



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-19-11-Transplant

DATE: March 29, 2019
TO: State Survey Agency Directors
FROM: Director
Quality, Safety & Oversight Group
SUBJECT: Transplant Program Survey Activity Transition

Memorandum Summary

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

Discussion

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

1. Initial Approvals:

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

Before any on-site survey activity may be scheduled for an initial approval, the SA must request and review information from the CMS Central Office (CO) regarding the number of transplants that the applicant has performed (clinical experience), the applicant's conformance with the Organ Procurement Transplantation Network (OPTN) reporting requirements, and the applicant's compliance with the performance outcome measure requirements under §482.80. The SA should submit a request for this information through the mailbox at SCG_transplantteam@cms.hhs.gov. SA requests should be made 15-30 days prior to the upcoming survey. The CMS CO will provide a report of compliance or noncompliance for each of the above requirements.

Regardless of whether the report indicates any noncompliance at §482.80(a), an initial survey must be scheduled. The applicant may, per §488.61, request consideration of mitigating factors causing the noncompliance with §482.80, except for situations of immediate jeopardy. The survey team should inform the program of any indicated noncompliance with the requirements at §482.80 at the time of the entrance and exit conferences. No survey activity is necessary on-site for non-compliance identified with these requirements. Because compliance with this requirement is based solely upon data submitted by the applicant to the Scientific Registry of Transplant Recipients (SRTR) and the applicant has already been provided with an opportunity to correct any errors, the applicant may not provide any information to the survey team on-site to change the non-compliance determination.

Initial surveys may not be scheduled until the SA receives an "approval recommended" notification from the MAC.

Office of Civil Rights clearance is not required separately for the transplant program located within the Medicare-certified hospital.

If at the time of the initial survey, the applicant is determined to be in compliance with all participation requirements, usual certification procedures, per State Operations Manual Chapter 2, should be followed for initial approval including requesting and receiving an acceptable plan of correction, if applicable, and providing recommendation for approval to the CMS Regional Office (RO) via the form CMS-1539. If approved, the CMS RO will notify the provider of its approval, issue the transplant program a CMS certification number (CCN) (one CCN within the 9800 series is assigned to all transplant programs operating within a single hospital) and will submit a Form CMS-2007 to the MAC.

If the applicant is determined to be out of compliance with any condition of participation other than §482.80, the initial application should be denied and all usual certification processes should be followed including sending a CMS-2007 to the MAC. If the applicant is determined to be out of compliance with the measures at §482.80(c), it should be cited on the Form CMS-2567. The applicant may request consideration of mitigating factors. The plan of correction must specifically state that the applicant is requesting such consideration.

All mitigating factors considerations are conducted by the Division of Continuing Care Providers (DCCP) within CMS CO. When the SA receives a plan of correction from an applicant indicating a request for consideration of mitigating factors, the CMS-2567 and plan of correction should be forwarded as soon as possible to DCCP via mailbox SCG_transplantteam@cms.hhs.gov.

DCCP will acknowledge the request from the provider and provide the timelines for the consideration. If the applicant does not wish to apply for mitigating factors for non-compliance at §482.80 the initial application should be denied, the provider notified of the denial and a Form CMS-2007 forwarded to the MAC.

2. Re-approvals:

Under the FY 2019 Mission and Priority Document, approved transplant programs are to be surveyed for re-approval at a 5 year survey interval. Approximately 15-30 days prior to the scheduled survey, the SA must request a report from the CMS CO regarding the current compliance status of the program with the requirements of §482.82.

The request should be submitted to DCCP via mailbox at SCG_transplantteam@cms.hhs.gov and should indicate for which organ program the information is being requested. The information will be provided directly to the person in the SA making the request and will be provided on a Transplant Program Quality Report (TPQR). Attachment B of this memorandum provides a sample of the TPQR.

If the TPQR indicates noncompliance with the requirements of §482.82, this finding should be cited on the CMS-2567 and the transplant program notified of the noncompliance at both the entrance and exit conference of the survey. Noncompliance with OPTN reporting requirements may be cited at the Standard level at §482.82(a). Noncompliance with the clinical experience requirements may be cited at the Standard level at §482.82(b). Noncompliance with the outcome measures at §482.82(c) should be cited at the Condition level for §482.82. For this noncompliance only, the transplant program may request consideration of mitigating factors in its plan of correction for the non-compliance at §482.80(c). The plan of correction must specifically state that the applicant is requesting such consideration.

SAs may follow usual certification procedures in cases where the survey determines that the program is in compliance with all conditions of participation. For surveys resulting in condition level noncompliance with requirements other than §482.82, the SA should issue the standard termination letter, request a plan of correction and conduct a follow-up visit. In cases where §482.82 is determined to be one of the conditions that is out of compliance, the termination letter must acknowledge both the 90 day termination track and the mitigating factors termination track. Sample language for these instances has been included in this memorandum as Attachment C.

SAs should schedule a minimum of two (2) surveyors for abdominal transplant program surveys and a minimum of two (2) surveyors for thoracic transplant program surveys. These are separate teams and should not be combined even if the programs are all surveyed simultaneously. Refer to the transplant program survey protocol for additional discussion on team composition.

When more than one transplant program is surveyed at a hospital, all deficiency citations from all the programs may be entered onto one Form CMS-2567. However, the deficiencies cited for each program must be separate and clearly identifiable for the applicable program. The Automated Survey Processing Environment (ASPEN) program allows for the selection of distinct programs.

Transplant programs are required to also meet the requirements for hospitals at §482.1 through §482.57. In the course of a transplant program survey, a surveyor may identify possible noncompliance with the hospital regulations. If the hospital in which the transplant program is located is not a deemed facility, these concerns may be investigated as a hospital complaint investigation and cited on a separate Form CMS-2567 under the name and CCN of the hospital in which the transplant program is located.

However, if the hospital is a deemed facility, the surveyor must contact his/her office and receive permission to conduct a hospital complaint investigation. Any deficiencies cited under the hospital requirements must be entered onto a separate CMS-2567.

3. Required Notifications to CMS:

Under §482.74, approved transplant programs must immediately notify CMS of any significant changes related to the transplant program that could affect its compliance with the conditions of participation. These changes include, but are not limited to, changes in key staff members such as the primary transplant surgeon, as designated to the OPTN and the primary transplant physician, as designated to the OPTN; and any inactivation by the transplant program (see further discussion on inactivation at section #6 below).

All approved transplant programs were notified by letter dated Dec. 21, 2018 that as of 1/1/2019 these notifications should be made to the applicable SA. Because they are associated with survey activity, these notifications must be maintained by the SA for reference at the time of re-approval surveys. If the surveyor determines that the transplant program failed to notify CMS (through notification to the SA) of these key changes, a deficiency should be cited at §482.74.

On January 23, 2019, DCCP forwarded to each SA the past notifications submitted to CMS (changes in key personnel and in-activations) by each approved transplant program within the SA's jurisdiction. These documents were provided to ensure that each SA has all available historical data for the programs for reference.

4. Reasonable Assurance:

All transplant programs that are involuntarily terminated from the Medicare program or that voluntarily withdraw from the program during an enforcement action in progress are subject to a reasonable assurance period if readmission is sought. This includes terminations based upon noncompliance with §482.82. CMS ROs may not waive reasonable assurance requirements for noncompliance with §482.82. A program may be eligible to re-enter the Medicare program if it meets the requirements specified in the SOM, Section 2016.

5. Program Inactivation:

A transplant program may choose to voluntarily inactivate its program. If they do so, they must notify the patients on their waitlist and CMS of the inactivation. The program must assist the patients if they want to transfer to another program as a result of the inactivation without loss of wait time. A voluntary inactivation may not exceed 12 consecutive calendar months (§488.61(e)).

The SAs should:

- Acknowledge the notification of a voluntary inactivation;
- Remind the provider that they must notify the SA when the inactivation ends; and,
- Remind the provider that the voluntary inactivation may be no longer than 12 consecutive calendar months for the program to retain its approval.

Sample language for the acknowledgment of inactivation has been included in this memorandum under Attachment D. The SA must monitor all inactive transplant programs to ensure that the inactivation does not exceed the 12 month limitation. Once the program reaches its 11th month of voluntary inactivation, the SA should contact the program again to inquire as to the intentions of the program. Sample language for this notification has been included in this memorandum under Attachment E.

Prior to going on site for a re-approval survey, the survey team should check to see if the program had any voluntary inactivation since the last survey. If so, confirm during the survey that patients on the program's waitlist were notified of the inactivation and assistance provided as indicated. Voluntary inactivation does not impact the survey interval clock. The program is responsible for continuing to meet all conditions of participation during an inactivation. If during the course of a survey it is determined that the provider implemented a voluntary inactivation but did not notify CMS, a deficiency should be cited for §482.74(a)(3). If a surveyor finds that patients were not notified properly of an inactivation or were not provided requested assistance, a deficiency should be cited for §482.102(c)(3).

6. Complaint Investigations:

The SAs resumed responsibility for all complaint investigations of transplant programs as of September 8, 2017. Refer to Admin Info Memorandum 17-28-Transplant.

7. The Survey Protocol:

The survey protocol for transplant programs focuses primarily on the transplant recipient and living donor experience as anticipated by the conditions of participation. The survey protocol has been included in this memorandum as Attachment I. A schematic that identifies the most critical aspects of the survey has also been included as Attachment F.

8. Websites (SAs):

It is recommended that SAs maintain the following transplant program information on their websites:

- Current Conditions of Participation;
- Current Interpretive Guidance;
- List of information and materials that must be submitted for initial applications;
- Contact person or mailbox for submission of Changes in Information and Inactivation;
- Survey training hyperlink for Transplant Basic Course;
- Contact name or mailbox for requests for verification of Medicare approval;
- Procedures for submission of request for consideration of mitigating factors (Included as Attachment G); and
- Contact person or mailbox for submission of questions by Transplant Providers.

9. Surveyor Training:

The Transplant Program Basic Surveyor Course went live on October 6, 2018. The course may be accessed via <https://surveyortraining.cms.hhs.gov/>.

10. Reference Information:

A Glossary of common terms for transplant programs has been included in this memorandum for your information as Attachment H. This memorandum also forwards final Interpretive Guidance for transplant programs as Attachment J. Final revised State Operations Manual revisions at Sections 2060, 2068 and 3012.3, which provide specific guidance for survey and approval of transplant programs, are included in this memorandum as Attachment K.

11. SA Funding:

Funding for transplant survey activity was added to the FY 2019 SA budget for survey activity beginning in January, 2019 as part of the state's overall allocation. States should work with their Regional Office for specific issues related to funding.

Contact: After the transition of the survey workload the staff from DCCP will be available for questions via mailbox SCG_transplantteam@cms.hhs.gov

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers, and State and RO training coordinators within 30 days of the memorandum.

/s/
Karen Tritz
Acting Director

Attachment (s)-

- A. Initial Application Information
- B. Transplant Program Quality Report
- C. Sample Language Non-Compliance
- D. Sample Language Acknowledgement of Voluntary Inactivation
- E. Sample Language Reminder of 12 Month Inactivation Deadline
- F. Survey Schematic
- G. Application for Requesting Consideration of Mitigating Factors
- H. Glossary
- I. Transplant Program Survey Protocol
- J. Transplant Program Interpretive Guidance
- K. State Operations Manual Section 2060,2068 and 3012.3

cc: Survey and Certification Regional Office Management

Attachment A: Required Information for all Applications for Medicare Approval of Transplant Programs

Name of Transplant Hospital

Address of Transplant Hospital

Type(s) of Transplant Program(s) for which Medicare Approval is Requested

Address of Transplant Program (if different from transplant hospital)

Name of the Transplant Program Director (for each program approval requested)

Telephone Number of Transplant Program Director (for each program approval requested)

E-Mail Address of the Transplant Program Director (for each program approval requested)

Fax Number of the Transplant Program Director (for each program approval requested)

National Provider Identifier (NPI) Number for the Transplant Hospital

CMS Certification Number for the Transplant Hospital in Which the Transplant Program is Located

Organ Procurement Transplant Network (OPTN) Membership Identifier

Name of the Primary Transplant Surgeon Designated to the OPTN (for each program approval requested)

Name of the Primary Transplant Physician Designated to the OPTN (for each program approval requested)

The Volume (number of transplants performed) Within the Last Year to Meet the Transplant CoP Volume Requirements for Initial Approval. See 42 CFR 482.80(b)

If you are requesting approval for a pediatric heart transplant program under the alternative approval criteria (42 CFR 482.76(d)) please include the following in your application:

- The National Provider Identifier (NPI) of the Other Facility
- Name of the Shared Transplant Surgeon

All requests for Medicare approval must be signed and dated by an authorized representative of the Transplant hospital.

Attachment B: CMS Transplant Program Quality Report (Example)

Hospital CMS Certification Number: XXXXXX
Hospital Name: Peggye's Medical Center
Address: _____
City: _____
State, Zip Code: _____, _____
Types of Transplant Programs: AHO

Transplant Program Type: Adult Heart-Only
CMS Transplant CCN: _____

A. **DATA SUBMISSION:** (42CFR 482.80 / 42CFR 482.82):

NOT MET

If No, the supporting evidence:

1907 OPTN forms submitted out of 1933 expected during the date range 04/01/2010 to 06/30/2014= 93.9%

B. **CLINICAL EXPERIENCE** (42CFR 482.80 / 42CFR 482.82):
Clinical Experience (Volume)

NOT MET

If No, Supporting Evidence:

Date Range: 07/01/2016 to 06/30/2017

Re-Approval: Average Number of Transplants Over Previous 3 Years **11**

C. **OUTCOME REQUIREMENTS:** (42CFR 482.80 / 482.82):

NOT MET

Patient or Graft Survival

If NO, Supporting Evidence:

SRTR Center Specific Report (CSR) Published: 10/10/2018

This program was identified with 2 flags for 1 year patient survival in July 2017 & January 2018.

- Observed/expected= O/E- 2.27
- Observed-expected= O-E- 5.6
- p-value- 0.015
- Expected survival rate 97.6%
- Actual survival rate 94.4%

Attachment C: Sample Language for Non-Compliance:

The following draft language may be inserted into a standard notice of pending termination letter for non-compliance at 42 CFR §482.80 or §482.82 when another condition (other than 42CFR 482.80 or 482.82) is also cited.

As a result of these findings, your transplant program has been given two prospective Medicare approval termination dates. Based on the deficiencies cited at *[list the condition(s) other than §482.80 or §482.82]*, a termination date of *[add 90 day date]* has been set. The deficiencies listed at these regulatory citations must be corrected before *[90 day date]*. If they are not corrected by that date the termination of your Medicare approval will proceed.

Based on the deficiencies cited at §482.80 or §482.82, a termination date of *[add 210 date]* has been set. This extended date accommodates the possibility for the program to apply for consideration of mitigating factors if you so desire.

While the 90 day termination date and the 210 day termination date is associated with separate deficiencies, if compliance is not achieved for the deficiencies associated with the 90 day perspective termination date and the program approval is terminated, the opportunity for consideration of mitigating factors will no longer be available.

All the deficiencies cited on the enclosed form CMS-2567 require a plan of correction which must be submitted within ten calendar days of receipt of this letter. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", aligning your responses to the deficiencies on the left side of the form CMS-2567, and include your anticipated completion dates in the column labeled "Completion Date"

For those deficiency citations that would lead to termination on *[insert 90 day termination date]*, you must provide a plan which includes the actions you will take and the expected date of completion of the corrections. For those deficiencies citations that would lead to termination on *[insert 210 day termination date]*, your plan of correction should include one of the following three options:

1. You expect your program will achieve compliance upon release of the next SRTR report. (Note: If the program does not achieve compliance at the time of the next report, the termination action will proceed.); or
2. You wish to apply for the consideration of mitigating factors pursuant to §488.61. If you do wish to be considered for mitigating factors by CMS, you must submit a complete application requesting mitigating factors to SCG_transplantteam@cms.hhs.gov.

Transplant programs should refer to the CMS website for additional information about the mitigating factors process. The website describes: 1) the information that must be submitted by the transplant program within 120 days; 2) the timeframe a program has to submit additional supporting information to CMS for consideration; and 3) where this request should be sent.

All requests for CMS approval based on the presence of mitigating factors should be sent to the Applicable RO and the CMS mailbox at SCG_TransplantTeam@cms.hhs.gov.

Attachment D: Acknowledgement of Transplant Program Voluntary Inactivation

Dear Sir/Madam:

On (date) we received your notification of a pending voluntary inactivation of your (organ type) program. You indicated in your notification that the date of inactivation will be (date). We have noted this in your approval file and remind you that:

1. As soon as possible before the inactivation, you must notify all the patients on your current waitlist of the pending inactivation and provide assistance to any patients who desires to transfer to another program without loss of wait time (42 CFR 482.102 (c)(3));
2. A voluntary inactivation may not exceed 12 consecutive calendar months (42 CFR 488.61(e));
3. You must notify this State Survey Agency when the inactivation ends (42 CFR 482.74(a)(3)); and,
4. A voluntary inactivation does not relieve the program of its responsibility to comply with all Conditions of Participation during the period of inactivation.

If you have questions, please contact SCG_TransplantTeam@cms.hhs.gov.

Sincerely,

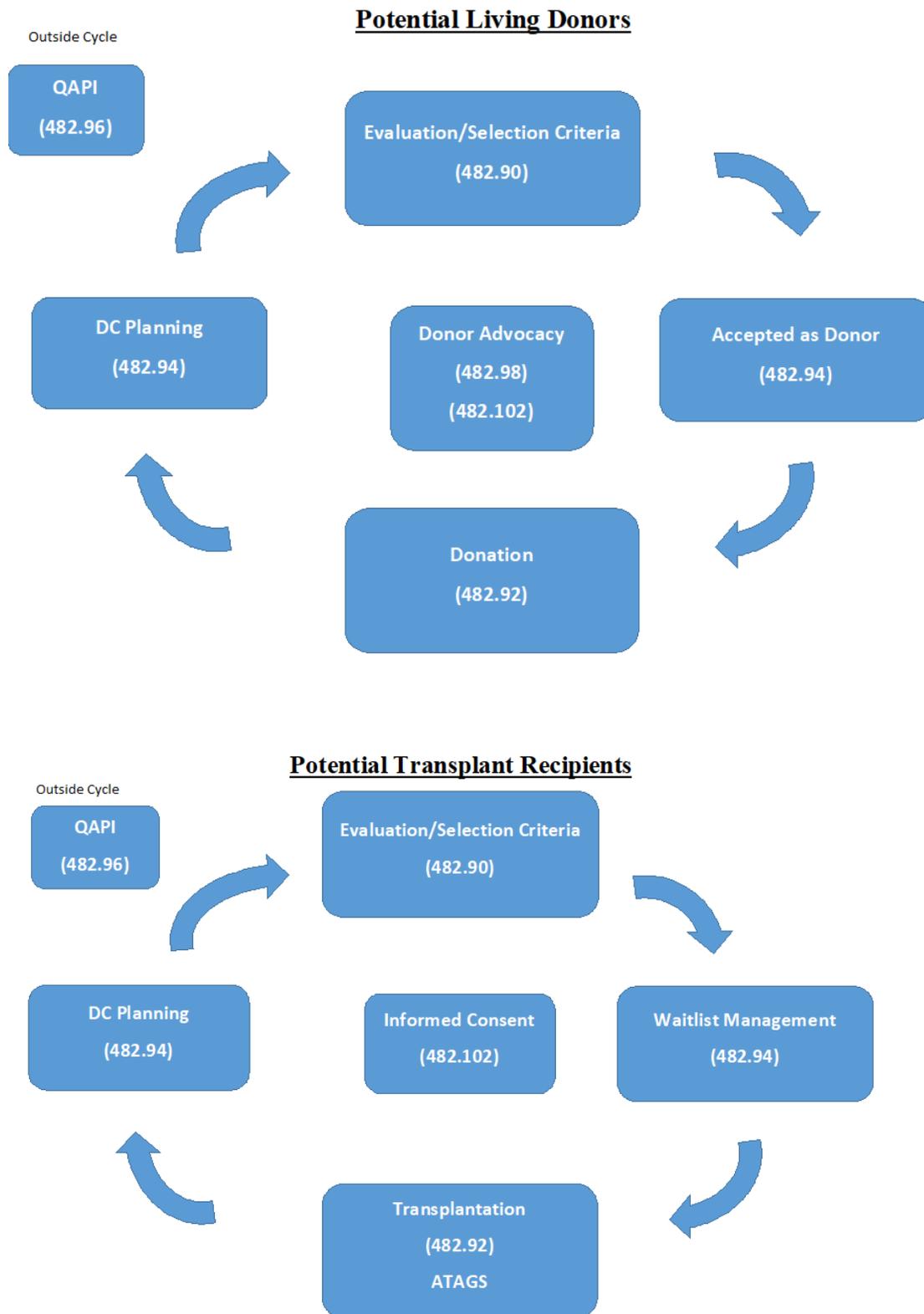
Attachment E: Transplant Program Reminder of 12 Month Inactivation Deadline

Dear Sir/Madam:

Our records indicate that your Medicare approved (insert organ type here) transplant program implemented a voluntary inactivation beginning on *[date]*. Under 42 CFR 488.61(e), a transplant program may remain inactive and retain its Medicare approval for up to 12 months. Your program will exceed this limitation on *[date]*. Since CMS does not have the authority to provide any extension beyond this 12 month period, if we do not receive notification of your plan to either reactivate or voluntarily withdraw the program from Medicare, your Medicare approval will be terminated on *[date]*.

If you have any questions please contact us at [RO contact].

Attachment F: Survey Schematic



Attachment G: Mitigating Factors Application Checklist

Hospital Name:	
OPTN Code/ Transplant CCN #:	
Organ/ Program Type:	
Address, City & State:	
Program Contact Name, phone number, and e-mail:	
Date Prepared:	

Note: Any changes in the program's contact person must be communicated to the CMS within 72 hours to ensure timely communication.

This checklist will assist the transplant program in the preparation of a mitigating factors application. The completed checklist must be submitted with the application. All of the information described on this checklist is required as part of the mitigating factors application review.

Note: Failure to submit a complete and timely application may be the basis for denial of mitigating factors.

Description	Application Page Number(s)
Section A - Program Application Summary	
(1) The completed Mitigating Factors Application Checklist .	
(2) An application summary in letter format on the organ transplant program's or hospital's letterhead that includes: (2a) The name of the transplant hospital and hospital address (as it appears on the Medicare-Approved Transplant Programs list on the CMS website) with the OPTN code and Transplant CCN #.	
(2b) The type of the organ transplant program for which approval of mitigating factors is being requested. <i>(Separate applications must be submitted if more than one organ transplant program at the same hospital is applying for consideration under mitigating factors.)</i>	
(2c) The Conditions of Participation (CoPs) that the program failed to meet: §42 CFR 482.80 – Data submission, clinical experience and outcome requirements for initial approval of transplant centers; or §42 CFR 482.82 – Data submission, clinical experience and outcome requirements for re-approval of transplant centers	
(2d) A brief summary of the mitigating factors requested for consideration (template provided in Appendix 3.2).	
(2e) Rationale/Supporting Evidence: The rationale for requesting approval of a given organ transplant program based on mitigating factors and a description of the evidence the program believes supports its request for mitigating factors.	

Description	Application Page Number(s)
<p>(2f) Internal Program Improvements: The extent to which the transplant program has identified, tracked, and analyzed the root causes of non-compliance. Additionally, the program must submit the specific findings of its analysis and the specific changes made by the program to address the non-compliance.</p>	
<p>(3) As attachments to the application summary, include copies of the following documentation relevant to the application process:</p> <p>(3a) Copy of the CMS written notification of CoP deficiency.</p>	
<p>(3b) Copy of the Letter of Intent sent to CMS to request mitigating factors, which was due 10 calendar days after the CMS' notice of CoP deficiency.</p>	
<p>(3c) Copy of Form CMS-2567 with the survey results (also with the program's Plan of Correction, if available).</p>	
<p>Section B – Data</p>	
<p>(4) Outcomes Data (if applicable): If the program is requesting approval based on mitigating factors for non-compliance with outcomes, provide the following information in 6-month intervals-starting from the most recent SRTR period under consideration to present date, as available:</p> <p>(4a) Total number of all patients that received transplants for that organ type;</p> <p>(4b) Total number of patient deaths at 1-month and 1-year post-transplant;</p> <p>(4c) Total number of organs transplanted (includes any re-transplants); and</p> <p>(4d) Total number of graft failures at 1-month and 1-year post-transplant (of the grafts transplanted in that 6-month period).</p>	
<p>Section C - QAPI Materials</p>	
<p>(5) Quality Assessment and Performance Improvement (QAPI) information specific to the organ transplant program for which approval of mitigating factors is requested, including, but not limited to:</p> <p>(5a) QAPI Plan.</p>	
<p>(5b) Quality dashboard and other performance indicators with definitions.</p>	
<p>(5c) QAPI Program meeting minutes from the most recent four meetings and attendance rosters from the most recent 12 months.</p>	

Description	Application Page Number(s)
<p>Section D: Root Cause Analysis Reports</p>	
<p>(6) Root Cause Analysis of patient deaths and graft failures: Root Cause Analysis report that includes the analyses of patient deaths and graft failures beginning from the most recent SRTR period under consideration to current. The required content for mitigating applications involving substandard patient or graft survival includes, but is not limited to, “Root Cause Analysis for patient deaths and graft failures, including factors the program has identified as likely causal or contributing factors for patient deaths and graft failures” and “Program improvements that have been implemented or improvements that are planned.”(42 CFR §§ 488.61(f)(2)(v)(A) and (B).</p> <p>Note: For purposes of the Root Cause Analysis component of a mitigating factors application, CMS will accept thorough analyses that used a methodology other than “Root Cause Analysis” if the documentation demonstrates that they were conducted consistent with the following guidelines:</p> <ul style="list-style-type: none"> • A description of the key facts of the event in enough detail so that one can clearly understand the facts and chronology of what occurred, the severity of the event, and how the transplant candidate/recipient or potential LD/LD was affected. • A review of whether or not similar events have occurred in the past. • Gathering all of the information needed to identify factors throughout the system that may have caused or contributed to the outcome, directly or indirectly. • Analyzing the information for actual and potential vulnerabilities and opportunities to reduce risks and improve care. • Using the results of the analysis to design improvement actions addressing the factors that caused or contributed to the event’s occurrence, including systems factors and processes. • Specifying the plan for implementing, evaluating and monitoring improvement actions (timeframes, responsible parties, measurement strategy to assess effectiveness, etc.). 	
<p>Section E - Additional Information</p>	
<p>(7) Pertinent policies, protocols, procedures, and practices specific to the organ transplant program for which approval of mitigating factors is requested, including, as applicable:</p> <p>(7a) Patient and donor/organ selection criteria and evaluation protocols, including methods for pre-transplant patient evaluation by cardiologists, hematologists, nephrologists, and psychiatrists or psychologists, etc.</p> <p>(7b) Waitlist management protocols and practices.</p> <p>(7c) Pre-operative management protocols and practices.</p> <p>(7d) Organ procurement protocols and practices.</p> <p>(7e) Intraoperative surgical protocols and practices.</p> <p>(7f) Immunosuppression/infection prophylaxis protocols.</p> <p>(7g) Post-transplant monitoring and management protocols and practices.</p>	

<p>(8) Information about the program’s personnel, including, but not limited to:</p> <p>(9a) Key personnel list with the names and roles of key personnel of the transplant program.</p> <p>(9b) Organizational chart with full-time equivalent levels, roles, and structure for reporting to hospital leadership.</p>	
<p>(9) Program improvements or innovations that have been implemented and planned improvements in response to the root cause analysis of poor outcomes, or as part of a performance improvement project.</p>	
<p>(10) Results/summary of any external review of the program in the past 3 years, including any recommendations that were made and follow-up actions in response to the recommendations.</p>	
<p>(11) Optional- Any other documentation to support the mitigating factors requested. <i>(It is <u>not required</u> to submit other documentation; any other documentation submitted must be relevant to your program’s non-compliance with the CoPs and to the mitigating factors review you have requested.)</i></p>	

Summary of Mitigating Factors Requested

Hospital Name:	
OPTN Code/ Transplant CCN #:	
Organ/ Program Type:	
Address, City & State:	
Program Contact: Name, phone number, and e-mail:	
Date Prepared:	

Summarize the mitigating factors requested on this template and provide it along with the narrative and documentation evidence in section A-2d of the program application summary section of the mitigating factors application. Refer to Appendix 2 for the mitigating factors that may be considered. Summarize in the “Description” column the program’s specific issues and activities that relate to the associated mitigating factor(s) being requested.

Category	Subcategory	Summary Description of Related Program

Attachment H: GLOSSARY

Resource for Surveyors

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

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

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

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

Alternative Treatments for Transplant Candidates (Examples):

Heart: Venticular Access Device, artificial heart

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

Liver: Hepatocyte Transplantation, partial liver transplant

Kidney: Dialysis, Peritoneal Dialysis

Pancreas: Pancreatic Islet Cell Transplantation, medication regimen

Intestine: Segmental reversal of the small bowel, medication regimen

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Commonly Used Acronyms and Abbreviations*

ARF: Acute Renal Failure

LOS: Length of Stay

QAPI: Quality assessment and performance improvement

SCD: Standard criteria donor

LRD: Live donor

ECD: Expanded criteria donor

PRA: Panel reactive antibodies

DGF: Delayed graft functions

PFO: Patent Foramen Ovale

BSI: Blood stream infection

DVT: Deep vein thrombosis

PE: Pulmonary embolism or Physical exam

VAP: Ventilator associated pneumonia

UTI: Urinary track infection

BMI: Body mass index

CIT: Cold Ischemic Time

CHF: Congestive Heart Failure

SRTR: Scientific Registry of Transplants Recipients

MELD: Model for End-Stage Liver Disease

LAS: Liver Allocation Score

THE STANDARD TRANSPLANT PROGRAM SURVEY PROTOCOL

Overview & Key Concepts

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

Program Types and Consideration of Adult versus Pediatric Program Types

Transplant program types including:

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

Survey Team Size and Composition

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

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

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

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

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

See Table below:

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

Survey Protocol Tasks

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

TASK 1 - PRE-SURVEY: OFF-SITE PREPARATION

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

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

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

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

TASK 2 - ENTRANCE ACTIVITIES

All transplant program surveys must include these entrance activities:

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

Activities conducted during the entrance conference include the following:

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

- Determine whether living donor transplants are performed at the transplant center.
- Determine whether the hospital uses any contracted services that also serve that transplant program.
- As applicable, determine whether adult transplants are performed under a pediatric program or pediatric transplants are performed under an adult program (to enable sample selection).
- Explain that interviews may be conducted with transplant program staff and patients as indicated.

Request that surveyors be granted access to medical records as indicated. Identify the areas in the hospital or on the hospital campus where transplant services including inpatient transplant care and outpatient care, are provided.

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

Lists Requested During Entrance Conference:

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

Request Program Administration Materials

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

TASK 3 – SAMPLE SELECTION

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

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

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

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

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

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

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

TASK 4 – TRACER FOR PATIENT AND LIVING DONORS

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

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

I. Patient Experience- Evaluation:

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

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

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

II. Patient Experience- Patient Selection

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

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

III. Patient Experience- Waitlist Management

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

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

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

IV. Patient Experience- Transplantation

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

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

V. Patient Experience- Living Donation

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

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

VI. Patient Experience- Patient Care

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

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

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

TASK 5 – Quality Assurance and Improvement

Review of Quality Assessment and Performance

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

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

TASK 6 – PERSONNEL RECORD REVIEW

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

TASK 7 - PRE-EXIT CONFERENCE

Survey Team Discussion Meeting

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

TASK 8 – EXIT CONFERENCE

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

During the conference:

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

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

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

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

TASK 9 - POST SURVEY ACTIVITIES

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

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

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

ALTERNATE SURVEY PROTOCOL: PEDIATRIC HEART PROGRAM

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

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

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

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

TASK 1 – PRE-SURVEY PREPARATION OFF-SITE

None required:

TASK 2 – ENTRANCE ACTIVITIES

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

Requested Items for Review:

Lists of Transplant Candidates and Patients:

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

Program Administration: Policies, Procedures, Personnel, and QAPI

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

TASK 2 – SAMPLE SELECTION

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

Pediatric Heart Transplant Recipients Sample Selection

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

TASK 3 – REVIEW OF TRANSPLANT PATIENT MEDICAL RECORDS

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

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

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

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

TASK 4 – STAFF INTERVIEW

Follow standard protocol for interviews.

TASK 5 – PERSONNEL RECORD REVIEW

Follow standard protocol for personnel file review.

TASK 6 – ADMINISTRATIVE REVIEW

Operating Agreement

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

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

TASK 7 – PRE-EXIT CONFERENCE

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

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

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

TASK 8 – EXIT CONFERENCE

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

TASK 9 – POST SURVEY ACTIVITIES

Refer to standard survey protocol. Approval of a pediatric heart transplant program does not

require a separate form CMS-2567, and may be listed with other types of transplant programs surveyed simultaneously.

CMS Manual System

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

Pub. 100-07 State Operations Provider Certification

Transmittal –

Date:

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

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

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

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	Appendix X/Interpretive Guidelines and Survey Procedures for Organ Transplant Programs/Entire Appendix

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

IV. ATTACHMENTS:

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

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

State Operations Manual

Appendix X - Interpretive Guidelines for Organ Transplant Programs

Table of Contents (Rev.)

Transmittals for Appendix X

Attachment A: Organ Transplant Surveys, Interpretive Guidelines:

- 42 C.F.R. 482.72 OPTN Membership*
- 42 C.F.R. 482.74 Notification to CMS*
- 42 C.F.R. 482.76 Pediatric Transplants*
- 42 C.F.R. 482.78 Emergency preparedness for transplant centers.*
- 42 C.F.R. 482.80 Data Submission, Clinical Experience and Outcome Requirements for Initial Approval*
- 42 C.F.R. 482.82 Data Submission, Clinical Experience and Outcome Requirements Re-approval*
- 42 C.F.R. 482.90 Patient and Living Donor Selection*
- 42 C.F.R. 482.92 Organ Recovery and Receipt*
- 42 C.F.R. 482.94 Patient and Living Donor Management*
- 42 C.F.R. 482.96 Quality Assessment and Performance Improvement (QAPI)*
- 42 C.F.R. 482.98 Human Resources*
- 42 C.F.R. 482.100 Organ Procurement*
- 42 C.F.R. 482.102 Patient and Living Donor Rights*
- 42 C.F.R. 482.104 Additional Requirements for Kidney Transplant Centers*

Abbreviations:

<i>CMS Certification Number</i>	<i>CCN</i>
<i>The Centers for Medicare & Medicaid Services</i>	<i>CMS</i>
<i>The Centers for Medicare & Medicaid Services Central Office</i>	<i>CO</i>
<i>The Centers for Medicare & Medicaid Services Regional Office</i>	<i>RO</i>
<i>Clinical Transplant Coordinator</i>	<i>CTC</i>
<i>Conditions of Participation</i>	<i>CoPs</i>
<i>Conditions for Coverage</i>	<i>CfCs</i>
<i>Contract Officer Representative</i>	<i>COR</i>
<i>End Stage Renal Disease</i>	<i>ESRD</i>
<i>Health Resources and Services Administration</i>	<i>HRSA</i>
<i>Hepatitis B Virus</i>	<i>HBV</i>
<i>Hepatitis C Virus</i>	<i>HCV</i>
<i>Human Leukocyte Antigen</i>	<i>HLA</i>
<i>Independent Living Donor Advocate</i>	<i>ILDA</i>
<i>Licensed Clinical Social Worker</i>	<i>LCSW</i>
<i>Licensed Practical Nurse</i>	<i>LPN</i>
<i>Licensed Vocational Nurse</i>	<i>LVN</i>

<i>Living Donor</i>	<i>LD</i>
<i>Lung Allocation Score</i>	<i>LAS</i>
<i>Master of Social Work</i>	<i>MSW</i>
<i>Model for End Stage Liver Disease</i>	<i>MELD</i>
<i>Model for Pediatric End Stage Liver Disease</i>	<i>PELD</i>
<i>Organ Procurement Organization</i>	<i>OPO</i>
<i>Organ Procurement and Transplantation Network</i>	<i>OPTN</i>
<i>Other Vital Data</i>	<i>OVD</i>
<i>Peripheral Parenteral Nutrition</i>	<i>PPN</i>
<i>Program Specific Reports</i>	<i>PSR</i>
<i>Project Officer</i>	<i>PO</i>
<i>Potential Living Donor</i>	<i>Potential LD</i>
<i>Quality Assessment and Performance Improvement</i>	<i>QAPI</i>
<i>Social Worker</i>	<i>SW</i>
<i>Scientific Registry of Transplant Recipients</i>	<i>SRTR</i>
<i>State Operations Manual</i>	<i>SOM</i>
<i>State Survey Agency</i>	<i>SA</i>
<i>Statement of Work</i>	<i>SOW</i>
<i>Transplant Program Quarterly Report</i>	<i>TPQR</i>
<i>Transplant Candidate</i>	<i>TC</i>
<i>Transplant Recipient</i>	<i>TR</i>
<i>United Network of Organ Sharing</i>	<i>UNOS</i>
<i>United Network of Organ Sharing Identification/OPTN (LD&TR)</i>	<i>UNOS/OPTN ID</i>

Definitions and Clarifications

Transplantation/Donation Phases—

Transplant Recipient Phases:

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

Living Donor Care Phases:

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

X-001

§482.68 – Special Requirements for Transplant Centers.

