



# Federal Register

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**Friday,  
March 30, 2007**

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## **Part II**

### **Department of Health and Human Services**

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**Centers for Medicare & Medicaid Services**

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**42 CFR Parts 405, 482, 488, and 498  
Medicare Program; Hospital Conditions of  
Participation; Requirements for Approval  
and Re-Approval of Transplant Centers  
To Perform Organ Transplants; Final Rule**

under this final rule, all transplant centers must be re-approved every 3 years, and some centers will be surveyed as part of our re-approval process. Thus, this final rule is likely to increase survey costs.

Nevertheless, to the extent possible, we will minimize costs by prioritizing surveys based on transplant centers performance on the outcome requirements and by conducting surveys in the most efficient way possible. For example, all transplant centers located in the same hospital will be surveyed at the same time.

In addition, since Medicare reimbursement rates are either directly or indirectly influenced by a hospital's costs, we may eventually increase Medicare reimbursement to transplant centers to cover some of the costs of their extra responsibilities. Medicare pays hospitals on a cost basis for certain "organ acquisition costs". Costs related to the requirement to have a donor advocate or donor advocate team are organ acquisition costs.

Medicare generally reimburses hospitals for organ transplant costs for beneficiaries using diagnosis related groups (DRGs) in all States, except for Maryland. DRG payments are periodically re-weighted in a budget neutral fashion to increase payments for procedures that have costs that are growing at a faster rate than most other procedures. Therefore, it is possible that DRGs for organ transplants will increase and therefore offset some of the hospitals' costs under the various transplant DRGs.

#### Conclusion

We believe that the requirements in this final rule will ensure that the organ transplants made available to patients are provided in a safe and effective manner. We also believe that this final rule will ensure that living donors receive the guidance and care that they deserve. We estimate that the first year cost of implementing this final rule is \$28,420,256. The cost of implementation in subsequent years is estimated to be \$9,566,291 annually.

#### List of Subjects

##### 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

##### 42 CFR Part 482

Grant programs—health, Hospitals, Medicare, reporting and recordkeeping requirements.

##### 42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, reporting and recordkeeping requirements.

##### 42 CFR Part 498

Administrative practice and procedure, Health Facilities, Health professions, Medicare, reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

#### PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

##### Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

■ 1. The authority citation for part 405, Subpart U continues to read as follows:

**Authority:** Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

##### § 405.2102 [Amended]

■ 2. Section 405.2102 is amended by—

■ A. Removing the definitions for "histocompatibility testing" and "organ procurement".

■ B. Amending the definition of "ESRD facility" by removing paragraph (a) and by re-designating paragraphs (b) through (e) as paragraphs (a) through (d).

■ C. Amending the definition of "ESRD service" by removing paragraph (a) and by re-designating paragraphs (b) and (c) as paragraphs (a) and (b).

■ D. Amending the definition of "Qualified personnel" by removing paragraph (g).

##### §§ 405.2120 through 405.2124 [Removed]

■ 3. Sections 405.2120 through 405.2124 are removed.

##### § 405.2130 [Removed]

■ 4. Section 405.2130 is removed.

##### §§ 405.2170 and 405.2171 [Removed]

■ 5. Section 405.2170 and 405.2171 are removed.

#### PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 6. The authority citation for part 482 is revised to read as follows:

**Authority:** Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 7. Part 482 is amended by revising subpart E to read as follows:

##### Subpart E—Requirements for Specialty Hospitals

Sec.

482.68 Special requirements for transplant centers.

482.70 Definitions.

##### General Requirements for Transplant Centers

482.72 Condition of participation: OPTN Membership.

482.74 Condition of participation: Notification to CMS.

482.76 Condition of participation: Pediatric Transplants.

##### Transplant Center Data Submission, Clinical Experience, and Outcome Requirements

482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.

482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

##### Transplant Center Process Requirements

482.90 Condition of participation: Patient and living donor selection.

482.92 Condition of participation: Organ recovery and receipt.

482.94 Condition of participation: Patient and living donor management.

482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

482.98 Condition of participation: Human resources.

482.100 Condition of participation: Organ procurement.

482.102 Condition of participation: Patient and living donor rights.

482.104 Condition of participation: Additional requirements for kidney transplant centers.

##### Subpart E—Requirements for Specialty Hospitals

##### § 482.68 Special requirements for transplant centers.

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

(a) Unless specified otherwise, the conditions of participation at § 482.72 through § 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

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

**§ 482.70 Definitions.**

As used in this subpart, the following definitions apply:

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

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

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

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

*Intestine transplant center* means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

*Network organization* means the administrative governing body to the network and liaison to the Federal government.

*Pancreas transplant center* means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

*Transplant center* means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

*Transplant hospital* means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

*Transplant program* means a component within a transplant hospital (as defined in this rule) that provides transplantation of a particular type of organ.

**General Requirements for Transplant Centers****§ 482.72 Condition of participation: OPTN membership.**

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

**§ 482.74 Condition of participation: Notification to CMS.**

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

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

(2) A decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with § 482.82;

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

(4) Inactivation of the transplant center.

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

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

**§ 482.76 Condition of participation: Pediatric Transplants.**

A transplant center that seeks Medicare approval to provide transplantation services to pediatric

patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at § 488.61 of this chapter.

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

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

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

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

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

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

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

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

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

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

(2) The unified program shares the same transplant surgeons and quality

improvement program (including oversight committee, patient protocol, and patient selection criteria); and

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

#### **Transplant Center Data Submission, Clinical Experience, and Outcome Requirements**

##### **§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.**

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

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

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

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

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

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

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

(i) A center's observed patient survival rate or observed graft survival

rate is lower than its expected patient survival rate or expected graft survival rate; and

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

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

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

(C) The number of observed events divided by the number of expected events is greater than 1.5.

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

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

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

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

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

##### **§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.**

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

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. Required data submissions

include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

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

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

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

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

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

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

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

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

(C) The number of observed events divided by the number of expected events is greater than 1.5.

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

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

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

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

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

#### **Transplant Center Process Requirements**

##### **§ 482.90 Condition of participation: Patient and living donor selection.**

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

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

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

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

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

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

(b) *Standard: Living donor selection.* The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

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

(2) Document in the living donor's medical records the living donor's suitability for donation, and

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

##### **§ 482.92 Condition of participation: Organ recovery and receipt.**

Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data

for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) *Standard: Organ recovery.* When the identity of an intended transplant recipient is known and the transplant center sends a team to recover the organ(s), the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

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

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

##### **§ 482.94 Condition of participation: Patient and living donor management.**

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(a) *Standard: Patient and living donor care.* The transplant center's patient and donor management policies must ensure that:

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

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

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

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

(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

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

(c) *Standard: Patient records.*

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

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

(i) The patient's placement on the center's waiting list;

(ii) The center's decision not to place the patient on its waiting list; or

(iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

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

(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

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

(d) *Standard: Social services.* The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and

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

(2) Is working as a social worker in a transplant center as of 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.

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

**§ 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.

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

(b) *Standard: Adverse events.* A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

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

(2) The transplant center must conduct a thorough analysis of and document any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

**§ 482.98 Condition of participation: Human resources.**

The transplant center must ensure that all individuals who provide

services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

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

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

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

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

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

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

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

(c) *Standard: Clinical transplant coordinator.* The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. 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. The clinical transplant coordinator's responsibilities must include, but are not limited to, the following:

(1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and

(2) Acting as a liaison between a kidney transplant center and dialysis facilities, as applicable.

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

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

(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.

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

(i) Representing and advising the donor;

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

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

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

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

**§ 482.100 Condition of participation: Organ procurement.**

The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific

responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

**§ 482.102 Condition of participation: Patient and living donor rights.**

In addition to meeting the condition of participation "Patients rights" requirements at § 482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.

(a) *Standard: Informed consent for transplant patients.* Transplant centers must implement written transplant patient informed consent policies that inform each patient of:

- (1) The evaluation process;
- (2) The surgical procedure;
- (3) Alternative treatments;
- (4) Potential medical or psychosocial risks;
- (5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;

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

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

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

(b) *Standard: Informed consent for living donors.* Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

- (1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.
- (2) The evaluation process;
- (3) The surgical procedure, including post-operative treatment;
- (4) The availability of alternative treatments for the transplant recipient;

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

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

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

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

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

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

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

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

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

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

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

**§ 482.104 Condition of participation: Additional requirements for kidney transplant centers.**

(a) *Standard: End stage renal disease (ESRD) services.* Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

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

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

**PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES**

**Subpart A—General Provisions**

- 8. The authority citation for part 488 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh) unless otherwise noted).

**§ 488.6 [Amended]**

- 9. Section 488.6(a) is amended by adding "transplant centers, except for kidney transplant centers;" after "psychiatric hospitals;" but before "SNFs."

**Subpart B—Special Requirements**

- 10. Section 488.61 is added to subpart B to read as follows:

**§ 488.61 Special procedures for approval and re-approval of organ transplant centers.**

For the purposes of this subpart, the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A apply to transplant centers, including the periodic review of compliance and approval described at § 488.20.

(a) *Initial approval procedures for transplant centers that are not Medicare-approved as of June 28, 2007.* A transplant center, including a kidney transplant center, may submit a request to CMS for Medicare approval at any time.

(1) The request, signed by a person authorized to represent the center (for example, a chief executive officer), must include:

- (i) The hospital's Medicare provider I.D. number;

(ii) Name(s) of the designated primary transplant surgeon and primary transplant physician; and,

(iii) A statement from the OPTN that the center has complied with all data submission requirements.

(2) To determine compliance with the clinical experience and outcome requirements at § 482.80(b) and § 482.80(c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) center-specific report.

(3) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, of the effective date of its approval.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements, CMS will review the center's compliance with the conditions of participation contained at § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter using the procedures described at 42 CFR part 488, subpart A. If the transplant center is found to be in compliance with all the conditions of participation at § 482.72 through § 482.104, except for § 482.82 of this chapter (Re-approval Requirements), CMS will notify the transplant center in writing of the effective date of its Medicare-approval.

CMS will notify the transplant center in writing if it is not Medicare-approved.

(6) A kidney transplant center may submit a request for initial approval after performing at least 3 transplants over a 12-month period.

(7) Transplant centers will be approved for 3 years.

(b) *Initial approval procedures for transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007.*

(1) A transplant center that wants to continue to be Medicare approved must be in compliance with the conditions of participation at §§ 482.72 through 482.104 as of June 28, 2007 and submit a request to CMS for Medicare approval under the conditions of participation no later than December 26, 2007, using the process described in paragraph (a)(1) of the section.

(2) CMS will determine whether to approve the transplant center, using the procedures described in paragraphs (a)(2) through (a)(5) of this section. Until CMS makes a determination whether to approve the transplant center under the conditions of participation at §§ 482.72 through 482.104, the transplant center will continue to be Medicare approved under the end stage renal disease (ESRD) conditions for coverage (CfCs) in part 405, subpart U of this chapter for kidney transplant centers or the pertinent national coverage decisions (NCDs) for extra-renal organ transplant centers, as applicable, and the transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

(3) Once CMS approves a kidney transplant center under the conditions of participation, the ESRD CfCs no longer apply to the center as of the date of its approval. Once CMS approves an extra-renal organ transplant center under the conditions of participation, the NCDs no longer apply to the center as of the date of its approval.

(4) If a transplant center that is Medicare approved as of June 28, 2007 submits a request for approval under the CoPs at §§ 482.72 through 482.104 of this chapter but CMS does not approve the transplant center, or if the transplant center does not submit its request to CMS for Medicare approval under the CoPs by December 26, 2007, CMS will revoke the transplant center's approval under the conditions for coverage for kidney transplant centers or the national coverage decisions for extra-renal transplant centers, as applicable, and the transplant center will no longer be reimbursed for services provided to Medicare beneficiaries. CMS will notify the transplant center in writing of the

effective date of its loss of Medicare approval.

(c) *Re-approval procedures.* Once Medicare-approved, transplant centers, including kidney transplant centers, must be in compliance with all the conditions of participation for transplant centers at § 482.72 through § 482.104 of this chapter, except for § 482.80 (initial approval requirements) throughout the 3-year approval period.

(1) Prior to the end of the 3-year approval period, CMS will review the transplant center's data in making re-approval determinations.

(i) To determine compliance with the data submission requirements at § 482.82(a) of this chapter, CMS will request data submission data from the OPTN for the previous 3 calendar years.

(ii) To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and § 482.82(c) of this chapter, CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent SRTR center-specific reports.

(2) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements at § 482.82, the transplant center will be reviewed for compliance with § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(3) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements at § 482.82, CMS may choose to review the transplant center for compliance with § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may re-approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) CMS will notify the transplant center in writing if its approval is being revoked and of the effective date of the revocation.

(d) *Loss of Medicare Approval.*

Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A center that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in § 488.61(a);

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter, except for § 482.82 (Re-approval

Requirements), at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status.

(e) *Transplant Center Inactivity.* A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months during

the 3-year approval cycle. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(d) of this chapter.

**PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM**

■ 11. The authority citation for part 498 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart A—General Provisions**

**§ 498.2 [Amended]**

■ 12. In § 498.2, the definition of “provider” is amended by adding

“transplant center” after “hospital” the first time it appears.

(Catalog of Federal Domestic Assistance Program No. 13.773 Medicare—Hospital Insurance Program; and No. 13.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 7, 2006.

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: December 12, 2006.

**Michael O. Leavitt**

*Secretary.*

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