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FED - X0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline

FED - X0001 - SPECIAL REQUIREMENTS FOR TRANSPLANT CENTERS

Title SPECIAL REQUIREMENTS FOR TRANSPLANT CENTERS

Type Condition

CFR 482.68

Regulation Definition

482.68 - Special Requirements for Transplant Programs. A transplant program 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 programs.

(b) In addition to meeting the conditions of participation specified in §482.72 through §482.104, a transplant program must also meet the conditions of participation specified in §482.1 through §482.57, except §482.15.

Interpretive Guideline

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.

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FED - X0002 - OPTN MEMBERSHIP

Title OPTN MEMBERSHIP

Type Condition

CFR 482.72

Regulation Definition

482.72 Condition of Participation: OPTN Membership. A transplant program 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.

Interpretive Guideline

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.

FED - X0011 - NOTIFICATION TO CMS

Title NOTIFICATION TO CMS

Type Condition

CFR 482.74

Regulation Definition

482.74 Condition of Participation: Notification to CMS. (a) A transplant program must notify CMS immediately of any significant changes related to the program's transplant program

Interpretive Guideline

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.

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or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow-up, as appropriate, should include, but are not limited to;

FED - X0012 - CHANGE IN KEY STAFF MEMBERS

Title CHANGE IN KEY STAFF MEMBERS

Type Element

CFR 482.74(a)(1)

Regulation Definition

482.74(a)(1): Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to, change in key staff members of the transplant team, such as a change in the individual the transplant program designated to the OPTN as the program's "primary transplant surgeon" or "primary transplant physician."

Interpretive Guideline

FED - X0014 - TERMINATION OF AGREEMENT WITH OPO

Title TERMINATION OF AGREEMENT WITH OPO

Type Element

CFR 482.74(a)(2)

Regulation Definition

482.74(a)(2): Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to, termination of an agreement between the hospital in which the transplant program is located and an OPO for the recovery and receipt of organs as required by §482.100; and

Interpretive Guideline

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

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must provide a copy of the decisional document to the SA.

FED - X0015 - INACTIVATION OF TRANSPLANT CENTER

Title INACTIVATION OF TRANSPLANT CENTER

Type Element

CFR 482.74(a)(3)

Regulation Definition

482.74(a)(3): Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to, inactivation of the transplant program.

482.74(b): Upon receiving notification of significant changes, CMS will follow-up with the transplant program as appropriate, including (but not limited to): (1) Requesting additional information; (2) Analyzing the information; or (3) Conducting an on-site review.

Interpretive Guideline

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 Program Inactivity, "A transplant program 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.

FED - X0021 - PEDIATRIC TRANSPLANTS

Title PEDIATRIC TRANSPLANTS

Type Condition

CFR 482.76

Regulation Definition

482.76 Condition of Participation: Pediatric Transplants. A transplant program 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.

482.76 (a) - Except as specified in paragraph (d) of this

Interpretive Guideline

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.

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section, a program 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.

FED - X0022 - ADULT MAJORITY/APPROVED BEFORE PED

Title ADULT MAJORITY/APPROVED BEFORE PED

Type Element

CFR 482.76(b)

Regulation Definition

482.76(b): A program 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.

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

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

Interpretive Guideline

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.

FED - X0023 - PED MAJORITY/APPROVED BEFORE ADULT

Title PED MAJORITY/APPROVED BEFORE ADULT

Type Element

CFR 482.76(c)

Regulation Definition

482.76(c) A program that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be

Interpretive Guideline

Guideline §§482.76(c)(1),(2) and (3)

An adult transplant program is permitted to perform pediatric transplants under its Medicare approval. However, if

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approved to perform pediatric transplants in order to be approved to perform adult transplants.

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

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

482.76(c)(3) A program 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 program.

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.

FED - X0024 - PED HEART OBRA87: JOINTLY OPERATED

Title PED HEART OBRA87: JOINTLY OPERATED

Type Standard

CFR 482.76(d)(1)

Regulation Definition

482.76(d)(1) [Instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant program 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 program's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved.

Interpretive Guideline

Guideline §482.76 (d)(1)

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

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FED - X0025 - PED HEART OBRA87: UNIFIED PROGRAM

Title PED HEART OBRA87: UNIFIED PROGRAM

Type Element

CFR 482.76(d)(2)

Regulation Definition

482.76(d)(2) [Instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant program 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:]
(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

Interpretive Guideline

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.