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

- (a) Unless specified otherwise, the conditions of participation at §§482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.***
- (b) In addition to meeting the conditions of participation specified in §§482.72 through 482.104, a transplant center must also meet the conditions of participation specified in §482.1 through §482.57.***

Guideline §482.68

As noted by their definitions in §482.70, pancreas and intestine programs are approved as a part of their associated "parent" approval (kidney and liver, , respectively) and therefore these programs are reviewed as a component of the survey of the associated parent transplant program.

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

General Requirements for Transplant Centers

X-002

§482.72 Condition of Participation: OPTN Membership.

A transplant center must be located in a transplant hospital that is a member of, and abides by

the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those rules and requirements approved by the Secretary pursuant to §121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

Guideline §482.72

The hospital in which the organ transplant program(s) is a part of must be a member of the Organ Procurement and Transplantation Network (OPTN) prior to Medicare approval and for as long as it is approved. In the event that the Secretary issues formal notice of his approval of a recommendation for the exclusion of a program from the OPTN, the associated Medicare approval will be terminated pursuant to non-compliance with 42 CFR 482.72.

X-011

§482.74 Condition of Participation: Notification to CMS

(a) A transplant center must notify CMS immediately of any significant changes related to the center’s transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow-up, as appropriate, include, but are not limited to:

Guideline §482.74

For purpose of this condition and its relative tags at X-012, X-014 and X-015, “immediately” means within seven business days of when the transplant program becomes aware that either a change will occur or has occurred.

X-012

§482.74(a)(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center’s “primary transplant surgeon” or “primary transplant physician;”

X-014

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

Guideline §482.74(a)(2)

Outside an approved waiver process, a hospital may not terminate its agreement with its designated OPO. Via a waiver request submitted to CMS, a hospital may request to work with an OPO in another OPO Donation

Service Area. Should the waiver be granted, a hospital may then terminate the agreement with its designated OPO. See also 42 CFR 486.308. The transplant program must notify the applicable State Survey Agency (SA) of its hospital's intention to seek a waiver of its designated OPO. The hospital must submit the actual request for an OPO waiver to the Center for Medicare within CMS Central Office in Baltimore. Once the waiver is granted or denied, the hospital must provide a copy of the decisional document to the SA.

X-015

§482.74(a)(3) Inactivation of the transplant center.

§482.74(b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to):

- (1) Requesting additional information;**
- (2) Analyzing the information; or**
- (3) Conducting an on-site review.**

Guideline §482.74(a)(3)

Upon notification of a program's plan for inactivation, CMS may request additional information from the program pertaining to the reason for the inactivation and the communications that have occurred to notify and assist the patients on the program's waitlist in association with the inactivation period.

Per §488.61(e) Transplant Center Inactivity, "A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months." Program inactivity does not preclude a program from survey for compliance with the Conditions of Participation during the inactivation period. If a program's inactivity period exceeds 12 months, it must reactivate, voluntarily withdraw from Medicare participation, or be subject to termination of its Medicare approval.

X-021

§482.76 Condition of Participation: Pediatric Transplants.

A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at §488.61 of this chapter.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at §482.72 through §482.74 and §482.80 through §482.104 with respect to its pediatric patients.

Guideline §482.76(a)

Upon application to the Medicare program, a transplant program must specify whether it requests approval as an adult or pediatric program.

X-022

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

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

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

Guideline §§482.76 (b)(1)-(2)

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

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

X 023

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

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

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

(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.

Guideline §§482.76(c)(1),(2) and (3)

An adult transplant program is permitted to perform pediatric transplants under its Medicare approval. However, if the number of pediatric transplants performed exceeds 50% of the total volume of transplants performed under the adult approval within a 12 month period, the program is required to seek separate pediatric approval. The pediatric transplant program would now represent the majority of transplants performed and therefore must maintain its Medicare approval in order for the adult program to continue to perform adult transplants,

If the pediatric program becomes the majority population served, loss of this approval would also mean a loss of the programs ability to perform adult transplants.

If the approval for the adult program is lost, the pediatric program may continue to perform transplants, but

could be subject to a program review.

X-024

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

(1)The center’s pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;

Guideline §482.76 (d)(1)

In order for a pediatric heart transplant program to be approved under the OBRA of 1987 criteria rather than the Conditions of Participation, there must be evidence that it is being operated jointly by the hospital in which it’s located and another Medicare hospital. Joint operation means that services and staff from both hospitals are required to accomplish the transplants performed at the pediatric hospital. See standards and guidance at §482.76(d)(2) and §482.76(d)(3) below. This joint operation may occur pursuant to a structured affiliation between the two hospitals or pursuant to a written agreement.

X-025

§482.76(d)(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

Guideline §482.76(d)(2)

The surgeons who perform the heart transplants at the pediatric hospital are credentialed for cardiac surgery at both the pediatric Medicare-approved hospital and the other approved hospital. The surgeons may be employed full time by the other Medicare-approved facility.

The pediatric heart transplant program must be able to provide evidence that the QAPI programs for both hospitals are shared and would include review, analysis and recommendations for the pediatric transplants. The other Medicare-approved facility reviews data as regards the pediatric surgical services and the pediatric hospital reviews the data concerning evaluation, pre and post operative care. Both QAPI programs would review and evaluate the need for any changes in the collaboration between the two entities.

X-026

§482.76(3) The center demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

Guideline §482.76(d)(3)

Facilities include (for example): surgical suites; recovery rooms; inpatient rooms.

Services include (for example): laboratory services; radiology.

Personnel include (for example): all required members of the Multidisciplinary Team; pre-operative and post-operative medical and nursing services.

§482.78 Condition of participation: Emergency preparedness for transplant centers. A transplant center must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

Interpretive Guidelines for §482.78.

A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness program, as required under §482.15(g)(1).

*Transplant centers would still be required to have their own emergency preparedness policies and procedures as required under §482.78(a), as well as participate in mutually-agreed upon protocols that address the transplant center, hospital, and OPO's duties and responsibilities during an emergency. ***Refer to State Operations Manual Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types for guidance and 42 C.F.R. 482.78 Emergency preparedness for transplant centers.*

Transplant Center Data Submission, Clinical Experience, and Outcome

X-031

§482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Centers.

Except as specified in paragraph (d) of this section, and §488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

Guideline §482.80

The Standards of this Condition are evaluated by the surveyor off-site, prior to the survey. The determination of compliance or non-compliance will be communicated to the program at the time of the survey entrance conference. Since this finding is based upon data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data, during the survey, to change the compliance determination.

X-032

§482.80(a) Standard: Data Submission.

No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living

donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up and living donor registration and follow-up.

Guideline §482.80 (a)

The determination of compliance or non-compliance with this Standard is made prior to the on-site survey. The determination is shared with the program at the time of the survey entrance conference. Since this finding is based upon data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data, during the survey, to change the compliance determination.

X-033

§482.80(b) Standard: Clinical Experience.

To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12-month period.

Guideline §482.80(b)

Generally means in all instances except where specifically exempted by the regulations.

The following types of programs are subject to a clinical experience requirement of having performed generally 10 transplants over a 12-month period for initial approval:

- *Adult Heart-Only*
- *Adult Lung-Only*
- *Adult Liver*
- *Adult Intestinal and/or Multivisceral*

For purposes of the clinical experience requirement, multi-organ transplantation will be included as separate transplants for each organ. For example, a combined liver-kidney transplant will account for one liver transplant and one kidney transplant.

X-035

§482.80(c) Standard: Outcome requirements. CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Beneficiaries (SRTR) center-specific report.

(2) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.85.

(d) Exceptions

(1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant center.

Guideline §§482.80(c) and (d)(1)-(4)

The program types subject to this requirement and not exempted include:

- Adult Kidney-Only*
- Adult Heart-Only*
- Adult Lung-Only*
- Adult Liver-Only*
- Pediatric Kidney-Only (Includes only 1-year graft survival)*
- Pediatric Heart-Only*
- Pediatric Lung-Only*
- Pediatric Liver-Only*

X-036

§482.80(d)(5) A kidney transplant center that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval

X-041

§482.82 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Re-approval of Transplant Centers.

Except as specified in paragraph (d) of this section, and §488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order

to be re-approved.

X-042

§482.82(a) Standard: Data Submission

No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed during the prior 3 years. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up and living donor registration and follow-up.

Guideline §482.82(a)

CMS receives required data submission reports directly from the OPTN and therefore no additional information or adjustments may be accepted by CMS during an onsite survey.

X-043

§482.82(b) Standard: Clinical Experience.

To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the prior 3 years.

Guideline §482.82(b)

Generally means in every instance except where specifically exempted by regulation.

The transplant programs listed below do not have any exemptions and must perform an average of 10 transplants per year.

- Adult Heart-Only*
- Adult Lung-Only*
- Adult Liver-Only*
- Adult Intestinal and/or Multivisceral*
- Adult Kidney-Only*

For purposes of the clinical experience requirement, volume for multi-organ transplantation will be included for each respective organ type. For example, a combined liver-kidney transplant will account for one liver transplant and one kidney transplant.

X-045

§482.82(c) Standard: Outcome requirements. CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft

failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTR center-specific report.

(2) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.85.

(d) Exceptions

(1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome requirements in paragraph (c) of this section for intestine, combined liver-intestine, and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section to be re-approved.

Guideline §482.82(c)

The program types subject to outcome requirements and are not exempted include:

- Adult Kidney-Only*
- Adult Heart-Only*
- Adult Lung-Only*
- Adult Liver-Only*
- Pediatric Kidney-Only (Includes only 1-year graft survival)*
- Pediatric Heart-Only*
- Pediatric Lung-Only*
- Pediatric Liver-Only*

Transplant Center Process Requirements

X-051

§482.90 Condition of Participation: Patient and Living Donor Selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

Guideline §482.90

Transplant programs are required to develop their own hospital-approved selection criteria to determine suitability for organ transplantation and living donation. There must be evidence that the written selection criteria are followed for the selection of transplant candidates to be placed on the transplant waitlist and, if applicable, potential living donors. Any changes to the hospital-approved, written selection criteria are approved according to the hospital policy approval process.

The selection criteria (medical, psychosocial, financial, etc.) must clearly define all the factors that are considered in determining suitability for transplantation or living donation. These criteria may not exclude groups or individuals without documentation supporting the exclusionary foundation(s).

X-052

§482.90(a) Standard: Patient Selection.

Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

Guideline §482.90(a)

The patient selection criteria must be followed consistently in a fair and non-discriminatory manner for all potential transplant candidates and living donors. For candidates that are placed on a transplant program's waiting list outside of the patient selection criteria, documented evidence must be present to support the exception.

Discrimination can mean exclusion of those who meet the transplant program's hospital approved selection criteria and should be included on the waitlist as well as inclusion on the waitlist of those who do not meet the hospital approved selection criteria

X-053

§482.90(a)(1) *Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.*

Guideline §482.90(a)(1)

An evaluation of each candidate's psychosocial status must be conducted in all situations in which it is possible to do so in order to determine suitability for transplantation and/or identify resources that potentially will be needed for the safe care and discharge of the patient post-discharge. The transplant program must conduct and document the psychosocial evaluation performed on a potential recipient before their placement on the waitlist. The only exception for not completing the psychosocial evaluation prior to placement on the waitlist would be an emergent situation where the need for transplant is imminent or the patient is very young. Justification for not conducting a psychosocial evaluation prior to a potential recipient's placement on the waitlist must be documented in the medical record.

