

§ 486.322

and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those rules and requirements approved by the Secretary. No OPO is considered out of compliance with section 1138(b)(1)(D) of the Act or this section until the Secretary approves a determination that the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such non-compliance has been determined in this manner.

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) *Standard:* Hospital agreements. An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms “timely referral” and “imminent death.”

(b) *Standard:* Designated requestor training for hospital staff. The OPO must offer to provide designated requestor training on at least an annual basis for hospital and critical access hospital staff.

(c) *Standard:* Cooperation with tissue banks.

(1) The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:

(i) Screening and referral of potential tissue donors.

42 CFR Ch. IV (10–1–06 Edition)

(ii) Obtaining informed consent from families of potential tissue donors.

(iii) Retrieval, processing, preservation, storage, and distribution of tissues.

(iv) Providing designated requestor training.

(2) An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

§ 486.324 Condition: Administration and governing body.

(a) While an OPO may have more than one board, the OPO must have an advisory board that has both the authority described in paragraph (b) of this section and the following membership:

(1) Members who represent hospital administrators, either intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO’s service area.

(2) Individuals who represent the public residing in the OPO’s service area.

(3) A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(4) A neurosurgeon or other physician with knowledge or skills in the neurosciences.

(5) A transplant surgeon representing each transplant hospital in the service area with which the OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the transplant hospital represented.

(6) An organ donor family member.

(b) The OPO board described in paragraph (a) of this section has the authority to recommend policies for the following:

(1) Procurement of organs.

(2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.

(3) Systematic efforts, including professional education, to acquire all usable organs from potential donors.

(4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immunodeficiency syndrome (AIDS).

(5) Appropriate tissue typing of organs.

(6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(7) Transportation of organs to transplant hospitals.

(8) Coordination of activities with transplant hospitals in the OPO's service area.

(9) Participation in the OPTN.

(10) Arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors.

(11) Annual evaluation of the effectiveness of the OPO in acquiring organs.

(12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) The advisory board described in paragraph (a) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. Members of the advisory board described in paragraph (a) of this section are prohibited from serving on any other OPO board.

(d) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members. (e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) pro-

gram, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(f) The OPO must have procedures to address potential conflicts of interest for the governing body described in paragraph (d) of this section.

(g) The OPO's policies must state whether the OPO recovers organs from donors after cardiac death.

§ 486.326 Condition: Human resources.

All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

(a) *Standard: Qualifications.* (1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services.

(2) The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.

(3) The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in