FED - X0026 - PED HEART OBRA87: QUALIFIED

Title PED HEART OBRA87: QUALIFIED

Type Element

CFR 482.76(d)(3)

Regulation Definition

482.76(d)(3) [Instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant program 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:]

Interpretive Guideline

Guideline §482.76(d)(3)
Facilities include (for example): surgical suites; recovery rooms; inpatient rooms.
Services include (for example): laboratory services; radiology.
Personnel include (for example): all required members of the Multidisciplinary Team; pre-operative and post-operative medical and nursing services.

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(3) The program 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.

FED - X0031 - DATA SUBMIT/EXPERIENCE/OUTCOMES,INIT APPROVAL

Title DATA SUBMIT/EXPERIENCE/OUTCOMES,INIT APPROVAL

Type Condition

CFR 482.80

Regulation Definition

482.80 Condition of Participation: data submission, clinical experience, and outcome requirements for initial approval of transplant programs.

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

Interpretive Guideline

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.

FED - X0032 - DATA SUBMISSION FOR INIT APPROVAL

Title DATA SUBMISSION FOR INIT APPROVAL

Type Standard

CFR 482.80(a)

Regulation Definition

482.80(a) Standard: Data Submission. No later than 90 days after the due date established by the OPTN, a transplant program 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

Interpretive Guideline

Guideline §482.80 (a)

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

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transplant candidate registration, transplant recipient registration and follow-up and living donor registration and follow-up.

FED - X0033 - CLINICAL EXPERIENCE FOR INIT APPROVAL

Title CLINICAL EXPERIENCE FOR INIT APPROVAL

Type Standard

CFR 482.80(b)

Regulation Definition

482.80(b) Standard: Clinical Experience. To be considered for initial approval, an organ-specific transplant program must generally perform 10 transplants over a 12-month period.

Interpretive Guideline

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:

- o Adult Heart-Only
- o Adult Lung-Only
- o Adult Liver
- o 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.

FED - X0035 - OUTCOME: PATIENT/GRAFT SURVIVAL - INIT APPROV

Title OUTCOME: PATIENT/GRAFT SURVIVAL - INIT APPROV

Type Element

CFR 482.80(c)

Regulation Definition

482.80(c) CMS will review outcomes for all transplants

Interpretive Guideline

Guideline §§482.80(c) and (d)(1)-(4)

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performed at a program, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a program requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant program's observed number of patient deaths and graft failures 1-year post-transplant to the program'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) program-specific report.

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

482.80(d) Exceptions. (1) A heart-lung transplant program 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 program 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 program.

(3) A pancreas transplant program is not required to comply with the clinical experience requirements in paragraph (b) of

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

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

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this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the program.

(4) A program 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 program.

FED - X0036 - KIDNEY TRANSPLANT RATE FOR INTIAL APPROVAL

Title KIDNEY TRANSPLANT RATE FOR INTIAL APPROVAL

Type Element

CFR 482.80(d)(5)

Regulation Definition

482.80(d)(5): A kidney transplant program 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.

Interpretive Guideline

FED - X0051 - PATIENT AND LIVING DONOR SELECTION

Title PATIENT AND LIVING DONOR SELECTION

Type Condition

CFR 482.90

Regulation Definition

482.90 Condition of participation: Patient and living donor selection. The transplant program 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 program performs living donor transplants, the program also must use written donor selection

Interpretive Guideline

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.

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criteria in determining the suitability of candidates for donation.

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).

FED - X0052 - PATIENT SELECTION

Title PATIENT SELECTION

Type Standard

CFR 482.90(a)

Regulation Definition

482.90(a) Standard: Patient Selection. Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

Interpretive Guideline

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.

FED - X0053 - PSYCHOSOCIAL EVALUATION FOR CANDIDATE

Title PSYCHOSOCIAL EVALUATION FOR CANDIDATE

Type Element

CFR 482.90(a)(1)

Regulation Definition

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

Interpretive Guideline

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

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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:

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

FED - X0054 - DOCUMENTATION OF CANDIDATE BLOOD TYPE

Title DOCUMENTATION OF CANDIDATE BLOOD TYPE

Type Element

CFR 482.90(a)(2)

Regulation Definition

482.90(a)(2) Before a transplant program 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.

Interpretive Guideline

FED - X0055 - DOCUMENTATION OF PATIENT SELECTION CRITERIA

Title DOCUMENTATION OF PATIENT SELECTION CRITERIA

Type Element

CFR 482.90(a)(3)

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Regulation Definition

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

Interpretive Guideline

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.

FED - X0056 - PROVIDE SELECTION CRITERIA TO PATIENT

Title PROVIDE SELECTION CRITERIA TO PATIENT

Type Element

CFR 482.90(a)(4)

Regulation Definition

482.90(a)(4) A transplant program 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.

Interpretive Guideline

FED - X0058 - PSYCHOSOCIAL EVALUATION FOR LIVING DONOR

Title PSYCHOSOCIAL EVALUATION FOR LIVING DONOR

Type Element

CFR 482.90(b)(1)

Regulation Definition

482.90(b) Standard: Living Donor Selection. The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant programs must: (1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

Interpretive Guideline

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:

- o Social, personal, housing, vocational, financial, and environmental supports;
- o Coping abilities and strategies;

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- o Understanding of the risks and benefits of donation;
- o Ability to adhere to a therapeutic regimen; and
- o Mental health history, including substance and alcohol use or abuse and how it may impact the success or failure of organ transplantation.

FED - X0059 - DOCUMENT SUITABILITY FOR DONATION

Title DOCUMENT SUITABILITY FOR DONATION

Type Element

CFR 482.90(b)(2)

Regulation Definition

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

Interpretive Guideline

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.

FED - X0060 - DOCUMENTATION OF INFORMED CONSENT

Title DOCUMENTATION OF INFORMED CONSENT

Type Element

CFR 482.90(b)(3)

Regulation Definition

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

Interpretive Guideline

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.

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FED - X0071 - ORGAN RECOVERY AND RECEIPT

Title ORGAN RECOVERY AND RECEIPT

Type Condition

CFR 482.92

Regulation Definition

482.92 Condition of participation: Organ recovery and receipt. Transplant programs 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 program is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

Interpretive Guideline

FED - X0073 - ORGAN RECEIPT

Title ORGAN RECEIPT

Type Standard

CFR 482.92(a)

Regulation Definition

482.92(a) Standard: Organ receipt. After an organ arrives at a transplant program, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient.

Interpretive Guideline

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

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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.

FED - X0074 - LIVING DONOR TRANSPLANTATION

Title LIVING DONOR TRANSPLANTATION

Type Standard

CFR 482.92(b)

Regulation Definition

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

Interpretive Guideline

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.

FED - X0081 - PATIENT AND LIVING DONOR MANAGEMENT

Title PATIENT AND LIVING DONOR MANAGEMENT

Type Condition

CFR 482.94

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Regulation Definition

482.94 Condition of participation: Patient and living donor management. Transplant programs must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant program performs living donor transplants, the program also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

Interpretive Guideline

Guideline §482.94

Transplantation and Living Donor Care Phases are generally defined as:

Transplantation Care Phases:

- o Transplant Phase: Begins when the potential transplant candidate is evaluated for transplantation and continues through completion of the transplantation surgery.
- o 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:

- o Evaluation Phase: Begins from first presentation by the potential donor until the time he/she enters the OR for the donation surgery.
- o 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.
- o 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.

FED - X0082 - PATIENT AND LIVING DONOR CARE

Title PATIENT AND LIVING DONOR CARE

Type Standard

CFR 482.94(a)

Regulation Definition

482.94(a) Standard: Patient and living donor care. The transplant program'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

Interpretive Guideline

Guideline §482.94(a)

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

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transplantation; and (2) If a program 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.

FED - X0083 - WAITING LIST MANAGEMENT

Title WAITING LIST MANAGEMENT

Type Standard

CFR 482.94(b)

Regulation Definition

482.94(b) Standard: Waiting list management. Transplant centers must keep their waiting lists up to date on an ongoing basis, including:

Interpretive Guideline

FED - X0084 - UPDATE PATIENT CLINICAL INFORMATION

Title UPDATE PATIENT CLINICAL INFORMATION

Type Element

CFR 482.94(b)(1)

Regulation Definition

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

Interpretive Guideline

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.

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FED - X0085 - REMOVAL FROM WAITING LIST

Title REMOVAL FROM WAITING LIST

Type Element

CFR 482.94(b)(2)

Regulation Definition

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

Interpretive Guideline

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.

FED - X0086 - NOTIFICATION OF REMOVAL TO OPTN

Title NOTIFICATION OF REMOVAL TO OPTN

Type Element

CFR 482.94(b)(3)

Regulation Definition

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

Interpretive Guideline

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.

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FED - X0087 - PATIENT RECORDS

Title PATIENT RECORDS

Type Standard

CFR 482.94(c)

Regulation Definition

482.94(c): Standard: Patient records. Transplant programs must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a program's waiting list and who is admitted for organ transplantation.