While the transplant program has flexibility in the selection of a specific psychosocial evaluation tool(s) to be used, it is expected that the psychosocial evaluation would be conducted by transplant program personnel who have the professional qualifications to administer psychosocial evaluations, make resultant assessments and make recommendations to the multidisciplinary team. Evaluations should include, at a minimum, the following:

- Social, personal, housing, vocational, financial, and environmental supports;*
- Coping abilities and strategies;*
- Understanding of the risks and benefits of transplantation;*
- Ability to adhere to a therapeutic regimen; and*
- Ongoing psychological issues that may impact the success or failure of organ transplantation.*

X-054

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

X-055

§482.90(a)(3) When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

Guideline §482.90(a)(3)

The potential recipient medical record must contain documentation that the multidisciplinary team considered all evaluations in the context of the hospital-approved selection criteria. If the potential recipient does not meet the hospital-approved selection criteria, but was placed on the waiting list anyway, the exception justification for listing must be clearly documented in the potential recipient's medical record.

X-056

§482.90(a)(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

Guideline 482.90(a)(4)

Interviews with transplant patients and dialysis facilities should confirm the receipt of the written selection criteria upon request.

X-058

§482.90(b) Standard: Living Donor Selection.

The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

Guideline §482.90(b)(1)

Each prospective living donor must receive a medical and psychosocial assessment prior to donation to ensure that any risks to the donor are identified and to assist in the determination of appropriateness for donation. It is expected that a psychosocial evaluation for living donors would address the following:

- Social, personal, housing, vocational, financial, and environmental supports;*
- Coping abilities and strategies;*
- Understanding of the risks and benefits of donation;*
- Ability to adhere to a therapeutic regimen; and*
- Mental health history, including substance and alcohol use or abuse and how it may impact the success or failure of organ transplantation.*

X-059

§482.90(b)(2) Document in the living donor’s medical records the living donor’s suitability for donation, and

Guideline §482.90(b)(2)

The potential living donor medical record must contain documentation that the multidisciplinary team considered all evaluations and made a determination as to donation suitability. If the potential donor is deemed as not suitable for donation by the team, no donation may occur.

X-060

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

Guideline §482.90(b)(3)

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

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

X-071

§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 beneficiary.

X-073

§482.92(a) Standard: Organ Receipt. *After an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed healthcare professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended beneficiary.*

Guideline §482.92(a)

The verification occurs once the organ arrives in the operating room, prior to transplantation. The second person verifying the blood type (and other data) may be any licensed health care professional who is in the operating room at the time of the verification. The transplant program should identify in its protocols which categories of health care professional(s) may do the second verification. If the transplant surgeon is already scrubbed and gloved, he/she may do a visual verification and sign that verification in the medical record at the end of the surgery. The time of the visual verification should be entered into the recipient's record by the second person at the time it is done and should state that the verification was visual by the transplant surgeon. The second person will sign their verification at that time. After the case is concluded, the surgeon confirms his visual verification in the record by either co-signing the verification entry by the second person or writing a separate progress note which chronicles the verification (including times).

The reference to "other vital data" is considered to be the OPTN Identification Number.

X-074

§482.92(b) Standard: Living Donor Transplantation.

If a center performs living donor transplants, the transplanting surgeon and another licensed healthcare professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the beneficiary's organ(s).

Guideline §482.92(b)

See above discussion at X073 regarding surgeon and other health care professional verification.

Verification that the living donor blood type and other vital data are compatible with the intended recipient must occur onsite, after the donor arrival in the operating room but prior to the induction of general anesthesia.

The verification must be completed by the transplanting surgeon and another licensed healthcare professional. The program should identify in its protocols which categories of health care professional(s) may do the second verification.

Verification by the transplant surgeon and another licensed healthcare professional must be documented. The documentation must include signatures and corresponding date and time of the verification. To ensure that verification is completed immediately before the removal of the donor organ(s), documentation must include the time of donor arrival into the operating room, time of organ verification and time general anesthesia was started.

Verification of correct organ for the correct recipient and verification that the blood type and other vital data are compatible with the potential recipient must occur immediately before the removal of the living donor organ(s).

If the donor organ recovery surgeon is also the transplanting surgeon, verification prior to removal of the living donor organ(s) and verification prior to transplantation must occur separately.

X-081

§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.

Guideline §482.94

Transplantation and Living Donor Care Phases are generally defined as:

Transplantation Care Phases:

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

Living Donor Care Phases:

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

Some transplant programs perform living donor services under arrangement with other hospitals. In these cases, the transplant program retains all responsibility for compliance with management of the living donor. The transplant program must communicate the donor management activities that are required as a part of the living donor organ recovery to the hospital under the arrangement and ensure that the activities are completed appropriately.

X-082

§482.94(a) Standard: Patient and Living Donor Care.

The transplant center's patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor

evaluation, donation, and discharge phases of donation.

Guideline §482.94(a)

In those instances where it is determined that the transplant recipient or living donor is not receiving or did not receive the services needed as identified by assessment, consultation and the multidisciplinary plan of care, the resulting deficiency should be cited at this regulatory cite.

X-083

§482.94(b) Standard: Waiting List Management.

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

X-084

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

Guideline §482.94(b)(1)

Timely updates to clinical information for patients on the waiting list affects: (1) organ allocation priority based on medical urgency and (2) a candidate's ability to receive a transplant. Transplant programs must update the waiting list with accurate, recent and timely clinical information to ensure that a candidate is able to receive a transplant should an organ become available. Transplant programs should determine how often waiting list patients should be evaluated and provided ongoing assessment.

X-085

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

Guideline §482.94(b)(2)

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

X-086

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

Guideline §482.94(b)(3)

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

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

X-087

§482.94(c) Standard: Patient Records.

Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

X-088

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

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

X-089

§482.94(c)(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

Guideline §482.94(c)(2)

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

X-090

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

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

Guideline §482.94(c)(3)

A multidisciplinary care plan includes ongoing assessments to identify any new patient needs and/or to determine if any currently identified patient's needs have changed. A multidisciplinary team must be identified for each patient at the time the evaluation for wait listing begins. This multidisciplinary team participates in the patient care planning from evaluation through transplantation. At the time of the initial evaluation, each

member of the team participates in the evaluation of the patient. It may not be necessary for all team disciplines to see the patient again until transplant is imminent unless there are identified needs. Following the transplant, each discipline must, as appropriate: 1) reassess the recipient following the surgery; 2) see the recipient as often as indicated by identified issues; and 3) see the recipient prior to discharge.

X-091

§482.94(c)(ii) Multidisciplinary discharge planning for post-transplant care.

Guideline §482.94(c)(ii)

Discharge planning begins on admission. Each member of the dedicated multidisciplinary team must be involved in assessing the needs of the patient in preparation for discharge from the hospital. Areas of assessment for discharge planning include medical, psychosocial and financial.

The recipient's medical record must contain documentation that the dedicated multidisciplinary team participated in the development of the discharge plan to address the individual needs of the recipient.

Components of a multidisciplinary discharge plan may include, but are not limited to:

- A description of the recommended follow-up appointments and the practitioners expected to perform the follow-ups (such as the transplant program, a local physician, or both);*
- Contact numbers of transplant program staff that can be contacted for questions;*
- The clinical signs and symptoms indicative of a potential complication from transplantation that would necessitate a call to the doctor;*
- A transplant recipient/living donor specific nutrition plan, as applicable;*
- A plan for addressing psychosocial issues (for example available supports, adaptation to stress of transplant, etc.);*
- Activity restrictions and limitations (for example driving after taking pain medication);*
- Need for coordination of other health services (for example physical or occupational therapies, home care, etc.) and assistance in securing these health services;*
- Medication and administration, including the transplant recipient's schedule for taking medication and the process to obtain the medication; and*
- Any assistance required to access local medical care, equipment or support.*

X-092

§482.94(d) Standard: Social Services.

The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families....

Guideline §482.94(d)

Making social services available means that if a social service need for a recipient/donor/family is identified at any point from evaluation through discharge, the program must provide a qualified social worker to address the need/issue and documentation in the medical record should confirm the social worker intervention.

X-093

§482.94(d)(cont'd)

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

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

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

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

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

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

X-094

§482.94(e) Standard: Nutritional Services.

Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

Guideline §482.94(e)

Transplant programs must have a process in place to ensure that a qualified dietitian is available to provide nutritional assessments or diet counseling to all transplant patients and living donors that require such services. Nutritional services include consultation, assessment, intervention(s) and education. If a need is identified by any member of the multidisciplinary team, and a request is made for nutritional services, but the requested services are not provided due to the lack of nutritional staff available in the hospital, a deficiency would be cited.

X-099

§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.

Guideline §482.96

The transplant center develops its transplant program-specific quality assessment and performance improvement (QAPI) program either individually or collaboratively with the transplant hospital QAPI program and functions as a component of the associated hospital QAPI program required at 42 CFR §482.21. There should be evidence of communication between the two entities to ensure that both entities are actively involved in QAPI activities which address the specific requirements of the transplant CoPs. If the transplant program has a separate QAPI program, it must provide evidence that it is interrelated with the hospital QAPI plan.

A comprehensive transplant QAPI program evaluates and monitors performance of transplantation services across every aspect of the program from the evaluation of a potential recipient/donor candidate through his/her discharge from the hospital. A comprehensive QAPI program approach embraces a broad, multidisciplinary, system-wide perspective. It encompasses all aspects of clinical care and all relevant hospital services and includes input from a broad representation of staff at all levels, including individuals with authority to make decisions about the transplant program's policies, practices and resources. It continuously monitors, evaluates and improves all organ transplantation services for transplant candidates, transplant recipients, potential living donors across all phases of transplantation and living donation, including transplant services provided under contract or arrangement..

A data-driven transplant QAPI program continually uses data to guide quality assessment and performance improvement activities with respect to all transplantation services. The program proactively, systematically and at regular specified intervals:

- Identifies, implements, assesses and re-assesses the data to be collected for each measure and other information needed to monitor and evaluate performance of transplantation services in all areas;*
- Collects, records and reviews the data for accuracy;*
- Analyzes the data and uses the data/analyses to assess the program's performance; and*
- Uses the results of its analyses to monitor, evaluate and improve the quality and safety of all transplantation/donation services on an ongoing basis.*

X-100

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

The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes.

Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and beneficiary matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights....

Guideline §482.96(a)

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

Transplantation and living donor care - including but not limited to the potential areas for measurement listed in this standard – involve multiple phases, activities and potential outcomes, each with various aspects that may be

amenable to objective measurement. Objective measures can mean that a transplant program will select some measures for routine monitoring on an ongoing basis; others will be identified and implemented in order to address, evaluate and monitor a particular problem or opportunity for improvement. Each transplant QAPI program should identify and implement multiple objective measures that are relevant and meaningful for evaluating its own performance with regard to both transplantation activities and outcomes to:

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

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

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

X-101

§482.96(a)(cont'd)

...The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

Guideline §482.96(a)(cont'd)

The transplant program must use what it learns from monitoring the objective measures described under Tag X100 to identify and implement actions to improve its performance.

The program should review the available evidence, if any, for particular performance improvement strategies and implement activities that are most likely to be effective in addressing the specific factors that are contributing to the program's performance. If successful, performance will need to be monitored over time to verify that improvements are sustained. If not, the program will need to re-evaluate, determine an appropriate alternative course of action, and track performance.

X-102

§482.96(b) Standard: Adverse Events.

A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

Guideline §482.96(b)(1)

An adverse event is defined at 42 CFR §482.70 as “an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.”

The facility policies should include:

- *A clear definition of what the transplant program considers an adverse event incorporating the CMS regulatory definition;*
- *The procedures for internal reporting of adverse events in all phases of transplant recipient or living donor care within the hospital;*
- *The process(es) used for analyzing adverse events in the transplant program;*
- *The process for developing, evaluating and tracking actions to prevent recurrence; and*
- *The required timeframe for reporting, investigating and analyzing adverse events.*

The policies should also address any external adverse event reporting obligations, such as:

- *External reporting of events to the OPTN, ESRD Network, etc. as required and applicable;*
- *Reporting to other federal or state agencies as required by law (e.g., for suspected medical device-related deaths or serious injury, transmission of an infectious disease, etc.); and*
- *Reporting to the OPO if a transplant recipient infection is related to an infectious disease present in a transplanted organ to ensure that other recipients who received organs from the same donor can be notified.*

X-103

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

Guideline §482.96(b)(2)

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

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

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

X-104

§482.96(b)(2)(cont'd)

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

X-109

§482.98 Condition of Participation:

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.

X-110

§482.98(a) Standard: Director of a Transplant Center.

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

Guideline §482.98(a)

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

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

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

X-111

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

X-112

§482.98(a)(1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

Guideline §482.98(a)(1)

Care of transplant patients and living donors is unique and complex, requiring clarification of roles and responsibilities and appropriate training for nursing staff and clinical transplant coordinators. The director of

the transplant center is responsible for coordination with the hospital's Nursing Department to determine the appropriate depth and type of orientation and training that will be provided to nursing staff that care for the transplant patients.

