§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the OPO and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) Standard: Organ transplantation responsibilities. (1) A hospital in which organ transplants are performed must be a member 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) and abide by its rules. The term “rules of the OPTN” means those rules provided
for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) Standard: Organization and staffing. The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(b) Standard: Delivery of service. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.

(ii) An updated examination of the patient, including any changes in the patient’s condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

(2) A properly executed informed consent form for the operation must be in the patient’s chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

[51 FR 22042, June 17, 1986, as amended at 72 FR 66933, Nov. 27, 2007]

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a