

§ 482.98

42 CFR Ch. IV (10–1–10 Edition)

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 trans-

plant 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;