Evidence of coordination should include:

- 1. The transplant director has participated in the development of training and orientation plans for nurses who work or will work with transplant recipients and living donors;*
- 2. The transplant director offers ongoing training opportunities for nursing staff; and*
- 3. The transplant director provides feedback to the Nursing Department on the clinical competency of those nursing staff working with transplant recipients or living donors.*

X-113

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

X-114

§482.98(a)(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).

Guideline §482.98(a)(3)

A transplant surgeon must be credentialed by the hospital in which the transplant program is located to perform transplant surgeries.

If a fellow or a resident participates in a surgery, the attending transplant surgeon must remain in the operating room or be physically present in the operating suite.

X-115

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

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

X-116

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

Guideline §482.98(b)(1)

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

X-117

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

Guideline §482.98(b)(2)

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

X-118

§482.98(c) Standard: *Clinical Transplant Coordinator.*

The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation... .

X-119

§482.98(c)(cont'd)

... The clinical transplant coordinator must be a registered nurse or clinician licensed by the State in which the clinical transplant coordinator practices, who has experience and knowledge of transplantation and living donation issues... .

Guideline §482.98(c)

Clinicians other than nurses may also serve in the role of the clinical coordinator. The expectations of the coordinator, as defined by the individual transplant program, will determine the particular professional clinical background required for the coordinator. However, regardless of the clinical background of the coordinator, the most critical factor of this Standard is the requirement for experience and knowledge. Clinical coordinators must have experience working with transplant patients or living donors in any setting.

X-120

§482.98(c)(cont'd)

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

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

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

Clinical transplant coordinators are important links between transplant recipients/living donors and the transplant program and dialysis facilities, as applicable. A transplant coordinator is often the patient's primary

contact for communication and direction on transplantation or donation related activities. This communication involves patients, families, medical team, organ procurement organizations, donor hospitals, and all other members of the transplant team.

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

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

X-121

§482.98(d) Standard: Independent Living Donor Advocate or Living Donor Advocate Team. The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

Guideline §482.98 (d)

Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) prior to the initiation of the evaluation and continuing to and through the discharge phase.

X122

§482.98(d)(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

Guideline §482.98(d)(1)

Because of the conflict of interest which would be created for an advocate to perform any transplant activities, even on an infrequent basis, the ILDA or ILDAT must not be associated with the transplant program in any capacity even on a temporary or intermittent basis.

X-123

§482.98(d)(2) The independent living donor advocate or living donor advocate team must demonstrate:

(i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and

(ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

Guideline §482.98(d)(2)

The advocate/team must be able to provide evidence of successful training which addressed the topics listed in

the standard.

Interviews with living donors confirm that the advocate/team provided information concerning:

- The organ donation process;*
- The requirements of the informed consent process;*
- The immediate and long-term expectations following donation;*
- The immediate and long-term risks of donation;*
- The expected outcomes for the recipient;*
- The potential financial responsibilities related to donation; and*
- Any alternative treatment(s) for the potential transplant recipient, if available.*

The living donor medical record should fully chronical the interactions between the advocate or advocate team and donor candidate including the assessed level of understanding by the donor candidate during interactions.

X-124

§482.98(d)(3) The independent living donor advocate or living donor advocate team is responsible for:

(i) Representing and advising the donor;

(ii) Protecting and promoting the interests of the donor; and

(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

Guideline §482.98(d)(3)

The ILDA or ILDAT are primarily the representatives of the donor candidate. There may be instances where the advocate/team advises the potential donor candidate where to seek additional information, encourages the candidate to ask pertinent questions, encourages the candidate to have additional discussions with the family or advises the donor candidate to delay the decision to donate at any point without reprisal if they choose. However, the advocate/team does not advise as to a decision on donation.

All discussions and meetings between the potential donor candidate and the advocate/team must center upon the needs, interests and choices of the potential donor. These discussions must not address the needs of the potential recipient. If at any point in the process the donor changes his/her mind and decides not to donate, the advocate must support and intercede on behalf of the donor candidate if indicated.

X-125

§482.98(e) Standard: Transplant Team.

The transplant center must identify a multi-disciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

Guideline §482.98(e)

While it is desirable that each multidisciplinary team include a pharmacist member, there may be other disciplines on the team who may also be qualified to provide pharmacology services. Examples of individuals other than a pharmacist who are also qualified to provide pharmacology services on the team, are a physician,

advanced nurse practitioner, or physician assistant.

X-126

§482.98(f) Standard: Resource Commitment.

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

X-139

§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.

Guideline §482.100

The hospital in which the transplant program is located must have a written agreement with their designated OPO for cooperation with the OPO in the recovery of donor organs. The agreement must meet the requirements of §482.45.

X-149

§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.

X-150

§482.102(a) Standard: Informed Consent for Transplant Patients.

Transplant centers must implement written transplant patient informed consent policies that inform each patient of:

Guideline §482.102(a)

As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide a potential transplant recipient with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose all available information to a potential recipient who makes the voluntary choice to accept or refuse treatment. The transplant physician must ensure each potential recipient that is considered for organ transplantation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to them.

The signed hospital surgical consent form alone is not considered evidence that the informed consent process for transplant patients was completed to include the requirements of §§482.102(a)(1)-(8).

X-151

§482.102(a)(1) The evaluation process;

Guideline §482.10(a)(1)

A part of the informed consent process is ensuring the candidate understands what the evaluation process entails prior to its initiation. Prior to a potential recipient making a decision to undergo an evaluation for transplantation, they must understand all that is involved in the evaluation process, which includes what the potential recipient and transplant program responsibilities will be; all possible decisions regarding waitlisting and transplantation that could be reached as a result of the evaluations; and what factors could result in their removal from the waiting list.

X-152

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

Guideline §482.102(a)(2)

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

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

X-153

§482.102(a)(3) Alternative treatments;

Guideline §482.102(a)(3)

Each potential recipient's options for treatment will vary based on organ type and individual medical condition(s). It is expected that discussions related to alternative treatments occur prior to a candidate undergoing an evaluation for transplantation.

The discussions of alternative treatments should be reviewed any time the candidate has significant changes in their medical condition and as other alternative treatments become available with advancements made in the science of disease management and treatment.

X-154

§482.102(a)(4) Potential medical or psychosocial risks;

Guideline §482.102(a)(4)

There are general risks applicable to all organ transplant types and there are risks specific to each organ type. The transplant program must address both categories of risk with the potential recipient prior to his/her decision to proceed with the evaluation process.

X-155

§482.102(a)(5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;

Guideline §482.102(a)(5)

Prior to undergoing an evaluation, the transplant program informs the potential recipient of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program's performance. The potential recipient should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website. This information allows the patient to make an informed decision about listing with the program.

X-156

§482.102(a)(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immune-deficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;

Guideline §482.102(a)(6)

During the pre-evaluation period, the program informs the potential recipient of the general risks as listed in this regulation. At the time an organ is offered, the potential recipient must be informed of any risk factors specific to the organ recovered or to be recovered.

The transplant program should utilize the PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation to identify those instances where the potential recipient must be informed as to increased risk with a particular organ condition. The PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation is available

at: <http://www.publichealthreports.org/issueopen.cfm?articleID=2975>

X-157

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

Guideline §482.102(a)(7)

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

X-158

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

X-159

§482.102(b) *Standard: Informed consent for living donors.*

Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

Guideline §482.102(b)

As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide patients with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose appropriate information to a patient which allows them to make the voluntary choice to accept or refuse treatment. The physician must ensure each patient that is considered for organ donation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to the recipient.

Transplant programs must develop and implement informed consent policies for living donors that delineate the information to be shared and the responsibilities of any transplant staff member that will consult with the patient.

The signed informed consent form and/or hospital surgical informed consent form alone is not considered evidence that the informed consent process for the prospective living donor is complete. Transplant programs must provide documentation that ensures the living donor candidate was informed of subparagraphs (1) through (8) of this standard.

X-160

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

Guideline §482.102(b)(1)

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

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

Accordingly, any information shared between the living donor candidate and the transplant program may not be

shared with the potential recipient and/or their families except as permitted by 45 CFR parts 160 and 164.

X-161

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

Guideline §482.102(b)(2)

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

The evaluation process is ongoing, beginning at the time an individual is identified as a possible candidate for donation and continues until donation. Routine re-assessments, as determined by the program's protocols must be conducted to ensure continued suitability for donation.

X-162

§482.102(b)(3) The surgical procedure, including post-operative treatment;

Guideline §482.102(b)(3)

Discussions by the transplant surgeon with the potential donor candidate would include:

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

X-163

§482.102(b)(4) The availability of alternative treatments for the transplant beneficiary;

Guideline §482.102(b)(4)

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

X-164

§482.102(b)(5) The potential medical or psychosocial risks to the donor;

Guideline §482.102(b)(5)

There are general risks applicable to all organ transplants and there are risks specific to each organ type. The transplant program must address both categories of risk with the potential donor prior to his/her decision to proceed with the evaluation process.

The informed consent discussion should include information regarding the fact that long term medical implications of organ donation have not been fully identified.

X-165

§482.102(b)(6) The national and transplant center-specific outcomes for beneficiaries, and the national and center-specific outcomes for living donors, as data are available;

Guideline §482.102(b)(6)

Prior to undergoing an evaluation, the transplant program informs the potential donor of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program performance. The potential recipient should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website.

There are currently no national or center specific outcomes for living donors calculated by the SRTR.

X-166

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

X-167

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

X-168

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

X169

§482.102(c) Standard: Notification to patients.

Transplant centers must notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

X-170

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

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

Guideline §482.102(c)(1)

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

X-171

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

- (i) Inform patients on the center's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list; and***
- (ii) Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.***

X-172

§482.102(c)(3) As soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list.

Guideline §482.102(c)(3)

A transplant program may choose to inactivate for reasons including: the inability to meet clinical experience (volume) requirements; temporarily lacking medical or surgical coverage; and a significant change in operations that require a temporary cessation of transplant activity.

Transplant programs that intend to become inactive must notify the patient group that will be affected by the inactivity. If the determination is made to inactivate a transplant program or a component of a transplant program, all potential recipients on the waiting list would be unable to receive an organ offer during the time period of inactivity. As such, transplant programs must notify all affected patients of the upcoming inactivation.. It must also inform the potential recipients of the expected time period of inactivation, if known, and options for waitlisted patients to transfer to a another facility.

Waiting list patients should receive notification of the program's voluntary inactivation at least 30 days prior to

the planned inactivation date. Transplant programs determine the method of communication with the potential recipients and the program must be able to document the communication.

If a transplant candidate elects to be transferred to a another transplant program, the inactivating transplant program must facilitate communication and help with the exchange of information. The transplant program should coordinate with the receiving facility to place the patient on their waiting list.

X-184

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

X-185

§482.104(a) Standard: End stage renal disease (ESRD) services. Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients... .

X-186

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

Guideline §482.104(a)(cont'd)

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

X-187

§482.104(b) Standard: Dialysis services. Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement.

X-188

§482.104(c) Standard: Participation in network activities. Kidney transplant centers must cooperate with the ESRD Network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.

Guideline §482.104(c)

The most current ESRD Network statement of work includes the direction and goals that are set by the Network and completed through partnership with other stakeholders, such as a transplant programs. Transplant programs are expected to cooperate, and participate if necessary, in fulfilling the goals set by the Networks.

*The most current Statement of Work can be found on the CMS website for ESRD Networks at:
<https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/>*

Information on the geographic areas of Networks and the SOW can be found on the [CMS Website](http://www.cms.hhs.gov/ESRDNetworkOrganizations) (<http://www.cms.hhs.gov/ESRDNetworkOrganizations>).

STATE OPERATIONS MANUAL

CMS Manual System	Department of Health & Human Services (DHHS)
Pub. 100-07 State Operations Provider Certification	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: There are new sections to the SOM outlining the requirements for organ transplant programs in Chapter 2 and Chapter 3.

In Chapter 2, we have added sections §2060 through §2068. These sections provide guidance specific for the survey and approval of organ transplant programs. (i.e., the transplant program application process, the specific procedures for surveying organ transplant programs, and data received from other sources to be used as part of the survey process).

We have also added a new section, §3012.3, which provides additional guidance regarding the termination procedures for 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/
N	2/2062/Survey and Approval Procedures for Organ Transplant Programs
N	2/2062/2062A /Transplant Surveys
N	2/2062/2062B/Types of Surveys and Related Guidance
N	2/2062/2062C/Resources and Special Issues Onsite
N	2/2062/2062D/ Determining Level of Deficiency for Clinical Experience (Volume) and Outcomes
N	2/2062/2062E/Post-Survey Activities
N	2/2062/2062F/Mitigating Factors Process and Systems Improvement Agreements
N	2/2062/2062G/Reasonable Assurance Period
N	2/2063/Relationship to Other Conditions of Participation
N	2/2064/Accreditation Status
N	2/2065/Data from External Sources
N	2/2066/Transplant Program Status Changes
N	2/2067/Surveyor Training and Tools
N	2/2068/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'
N	3/3012.3/Termination Procedures for Organ Transplant Programs
R	9/Exhibits/Table of Contents
N	9/Exhibits/Exhibit #

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

State Operations Manual

Chapter 2 - The Certification Process

2060 - Organ Transplant Programs (Rev.)

2060A - Citations

The Conditions of Participation (CoPs) for Transplant Centers were established under several statutory authorities. Section 1102 of the Social Security Act (the Act) authorizes the Secretary to publish rules and regulations “necessary for the efficient administration of the functions” with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to “prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title.” Section 1881(b)(1) of the Act contains specific authority for prescribing the health and safety requirements for facilities, including renal transplant centers, that furnish end stage renal disease (ESRD) care to beneficiaries. Section 1861(e)(9) of the Act authorizes developing standards necessary for the health and safety of individuals furnished services in hospitals. Organ transplant programs are required to be in compliance with the federal requirements set forth in the Medicare CoPs in order to be eligible to receive Medicare payment. In addition to meeting the CoPs for Transplant Centers in 42 CFR Part 482, Subpart E, transplant programs must also meet the Hospital CoPs specified in §§482.1 through 482.57.

2060B - DEFINITIONS

2060B-1 Organ Procurement and Transplantation Network (OPTN)

The OPTN is a public-private partnership that links all professionals involved in the donation and transplantation system. The OPTN operates the national network for organ procurement and allocation and works to promote organ donation. The OPTN was established by the National Organ Transplant Act of 1984 and is operated by United Network for Organ Sharing (UNOS) under a contract from the Health Resources and Services Administration (HRSA) in accordance with section 372 of the Public Health Service (PHS) Act. Through its policies the OPTN works to increase the number of transplants, provide equity in access to transplants, improve outcomes for waitlisted patients, living donors and transplant recipients, and promote living donor and transplant recipient safety.

2060B-2 Scientific Registry of Transplant Recipients (SRTR)

The SRTR, founded in 1987, is a national database of transplant statistics that provides analytic support for the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States. It was established pursuant to section 373 of the PHS Act.

2060C - Regulatory Background

The Conditions of Participation for transplant programs were published in the Federal Register on March 30, 2007 (72 FR 15198) and became effective 90 days after publication on June 28, 2007.

2061 – Request for Medicare Approval of an Organ Transplant Program (Rev.)

Effective January 1, 2019, transplant programs seeking to participate in the Medicare program must submit a request for Medicare approval to the applicable State Survey Agency and not the CMS RO. The SA will provide a packet of information to the applicant including a list of documents that must be submitted to the SA.

The hospital in which the transplant center is located must submit a revised CMS-855A to its Medicare Administrative Contractor (MAC) to indicate the addition of a service.

2061A Programs Serving both Adult and Pediatric Populations

A transplant program can apply for and be approved for both an adult (age 18 and over) and a pediatric (under age 18) transplant program for the same organ type. They can apply to be approved separately, but are not required to do so.

If a transplant program is seeking separate approval of its adult and pediatric programs, the programs will be surveyed separately. If a program seeks a single approval for both age groups, the program must apply for the primary age group that it serves. That is, a program that provides more than 50 percent of its transplants in a 12-month period to pediatric patients must apply as a pediatric program. A program that provides more than 50 percent of its transplants in a 12-month period to adults must apply as an adult program.

2061B Organ Procurement and Transplantation Network Membership

Membership in the OPTN by the transplant hospital in which the transplant program is located is a requirement for Medicare approval.

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

2062A - The Transplant Program Quarterly Report (TPQR)

The TPQR is a pre-survey report generated by CMS. It conveys information from transplant program data received from the SRTR and the OPTN. The TPQR includes:

- Types of transplant programs;
- Program data including data submission, clinical experience (the number of transplants performed) and program outcomes for patient and graft survival.

During pre-survey, the survey team reviews the TPQR to determine the number of surveyors that will be indicated based upon the number of programs that will be reviewed. The team also identifies any non-compliance with the requirements of §482.80 and §482.82. Any non-compliance identified during the pre-survey will be communicated to the applicable program at the entrance conference of the survey. There is no additional survey activity required regarding the TPQR.

During the process of the transplant program survey, the surveyors review compliance with both the transplant program and general hospital regulations. If a deficiency with the hospital requirements is identified in the hospital in which the transplant program is located and that hospital is a deemed provider, the surveyor (or their management) must contact the applicable CMS Regional Office for approval to investigate and cite the deficiency on a hospital survey report.

2062B Types of Surveys and Related Guidance (Rev.)

2062B.1 Initial Survey for Medicare Approval

Once the MAC notifies the SA/RO of its approval of the revised CMS-855A, a survey may be scheduled. Initial surveys are unannounced. If the applicant transplant program is found to be in compliance with the CoPs, it is assigned a CCN. The program will not be issued a separate provider agreement. Once transplant program approval is completed, the RO will forward a form CMS-2007 (Provider Tie-In Notice) to the MAC. In order for CMS to make a compliance determination with §482.80, the applicant must have submitted sufficient data to the SRTR for CMS to review.

2062B.2 Re-approval Surveys (Rev.)

Once a transplant program has been approved to participate, it will be periodically re-surveyed for compliance with the CoPs. Re-approval surveys are unannounced surveys and are performed at a frequency consistent with the CMS Mission and Priority Document (MPD).

A transplant program may voluntarily declare an “Inactive Status” with the CMS and may remain inactive and retain its Medicare approval for a period not exceeding 12 months under §488.61(e). The program must provide immediate written notification to its SA of the anticipated inactivity period. Notification to the SA and to the potential recipients must occur prior to the beginning of the planned inactivity period. During its inactivity period, the program must continue to comply with all of the Medicare CoPs and routine surveys or complaint investigations should not be delayed based on an “Inactive Status.” During survey activity either during the inactive status or following an inactive status, the surveyor should determine that:

- The patients on the waitlist during the period of inactivity were notified of the inactive status; and
- The notifications were accomplished in a manner consistent with §482.102(c)(3).

2062B.3 Outcomes Non-Compliance

2062B.4 Clinical Experience (Rev)

To be considered for an initial approval, a transplant program must generally perform 10 transplants over a 12 month period. If the program performs at least 8 transplants over a 12 month period, it may be approved with an acceptable plan of correction.

Currently approved transplant programs must perform at least 10 transplants a year over the prior three years. Programs not meeting this standard should be cited for non-compliance at the Standard level. The program may be reapproved with an acceptable plan of correction if all other CoPs are in compliance.

2062B.4 Complaint Surveys

(Rev.)

See SOM, Chapter 5, for a description of the general complaint investigation process.

For complaint investigations of a transplant program, the scope of survey activities is generally limited to the specific transplant CoPs associated with the allegation(s). If allegations are substantiated, the scope may be expanded to review any associated CoPs.

Complaints related to disease transmission via an organ from a deceased donor should be communicated to the RO for their determination of the need for an OPO complaint investigation.

* There must be a formal arrangement between the hospital in which the transplant program is located and any other hospital which provides living donor services for the transplant program. It is the transplant program's responsibility to ensure that the CoPs applicable to living donors are met by the associated hospital providing the living donor services. The medical record of the living donor must confirm that all the requirements of the CoPs were met.

2062 C - Determining Level of Deficiency for Clinical Experience (Volume) and Outcome Requirements Standards:

Compliance with the clinical experience (volume) standards at 42 CFR §§482.80(b) and 482.82(b) and the outcome requirements standards at 42 CFR §§482.80(c) and 482.82(c) is determined by reviewing the program's performance compared to the objective standards outlined in the regulation. The goal of this section is to achieve consistency in determining the level of a deficiency citation, (i.e., condition level, or standard level) under these CoPs. The information outlined below will be provided to surveyors in the TPQR.

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

A program's inactivation does not create an exception to the clinical experience requirement for the entire 3 year period.

Initial Approval of Transplant Programs under §482.80(b):

If the transplant program has not performed at least eight transplants in the past 12 months, a deficiency will be cited at the condition-level deficiency and it will not be approved for Medicare participation. If the program has performed at least eight but less than 10 transplants in that time period, a deficiency should be cited at the standard-level. The program may still be approved with a standard-level citation for Clinical Experience if an acceptable plan of correction is received and the program is in compliance with all remaining CoPs. Kidney programs that have not performed at least three transplants in a 12 month period may not be surveyed for initial approval.

Re-approval of Transplant Programs under §482.82(b):

If the transplant program has performed an average of less than 10 transplants per year over the re-approval period (three years), a deficiency should be cited at the standard-level. The program may be re-approved with a standard-level citation for Clinical Experience if an acceptable plan of correction is received and the program is determined to be in compliance with all remaining CoPs.

The determination of condition-level non-compliance is made based upon the extent of non-compliance findings with the standards within a Condition. A finding of non-compliance for the Clinical Experience standard alone with no other non-compliance within the Condition would generally not result in condition-level non-compliance at §482.80 or §482.82.

Determining the Level of the Deficiency for Non-Compliance with the Outcome Requirements at 42 CFR §482.80(c) and §482.82(c)

Compliance with outcome measures is assessed using data from the most recent Center-Specific Report from the SRTR. Surveyors must utilize the SRTR information reported in the TPQR that is provided by the CMS CO. The SRTR outcome measures reported in the TPQR are risk-adjusted, 1-year post transplant graft and patient survival measures. The SRTR reports are released every six months and CMS compares the results for the programs' outcomes to the outcome requirements at 42 CFR §482.80(c) and §482.82(c) for transplants performed over a 2.5 year window (between one year prior and 3.5 years prior to the date the report is published) and enters the compliance determination onto the TPQR. The TPQR identifies the number of center-specific SRTR reports in that timeframe that failed to meet the outcome requirements. Surveyors do not conduct the statistical analysis to determine compliance nor may the program provide any information to the surveyor on-site to change the compliance determination.

The following transplant program types are subject to the outcome requirements:

- Adult Kidney-Only (AKO)
- Adult Heart-Only (AHO)
- Adult Lung-Only (ALO)
- Adult Liver-Only (ALI)
- Pediatric Kidney-Only (PKO) (includes only 1-year graft survival)
- Pediatric Heart-Only (PHO)
- Pediatric Lung-Only (PLO)
- Pediatric Liver-Only (PLI)

The following transplant program types are not subject to the outcome requirements:

- Adult Pancreas- (APA)
- Pediatric Pancreas- (PPA)
- Adult Intestine/Multivisceral- (AIM)
- Pediatric Intestine/Multivisceral- (PIM)

Standard – If the most recent SRTR report shows that the program did not meet outcome requirements, but none of the four outcome reports prior to the most recent one show that the program was out of compliance, a deficiency should be cited at **the standard-level**.

Condition – If the most recent SRTR report shows that the program has not met outcome requirements in two consecutive reports and there is either unchanged or a decline in outcome data, a deficiency should be cited at the **condition-level**.

Every six months, CMS CO receives a list of transplant programs that exceed the outcomes thresholds for patient and graft survival. When a program is identified to be out of compliance with the measures, CMS CO will notify the provider of its non-compliance. More current SRTR data will be reviewed by CMS to determine if the program is improving.

At the time of the next bi-annual SRTR report, if a program continues to exceed the acceptable patient and graft survival rate, with all thresholds crossed over, more recent SRTR data will again be requested and reviewed. If the more recent data indicates that the program's outcomes are not improving, CMS will consider the program to be non-compliant at a condition level and an on-site survey may be scheduled to review/identify associated process requirement concerns.

Deficiencies for non-compliance with the outcome requirements, as well as any additional deficiencies identified at the time of the on-site survey, will be cited upon completion of the survey. If an on-site survey is not conducted, the program will be notified of its non-compliance with the outcome requirements by letter that includes the form CMS-2567.

