Centers for Medicare & Medicaid Services, HHS

§ 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 pretransplant, 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: