	2/2062/Survey and Approval Procedures for Organ Transplant Programs
N	2/2062/2062A/Prioritizing Transplant Surveys and Survey Workload
N	2/2062/2062B/Post-Survey Activities
N	2/2062/2062C/Transmission of Program Approval Information
N	2/2062/2062D/Program Approval Based on Mitigating Factors
N	2/2062/2062E/Re-Approvals
N	2/2062/2062F/Determining Level of Deficiency for Clinical Experience (Volume) and Outcomes
N	2/2062/2062G/Approval/Re-approval Contingent Upon Another Program
N	2/2063/Relationship to Other Conditions of Participation
N	2/2064/Accreditation Status
N	2/2065/Data Received from Other Sources for the Transplant Survey Process
N	2/2066/Notification to CMS by Transplant Programs of Significant Changes
N	2/2067/Conditions of Participation
R	3/Table of Contents
R	3/3010B/Special Procedures for Findings of Immediate Jeopardy in Organ Transplant Program Surveys Conducted by CMS' Contractor
N	3/3012.3/Termination Procedures for Organ Transplant Programs
N	Appendix X: Survey Protocol and Interpretive Guidelines for Organ Transplant Programs

III. FUNDING: Funding has been allocated for these survey activities within CMS' existing resources.

IV. ATTACHMENTS:

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

***Unless otherwise specified, the effective**

State Operations Manual
Chapter 2 - The Certification Process

2060 - Organ Transplant Programs (Rev.)

2060A - Citations

The Conditions of Participation for Transplant Programs were established under several statutory authorities. Section 1102 of the Social Security Act (the Act) authorizes the Secretary to publish rules and regulations "necessary for the efficient administration of the functions" with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title." Section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with Medicare Conditions of Participation (CoPs). Organ transplant programs are required to be in compliance with the federal requirements set forth in the Medicare CoPs Participation in order to receive Medicare payment. The CoPs for Transplant Centers are found in 42 CFR Part 482.

2060B - DEFINITIONS

2060B-1 Adverse events
Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient.

2060B-2 ESRD Network
ESRD Network means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

2060B-3 Transplant Program/Transplant Center
Transplant program means a component within a transplant hospital that provides transplantation of a particular type of organ, (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

2060B-4 Heart-Lung Transplant Center
Heart-Lung transplant center means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

2060B-5 Intestine Transplant Center
Intestine transplant center means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

2060B-6 Pancreas Transplant Center
Pancreas transplant center means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

2060B-7 Transplant Hospital
Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

2060C - Regulatory Background

The final regulations for transplant programs were published in the Federal Register on March 30, 2007, and became effective 90 days after publication on June 28, 2007. Previously approved transplant programs were required to apply for approval under the regulations within 180 days of the regulation's effective date, December 26, 2007. Until previously approved programs are surveyed and approved under the CoPs, they may continue to participate in Medicare under the aegis of the current National Coverage Determination or End-Stage Renal Disease Conditions for Coverage. Once surveyed, the transplant program is required to operate under the new rules. <u>New</u> transplant programs (which are not Medicare approved prior to June 28, 2007) may only participate pursuant to the process established under the regulation.

2061 - Organ Transplant Program Application Process

Transplant programs must submit a request to CMS Central Office (CO) for approval under the Conditions of Participation. There is no application form. A list of the

information that the provider must submit with their application for approval is posted on the CMS Survey and Certification website:
http://www.cms.hhs.gov/CertificationandComplianc/Downloads/Tranplantappinfo.pdf

CMS CO will log each application received and send a letter to the provider that acknowledges receipt of the application. If an application is incomplete, CO will notify the provider via phone, e-mail, or letter of the additional information that must be submitted before the application can be processed. The provider will also be provided information in the letter concerning any necessity for them to complete or change their CMS-855A provider enrollment form. However, the survey and approval process is not contingent upon completion or revision of the hospital's 855A form.

2062 - Survey and Approval Procedures for Organ Transplant Programs

2062A - Prioritizing the Transplant Surveys and Survey Workload

CMS is prioritizing the onsite surveys based on an evaluation of the transplant program's outcomes, volume, and data submission rates. In order to ensure that CMS is using current data for this prioritization, CO has made arrangements with the contractor for the Organ Procurement Transplantation Network (OPTN), and the University of Michigan, Kidney Epidemiology and Cost Center (UM-KECC) to receive ongoing performance data for the transplant programs that are either seeking approval or have been approved for Medicare participation. As part of the information system developed for the transplant program survey and certification process, the priority ranking for each transplant program will be assigned automatically at CO. If a transplant hospital has multiple transplant programs, the highest priority program will be used in setting the priority for the survey. Since the priority ranking is based on national data that is periodically updated, the priority of a survey may change. CMS CO will distribute the priority rankings to the RO and SA (those performing the surveys in their State) on a periodic basis. The rankings will also be used to establish the prioritization of surveys by National Contractor as some SAs have elected to have the National Contractor perform the transplant program surveys in their state.

Transplant Program Quarterly Report (TPQR)
In addition to the priority ranking of transplant programs described above, CO will also distribute a report known as the "Transplant Program Quarterly Report" (TPQR) to all Regional offices and the National Contractor. The RO will distribute this report to the SA who will be performing the surveys. This report will give surveyors key information about each transplant program to be surveyed and any notifications that CMS has received regarding significant changes to a transplant program, as required in the regulation (42 CFR §482.74).

Specifically the TPQR report includes:

- *Contact information for representatives of the hospital and transplant program;*

- *Survey and certification information including the survey priority, status, and approval or re-approval due date (if applicable);*
- *Affiliations including membership with the OPTN, and an agreement with an organ procurement organization (OPO);*
- *Key personnel of the transplant program (i.e., the primary transplant surgeon and transplant physician);*
- *Program data including data submission, the number of transplants performed and the program's outcomes; and*
- *Notifications of program changes and inactivity.*

Surveyors will be expected to review the TPQR prior to going onsite and to use the information in the report to verify that a transplant program meets various regulatory requirements (such as notifications to CMS, key personnel, outcomes, etc.).

The TPQR report will also be used to determine the interrelationships of programs for approval as certain transplant programs may not be approved under the survey and certification process unless other related programs can be approved. For example, the regulation requires that a heart/lung program be located in a transplant hospital that is also Medicare-approved to perform heart-only and lung-only transplants.

<u>For States surveying their own transplant programs</u>:
In cases where a transplant hospital operates more than one transplant program, CO will forward the priority ranking for each individual program within the hospital. The SA should schedule and complete the survey of all programs within that hospital based upon the highest priority ranking of the individual programs within that hospital.

For the estimated yearly workload of surveys to be conducted, refer to the Mission and Priority Document. This estimate is based on existing Medicare-approved transplant programs; it does not include any revisits or complaint surveys that may be required. It also does not include any initial surveys of new programs that may seek Medicare-approval.

<u>For surveys of transplant programs done by the National Contractor:</u>
CO will have regular calls with the National Contractor to outline the priority rankings and will set the schedule for the surveys to be completed in the various States. The Regional Offices will be notified of any impending survey activity within their region by the National Contractor within 10 days prior to the survey.

Upon notification of an upcoming survey, the RO will create a new facility if the hospital does not have any other transplant programs, the certification kit (if applicable) and survey shell in ASPEN and send the survey shell information to the National Contractor. The National Contractor will conduct the survey following the timeframe discussed with CO.

2062B - Post-Survey Activities

For States Conducting Transplant Program Surveys:
Following the survey, the State will:

- *Complete the Organ Transplant Hospital Worksheet, and fax the worksheet to CO within 3 business days following the survey, with a copy to the applicable CMS Regional Office;*
- *Update the Hospital /CAH Database Worksheet information under the parent hospital's certification for that hospital in ASPEN; and*
- *Complete Form 670 in ASPEN regarding surveyor workload information.*

The SA will prepare the CMS-2567 with the survey findings. There will be one CMS-2567 prepared even if the survey was conducted on multiple transplant programs within a hospital. When preparing the CMS-2567, after selecting a tag in the "Citation Manager" section of ASPEN (i.e., citing a deficiency for a survey), a box titled "Citation Properties" will be opened. To identify the transplant program type for each tag, click on "Transplant Types" and select the appropriate program(s).

In the case of multi-program surveys, the CMS-2567 may include deficiencies from more than one transplant program at an individual tag. Therefore, the surveyor must identify the applicable program within the body of each citation including identifying each sample size in the Deficient Practice Statement as well as in the findings. For example, in the Citation Properties for a given tag, the surveyor may select the adult heart-only and adult kidney-only programs as not meeting a standard related to nutritional services. In the narrative deficiency statement for the tag, it is necessary to specify the program type, and each finding must clearly be attributed to a specific program. See examples of the deficiency statement and related findings below:

> *"Based on observation, interview and record review, the transplant hospital failed to ensure that there was consistent and complete documentation of the verification of blood type compatibility between donors and recipients prior to the commencement of transplant surgery for 5 of 5 sampled adult heart patients (5, 6, 7, 8, 9) and 2 of 5 sampled adult kidney patients (1, 3)."*
>
> *Findings:*
> *1. Patient 5 received an adult heart transplant on 7/14/2007 according to the patient's medical record. The operating room nurse confirmed the blood type compatibility of the donor and patient prior to the surgery….*

If the specific program reference is not included in the narrative deficiency statement, one would not be able to determine which transplant program failed to meet the regulatory requirement for verifying blood type compatibility.

The RO has the discretion to request review of the CMS-2567 prior to sending this document to the provider. The SA will send the following: 1) a cover letter (that provides the transplant program with proper notifications) using a template provided by

CO; 2) the CMS-2567 (including any Condition or Standard-level deficiencies) to the hospital administrator; and 3) a request for a plan of correction (note the plan of correction may require a response from more than one transplant program within the hospital). Once an acceptable plan of correction has been submitted, the SA is responsible for scheduling any follow up activity, as indicated (See Chapter 3 of the State Operations Manual for additional information regarding revisits.) The SA will make a recommendation to the RO regarding approval/disapproval for each program surveyed within the hospital. See section ***2062C*** *for information about this process.*

The RO will notify transplant program(s) of their Medicare approval or disapproval via a notification letter using a template provided by CO. A copy of all notification letters should be provided to CO, the fiscal intermediary, and, in the case of a kidney or pancreas transplant program, the ESRD Network. A single notification letter listing all the transplant programs within the hospital may be sent to the hospital. There may be both an approval and disapproval notice sent to the hospital if only some of the transplant programs surveyed are able to be approved.

If any single program of a multi-program survey has Condition-level deficiencies, the SA will notify the provider after discussion (via e-mail or telephone) with RO and CO. See Chapter 3 of the SOM for additional information regarding adverse actions.

<u>For Surveys Completed by the National Contractor:</u>
Following the survey the National Contractor will complete:

1) *The Organ Transplant Hospital Worksheet;*
2) *CMS-670; and*
3) *CMS-2567 form.*

These forms should be forwarded within 5 business days for transplant hospitals with 4 or fewer transplant programs and 10 business days for more than 4 transplant programs following the survey to:

CMS Central Office Project Officer
Survey and Certification Group
7500 Security Blvd. Mail Stop S2-12-25
Baltimore, MD 21244

On a case-by-case basis, the Project Officer for the Contractor may approve an extension beyond on the timeframe specified for completion of the CMS-2567 form.

A copy of these documents should also be sent to the applicable RO. If the RO would like edits to or clarification of any aspects of the CMS-2567, the RO would, at a minimum, include the CO Project Officer on any correspondence and/or associate conference calls with the Contractor.

Please refer to the previous section "<u>For States Conducting Transplant Program Surveys</u>" for a description of how the CMS-2567 form should be prepared for this type of

survey including the selection of transplant types and the identification of programs within the Deficient Practice Statement and findings.

Once the CMS-2567 is finalized, the RO will send the CMS-2567 to the hospital administrator and get a plan of correction from the provider (note the plan of correction may require a response from more than one program within the hospital). The RO will have responsibility for approval of plans of correction and discussing the need for scheduling follow-up visits with the CO Project Officer. In the case of a finding of Immediate Jeopardy, see Section 3010B of the SOM for a description of the special procedures to be followed for the Contractor.

2062C - Transmission of Program Approval Information

The ASPEN system has not been modified to have a full certification kit attached to the survey that recommends whether a given transplant program can be approved under the Medicare CoP. To transmit program approval/ disapproval recommendations, the state surveyors should complete relevant sections of the CMS-1539 form that is part of the facility's record in ACO (this information can not be entered into ASPEN Survey Explorer (ASE) and then uploaded, it must be entered directly into ACO). In the "Remarks" section, identify the program(s) being approved, approved with an acceptable plan of correction, or disapproved. After completing the CMS-1539 form, the SA will notify the RO that the form has been completed and may be viewed in ACO. This will facilitate the RO completion of the transplant program approval process (e.g., assigning the CMS Certification Number, etc).

2062D - Program Approval Based on Mitigating Factors

Transplant programs may request initial approval or re-approval based on mitigating factors that cause the program to be out of compliance with the data submission, clinical experience, outcome requirements, and other Conditions of Participation. CO in consultation with the applicable RO will consider on a case-by-case basis any request for approval under this section.

For additional information, please refer to the mitigating factors description on the CMS Web site at:
http://www.cms.hhs.gov/CertificationandComplianc/Downloads/ConsiderationofMitigatingFactors.pdf

2062E - Re-approvals

Transplant programs must be re-approved every 3 years. Programs are not required to submit an application for re-approval.

2062F - Determining Level of Deficiency for Clinical Experience (Volume) and Outcomes

Compliance with the clinical experience (volume) and outcome measures is evaluated by reviewing the program's performance compared to objective standards outlined in the regulation (e.g., performed 10 transplants in previous 12 months). The goal of this section is to establish guidelines that will create as much consistency as possible across survey teams in the level of the deficiency cited, (i.e., condition level, or standard level) in these areas. Information will be provided in the TPQR to give the surveyors the information outlined in this section. This section applies to initial approvals only.

Determining the Level of the Deficiency for Non-Compliance with Clinical Experience Requirements

To determine the level of the deficiency for the clinical experience (volume) requirement outlined under 482.80(b), follow the guidance below:

> *For Initial Approval under 482.80(b):*
> *Part 1: If the transplant program has done 8 or more transplants in the past 12 months (after consideration of the most recent data and related program types), cite deficiency at a Standard Level*
>
> *Part 2: If the transplant program has done less than 8 transplants in the past 12 months cite the deficiency at the Condition Level*
>
> *For Re-approval under 42 CFR 482.82(b):*
> *If the transplant program has done an average of 8 or more per year over the re-approval period and has done 4 transplants in the past 12 months, cite a deficiency at the Standard Level. Otherwise, cite the deficiency at the Condition Level.*

Note that under Chapter 3 of the SOM, transplant programs are given an extended timeframe to come into compliance with Condition-level deficiencies in this area.

A program's inactivation does not create an exception to the clinical experience requirements.

Determining the Level of the Deficiency for Non-Compliance with the Outcome Requirements of the Regulation

The regulation requires that the outcome measures evaluated are from the most recent Center-Specific Report from the Scientific Registry of Transplant Recipients. Since the outcome measures reported are 1-year post transplant, the risk-adjusted outcomes are based on transplants performed between 1 year and 3.5 years prior to the date the report is published.

To determine the level of the deficiency for the outcome requirement, surveyors should review the number of Center-Specific SRTR reports that identify that the transplant programs outcomes were significantly lower than expected based on the:

Area of Evaluation - *Number of Recent SRTR Center-Specific Reports that Do Not Meet the Outcome Requirements.*

Method of Receiving Information Standard *- To be provided by CMS CO in the Transplant Program Quarterly Report (TPQR).*

Cite the deficiency using the following criteria:

Standard *- The most recent SRTR report shows that the program did not meet outcome requirements, <u>but</u> none of the four outcome reports prior to the most recent show that the program was not in compliance,* ***then cite at the Standard Level***

Condition - *The most recent SRTR report shows that the program did not meet outcome requirements, <u>and</u> 1 or more of the four outcome reports prior to the most recent show noncompliance, then cite at the* ***Condition Level***

If based on the criteria above the pervasiveness of poor outcomes indicate that a Condition-level deficiency is warranted, then, a Condition-level deficiency must be cited.

The guidance presented in this section does not change the surveyor's discretion to also cite the Condition if more than one Standard under this Condition (i.e., data submission, clinical experience, and outcomes) is out of compliance.

2062G - Approval/Re-approval Contingent upon Another Program (Rev.)

- *An adult or pediatric heart/lung program must be located within a Medicare-approved heart only and Medicare-approved lung only program for its respective age group.*
- *An adult or pediatric intestine/multivisceral program must be located within a Medicare approved liver program for its respective age group.*
- *An adult or pediatric pancreas program (i.e., performing pancreas-only or kidney/pancreas transplants) must be located within a Medicare-approved kidney program for its respective age group.*
- *If <u>both</u> the adult and pediatric program of a given organ type have applied for or are Medicare-approved, review the number of transplants performed for each of these age groups. Determine whether the adult or the pediatric program is the predominant program (performing 50% or more of the transplants for that organ type).* ***The predominant program must be able to be approved before the related program can be approved.***

2063 - Relationship to Other Conditions of Participation
(Rev.)

Hospital Conditions of Participation
If while conducting a transplant program survey findings are observed which are uniquely associated with the Hospital CoP (42 CFR §482.1 through §482.57), the surveyor will refer the findings to the SA for whatever action they deem appropriate. If a hospital (within which the transplant program(s) are located) loses Medicare certification, the transplant program(s) within the hospital will also lose their Medicare approval.

ESRD Conditions for Coverage and OPO Conditions for Coverage

If while conducting a transplant program survey, findings are observed which are uniquely associated with either the ESRD or OPO Conditions for Coverage, the surveyor will refer the findings to the SA for whatever action they deem appropriate.

2064 - Accreditation Status

Currently there is no accreditation organization with deeming authority to approve transplant programs. The statutory provision Section 1865(b)(1) of the Social Security Act prohibits deeming authority for the approval of kidney transplant programs.

2065 - Data Received from Other Sources for the Transplant Survey process

OPTN's contractor, UNOS will provide key information about organ transplant programs to CO with a copy to the OPTN project officer at HRSA at the beginning of each calendar quarter (January, April, July, October) including OPO agreements and key personnel.

2066 - Notifications to CMS by Transplant Programs of Significant Changes

The regulation at 42 CFR §482.74 requires that a transplant program notify CMS immediately of any significant changes related to the transplant program or changes that could affect the program's compliance with the Medicare CoP (as outlined under 42 CFR §482.72 through 42 CFR 482.104).

Significant changes or events in which CMS must be notified include key personnel changes, changes to the clinical experience (volume) or outcomes, the agreement with their OPO, and the inactivation of the program. Additional details on the notification requirements can be found at http://www.cms.hhs.gov/CertificationandComplianc/20_Transplant.asp.

Providers must notify CO of the changes described above. A copy of any notifications (letters, e-mails, etc) received by the RO or SA should be forwarded to CMS Central Office.

2067 - Conditions of Participation

2067A §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 OPTN established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. section 274).

2067B §482.74 Condition of participation: Notification to CMS.
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.

2067C §482.76 Condition of participation: Pediatric Transplants.
A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients (under age 18) must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at §488.61. If a transplant hospital has both an adult and pediatric program, the predominant program must be Medicare approved before the other can become Medicare approved. Pediatric heart transplant programs may apply for approval under an alternate option if they are jointly operated with another Medicare-approved program.

2067D §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, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

2067E §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, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.

2067F §482.90 Condition of participation: Patient and living donor selection.
The transplant center must use written patient selection criteria to determine 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.

2067G §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.

2067H §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.

2067I §482.96 Condition of participation: Quality assessment and performance improvement (QAPI).
Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

2067J §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.

2067K §482.100 Condition of participation: Organ procurement.
The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

2067L §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.

2067M §482.104 Condition of participation: Additional requirements for kidney transplant centers
Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities. Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement. 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.