Interpretive Guideline

FED - X0088 - PATIENT INFORMED OF WAITLIST STATUS

Title PATIENT INFORMED OF WAITLIST STATUS

Type Element

CFR 482.94(c)(1)

Regulation Definition

482.94(c)(1): For each patient who receives an evaluation for placement on a program's waiting list, the program 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 program's waiting list;
- (ii) The program's decision not to place the patient on its waiting list; or
- (iii) The program's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

Interpretive Guideline

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FED - X0089 - PATIENT NOTIFICATION OF REMOVAL FROM LIST

Title PATIENT NOTIFICATION OF REMOVAL FROM LIST

Type Element

CFR 482.94(c)(2)

Regulation Definition

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 program 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.

Interpretive Guideline

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.

FED - X0090 - CARE PLANNING DURING TRANSPLANT PERIOD

Title CARE PLANNING DURING TRANSPLANT PERIOD

Type Element

CFR 482.94(c)(3)(i)

Regulation Definition

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

Interpretive Guideline

Guideline

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.

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FED - X0091 - DISCHARGE PLANNING FOR POST-TRANSPLANT CARE

Title DISCHARGE PLANNING FOR POST-TRANSPLANT CARE

Type Element

CFR 482.94(c)(3)(ii)

Regulation Definition

482.94(c)(3)(ii): Multidisciplinary discharge planning for post-transplant care.

Interpretive Guideline

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:

- o 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);
- o Contact numbers of transplant program staff that can be contacted for questions;

- o The clinical signs and symptoms indicative of a potential complication from transplantation that would necessitate a call to the doctor;
- o A transplant recipient/living donor specific nutrition plan, as applicable;
- o A plan for addressing psychosocial issues (for example available supports, adaptation to stress of transplant, etc.);
- o Activity restrictions and limitations (for example driving after taking pain medication);
- o Need for coordination of other health services (for example physical or occupational therapies, home care, etc.) and assistance in securing these health services;
- o Medication and administration, including the transplant recipient's schedule for taking medication and the process to obtain the medication; and
- o Any assistance required to access local medical care, equipment or support.

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FED - X0092 - SOCIAL SERVICES

Title SOCIAL SERVICES

Type Standard

CFR 482.94(d)

Regulation Definition

482.94(d): Standard: Social services. The transplant program must make social services available, furnished by qualified social workers, to transplant patients, living donors and their families.

Interpretive Guideline

FED - X0093 - QUALIFIED SOCIAL WORKER

Title QUALIFIED SOCIAL WORKER

Type Standard

CFR 482.94(d)

Regulation Definition

482.93(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 program as of the 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.

Interpretive Guideline

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 Programs 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:

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

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FED - X0094 - NUTRITIONAL SERVICES

Title NUTRITIONAL SERVICES

Type Standard

CFR 482.94(e)

Regulation Definition

482.94(e) : Standard: Nutritional services. Transplant programs 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.

Interpretive Guideline

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.

FED - X0099 - QUALITY ASSESSMENT/PERFORMANCE IMPROVEMENT

Title QUALITY ASSESSMENT/PERFORMANCE IMPROVEMENT

Type Condition

CFR 482.96

Regulation Definition

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.

Interpretive Guideline

Guideline §482.96

The transplant program 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

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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:

- o 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;
- o Collects, records and reviews the data for accuracy;
- o Analyzes the data and uses the data/analyses to assess the program's performance; and
- o Uses the results of its analyses to monitor, evaluate and improve the quality and safety of all transplantation/donation services on an ongoing basis.

FED - X0100 - COMPONENTS OF QAPI PROGRAM

Title COMPONENTS OF QAPI PROGRAM

Type Standard

CFR 482.96(a)

Regulation Definition

482.96(a): Standard: Components of a QAPI program. The transplant program's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights...

Interpretive Guideline

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:

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- o Collect and analyze data to assess its baseline performance and to track performance on the selected measures over time; and
- o 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.

FED - X0101 - ACTIONS TO IMPROVE PERFORMANCE/TRACKING

Title ACTIONS TO IMPROVE PERFORMANCE/TRACKING

Type Standard

CFR 482.96(a)

Regulation Definition

482.96(a): ...The transplant program must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

Interpretive Guideline

Guideline §482.96(a)(cont'd)

The transplant program must use what it learns from monitoring the objective measures described under Tag X 100 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.

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FED - X0102 - ADVERSE EVENTS

Title ADVERSE EVENTS

Type Standard

CFR 482.96(b)(1)

Regulation Definition

482.96(b)(1): Standard: Adverse events. A transplant program 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.

Interpretive Guideline

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:

- o A clear definition of what the transplant program considers an adverse event incorporating the CMS regulatory definition;
 - o The procedures for internal reporting of adverse events in all phases of transplant recipient or living donor care within the hospital;
 - o The process(es) used for analyzing adverse events in the transplant program;
 - o The process for developing, evaluating and tracking actions to prevent recurrence; and
 - o The required timeframe for reporting, investigating and analyzing adverse events.
- The policies should also address any external adverse event reporting obligations, such as:
- o External reporting of events to the OPTN, ESRD Network, etc. as required and applicable;
 - o 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
 - o 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.

FED - X0103 - ANALYSIS/DOCUMENTATION OF ADVERSE EVENT

Title ANALYSIS/DOCUMENTATION OF ADVERSE EVENT

Type Element

CFR 482.96(b)(2)

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Regulation Definition

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

Interpretive Guideline

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:

- o 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;
- o A review of whether similar events have occurred in the past;
- o All of the information needed to identify factors that may have caused or contributed to the outcome, directly or indirectly;
- o Analysis of the information to identify actual and potential vulnerabilities and opportunities to reduce risks and improve care;
- o 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
- o Specific plan for implementing, evaluating and monitoring improvement actions

(timeframes, responsible parties, measurement strategy to assess effectiveness, etc.).

FED - X0104 - EFFECT CHANGES TO PREVENT REPEAT INCIDENTS

Title EFFECT CHANGES TO PREVENT REPEAT INCIDENTS

Type Element

CFR 482.96(b)(2)

Regulation Definition

482.96(b)(2): The transplant program must utilize the adverse event analysis to effect changes in the transplant program's policies and practices to prevent repeat incidents.

Interpretive Guideline

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FED - X0109 - HUMAN RESOURCES

Title HUMAN RESOURCES

Type Condition

CFR 482.98

Regulation Definition

§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.

Interpretive Guideline

FED - X0110 - DIRECTOR OF A TRANSPLANT CENTER

Title DIRECTOR OF A TRANSPLANT CENTER

Type Standard

CFR 482.98(a)

Regulation Definition

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

Interpretive Guideline

Guideline §482.98(a)

The designated director of a transplant program 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.

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FED - X0111 - DIRECTOR RESPONSIBILITIES

Title DIRECTOR RESPONSIBILITIES

Type Standard

CFR 482.98(a)

Regulation Definition

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:

Interpretive Guideline

FED - X0112 - ADEQUATE TRAINING OF NURSING STAFF

Title ADEQUATE TRAINING OF NURSING STAFF

Type Element

CFR 482.98(a)(1)

Regulation Definition

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

Interpretive Guideline

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 program 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.

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FED - X0113 - TISSUE TYPING/ORGAN PROCUREMENT SERVICES

Title TISSUE TYPING/ORGAN PROCUREMENT SERVICES

Type Element

CFR 482.98(a)(2)

Regulation Definition

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

Interpretive Guideline

FED - X0114 - SURGERY BY QUALIFIED TRANSPLANT SURGEON

Title SURGERY BY QUALIFIED TRANSPLANT SURGEON

Type Element

CFR 482.98(a)(3)

Regulation Definition

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).

Interpretive Guideline

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.

FED - X0115 - TRANSPLANT SURGEON AND PHYSICIAN

Title TRANSPLANT SURGEON AND PHYSICIAN

Type Standard

CFR 482.98(b)

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Regulation Definition

482.98(b) Standard: Transplant Surgeon and Physician. The transplant program 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.

Interpretive Guideline

FED - X0116 - SURGEON RESPONSIBLE FOR SURGICAL SERVICES

Title SURGEON RESPONSIBLE FOR SURGICAL SERVICES

Type Element

CFR 482.98(b)(1)

Regulation Definition

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

Interpretive Guideline

Guideline §482.98(b)(1)

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

FED - X0117 - PHYSICIAN RESPONSIBLE FOR TRANSPLANT CARE

Title PHYSICIAN RESPONSIBLE FOR TRANSPLANT CARE

Type Element

CFR 482.98(b)(2)

Regulation Definition

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

Interpretive Guideline

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.

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FED - X0118 - CLINICAL TRANSPLANT COORDINATOR

Title CLINICAL TRANSPLANT COORDINATOR

Type Standard

CFR 482.98(c)

Regulation Definition

482.98(c) Standard: Clinical Transplant Coordinator. The transplant program 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...

Interpretive Guideline

FED - X0119 - LICENSED RN OR CLINICIAN

Title LICENSED RN OR CLINICIAN

Type Standard

CFR 482.98(c)

Regulation Definition

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...

Interpretive Guideline

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.

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FED - X0120 - TRANSPLANT COORDINATOR RESPONSIBILITIES

Title TRANSPLANT COORDINATOR RESPONSIBILITIES

Type Standard

CFR 482.98(c)

Regulation Definition

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 program and dialysis facilities, as applicable.

Interpretive Guideline

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.

FED - X0121 - INDEPENDENT LIVING DONOR ADVOCATE/TEAM

Title INDEPENDENT LIVING DONOR ADVOCATE/TEAM

Type Standard

CFR 482.98(d)

Regulation Definition

482.98(d) Standard: Independent Living Donor Advocate or Independent Living Donor Advocate Team. The transplant program 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.

Interpretive Guideline

Guideline §482.98 (d)

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

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FED - X0122 - ADVOCATE NOT INVOLVED IN TRANSPLANT ACTIVITY

Title ADVOCATE NOT INVOLVED IN TRANSPLANT ACTIVITY

Type Element

CFR 482.98(d)(1)

Regulation Definition

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

Interpretive Guideline

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.

FED - X0123 - ADVOCATE/TEAM KNOWLEDGE OF ORGAN DONATION

Title ADVOCATE/TEAM KNOWLEDGE OF ORGAN DONATION

Type Element

CFR 482.98(d)(2)

Regulation Definition

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.

Interpretive Guideline

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:

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

The living donor medical record should fully chronical the interactions between the advocate or advocate team and

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donor candidate including the assessed level of understanding by the donor candidate during interactions.

FED - X0124 - ADVOCATE/TEAM RESPONSIBILITIES

Title ADVOCATE/TEAM RESPONSIBILITIES

Type Element

CFR 482.98(d)(3)

Regulation Definition

482.98(d)(3) The independent living donor advocate or independent 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.

Interpretive Guideline

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.

FED - X0125 - MULTIDISCIPLINARY TRANSPLANT TEAM

Title MULTIDISCIPLINARY TRANSPLANT TEAM

Type Standard

CFR 482.98(e)

Regulation Definition

482.98(e) Standard: Transplant Team. The transplant program must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant

Interpretive Guideline

Guideline §482.98(e)

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

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coordination, and pharmacology.

FED - X0126 - RESOURCE COMMITMENT

Title RESOURCE COMMITMENT

Type Standard

CFR 482.98(f)

Regulation Definition

482.98(f) Standard: Resource Commitment. The transplant program 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.

Interpretive Guideline

FED - X0139 - ORGAN PROCUREMENT

Title ORGAN PROCUREMENT

Type Condition

CFR 482.100

Regulation Definition

482.100 Condition of Participation: Organ Procurement. The transplant program 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.

Interpretive Guideline

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.

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FED - X0149 - PATIENT AND LIVING DONOR RIGHTS

Title PATIENT AND LIVING DONOR RIGHTS

Type Condition

CFR 482.102

Regulation Definition

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 program must protect and promote each transplant patient's and living donor's rights.

Interpretive Guideline

FED - X0150 - INFORMED CONSENT FOR TRANSPLANT PATIENTS

Title INFORMED CONSENT FOR TRANSPLANT PATIENTS

Type Standard

CFR 482.102(a)

Regulation Definition

482.102(a) Standard: Informed Consent for Transplant Patients. Transplant programs must implement written transplant patient informed consent policies that inform each patient of the following specific requirements.

Interpretive Guideline

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).

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FED - X0151 - PATIENT INFORMED OF EVALUATION PROCESS

Title PATIENT INFORMED OF EVALUATION PROCESS

Type Element

CFR 482.102(a)(1)

Regulation Definition

482.102(a)(1) Each patient is informed of the evaluation process.

Interpretive Guideline

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.

FED - X0152 - PATIENT INFORMED OF SURGICAL PROCEDURE

Title PATIENT INFORMED OF SURGICAL PROCEDURE

Type Element

CFR 482.102(a)(2)

Regulation Definition

482.102(a)(2) Each patient is informed of the surgical procedure.

