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# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

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Transmittal 189

Date: May 24, 2019

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**SUBJECT: New to State Operations Manual (SOM), Appendix X, Survey Protocol and Interpretive Guidelines for Organ Transplant Programs**

**I. SUMMARY OF CHANGES:** CMS has established a new Appendix X in the SOM that outlines the survey process and 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:** May 24, 2019

**IMPLEMENTATION DATE:** May 24, 2019

*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.)**

<b>R/N/D</b>	<b>CHAPTER/SECTION/SUBSECTION/TITLE</b>
N	Appendix X/Guidance to Surveyors: 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:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>Recurring Update Notification</b>

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

# ***State Operations Manual***

## ***Appendix X – Guidance to Surveyors: Organ Transplant Programs***

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**Abbreviations:**

<i>Abbreviations:</i>	
<i>CMS Certification Number</i>	<i>CCN</i>
<i>The Centers for Medicare &amp; Medicaid Services</i>	<i>CMS</i>
<i>The Centers for Medicare &amp; Medicaid Services Central Office</i>	<i>CO</i>
<i>The Centers for Medicare &amp; 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>Abbreviations:</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&amp;TR)</i>	<i>UNOS/OPTN ID</i>

# ***Part I- The Standard Organ Transplant Program Survey Protocol (Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

## ***I. Introduction***

### *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:

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

## ***II. Survey Protocol Tasks***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

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

8	<i>Exit Conference</i>
9	<i>Post Survey Activities</i>

### **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.

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

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

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

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

## **TASK 4 – TRACER FOR PATIENT AND LIVING DONORS**

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

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

### **I. Patient Experience- Evaluation**

*Each patient experience should begin with an evaluation regardless of whether they are or are not ultimately placed on the waitlist. This evaluation must include multidisciplinary involvement to identify all the patient characteristics and attributes to determine suitability for transplant. Multidisciplinary involvement means that each member of the patient care team (designated by the facility) must complete an evaluation of the potential recipient. The evaluation process may appear differently based on the individualized needs of the patient during the evaluation. When reviewing the medical record, identify the members of the multidisciplinary team that have been involved in the care of the patient, identify recommendations, and review for follow-up on these recommendations. Please note that there are specifics in the evaluation that must occur such as medical evaluation, psychological evaluation, and the informed consent process.*

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

### **II. Patient Experience- Patient Selection**

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

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

*placed on the waitlist.*

### *III. Patient Experience- Waitlist Management*

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

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

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

### *IV. Patient Experience- Transplantation*

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

### *V. Patient Experience- Living Donation*

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

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

### *VI. Patient Experience- Patient Care*

*Once the medical record has been reviewed for each sampled patient, the survey should move to the clinical areas where inpatient and outpatient care is provided. During the time the surveyor*

*spends in the clinical areas, all available inpatient and outpatients receiving transplant care on the unit or in the clinic are interviewed. If an interviewed patient was part of the original sample, then compare the information received from the patient with the information received in his/her medical record. . If an interviewed patient is not part of the original sample, the medical record must be reviewed and the information compared to the information provided by the patient regarding his/her patient experience.*

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

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

## ***TASK 5 – QUALITY ASSURANCE AND IMPROVEMENT***

### ***Review of Quality Assessment and Performance***

*Review the medical records for the adverse events sample. The surveyor should examine the record for events leading up to the event. In addition, the QAPI materials associated with the adverse event should be reviewed for each sampled event. Review the QAPI materials to look for the analysis of the event, actions taken following the event, and safeguards to prevent future occurrence. Review the data the program is tracking associated with the adverse event to ensure there is no recurrence. If the program has effectively addressed all the activities outlined above, the surveyor concludes from the sample review that the program does do QAPI activities reactively. However the QAPI director must be interviewed to determine the proactive activities of the QAPI program and the integration of the transplant program QAPI and the hospital QAPI program.*

## ***TASK 6 – PERSONNEL RECORD REVIEW***

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

## ***TASK 7 - PRE-EXIT CONFERENCE***

### ***Survey Team Discussion Meeting***

*Each team member will review and share the evidence he/she has gathered with the other team members. The team should determine any non-compliance and document any such findings*

*including making photocopies of medical records or other documents needed to support the non-compliance. Make all copies prior to the exit conference.*

### **TASK 8 – EXIT CONFERENCE**

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

*During the conference:*

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

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

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

### **TASK 9 - POST SURVEY ACTIVITIES**

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

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

*Once the CMS-2567 is finalized, the SA is responsible for sending the CMS-2567 to the hospital administrator and requesting a plan of correction (note the plan of correction may address more than one type of transplant program). Once an acceptable plan of correction*

*has been submitted, the SA is responsible for scheduling the follow-up visit (if applicable) to ensure that any cited deficiencies have been corrected.*

### ***III. Alternate Survey Protocol: Pediatric Heart Program (Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

#### ***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 3 – 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 4 – 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 5 – STAFF INTERVIEW**

*Follow standard protocol for interviews.*

#### **TASK 6 – PERSONNEL RECORD REVIEW**

*Follow standard protocol for personnel file review.*

#### **TASK 7 – 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 8 – 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 9 – 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 10 – 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.*



**Part II- Interpretive Guidelines for Organ Transplant Programs**  
(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)

**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**

(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)

**§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, except for §482.15.***

**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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

#### ***§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

#### ***§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

***§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.***

#### **Guideline §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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

#### **§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

#### **§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

#### **§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

#### ***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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***

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

#### ***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

### ***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§482.94(b) Standard: Waiting List Management.***

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

## **X-084**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

**§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

**§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

**§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

**§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

#### ***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

#### ***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

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

#### **X-099**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

##### **§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

### **§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

#### **§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

#### **§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

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

## **X-114**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

### **§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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 chronicle 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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

**§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

**§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

**§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**



***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

**§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**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

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

### **X-168**

**(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)**

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

*§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**

*(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)*

***§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

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

***X-185***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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***

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§482.104(b) Standard: Dialysis services.***

***Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement.***

**X-188**

***(Rev. 189, Issued: 05-24-19, Effective: 05-24-19, Implementation: 05-24-19)***

***§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>).*