If a transplant program is cited at a condition-level for §482.82, include the following language in the letter accompanying the CMS-2567:

“The prospective termination date based on noncompliance determination with 42 CFR §482.82 will be set at 210 days. This deficiency must be corrected by [Date] in order for Medicare approval to continue for the program. The program has two options for a plan of correction for §482.82:

1. The program may state that it expects to be back into compliance with §482.82 within 210 days; or
2. The program will apply for mitigating factors review under §488.61(f).”

2062 D - Post-Survey Activities

Following the survey, the surveyor will complete the following forms:

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

Once the CMS-2567 is finalized, it will be forwarded to the hospital administrator with a request for a Plan of Correction (PoC) if substantial compliance with all the requirements was not found. The SA will review and accept or not accept the PoC. 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.

Plan of Correction Transplant Centers

The PoC should include plans for completion of corrective actions at a maximum of 90 days.

The PoC for all deficiency citations, with the exception of §482.80 or §482.82, must indicate projected correction within 90 days from the receipt of the notification of non-compliance. The plan of correction for §482.80 or §482.82 must indicate whether the provider intends to submit mitigating factors to CMS. Prior to the 90th day follow-up by the SA should occur. If the provider has not been determined to have achieved compliance with the CoPs (other than §482.80 or §482.82), the program approval must be terminated.

2062E - Transmission of Program Approval Information (Rev.)

The RO will assign one CMS Certification Number (CCN), within the 9800 series, to all transplant programs operating within a single hospital. The Medicare approval date for the individual program will be determined as follows:

- When there are no deficiencies cited, the approval date is the last date of the survey.
- When there are standard-level deficiencies cited, the approval date is the date on which an acceptable Plan of Correction was received by the SA.
- When there are condition-level deficiencies cited, the approval date is the date on which the transplant program is determined to be back in compliance either through a revisit or, as determined by the CMS based on the approval of mitigating factors.

2062F - Mitigating Factors (Rev.)

2062F.1 Medicare Approval Based on Mitigating Factors (Rev.)

Under §488.61(f), a transplant program may request that CMS consider mitigating factors in the initial approval and re-approval of a transplant program that does not meet the CoPs at §482.80 or §482.82. Mitigating factors will not, however, be considered in situations of immediate jeopardy.

§488.61(f)(1) describes the general areas that will be reviewed in determining whether a program can be initially approved or re-approved based on mitigating factors. These areas include (but are not limited to):

1. The extent to which outcome measures are not met or exceeded;
2. The availability of Medicare-approved transplant centers in the area;
3. Extenuating circumstances (such as natural disasters) that may have a temporary effect on the program;
4. Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available SRTR report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at §482.80(c)(2)(ii)(C) or §482.82(c)(2)(ii)(C);
5. Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone the Fontan procedure, where CMS finds that the innovative practices are supported by evidence-based, published research or nationally recognized standards or Institutional Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and
6. If the program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

2062F.2 Mitigating Factors Application and Review Process (Rev.)

A. Intent to Apply for review of mitigating factors.

1. The program must state on the CMS-2567, which is submitted to the SA that it will apply for mitigating factors as its plan of correction (POC) for non-compliance with data submission, clinical experience, or outcomes noncompliance.

2. Upon receipt of a POC that includes an intent to apply for mitigating factors by the provider, the SA will provide a copy of the POC to the CMS CO mailbox at SCG_TransplantTeam.cms.hhs.gov and the SA will refer the provider to 488.61(f) for the list of the information that should be submitted for the mitigating factors application.

B. Applying for mitigating factors

All information necessary for consideration of mitigating factors must be received within 120 calendar days of receipt of the formal written notification of noncompliance at §482.80 or §482.82. Failure to submit a complete and timely application within 120 calendar days may be the basis for denial of mitigating factors. See 488.61(f) for the materials required for a mitigating factors application.

A request for consideration of mitigating factors must include sufficient information to permit an adequate review of the transplant program, factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and in the case of natural disasters, the recovery actions planned.

The provider must submit the specific information requested by CMS for review.. Information and documents submitted for mitigating factors review should must have all Personally Identifiable Information (PII) removed prior to its submission.

C. The CMS Process for Reviewing Requests for Approval Based on Mitigating Factors

The CMS CO reviews all requests for mitigating factors review. It will include analysis by CMS staff with programmatic and clinical expertise for each transplant program and will be conducted on a case-by-case basis in accordance with §488.61.

D. CMS Determination

According to §§488.61(g)(1)(i)-(iii), CMS has three options after considering applications for mitigating factors. CMS may:

1. Approve or re-approve a program's request for approval based on the consideration of mitigating factors;
2. Deny the program's request for approval or re-approval based on the consideration of mitigating factors; or
3. Offer the program an opportunity to enter into a time-limited **Systems Improvement Agreement (SIA)** with CMS, under certain conditions.

2062 F.3 Processing Medicare Approval based on Mitigating Factors (Rev.)

If a request for approval based on a mitigating factors application is approved, the condition-level non-compliance under §482.80 or §482.82 is rescinded and the prospective termination date is rescinded. Generally:

1. The CO will send an approval letter for mitigating factors to the program with a copy to the SA and RO.
2. The RO will send an approval letter (if it's an initial application) or a letter that removes the prospective termination date (if it is already a Medicare-approved transplant program).
3. The SA/RO will enter an offsite revisit survey into ASPEN and the RO will document the program's approval based on the presence of mitigating factors.
4. The approval based on mitigating factors does not carry forward to future re-certification periods, and CMS may remove approval based on mitigating factors at any time if improvements are not sustained, subject to prior notice to the program and an opportunity to reply.

2062 F.4 Processing Denial of a Mitigating Factors Request (Rev.)

CMS will deny approval based on mitigating factors if it finds that a basis for approval consistent with §488.61(f) has not been adequately established by the transplant program.

If a mitigating factors request is denied, CMS CO will send a letter to the program communicating its denial of the mitigating factors request and copy of that letter will be sent to the SA and RO.

2062 F. 5 Systems Improvement Agreements (SIA) (Rev.)

When a transplant program has condition-level non-compliance with the CoP requirements at §482.80 or §482.82 triggering a pending termination date, CMS may extend the termination date and offer the hospital the opportunity to enter into a time-limited Systems Improvement Agreement (SIA) with CMS. A SIA is a binding agreement that may be offered by CMS pursuant to §488.61(h). The SIA is entered into voluntarily by the hospital. Under an SIA, CMS extends the prospective Medicare termination date and offers the program additional time to achieve compliance with the CoPs, contingent upon the hospital's agreement to participate in a structured regimen of quality improvement activities, to demonstrate improved outcomes, and to waive their right to appeal the noncompliance determination leading to the termination.

To be considered for a SIA, the program must demonstrate that it has developed, implemented, and evaluated interventions that are designed to address root causes that are institutionally supported by the hospital's governing body on a sustainable basis and has requested more time for further improvements or demonstrate compliance with the outcome requirements. SIAs include a mechanism for monitoring the program to ensure that the terms of the SIA are being met and program efforts to undertake targeted and systemic improvements to ensure ongoing and sustainable compliance with the regulatory requirements are occurring.

The SIA is signed by program individuals who have the authority to commit the hospital to the terms of the Agreement. The Agreement is between CMS and the transplant hospital.

In exchange for the additional time to initiate or continue activities to achieve compliance with the CoPs, the hospital must agree to a regimen of specified activities, including (but not limited to) all of the following:

(i) Peer Review: An external independent peer review team that conducts an onsite assessment of the program. The peer review must include—

(A) Review of policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes;

(B) Both verbal and written feedback provided directly to the hospital;

(C); and

(E) Onsite review by a multidisciplinary team that includes a transplant surgeon with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. Except for the transplant surgeon, CMS may permit substitution of one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker;

(iii) Action Plan: An action plan that addresses systemic quality improvements and is updated after the onsite peer review;

(iv) Onsite Consultant: An onsite consultant whose qualifications are approved by CMS, and who provides services for eight (8) days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first three (3) months of the SIA. The function of the onsite consultant is established under the discretion of the program.

(v) Policy & Procedures Review: A comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;

(vi) Outcomes Data Proficiency: Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the SRTR and the use of registry data to analyze outcomes and inform quality improvement efforts;

(vii) Staffing Review: A staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff;

(viii) QAPI: Activities to strengthen performance of the QAPI program to ensure full compliance with the requirements of §482.96 and §482.21;

(ix) Monthly Dialogue: Monthly (unless otherwise specified) reporting with designated monitor regarding the status of programmatic improvements, results of the deliverables in the SIA, and

the number of transplants, deaths, and graft failures that occur within one (1) year post-transplant; and

(x) **Other:** Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances.

The content elements under (v), (vi), (vii), or (viii) above may be waived if CMS finds that the program has already adequately conducted the activity, the program is already proficient in the function, or the activity is clearly inapplicable to the deficiencies that led to the SIA.

When CMS has offered a SIA to a transplant program, and the program agrees to enter into it, the following occurs:

1. CMS develops the initial draft of the proposed SIA, based on (i)-(x) above, and forwards the draft to the program for review and comment;
2. CMS reviews the program's comments and provides feedback regarding any changes to the SIA;
3. CMS and the program will negotiate the final SIA document.
4. CMS completes the final SIA and forwards it to the program for signature. The SIA becomes effective on the date CMS signs the agreement.

2063 - Relationship Between the Transplant CoPs and Hospital CoPs.

The transplant program must be in compliance with all hospital CoPs as well as all transplant program CoPs. Certain hospital requirements are inherently included in the transplant program survey process. When hospital requirements are thought to be out of compliance and in need of investigation the transplant program survey team must contact their supervisor to consult with the CMS RO for further instructions on citing the hospital deficiencies and must notify the hospital administration of any such citation.

The transplant program and hospital survey findings are documented on separate CMS-2567 forms even though the surveys are conducted together.

State Operations Manual Chapter 3 - Additional Program Activities

3012 – Termination of Organ Transplant Programs (Rev.)

Transplant programs with one or more condition-level deficiencies other than 482.80 and 482.82 are placed on a 90 calendar-day termination track.

However, if the program is found to be out of compliance with CoPs 482.80 or 482.82 and submits a request for reconsideration based on mitigating factors, the program will be given 210 days to come into compliance with these conditions

The 90 day termination track is enforced if the program does not come back into compliance regardless of whether the program is also on a 210 day termination track.

Please note that the termination of the transplant program's Medicare approval does not affect the associated hospital's provider agreement for participation as a Medicare-certified hospital. However, condition level findings at the hospital CoPs, may affect the hospitals provider agreement if corrections are not made timely.

HRSA and, if applicable the ESRD Network for a kidney program, are notified by the applicable RO of either a voluntary or involuntary termination of Medicare participation.

“The Health Resources Administration (HRSA) (and if kidney program add ESRD Network) will be notified of this termination in order for them to provide assistance as indicated with potential recipient transfers to another Medicare-approved program.”

Timeframe for Determining Compliance with CoPs

Non-compliance with §482.80 or §482.82 due to outcomes.

180th Calendar Day - If the program has made a credible allegation of compliance (see §3016.A.), acceptable progress is assessed using the information from the most recent SRTR Center Specific Report as required by **§482.80 or §482.82**. An onsite revisit is not required to make a determination of compliance or non-compliance.

180th Calendar Day – For a transplant program initial applicant, if compliance has not been achieved as evidenced by the latest SRTR report, participation is denied. 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 – If compliance has not been achieved as evidenced by the latest SRTR report, the program approval termination date is effective.

LIST OF EXHIBITS

1. Options letter when program is inactive at 12 months.

Exhibit 1: - Program is inactive at 12 months, must re-activate, voluntarily withdraw or be terminated.

Dear [Hospital ADM]:

We received notification that the [organ type] transplant program(s) at [Hospital] will become/became inactive as of [Date].

Pursuant to Transplant Center requirements at 42 CFR 488.61(e), a transplant program is permitted to be inactive for up to 12 months and retain its Medicare approval. The [Organ Type] transplant program at [Hospital] will reach the maximum 12-month period of inactivity on [Date]. CMS does not have the authority to provide an extension beyond this 12-month period and therefore the transplant program will be terminated unless it reactivates prior to the completion of the 12 month period.

We remind you that per §482.102(c)(3), the program must inform all patients on the waitlist of its inactivation and assist those patients who choose to transfer to the waitlist of another Medicare-approved transplant center without loss of time accrued on the waiting list.

If you have any questions please contact [x] at [phone], [e-mail].

Sincerely,

[Name, Title of Authorized Representative]