Interpretive Guideline

Guideline §482.102(a)(2)

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

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

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FED - X0153 - PATIENT INFORMED OF ALTERNATIVE TREATMENTS

Title PATIENT INFORMED OF ALTERNATIVE TREATMENTS

Type Element

CFR 482.102(a)(3)

Regulation Definition

482.102(a)(3) Each patient is informed of alternative treatments.

Interpretive Guideline

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.

FED - X0154 - PATIENT INFORMED OF POTENTIAL RISKS

Title PATIENT INFORMED OF POTENTIAL RISKS

Type Element

CFR 482.102(a)(4)

Regulation Definition

482.102(a)(4) Each patient is informed of potential medical or psychosocial risks.

Interpretive Guideline

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.

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FED - X0155 - PATIENT INFORMED OF NATIONAL/CENTER OUTCOMES

Title PATIENT INFORMED OF NATIONAL/CENTER OUTCOMES

Type Element

CFR 482.102(a)(5)

Regulation Definition

482.102(a)(5) Each patient is informed of national and transplant program-specific outcomes, from the most recent SRTR program-specific report, including (but not limited to) the transplant program's observed and expected 1-year patient and graft survival, and national 1-year patient and graft survival;

Interpretive Guideline

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.

FED - X0156 - PATIENT INFORMED OF DONOR RISK FACTORS

Title PATIENT INFORMED OF DONOR RISK FACTORS

Type Element

CFR 482.102(a)(6)

Regulation Definition

482.102(a)(6) Each patient is informed of organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor.

Interpretive Guideline

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>

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FED - X0157 - PATIENT INFORMED OF RIGHT TO REFUSE

Title PATIENT INFORMED OF RIGHT TO REFUSE

Type Element

CFR 482.102(a)(7)

Regulation Definition

482.102(a)(7) Each patient is informed of his or her right to refuse transplantation; and

Interpretive Guideline

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.

FED - X0158 - PATIENT INFORMED OF DRUG PAYMENT FACTORS

Title PATIENT INFORMED OF DRUG PAYMENT FACTORS

Type Element

CFR 482.102(a)(8)

Regulation Definition

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

Interpretive Guideline

FED - X0159 - INFORMED CONSENT FOR LIVING DONORS

Title INFORMED CONSENT FOR LIVING DONORS

Type Standard

CFR 482.102(b)

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Regulation Definition

482.102(b) Standard: Informed consent for living donors. Transplant programs 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 programs must ensure that the prospective living donor is fully informed about the following:

Interpretive Guideline

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.

FED - X0160 - DONOR INFORMED OF CONFIDENTIAL COMMUNICATION

Title DONOR INFORMED OF CONFIDENTIAL COMMUNICATION

Type Element

CFR 482.102(b)(1)

Regulation Definition

482.102(b)(1) The prospective living donor is fully informed about the fact that communication between the donor and the transplant program will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

Interpretive Guideline

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.

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FED - X0161 - DONOR INFORMED OF EVALUATION PROCESS

Title DONOR INFORMED OF EVALUATION PROCESS

Type Element

CFR 482.102(b)(2)

Regulation Definition

482.102(b)(2) The prospective living donor is fully informed about the evaluation process.

Interpretive Guideline

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.

FED - X0162 - DONOR INFORMED OF SURGICAL PROCEDURE

Title DONOR INFORMED OF SURGICAL PROCEDURE

Type Element

CFR 482.102(b)(3)

Regulation Definition

482.102(b)(3) The prospective living donor is fully informed about the surgical procedure, including post-operative treatment;

Interpretive Guideline

Guideline §482.102(b)(3)

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

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

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FED - X0163 - DONOR INFORMED OF ALT TRTMNTS FOR RECIPIENT

Title DONOR INFORMED OF ALT TRTMNTS FOR RECIPIENT

Type Element

CFR 482.102(b)(4)

Regulation Definition

482.102(b)(4) The prospective living donor is fully informed about the availability of alternative treatments for the transplant recipient;

Interpretive Guideline

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.

FED - X0164 - DONOR INFORMED OF POTENTIAL RISKS

Title DONOR INFORMED OF POTENTIAL RISKS

Type Element

CFR 482.102(b)(5)

Regulation Definition

482.102(b)(5) The prospective living donor is fully informed about the potential medical or psychosocial risks to the donor;

Interpretive Guideline

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.

FED - X0165 - DONOR INFORMED OF NATIONAL/CENTER OUTCOMES

Title DONOR INFORMED OF NATIONAL/CENTER OUTCOMES

Type Element

CFR 482.102(b)(6)

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Regulation Definition

482.102(b)(6) The prospective living donor is fully informed about the national and transplant program-specific outcomes for recipients, and the national and program-specific outcomes for living donors, as data are available;

Interpretive Guideline

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 program specific outcomes for living donors calculated by the SRTR.