State Operations Manual
Chapter 3 - Additional Program Activities

3010B - Processing of Immediate Jeopardy Terminations (Amended to include)
(Rev.)

Special Procedures for Findings of Immediate Jeopardy in Organ Transplant Program Surveys Conducted by CMS' Contractor

The RO is responsible for making the determination of non-compliance when an immediate jeopardy to patient health or safety exists and completing the termination procedures within 23 calendar days. The CMS contract surveyors will telephone the CMS Project Officer and RO when an immediate jeopardy to patient health or safety exists. The CMS contract surveyors should discuss their findings with the provider and tell the providers that they are mailing to the CO and RO by overnight express mail the completed CMS-2567 and all supporting documentation (e.g., correspondence, contact reports). The RO reviews the survey package and CMS-2567, and consults with CO. If the RO determines noncompliance, it mails Form CMS-2567 to the provider. After doing so, the RO follows the 23 calendar day termination procedure as outlined below beginning with the fifth working day.

3012.3 – Termination Procedures for Organ Transplant Programs
(Rev.)

A provider that does not substantially meet the CoPs is considered to be limited in its capacity to furnish services at an adequate level or quality. CoPs (i.e., Condition-level deficiencies) must be corrected before a transplant program can be approved or re-approved.

For transplant programs that have not been previously Medicare-approved and do not comply with the transplant program CoPs, the State Survey Agency (SA) and CMS Regional Office (RO) should follow the procedures outlined in Section 3001 of the SOM.

The termination process for currently participating organ transplant programs (i.e., programs previously approved by CMS that have not yet been approved under the CoPs) that do not comply with one or more CoP (i.e., has Condition-level deficiencies) is generally consistent with the 90 calendar-day timeframe used for termination of other provider types; however in two cases, the transplant programs should be allowed additional time for initial approval only under the CoPs to accomplish the corrective action necessary to attain compliance with the regulation. Please note that the termination would not affect the hospital's Medicare provider agreement; it would only apply to a hospital's Medicare approval for a given transplant program.

*(1) If the transplant program does not meet Condition 42 CFR §482.80 because of the clinical experience (volume) requirements outlined in (b) of this Section, the program will be given **210 days** to come into compliance with this Condition, contingent upon CMS receipt of an acceptable and implemented plan of correction.*

*(2) If the transplant program does not meet Condition 42 CFR §482.80 because of the outcome requirements outlined in (c) of this Section, the program will be given **210 days** to come into compliance with this Condition, contingent upon CMS receipt of an acceptable and implemented plan of correction. This additional time will also allow for the release of the next SRTR Center-Specific Report which occurs every 6 months and sufficient time to provide the necessary steps regarding public notification, etc.*

The additional time to come into compliance with the clinical experience or outcome requirements does not eliminate a transplant program's responsibility to immediately develop and implement a comprehensive plan of correction that address these issues. Similar to other types of deficiencies, this plan of correction should be submitted within 10 calendar days of the program's receipt of the CMS-2567 form. A plan of correction for these deficiencies must include an analysis of why the clinical experience and/or outcomes are not in compliance, an outline of the specific steps that the program will put in place to come into compliance, and the timeframe for when these steps will be accomplished. A general note that the program will wait until the next round of outcome or volume data become available, or that the program is working with the Organ Procurement Transplantation Network to improve its outcomes does not provide sufficient evidence that the program is taking the necessary steps to come into compliance with these requirements.

Organ transplant surveys in some states are being conducted by CMS contract surveyors. Due to the additional administrative process of the contractor forwarding survey findings to the RO and Central Office for review, day one (1) of the termination timeframe should begin on the date the RO receives a complete form CMS-2567 report from the Contractor. Day one of the termination timeframe for state surveyors begins once CMS RO has reviewed and considered the CMS-2567 acceptable and able to be sent to the provider.

Timeframe for Determining Compliance with CoPs

Non-compliance with all Transplant Conditions of Participation.

***Day One–** For the SA, it is the date that CMS RO has reviewed and considered the CMS-2567 acceptable and able to be sent to the provider. For the CMS' Contractor surveys it is the date the RO receives the completed transplant survey.*

***Tenth Working Day –** On the 10th working day, there is a warning letter sent with the 2567 containing the deficiencies to the organ transplant provider. The provider is*

informed in writing that there is a determination of noncompliance and that termination is recommended effective within 90 days from Day One (or within 210 days, as applicable). The recommended termination date(s) should be included in the letter. The organ transplant program is informed that the termination process provides an opportunity to make corrections and achieve compliance. This opportunity allows the transplant hospital ten calendar days to complete and return a plan of correction on the 2567 that addresses all transplant programs that have deficiencies. The letter should state that for certain Condition-level deficiencies there will be a revisit within 45 calendar days of Day One if a credible allegation of compliance is received (See table below regarding revisit requirements.). Termination takes effect as planned if compliance is not achieved. This notice serves as a warning letter to the provider.

For transplant program surveys conducted by the SA, the letter is sent by the SA with a copy to the RO and CO. For transplant program surveys conducted by CMS' Contractor, the RO will send the letter with a copy to the SA and CO.

Non-compliance with all Transplant Conditions of Participation.

45th Calendar Day *- Where there is a credible allegation of compliance (§3016.A.)*

The surveyor (SA or Contractor) determines whether compliance or acceptable progress has been achieved by conducting a revisit (See table below for requirements for an onsite revisit). Only 2 revisits are permitted; one within 45 calendar days and one between the 46th and 90th calendar days. If a second credible allegation of compliance is made prior to the effective date of termination, the SA telephones the RO and submits documentation to support the second revisit (only the second revisit is subject to RO approval).

If a second credible allegation of compliance is made directly to the RO (in the case of a provider surveyed by CMS' Contractor), the RO would discuss with CMS CO the need for a second revisit by the Contractor. If the facility fails to make a credible allegation, no revisit is necessary.

Non-compliance with §482.80 due to clinical experience (volume) or outcomes.

180th Calendar Day *- Where there is a credible allegation of compliance (§3016.A.).*

For outcomes, acceptable progress is assessed using the information from the most recent SRTR Center Specific Report as required by the regulation. For volume, acceptable progress will be determined using the number of transplants performed. An onsite revisit is not required.

Non-compliance with all Transplant Conditions of Participation.

55th Calendar Day*- *If compliance has not been achieved with all Conditions (except 482.80 or 482.82), the SA or RO certifies noncompliance.*

Non-compliance with §482.80 due to clinical experience (volume) or outcomes.

185th Calendar Day* - *If compliance has not been achieved with §482.80 as a result of continuing deficiencies in (b) or (c), the SA or RO certifies noncompliance.*

** In the case of a provider surveyed by the SA, the SA forwards the certification and supporting documentation to the RO. The SA or RO notifies the provider/supplier that termination is recommended and alerts the SMA if the provider/supplier is also participating in Medicaid.*

Non-compliance with the Transplant Conditions of Participation except as noted.

65th Calendar Day - *Within 65 calendar days of Day One, the RO determines whether survey findings continue to support a determination of noncompliance with the Conditions of Participation.*

70th Calendar Day - *The RO sends an official termination notice to the provider, the public, and the SMA if the provider also participates in Medicaid. Notices must be made at least 15 calendar days before the effective date of termination.*

90th Calendar Day - *Termination takes effect if compliance is not achieved with all Conditions of Participation (not including extended circumstances of 42 CFR 482.80 and 482.82). It can take effect in fewer than 90 calendar days if required procedures are completed.*

Non-compliance with §482.80 due to clinical experience (volume) or outcomes.

190th Calendar Day *– Within 190 calendar days of Day One, the RO determines whether survey findings continue to support a determination of noncompliance*

195th Calendar Day - *The RO sends an official termination notice to the provider, the public, and the SMA if the provider also participates in Medicaid. Notices must be made at least 15 calendar days before the effective date of termination.*

210th Calendar Day - *Termination takes effect if compliance is not achieved with Conditions of Participation 42 CFR 482.80 based on clinical experience or outcome requirements. For deficiencies related to outcomes, the termination may occur earlier than the 210th Calendar Day if a SRTR center-specific report is available which continues to find the program out-of-compliance.*

NOTE: *All timeframes are maximum. The RO may terminate more quickly as long as the regulatory requirements for notification of the public and provider are satisfied.*

Revisit Requirements for Condition-Level Deficiencies

Determining Compliance with Conditions of Participation	***Requirements for an Onsite Revisit***
§482.72: OPTN Membership	*Onsite revisit not required. Compliance can be determined off site.*
§482.74: Notification to CMS	
§482.74 (a)(1) and (a) (3)	*Onsite revisit discretionary. Compliance can be determined off site.*
§482.74 (a)(2) and (a)(4)	*Onsite revisit required.*
§482.76: Pediatric Transplant	
§482.76 (a) through 482.76(c)	*Onsite visit not required. Compliance can be determined off site.*
§482.76 (d)	*Onsite revisit required.*
§482.80 and §482.82: Data Submission, Clinical Experience and Outcomes	*Onsite revisit not required. Compliance can be determined off site.*
§482.90 through §482.104	*Onsite revisit required.*

Note: Onsite revisit surveys for assessing compliance with standard-level deficiencies remain at the discretion of the SA, or the RO (in consultation with CMS Central Office in the case of surveys conducted by CMS' contractor).

Attachment B: ADVANCE COPY OF SURVEY PROTOCOL

A. USE OF THE SURVEY PROTOCOL AND INTERPRETIVE GUIDELINES IN THE SURVEY PROCESS

Conduct surveys of the organ transplant programs using the regulations at 42 CFR parts 482, Subpart E 488, and 498. There are 14 different types of transplant programs. Each program must meet the Conditions of Participation at 482.72 through 482.104 and must be surveyed and approved separately. The program types include the following:

- Adult Kidney-only
- Adult Pancreas (includes kidney/pancreas, subsequent to kidney, and pancreas-only transplants – the program must be located within a Medicare-approved adult kidney program. There is no separate approval from a Medicare-approved kidney program.)
- Adult Heart-only
- Adult Heart/Lung (must be located within an approved adult heart-only and adult lung-only program that performs combined heart/lung transplants)
- Adult Lung-only
- Adult Liver
- Adult Intestine/Multivisceral (must be located within an approved adult liver program that performs intestine, combined liver and intestine, or multivisceral transplants)
- Pediatric Kidney-only
- Pediatric Pancreas (includes kidney/pancreas, subsequent to kidney, and pancreas-only transplants – the program must be located within an approved pediatric kidney program. There is no separate approval from a Medicare-approved kidney program)
- Pediatric Heart-only
  Pediatric Heart/Lung (must be located within an approved pediatric heart-only and pediatric lung-only program that performs combined heart/lung transplants)
- Pediatric Lung-only
- Pediatric Liver
- Pediatric Intestine/Multivisceral (must be located within an approved pediatric liver program that performs intestine, combined liver and intestine, or multivisceral transplants)

Note: A transplant program that performs 50% or more (majority) of their total transplants (in a 12-month period) on a given age group, adult or pediatric, may, but is not required to apply and be approved separately for the minority age group.

If a program is not seeking separate approval for the minority age group, during the survey process all patients served by the program regardless of age will be included within the review. For example, the onsite review for a pediatric program could include any adults served by that program in selecting the random sample of patient records, interviews, etc. In addition, the survey process will assess the program's compliance

with the requirements for data submission and the outcome report(s) that encompass all patients that are served by that program.

B. THE SURVEY PROTOCOL

The survey protocol represents guidance by the Centers for Medicare & Medicaid Services (CMS) to surveyors of hospital transplant programs. The use of the protocol will promote consistency in the survey process and provide the surveyor with sufficient information to make decisions about compliance with the Medicare Conditions of Participation. The surveyors are expected to follow the survey protocol.

C. THE INTERPRETIVE GUIDELINES

The interpretive guidelines contain authoritative interpretations, clarifications of the regulatory requirements and examples to support the regulatory text. The interpretive guidelines are an aide and do not replace or supersede the law or regulations, and therefore, may not be used as the documentation basis for a citation.

Citation of a deficiency must be based on a violation of the statute or the regulations. Where the surveyor observes that practices of a program do not meet a particular section of the regulation, the interpretive guidelines should be used to provide the surveyor with examples and guidance as to whether or not a deficiency occurred. In each case the surveyor must determine whether a deficiency, based on the applicable regulatory provision, is appropriate.

PART II - THE STANDARD TRANSPLANT PROGRAM SURVEY PROTOCOL

The STANDARD SURVEY protocol is a full survey of all transplant program Conditions of Participation and is to be used for initial and re-approval surveys. For complaint surveys, surveyors should follow the general tasks associated with all surveys (e.g., entrance conference, pre-exit discussion, exit conference, etc.); however, the scope of the survey should be limited to the relevant Conditions of Participation (CoPs) outlined in the complaint. Once the survey team is onsite other transplant CoPs can be added if needed, based on the findings from the investigation. Each hospital may have more than one transplant program, and each program must be surveyed and approved individually.

Please keep in mind that the transplant program Conditions of Participation became effective on June 28, 2007. The survey should be limited to the policies and practices of the transplant program on and after that date. Policies prior to that date may be reviewed only to the extent that they either are currently in effect or were in effect after June 28, 2007.

The review of medical records should also be limited to practices and activities after June 28, 2007. For example, if an individual was placed on the waiting list in February 2007, and transplanted on August 15, 2007, only practices after June 28, 2007 should be reviewed for compliance with the regulation. Surveyors may want, wherever possible, to use records where the transplant process was conducted after June 28, 2007, to avoid having to request additional records.

The Components of the Standard Transplant Program Survey Protocol

Task 1 - Pre-survey Preparation Off-site
Task 2 - Entrance Activities
Task 3 - Orientation to Transplant Program Areas
Task 4 - Observations of Care
Task 5 - Sample Selection
Task 6 - Patient Interviews
Task 7 - Review of Transplant Patient and Living Donor Medical Records
Task 8 - Staff Interviews
Task 9 - Personnel Record Review
Task 10 - Administrative Review
Task 11 - Pre-exit
Task 12 - Exit Conference
Task 13 - Post Survey Activities

Survey Team Size and Composition

The State Agency or CMS Contractor decides the composition and size of the team. In general, a suggested survey team would include at least 2 to 3 surveyors, but will be based on the program's size. For example, some states have found it useful to have one survey team member per transplant program. The length of the survey will vary based on the number and size of the programs that the survey team is reviewing. The timeframes given in this section are intended to facilitate survey planning and scheduling given the framework of the survey protocol and assuming a team size of 2 to 3 surveyors. However, these are only estimates; for example, if the number in the survey team is higher, then the timeframe would likely be shortened; if the findings warrant extending the survey, then the survey may take longer.

Surveyors who have not received the CMS-sponsored transplant training may accompany and assist the survey team with survey activities. However, the number of individuals without training should be less than 50% of the number of trained individuals. Untrained individuals should not be given lead responsibility for reviewing a transplant program, or conducting interviews with transplant program staff. Those individuals who have not had training and who are assisting in the survey should ensure that they are very familiar with the regulation, interpretive guidelines, and the various transplant surveyor tools that available.

Number of Transplant Programs	Estimated Survey Length
1 to 3	2 to 4 working days
4 to 6	3 to 6 working days
7 to 10	5 to 9 working days
11 to 14	7 to 11 working days

Each survey team should have at least one member with a clinical background (i.e., physician, nurse, nurse practitioner).

TASK 1 - PRE-SURVEY PREPARATION OFF SITE

Prior to each survey, determine the number and types of transplant programs that are to be reviewed during a given survey, and review the information below for each program type:

- Review the transplant program's history for any prior survey and certification issues.
- Review complaint allegations in ACTS. Note the frequency, significance, severity, types of complaints and (if substantiated) the resolution;
- Review the CMS Transplant Program Quarterly Report (TPQR) to assess the following:
  - Is the program listed as a member of the OPTN, and what is the status of that membership;
  - Has the program submitted the required percentage of data to the OPTN;
  - Has the program completed the number of transplants required to meet the clinical experience requirements, if applicable;
  - Has the program met the outcome requirements of the regulation for both its adult and pediatric patients, if applicable;
  - Have any periods of inactivity been reported immediately;
  - Is an agreement with an Organ Procurement Organization listed;
  - Have a primary transplant surgeon and physician been designated to the OPTN; and
  - Have any significant changes that have occurred been reported to CMS immediately?
  - Determine if the hospital is seeking approval for both an adult and pediatric program of a given organ type(s) (for example, heart, kidney/pancreas, etc.). If both an adult and pediatric program are present, review the number of transplants performed for each of these age groups. Determine whether the adult or the pediatric program is the predominant (majority) program (performing 50% or more of the transplants for that organ type). The predominant program must be able to be approved before the related (or minority) program can be approved.
  - To determine whether or not the program is a pediatric heart transplant program that is seeking alternate approval by operating jointly with another Medicare-approved heart transplant program. If yes, refer to the ***Alternate Survey Protocol for Approval of Pediatric Heart Transplant Programs*** described in a later section of this document.

The team coordinator should arrange an off-site meeting or conference call prior to the survey with as many team members as possible. The meeting should address the following:

- Significant information from the CMS Transplant Program Quarterly Report (TPQR) or previous survey results that were reviewed;
- Layout of the transplant program, and hospital (location within the hospital of all the transplant programs to be surveyed, lab, outpatient center, clinic, etc);
- Date, location and time the team members will meet to enter the hospital to begin the survey;
- Individual team member assignments for the survey. The survey team should include at least one clinical personnel (i.e., physician, nurse, nurse practitioner);
- Organization of the survey – The order in which programs will be reviewed. Will all survey team members review programs as a group? Will programs be assigned to different team members for review?
- The time for the daily team meetings (if necessary); and
- Projected date and time of the exit conference.

TASK 2 - ENTRANCE ACTIVITIES

The entire survey team should enter the hospital together. Upon arrival, surveyors should present their identification. Generally, the surveyor(s) will need to go to the Hospital Administration Office to initiate the unannounced survey. The team coordinator will request to see the Hospital Administrator (or his or her selected representative) and explain that the team will be conducting a survey of one or more organ transplant programs within that hospital. Identify for the Hospital Administrator the organ transplant programs that will be surveyed, and inform him or her of the name of the representative(s) of the transplant program(s) that are listed on the TPQR report.

Activities conducted during the entrance conference would include the following:

- Introduce the surveyors to the hospital and program administration;
- Identify the program(s) that will be surveyed;
- Inform the transplant program staff how long the survey is expected to take;
- Provide a brief description of the surveyors assignments;
- Describe the materials that will be needed for review;
- Identify the transplant program staff that will need to be interviewed;
- Provide a projected date and time for the exit interview;
- Request a designated, secure place to work, and access to any necessary hospital facilities, such as copying and electronic medical records (if applicable);
- Explain the purpose of the survey and that the survey will include observations within any associated transplant program facilities, a review of medical records and transplant program policies and procedures, and interviews with staff, patients and living donors; and

- Present a previously prepared list of the documents that the survey team will need during the survey. (See below for a list of the materials to be requested).

The entrance conference should be brief and should begin as soon as possible following the entrance to the facility to allow the survey team to start the survey as quickly as possible.

Suggested Transplant Program Document Request List:

Lists of Transplant Candidates, Recipients and Living Donors

1. The transplant program's complete current active waiting list including the following information: name, address, country of primary residence, resident alien or non-resident alien status, race and gender and number of individuals on the waiting list (this would not include patients categorized as a "status 7" which means their waiting list status is "inactive");
2. List and number of persons evaluated for transplant that were not placed on the waiting list within the past 12 months or after June 28, 2007, whichever date is later;
3. List and number of all patients removed from the waiting list including the reason for the removal within the past 12 months, or after June 28, 2007, whichever date is later;
4. List and number of the transplants performed including name, organ(s) transplanted and date of transplant within the past three years, or after June 28, 2007, whichever date is later;
5. List and number of living donors including name, living donor organ(s) transplanted and date of transplant (if applicable) within the past three years, or after June 28, 2007, whichever date is later;
6. List and number of transplant patients and donors that are currently an inpatient and the location of patient (unit, and floor);
7. List and number of post-transplant patients and post-donation individuals that are scheduled for follow-up visits during the survey timeframe;

List of Organ Recovery and Organ Offers

8. List and number of all instances where the transplant program's own recovery team went to another hospital to recover the organ within the last three years or after June 28, 2007, whichever date is later. In each instance include the name of the transplant recipient. *[This list is not needed if the transplant program recovers all of the deceased donor organs for a given program type];*
9. List and number of the organs that the transplant program received offers for after June 28, 2007, and declined, and the reason for the declination;

Program Administration: Policies, Procedures, Personnel, and QAPI

10. The policy and procedure manuals;
11. A copy of the transplant program's written waiting list selection criteria for patients and donors (if applicable);
12. A copy of the written material that is distributed to patients to explain the selection criteria (if different than #11);

13. The hospital and transplant program's written agreement with their designated Organ Procurement Organization (OPO);
14. An organizational chart of the transplant program;
15. A schedule of any multidisciplinary team meetings that will be held during the survey;
16. List of all transplant associated professional personnel and their titles;
17. The training schedule for all personnel, agenda of training, dates, and attendance records;
18. On-call schedule for transplant surgeons and transplant physicians for the past 30 days;
19. Any current contracts with external parties that the hospital or transplant program have for services relevant to transplantation including: nursing, anesthesiology, immunology, pathology, surgery, internal medicine, infectious disease control, pathology, radiology, blood banking and patient education;
20. Any written transplant patient or living donor educational materials;
21. The written copy of the Quality Assessment and Performance Improvement (QAPI) program;
22. Any post-June 28, 2007, QAPI reports, records and minutes of QAPI committee meetings, or consultation reports about the QAPI program;
23. Log of any reported adverse events for the past 12 months (but not prior to June 28, 2007) and corresponding documentation of the investigation and analysis of those events.

TASK 3 - ORIENTATION TO TRANSPLANT PROGRAM AREAS

Observe the areas where pre- and post-operative transplant care is provided. These observations provide information about the structure of the transplant program, staffing and overall patient care delivery. Incorporate these observations into the survey process. This task is intended to provide the surveyor with a general orientation to the physical layout of the facility and the location of key areas such as patient care rooms, the outpatient clinic, pharmacy, laboratory and surgical services, personnel, and the training office.

In some cases, the number of transplant programs that must be surveyed, or the layout of a particular hospital are not conducive to a physical orientation to all of the areas at the start of a survey. For example, the hospital may have multiple intensive care units in different parts of the hospital. In these cases, the survey team should keep the orientation brief to a sample of areas, or consider a periodic or phased orientation as the survey progresses from one type of transplant program to another. The orientation does not need to include the operating rooms.

As stated earlier, there may be multiple transplant programs surveyed during a single onsite visit. Some areas of the facility or personnel may be shared among different transplant programs; others may be specific to a single program.

Guided tours of the hospital are not encouraged and should be avoided.

TASK 4 – OBSERVATIONS OF CARE

Incorporate opportunities into the survey process to directly observe patient or donor care (either for individuals that are currently admitted, or that are coming in for a follow-up visit during the scheduled timeframe of the survey). Opportunities for observation of care include patient care services provided by transplant program staff (e.g., nurses, clinical transplant coordinator, social worker, dietitian, physician, independent living donor advocate/team, etc.), multi-disciplinary team meetings, etc. Do not observe the operating suites. Ensure the provision of privacy during all observations and compare observation findings to medical record documentation.

TASK 5 – SAMPLE SELECTION

Use the lists of patients and donors provided by the transplant program as the universe for sample selection. Request the samples of medical records described below as early in the survey as possible so that the transplant program has time to obtain all records timely. Add additional records to any sample if further investigation of patterns of deficiencies, or resulting from observations or interviews.

If surveying more than one transplant program simultaneously, the surveyor should ensure that the medical record universes, the sample selections and record reviews correspond with and are maintained separately with the correct program(s).

The review of medical records should be limited to practices and activities after June 28, 2007.

A. Waiting list Sample (X054, X055, X084, X085, X088, X169, X170, X172, X186)
Select a random sample from the list of potential transplant recipients that are listed on the transplant program's waiting list. *[Note: If transplant recipients described in Sample E were both evaluated for transplant and placed on the waiting list after June 28, 2007, the surveyor may use medical records from Sample E to review the requirements for this section. Otherwise a separate sample is required.]*

Determine the size of the sample based on the guidelines below:

Size of Transplant Program's Waiting List	**Number of Recipients' Medical Records in sample size**
Between 1 and 50 individuals	3
Between 51 and 100 individuals	5
101 Individuals or More	8

B. Sample of patients removed from the transplant program's waiting list (if applicable): (X086)
This random sample is selected from the list of persons that were on the transplant program's UNET waiting list but were removed from that list within the last 12 months (after June 28, 2007). Select 3 recipients' medical records for review. If any of the 3

medical records indicate a deficiency, expand the sample size to a total of 5 records. This sample does not include patients whose waiting list status has been changed to inactive (i.e., a status "7" on the OPTN waiting list).

C. Sample of patients removed from the waiting list for reasons other than death or transplantation (if applicable). (X089)
Randomly select up to 3 individuals that were removed from the transplant program's waiting list over the last 12 months (but not before June 28, 2007), and request their medical records for review. If any of the 3 medical records indicate a deficiency, expand the sample size to a total of 5 records.

D. Sample of persons evaluated for transplant that were not placed on the waiting list (if applicable). (X088)
Randomly select up to 3 individuals that were evaluated over the previous 12 months (but not prior to June 28, 2007) for a transplant, but were not placed on the transplant program's waiting list. Request their medical records for review. If any of the 3 medical records indicate a deficiency, expand the sample size to a total of 5 records.

E. Transplant Recipient Sample (X053, X055, X072, X073, X081, X082, X90-X092, X094, X114, X116, X117, X118, X120, X125, X126, X149, X150-X158)

Based on the list of transplants that were done over the past 3 years (or after June 28, 2007) select the following number of medical records for review:

Number of transplants within last 3 years or after June 28, 2007.	**Number of records**	**Inpatient Interviews (if available)**	**Interviews Scheduled for Follow-Up Visit (if available)**	**Telephone Interviews (*only* if no inpatient or follow-up interview are possible)**
0 to 20	3	2	2	Up to 3
21 to 50	5	2	2	Up to 3
51 to 100	7	2	2	Up to 3
101 or more	10	2	2	Up to 3

F. Transplant Recipients In Which the Program's Recovery Team Was Sent to Recover the Organ for a Recipient at that Transplant Program (X072)
Based on the list of transplants that were done over the last 3 years (or after June 28, 2007) where the organ recovery was performed by the transplant program's own team for an intended recipient at that program, select up to 3 medical records for review. If any of the 3 medical records indicate a deficiency, expand the sample size to a total of 5 records. *[Note: if the transplant program recovered all deceased donor organs for recipients of a given organ type, surveyors may use the medical records of transplant recipients from Sample E for reviewing tag X072.]*

G. Living Organ Donor Sample (X058-X060, X074, X081, X082, X092, X094, X118-X124, X126, X149, X 159-168)

Based on the list of transplants that were done over the past 3 years (or after June 28, 2007) select the following number of medical records for review:

Number of living donors within last 3 years or after June 28, 2007	**Number of donor records**	**Interviews with Living Inpatient Donors (if available)**	**Interviews with Living Inpatient Donors Scheduled for Follow-Up Visit (if available)**	**Telephone Interviews with Living Inpatient Donors (*only* if no inpatient or follow-up interview are possible)**
0 to 20	3	2	2	Up to 3
21 to 50	5	2	2	Up to 3
51 to 100	7	2	2	Up to 3
101 or more	10	2	2	Up to 3

TASK 6 – PATIENT AND LIVING DONOR INTERVIEWS

Based on the lists of individuals that are currently admitted as an inpatient, and those scheduled for a follow-up visit during the survey, select 2 individuals from each group for interviews. If the transplant program does not have any individuals admitted as inpatients or scheduled for follow-up, identify up to 3 individuals for telephone interviews. For telephone interviews, the survey team may wish to have transplant program staff initially introduce the surveyor to the patient or donor being interviewed.

Refer to the interview guides following this survey protocol for suggested interview questions for the patient and living donor interviews.

If the interview is done in-person, locate a private place for the interview, and arrange the interview time(s) at the patient or donor's convenience. Interviews should be conducted privately unless the patient or donor expresses a preference to have a family member or staff member present during the interview. Discuss with the patient/donor that his or her answers may be written down, and confirm that this is acceptable to them.
After the interview, follow-up on any concerns the patient/donor has raised. Share any concerns with other team members so that they can follow-up as needed during the remainder of the survey.

In interviewing inpatients, as with other types of surveys, all patient interviews are voluntary, and surveyors should focus on those patients whose condition is sufficiently stable to permit being interviewed (e.g., not in the intensive care unit).

TASK 7 – REVIEW OF TRANSPLANT PATIENT AND LIVING DONOR MEDICAL RECORDS

Task 5 describes the number of transplant patient and living donor medical records that must be selected for review. These medical records will include pre-transplant evaluations inpatient records, and post-transplant follow-up records. These records may be in different locations, and/or be a combination of electronic and paper medical records. Please ensure that the transplant program understands that the surveyors will be reviewing records addressing the entire transplantation process and that all records should be made available. In addition, given the number of transplant programs that may need to be reviewed in a given survey, the onsite organization of the various types of medical records is important to ensuring that records are tracked to the appropriate program.

Generally, surveyors will not have time to review the entire medical record for transplant patients. Surveyors should focus the review of medical records on the following sections.

- Evaluations: Psychosocial and Medical;
- Patient Selection Criteria;
- Copies of notification or patient education materials provided;
- Informed Consent Process;
- Listing of blood type prior to activation on the waitlist (labs section and progress note section for note of waitlist activation);
- Progress Notes on patient care, staff activities, informed consent discussions, etc.;
- Multidisciplinary Care Plan, Multidisciplinary patient teaching tools – look for involvement of all key personnel;
- Discharge planning tool; and
- Follow-up (outpatient) chart or section of record.

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

TASK 8 – STAFF INTERVIEW

Inform the hospital administrator and the transplant program that any staff may be selected for an interview. If staff have responsibilities for more than one type of organ transplant program, it is permissible to cover both programs in a single interview, but please make sure to provide an opportunity for them to discuss any differences between the programs.

The following personnel should be interviewed:

Title	Number to be Interviewed
Director of the Transplant Program	Interview the Director (1)
Transplant Surgeon	Interview at least 1 - others as needed. It may, but does not have to be the primary surgeon
Transplant Physician	Interview at least 1 - others as needed. It may, but does not have to be the primary physician
Staff Nurse	Interview at least 2 - others as needed
Clinical Transplant Coordinator	Interview at least 1 - others as needed
Social Worker	Interview at least 1 - others as needed
Consultative Social Worker	Interview at least 1 if applicable
Dietitian	Interview at least 1 - others as needed
Pharmacist	Interview only if needed
Independent Living Donor Advocate(s)	Interview at least 1 - others as needed
Nursing staff hired within the last 3 months	If applicable, interview at least 1 - others as needed

Refer to the interview guides following the survey protocol that include suggested interview questions for the staff interviews.

TASK 9 - PERSONNEL RECORD REVIEW

The Surveyor should request specific personnel records from the Personnel or Human Resources Department (based on the list below) and review these records in a secure area. The review of personnel records should be focused on areas related to transplantation including qualifications, current licensure and/or certification in the state of practice (if applicable), and orientation and training related to transplantation. *Also, review the place of residence for transplant surgeons and physicians who were on-call within the last 30 days.*

Review the personnel records for the following staff working in the transplant program (the number in the parenthesis identifies the number of records to review):
Director of the Transplant Program
Transplant Surgeons (2)
Transplant Physicians (2)
Social Worker (2)
Dietitian (1)
Pharmacist (1)
Nurses (at least 2 in the transplant unit and 2 in the outpatient clinic)
Clinical Transplant Coordinators (maximum of 3 records)
Living Donor Advocate or Living Donor Advocate Team Members (up to 3)

As in other parts of the survey, the review of personnel records can be expanded to include other individuals as needed.

Surveyors should make photocopies of any documents needed to support survey findings. If requested the surveyor should provide the hospital with a copy of all items photocopied. The photocopies must include the person's anonymous code, the type of document and the date and time the photocopy was made, for example, "Nurse #5, Personnel File, 2/25/07, 1800."

TASK 10 - ADMINISTRATIVE REVIEW/COMPLETION OF HOSPITAL INFORMATION

The hospital or transplant program must have written policies and procedures and a written Quality Assessment and Performance Improvement Program (QAPI), and may have agreements or contracts for various types of services that support the transplant program's operations. Under this task, surveyors should also request updated information about the hospital. Surveyors should review the following:

Transplant Program's Policy and Procedure Manual(s)
For each transplant program being surveyed, the Surveyor must review the policies and procedures governing the operations of that program. Ensure that the program's policies and procedures are current and address the areas required in the Conditions of Participation, and that are being followed by the program.

Patient Education Materials
Review the patient education materials for compliance with the relevant areas of the regulation.

Organ Procurement Organization Agreement
The hospital must have an agreement with an Organ Procurement Organization (OPO) to recover, provide information about the donor, and ensure the proper transfer of all organs being transplanted. Review the Transplant Center and OPO Agreement to ensure that it meets the requirements of the Guidelines. Ensure that it is current and signed. (X126, X139)

Hospital Contracts
The surveyor must also review the hospital's contracts that are relevant for transplantation. Any contracts that provide transplant-related services must list the responsibilities of each party, must be current, be signed by appropriate staff, and must have 24-hour availability (this would not include tissue typing which as outlined in the interpretive guidelines (X113) is not required on a 24-hour basis). It is not required that the contract be directly with the transplant program. For example, there may be a contract for laboratory services that covers all laboratory services performed in the hospital (including the transplant program).

Review of Quality Assessment and Performance Improvement Program

The Surveyor must review the transplant program's Quality Assessment and Performance Improvement (QAPI) program and the analysis of any adverse actions that occurred in the transplant program to ensure that it meets the requirements of the Guidelines (X099 through X104).

Completion of Hospital/CAH Medicare Database Worksheet

The Hospital/CAH Medicare Database Worksheet collects information about the entire hospital's services, locations, and staffing and must be completed by state surveyors during every transplant hospital review. The worksheet must be completed by surveyors from the State Agency.

TASK 11 - PRE-EXIT CONFERENCE

During the pre-exit meeting review and analyze all the information collected from the observations, interviews, and record reviews to determine whether or not the program meets the Conditions of Participation found at 42 CFR part 482.

Survey Team Discussion Meeting

Each team member will share their survey findings, evaluate the evidence and present findings regarding compliance with each requirement. The team should document their decision, the supporting documentation of the decision and findings, and the number of patients impacted in order to determine the extent of the program's noncompliance. The team must ensure that all findings are supported by adequate documentation of the observations, interviews and document reviews. This evidence should include photocopies and any additional documentation or evidence needed to support identified non compliance prior to the exit conference. All supporting documentation must be gathered prior to the exit conference.

Determination of Compliance

A deficiency at a Condition level may be due to noncompliance with requirements in a single standard or several standards within the condition, or within the requirements of noncompliance with a single tag representing a severe or critical health or safety violation.

When a deficiency is based upon events which took place prior to the survey and the transplant program has subsequently corrected the deficient practice/issue, then the survey team must determine whether the corrective action was adequate and systemic, and has been fully implemented.

The survey team will use their judgment to determine if any actions(s) taken by the transplant program prior to the survey are sufficient to correct the deficiency or previous non-compliance and prevent the deficient practice from continuing or recurring. If the program has sufficiently corrected the deficiency and proper policies/procedures are in

place to prevent the practice from continuing or recurring, then no deficiency should be cited.

TASK 12 – EXIT CONFERENCE

Provide the Hospital Administrator (and/or designated representative) with an overview of your findings. Please ensure that an exit discussion on the survey findings for *each program* is reviewed, and that the hospital/transplant program staff understand the findings and next steps for *each program type*.

During the exit conference, the Surveyor should accomplish the following for each type of organ transplant program reviewed during the survey:

- Identify each deficiency found (including those deficiencies based on information in the TPQR);
- Provide the transplant program with specific examples of noncompliance (what the Surveyor looked at, why it did not meet the requirements of the regulation, and how the surveyor confirmed the finding);
- Provide an opportunity for the transplant program to rebut the finding by presenting additional information;
- Outline for the hospital/transplant program staff the next steps. The hospital administration will receive by mail a written form (known as the CMS-2567 form) that describes the deficiencies for all of the transplant programs that were reviewed during the survey. Following receipt of the CMS-2567, a transplant program must submit a combined plan of correction for all of the transplant programs within 10 days; and
- Explain that all findings are preliminary and subject to administrative review.

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

TASK 13 - POST SURVEY ACTIVITIES

Post-Survey Activities

Surveys Conducted by State Agencies

Following the survey, the State will complete the Hospital Worksheet, the Organ Transplant Hospital Worksheet, Form 670, and the CMS-2567 form. The Hospital Worksheet, Form 670, and the CMS-2567 should be entered into ASPEN. The Organ Transplant Hospital Worksheet should be sent to CMS CO within 3 business days following the survey, with a copy to their CMS RO.

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

The CMS RO may, at its discretion, require their review of the CMS-2567 prior to its finalization. Once the CMS-2567 is finalized, the SA is responsible for sending the CMS-2567 to the hospital administrator and requesting a plan of correction from the provider (note the plan of correction may include more than one type of transplant program). Once an acceptable plan of correction has been submitted, the State is responsible for scheduling the follow-up visit to ensure that any deficiencies have been corrected. The SA will notify the CMS RO whether or not the transplant program(s) can be approved. The certification kit in ASPEN has not yet been adapted to allow SAs to communicate transplant program approval or disapproval information to the regional offices. Until these changes are made, a workaround process with the form CMS-1539 will be necessary.

The RO will notify transplant programs of their approval or disapproval under the new survey and certification process. If a transplant program is approved, the RO will send an initial approval letter using a template provided by CMS CO with a copy to CMS CO and the fiscal intermediary. If a transplant program cannot be approved, the RO will notify the provider after discussion with CMS CO via e-mail or phone. See Chapter 3 of the State Operations Manual for additional information.

Surveys Conducted by the National Contractor

Following the survey the National Contractor will complete the Organ Transplant Hospital Worksheet, Form 670, and CMS-2567, and send these documents to CMS CO within 3 business days following the survey, with a copy to the applicable CMS RO. If the RO has comments, or would like edits or clarification about any aspects of the CMS-2567, the RO may contact the CO Project Officer, or, at a minimum, should include the CO Project Officer on any correspondence and/or conference calls to provide this feedback to the Contractor.

There will be one CMS-2567 prepared even if the survey was conducted on multiple transplant programs within a hospital. Each tag that is cited must specify the applicable transplant program. ASPEN has been modified to include this information.

The RO will load the CMS-2567 into ASPEN, send the CMS-2567 to the hospital administrator, and get a plan of correction from the provider (note the plan of correction may include more than one type of transplant program). The RO will approve any plan of correction, and notify the CMS CO Project Officer when the Contractor should schedule a follow-up survey to ensure that any deficiencies have been corrected.

The RO will notify transplant programs of their approval or disapproval under the new survey and certification process. If a transplant program is approved, the RO will send an initial approval letter including the information provided by CMS CO, with a copy to CMS CO, the fiscal intermediary, and the ESRD Network if the program is a kidney

program. If a transplant program cannot be approved, the RO will notify the provider following a discussion with CMS CO via e-mail or phone.

ALTERNATE SURVEY PROTOCOL: PEDIATRIC HEART PROGRAM

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

INTRODUCTION

The transplant program survey and certification process includes an option established by the *Omnibus Budget Reconciliation Act of 1987* (Section 4009(b), P.L. 100-203). Under this option, a pediatric heart transplant program may receive Medicare approval by meeting an alternate set of criteria instead of the Medicare Conditions of Participation that are outlined under the regulation (Sections §482.72 through §482.74, and §482.80 through §482.104). For approval under this option, a pediatric heart transplant program must be jointly operated with another Medicare-approved hospital with a Medicare-approved heart transplant program, the programs must be operated in a unified manner, and the program must demonstrate that it can provide for the specialized needs of pediatric heart transplant patients. (See Tags X024 through X026).

The requirements under this pediatric heart transplant program option are different enough from the Medicare Conditions of Participation for other types of transplant programs, that an alternate survey protocol is required. Use the alternate survey protocol outlined below for reviewing any pediatric heart transplant program that seeks Medicare approval under this option.

TASK 1 – PRE-SURVEY PREPARATION OFF SITE

- Review the Transplant Program Quarterly Report (TPQR) for the Name and identification number of the associated heart transplant program that is jointly operating the pediatric transplant program;
- Review both the pediatric heart transplant program's history and the history of the associated heart transplant program for any prior survey and certification issues; and
- Review complaint allegations in ACTS for both the associated heart transplant program and the pediatric program. Note the frequency, significance, severity, types of complaints and (if substantiated) the resolution.

Refer to the standard survey protocol for a description of the pre-survey team meeting and areas to be discussed. Similar to the standard survey protocol, the pre-survey preparation should still identify any issues associated with this type of program and prepare for conducting the survey.

TASK 2 – ENTRANCE ACTIVITIES.

Refer to the standard survey protocol for a description of the entrance conference. For the alternate survey protocol, the list of suggested documents includes the following:

Suggested Survey Document List:

Lists of Transplant Candidates, Patients and Living Donors:

1. Log of the transplants performed including name and date of transplant for both the pediatric heart transplant program and the associated heart transplant program within the past three years or after June 28, 2007, whichever is later;
2. List of transplant inpatients and their location in the hospital (unit, and floor) for both the pediatric heart transplant program and the associated heart transplant program;
3. List of post-transplant patients that are scheduled for follow-up visits during the survey timeframe for both the pediatric heart transplant program and the associated heart transplant program;

Program Administration: Policies, Procedures, Personnel, and QAPI

4. The current policy and procedure manual of the pediatric heart transplant program;
5. The current policy and procedure manuals of the associated heart transplant program (if different from the pediatric heart transplant program);
6. A copy of the joint operating agreement between the program and the associated heart transplant program that is jointly operating this program;
7. A copy of the transplant program's written waiting list selection criteria for patients;
8. An organizational chart of the pediatric heart transplant program and the associated program;
9. Any written transplant patient or living donor educational materials;
10. A copy of the written Quality Assessment and Performance Improvement (QAPI) program;
11. Any post June 28, 2007, QAPI reports, records and minutes of QAPI committee meetings, or consultation reports about the QAPI program;
12. Log of any reported adverse events (by the pediatric heart transplant program and associated program) and corresponding documentation of the investigation and analysis of those events for the past 12 months or after June 28, 2007, whichever is later.

TASK 3 – ORIENTATION TO TRANSPLANT PROGRAM AREAS

Refer to standard survey protocol.

TASK 4 – OBSERVATIONS OF CARE

Refer to standard survey protocol.

TASK 5 – SAMPLE SELECTION

Using the lists of patients of the pediatric heart transplant program and the associated heart transplant program, request the samples of records described below as early in the survey as possible so that the transplant program has time to obtain all the records you

request. At any time, the Surveyor may add additional records to any sample based on observations or interviews.

Pediatric Heart Transplant Recipients
Based on the list of transplants done over the past 3 years (but not prior to June 28, 2007) by the pediatric heart transplant program, select up to 5 pediatric heart transplant recipients and request their medical records for review.

Heart Transplant Recipients in the Associated Heart Transplant Program
Based on the list of transplants done over the past 3 years (but not prior to June 28, 2007) by the associated heart transplant program, select up to 5 transplant recipients and request their medical records for review.

TASK 6 – PATIENT INTERVIEWS

Not required. Interviews may be conducted if the survey findings indicate that interviews are necessary to determine compliance with 42 CFR 482.76(d).

TASK 7 – REVIEW OF TRANSPLANT PATIENT AND LIVING DONOR MEDICAL RECORDS

Task 5 describes the number of transplant patient medical records that must be selected for review both in the pediatric heart transplant program and the associated program.

Surveyors should focus the review of medical records on the following sections.

- Evaluations: Psychosocial and Medical
- Patient Selection Criteria
- Informed Consent Process
- Listing of blood type prior to activation on the waitlist (labs section and progress note section for note of waitlist activation)
- Operative Reports
- Progress Notes for patient care, staff activities, informed consent discussions, etc.
- Multidisciplinary Care Plan, Multidisciplinary patient teaching tools – look for involvement of all key personnel
- Discharge planning tool
- Follow-up (outpatient) chart or section of record

The primary objective of this task is not to determine whether the program meets all of the requirements of the Medicare Conditions of Participation, but to compare the medical records of the pediatric heart transplant program and the associated heart transplant program. This comparison should provide evidence that 1) the program is operating in a unified manner with the associated heart transplant program; and 2) the pediatric heart transplant patients are receiving the specialized facilities, services and personnel as required by the regulation.

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

TASK 8 – STAFF INTERVIEW

Inform the hospital administration and the transplant program that any staff may be selected for an interview.

If the survey findings indicate that the pediatric heart transplant program is either 1) not operating jointly with an associated transplant program, or 2) is not able to provide the specialized facilities, services, and personnel required by pediatric patients, the Surveyor may interview any transplant program staff of the pediatric heart transplant program or the associated heart transplant program (e.g., the Administrator, transplant surgeons, clinical transplant coordinators, etc.) to seek additional information.

Refer to the handout of suggested interview questions for the patient and living donor interviews.

TASK 9 – PERSONNEL RECORD REVIEW

Personnel Sample

To review personnel records, the Surveyor should request specific personnel records from the Personnel or Human Resources Department (based on the sample described below) and review the records in a secure area. Personnel records may be reviewed for any staff working with pediatric heart transplant program to verify that they meet the qualifications required in the joint operating agreement.

Review the personnel records for the following staff working in the transplant program:

Director of the Transplant Program
Transplant Surgeons (1)
Transplant Physicians (1)
Social Worker (1)
Nurses (at least 1 in the transplant unit)
Clinical Transplant Coordinator (1)

TASK 10 – ADMINISTRATIVE REVIEW

Operating Agreement

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

Completion of Hospital/CAH Medicare Database Worksheet

Refer to standard survey protocol.

TASK 11 – PRE-EXIT CONFERENCE

Review and analyze all the information collected from the observations, interviews, and record reviews to determine whether or not the program meets the requirement of 42 CFR 482.76(d) for approval of a pediatric heart transplant program. The survey team's analysis of the findings is then prepared for presentation at the exit conference.

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

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

TASK 12 – EXIT CONFERENCE

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

TASK 13 – POST SURVEY ACTIVITIES

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

SUGGESTED INTERVIEW GUIDES

Suggested Questions for Organ Transplant Recipients

1. When you were considering whether or not to have an organ transplant, what types of information did the transplant program discuss with you, or give you in writing?

2. Did staff from the transplant program talk with you about the criteria they use to add someone to the transplant waiting list? Who from the transplant program discussed this with you? Did you request a written copy their selection criteria?

3. Were you notified of your status on the waiting list? Did the program staff keep you up-to-date with program changes that affected their ability to transplant (such as changes in personnel, vacations, etc)? Who from the transplant program notified you of your status and program changes?

4. During the transplant process, did you talk with the social work staff of the hospital? When did he/she talk with you? Was there specific assistance that he or she provided? Were there specific things that he or she discussed with you about getting the transplant, how things might change, or what would be needed after the transplant?

5. Was there a team of people from the transplant program staff (medical personnel, social workers, dietitians, etc) that are (were) working with you?

6. Did you/ or do you know what the general timeframe is for your care, the recovery from the surgery (if applicable), and what is needed to make sure the transplant is successful?

7. Could you talk about what the staff told you about the transplant, what the surgery would involve, what your options were, what their experience is with this type of transplant surgery, and how this would affect various areas of your life? Was there anything that surprised you, that you wish that someone would have talked with you about, but didn't?

8. What have you been told about the medications for your new organ? Do these medications have any side effects?

9. Did the staff from the transplant program talk with you about getting or paying for the medications that you need? Who discussed this with you?

10. Were there areas that the transplant program talked with you about related to your nutrition or diet with your new organ? Who discussed this with you?

11. Did the transplant program talk with you about any signs and symptoms that may indicate that you need to contact the doctor? Do you know which doctor(s) you should contact?

12. What information or education have you received about your care after you go home? How often will you need to return to clinic? Do you have the pertinent phone numbers for questions? What other information have you been given?

13. Are there any areas that we didn't cover, that are important for me to know about in the care that you received, or things that you wish you would have known or received more information about before the transplant?

    Thank you for sharing this information with me. Do you have any questions about this interview?

Suggested Questions for Living Organ Donors

1. When you were considering whether or not to donate an organ, what types of information did staff from the transplant program provide to you? (This could be information about the donation itself or about the options that a transplant recipient would have.)

2. While you were being considered as a potential donor and after the donation surgery, did you talk with the social work staff of the hospital? Was there specific assistance that he or she provided? Were there specific things that he or she discussed with you about donating the organ, how things might change, or what supports you might need in recovering from the donation surgery?

3. While you were being considered as a potential donor and after the donation surgery, did you talk with someone who was designated to work with just living donors? What types of assistance or information did he or she provide?

4. Did you/ or do you know what the general timeframe is for your care, and the recovery from the donation surgery?

5. Is (Was) there a team of people from the transplant program staff (medical personnel, social workers, dietitians, etc) that are (were) working with you? Did you participate in any team meetings with the staff to discuss your donation surgery and recovery?

6. What information or education have you received about the medications related to donation?

7. Could you talk about what the staff told you about the donation, what was involved in the surgery, what your options were, what their experience is with this type of transplant surgery, and how this would affect various areas of your life? Was there anything that surprised you, that you wish that someone would have talked with you about, but didn't?

8. Were there areas that the transplant program talked with you about related to your nutrition or diet in the recovery from donation or following donation?

9. What information and education have you received about your care after you go home? Did staff from the transplant program talk with you about any signs and symptoms following discharge that may indicate that you need to contact the doctor? Do you know which doctor(s) you should contact?

10. Are there any areas that we didn't cover, that are important for me to know about in understanding the care that you are receiving (have received), or things that you wish you would have known or received more information about prior to donation.

Thank you for sharing this information with me. Do you have any questions about this interview.

1) DIRECTOR OF THE TRANSPLANT PROGRAM
   a) *General Questions*
      1. What responsibilities do you have as the director of the transplant program?
      2. What role do you have in evaluating the quality of patient care, reviewing adverse events, or other quality assurance or quality improvement activities?
      3. How is it decided what type of training will be offered for the transplant program staff?
      4. How do you assess the need for staffing, and the patient or resource needs for your program?

   [Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

2) TRANSPLANT SURGEON or TRANSPLANT PHYSICIAN
   a) *General Questions*
      1. What are your responsibilities as a transplant surgeon/physician?
      2. What role do you have in the overall coordination of the transplant process for the patient from pre-transplant to discharge and follow-up care?
      3. How does the multidisciplinary team develop an on-going plan of care for the organ transplant recipient and how often is that plan updated?
      4. Have there been any instances when a transplant was unable to be performed because a transplant surgeon or physician was not available?
      5. For Surgeons: Are you ever responsible for direct supervision of a transplant surgery, versus performing the surgery itself? If yes, how is the direct supervision accomplished?
   b) *For Programs with Living Donors (generally kidney and liver)*
      6. When there is a living donor transplant, what is your role, if any, in the care for that living donor?
      7. How does the multidisciplinary team develop an on-going care plan for the organ transplant donor and how often is this updated, is this care provided by a different team?
      8. Is there a formal process for reviewing the living donor's suitability for donation with the living donor advocate?

   c) *When the surgeon/physician works with more than one type of transplant programs (e.g., heart and heart/lung).*
      9. Given your role working with transplants for several types of organs, are there any differences in terms of how the teams function, care planning, etc.

   [Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

3) STAFF NURSE

a) *General Questions*

1. What are your responsibilities as a staff nurse for the organ transplant patient?
2. What specialized training did you receive prior to caring for an organ transplant recipient?
3. What type of continuing training is provided for you?
4. What do you teach patients about post-hospitalization follow-up, medications and side effects of medications, reportable signs and symptoms of infection and rejection? What do you teach patients about contacting the doctor(s) if they experience certain symptoms?
5. Describe in detail your role on the multidisciplinary transplant team. How does the multidisciplinary team develop an on-going plan of care for the organ transplant recipient and how often is that plan updated?
6. Have there been any instances when a transplant was unable to be performed because a transplant surgeon or physician was not available?

b) *For Programs with Living Donors (generally kidney or liver)*

7. When there is a living donor transplant, what is your role, if any, in working with that living donor?
8. How does the multidisciplinary team develop an on-going care plan for the organ transplant donor and how often is this updated, is this care provided by a different team?

c) *When the nurse works with more than one transplant programs.*

9. Given your role working with transplants for several types of organs, are there any differences in terms of how the teams function, how care is planned, your role in patient education, etc.

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

4) CLINICAL TRANSPLANT COORDINATOR

a) *General Questions*

1. What are your responsibilities as a clinical transplant coordinator?
2. Describe evaluation process for potential organ transplant candidates.
3. What is the process for determining who is selected to be placed on the waiting list? Who is involved in the decision?
4. Who is responsible for monitoring changes to the clinical information of the patients on your transplant program's waiting list and updating UNET with any changes?
5. What are your responsibilities for patient education, pre-op, post-op?
6. What are your responsibilities in working with the Organ Procurement Organization (OPO) when a potential donor organ becomes available?

7. Describe the informed consent process. When does this process start and when does this process end? What is your direct role in this process? (This question is focusing on the entire process of informed consent, not a document signature prior to surgery.)
8. How do you determine a patient is competent for self-care at home? What are your discharge criteria for organ transplant patients?
9. Describe in detail your role on the multidisciplinary transplant team.
10. Have there been any instances when a transplant was unable to be performed because a transplant surgeon or physician was not available?
11. Do you have a regular schedule or process for communicating with the dialysis facilities that are serving patients on the waiting list? *[Applies to kidney-only and kidney/pancreas programs]*
12. Please describe how inpatient dialysis services are available if needed. *[Applies to kidney-only and kidney/pancreas programs]*

b) *For Programs with Living Donors (generally kidney or liver)*

13. When there is a living donor transplant, what is your role, if any, in working with that living donor?
14. How does the multidisciplinary team develop an on-going care plan for the organ transplant donor and how often is this updated, is this care provided by a different team?

c) *When the clinical transplant coordinator has responsibilities for more than one type of transplant program (e.g., kidney and pancreas).*

15. Given your role working with transplants for several types of organs, are there any differences in terms of how the teams function, care planning, etc.

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

5) SOCIAL WORKER

a) *General Questions*

1. What are your responsibilities as a Social Worker within the organ transplant program?
2. Please discuss any initial or ongoing training you received regarding working with transplant recipients.
3. Describe in detail your role on the multidisciplinary transplant team.
4. Do you have responsibilities for communicating with referring hospitals, dialysis facilities, etc? If yes, please describe. If no, who is responsible for these activities?
5. What are your responsibilities for evaluating pre-transplant patients and working with post-transplant patients?
6. How is the waiting list information kept up to date for pre- transplant patients?
7. Describe the psychosocial evaluation process for organ transplant candidates.
8. What are your responsibilities for patient education, pre-op, post-op?

9. If you are not an MSW, is there someone in the hospital who is an MSW who you consult with on transplantation and social work issues.
10. How do you determine a patient is competent for self-care at home? What are your discharge criteria for organ transplant and organ donor patients?
11. Have there been any instances when a transplant was unable to be performed because a transplant surgeon or physician was not available?

b) *For Programs with Living Donors (generally kidney or liver)*

12. What are your responsibilities for evaluating potential donors and working with patients post-donation?
13. Please discuss any initial or ongoing training you received regarding working with transplant recipients.
14. Describe the psychosocial evaluation process for prospective organ donors.
15. Are you involved in the multidisciplinary team for living donors?
16. What is your involvement, if any, with the independent living donor advocate?

c) *When the social worker works with more than one transplant programs.*

17. Given your role working with several types of organ transplants, are there any differences in terms of how the teams function, care planning, etc.

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

6) CONSULTATIVE MSW social worker (if applicable)

For MSW social workers in the hospital that provide consultation to a non-MSW transplant social worker.

a) *General Questions*

1. What role do you have in working with the non-MSW social worker (for example, supervisor, mentor, colleague)?
2. Describe examples of cases or situations where you provided consultation to the non-MSW transplant social worker.

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

7) DIETITIAN

a) *General Questions*

1. What are your responsibilities as a transplant dietitian?
2. Do you (or another dietitian) see all transplant patients. If not, what type of transplant cases are typically referred to you?
3. Please discuss any initial or ongoing training you received regarding working with transplant recipients.
4. Describe the complete dietary evaluation for organ transplant.

5. What are your responsibilities during evaluation and follow-up of pre-transplant and post transplant patients?
6. Describe your role on the multidisciplinary transplant team.
7. Do you have any responsibilities for patient education, pre-op, post-op?
8. What are your discharge criteria for organ transplant and organ donor patients?

b) *For Programs with Living Donors (generally kidney or liver)*

9. What are your responsibilities for evaluating potential donors and working with patients post-donation?

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

8) PHARMACIST

a) *General Questions*

1. What are your responsibilities as a Transplant Pharmacist?
2. Please discuss any initial or ongoing training you received regarding the transplantation process, or working with transplant recipients.
3. Describe your role in evaluation and follow-up of organ transplant patients.
4. Describe your responsibilities and participation in the multi-disciplinary team.
5. Are there pharmacological screening criteria used in the transplant program evaluation, are these selection criteria followed?
6. How are the medications updated on the patient profile, how is this communicated and verified by the transplant team. How are medication changes and updates communicated to the transplant or donor patient pre and post procedure?
7. What are your responsibilities for patient education, pre-op, post-op?
8. What are your discharge criteria for organ transplant patients?

b) *For Programs with Living Donors (usually kidney or liver)*

9. How are you involved in the care provided to living donor patients?

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

9) INDEPENDENT LIVING DONOR ADVOCATE

a) *General Questions*

1. What are your responsibilities as a Living Donor Advocate?
2. Please discuss any initial or ongoing training you received regarding the transplantation process and working with living donors.
3. What role do you have in determining whether a potential organ donor is suitable for donation?
4. What role do you play in the informed consent process for living donors?

5. Explain the discussion you have with the donor related to emotional/psychological aspects of living donation prior to donation. For example what do you discuss with them related to family support, donor decision to donate or not to donate, future support of the donor and potential need for medical, social and financial care of donor related to adverse events.
6. Discuss the physical aspects of living donation that you discuss with the patient related to all phases and aspects of living donation
7. Discuss the financial aspects of living donation that you review and discuss with the patient, health insurance, future medical needs and coverage, private insurance vs. Medicare coverage.
8. How do you ensure that the donor understands the donation process?
9. Have there been any instances in which there were differences of opinion about a living donor's suitability? Is so, what steps were taken to resolve these differences? If not, what would you do if the situation came up, is there a process for resolving these issues?
10. Please describe any other responsibilities you may have in the hospital other than working as a Living Donor Advocate.

b) When the independent living donor advocate works with more than one transplant program.

11. Given your responsibilities in several types of organ transplants, are there any differences in how the different multidisciplinary teams function for living donors, or in the decision-making process for determining the suitability of a living donor.

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]

10) NEWLY EMPLOYED STAFF NURSES (If applicable):

a) *General Questions*

1. Discuss your first 3 months working in the transplant program:
   - What supervision did you have?
   - Did you have a preceptor?
   - What role did he/she serve?
   - What training did you receive?

[Note: Also include areas that require follow-up discussion and/or confirmation based on the findings from record reviews and observations.]