FED - X0166 - DONOR INFORMED OF POSSIBLE NON-COVERAGE

Title DONOR INFORMED OF POSSIBLE NON-COVERAGE

Type Element

CFR 482.102(b)(7)

Regulation Definition

482.102(b)(7) The prospective living donor is fully informed about 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.

Interpretive Guideline

FED - X0167 - RIGHT TO OPT OUT OF DONATION

Title RIGHT TO OPT OUT OF DONATION

Type Element

CFR 482.102(b)(8)

Regulation Definition

482.102(b)(8) The prospective living donor is fully informed about the donor's right to opt out of donation at any time during the donation process; and

Interpretive Guideline

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FED - X0168 - RISK OF RECIPIENT DRUG NON PAYMENT

Title RISK OF RECIPIENT DRUG NON PAYMENT

Type Element

CFR 482.102(b)(9)

Regulation Definition

482.102(b)(9) The prospective living donor is fully informed about the fact that if a transplant is not provided in a Medicare-approved transplant program it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

Interpretive Guideline

FED - X0169 - NOTIFICATION TO PATIENTS

Title NOTIFICATION TO PATIENTS

Type Standard

CFR 482.102(c)

Regulation Definition

482.102(c) Standard: Notification to patients. Transplant programs must notify patients placed on the program's waiting list of information about the program 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.

Interpretive Guideline

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FED - X0170 - POTENTIAL UNAVAILABILITY OF SURGEON

Title POTENTIAL UNAVAILABILITY OF SURGEON

Type Element

CFR 482.102(c)(1)

Regulation Definition

482.102(c)(1)A transplant program served by a single transplant surgeon or physician must inform patients placed on the program'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.

Interpretive Guideline

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.

FED - X0171 - INFORM PATIENTS OF MEDICARE TERMINATION

Title INFORM PATIENTS OF MEDICARE TERMINATION

Type Element

CFR 482.102(c)(2)

Regulation Definition

482.102(c)(2) At least 30 days before a program's Medicare approval is terminated, whether voluntarily or involuntarily, the center must: (i) inform patients on the program's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant program without loss of time accrued on the waiting list; and (ii) inform Medicare beneficiaries on the program's waiting list that Medicare will no longer pay for transplants performed at the program after the effective date of the program's termination of approval.

Interpretive Guideline

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FED - X0172 - INFORM PATIENTS OF VOLUNTARY INACTIVATION

Title INFORM PATIENTS OF VOLUNTARY INACTIVATION

Type Element

CFR 482.102(c)(3)

Regulation Definition

482.102(c)(3) As soon as possible prior to a transplant program's voluntary inactivation, the program must inform patients on the program'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 program without loss of time accrued on the waiting list.

Interpretive Guideline

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

Waiting list patients should receive notification of the program's voluntary inactivation at least 30 days prior to the planned inactivation date. Transplant programs determine the method of communication with the potential recipients and the program must be able to document the communication.

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

FED - X0184 - ADDITIONAL REQUIREMENTS FOR KIDNEY TRANSPLANT

Title ADDITIONAL REQUIREMENTS FOR KIDNEY TRANSPLANT

Type Condition

CFR 482.104

Regulation Definition

482.104 Condition of Participation: Additional requirements

Interpretive Guideline

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FED - X0185 - END STAGE RENAL DISEASE (ESRD) SERVICES

Title END STAGE RENAL DISEASE (ESRD) SERVICES

Type Standard

CFR 482.104(a)

Regulation Definition

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

Interpretive Guideline

FED - X0186 - ONGOING COMMUNICATION WITH DIALYSIS FACILITY

Title ONGOING COMMUNICATION WITH DIALYSIS FACILITY

Type Standard

CFR 482.104(a)

Regulation Definition

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

Interpretive Guideline

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.

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FED - X0187 - DIALYSIS SERVICES

Title DIALYSIS SERVICES

Type Standard

CFR 482.104(b)

Regulation Definition

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

Interpretive Guideline

FED - X0188 - PARTICIPATION IN ESRD NETWORK ACTIVITIES

Title PARTICIPATION IN ESRD NETWORK ACTIVITIES

Type Standard

CFR 482.104(c)

Regulation Definition

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

Interpretive Guideline

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>).

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FED - X9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline