Centers for Medicare & Medicaid Services, HHS

§ 486.348 Condition: Organ recovery, and organ placement, including donation after cardiac death, if the OPO has implemented a protocol for donation after cardiac death.

(2) The protocol must ensure that:
   (i) The OPO is responsible for two separate determinations of the donor’s blood type;
   (ii) If the identity of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO’s staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual;
   (iii) Documentation of the donor’s blood type accompanies the organ to the hospital where the transplant will take place.

(3) The established protocols must be reviewed regularly with the transplant programs to incorporate practices that have been shown to maximize organ donation and transplantation.

(e) Documentation of recipient information. If the intended recipient has been identified prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended organ recipient’s ranking in relation to other suitable candidates and the recipient’s OPTN identification number and blood type.

(f) Donation after cardiac death. If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:
   (1) Criteria for evaluating patients for donation after cardiac death;
   (2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;
   (3) Use of medications and interventions not related to withdrawal of support;
   (4) Involvement of family members prior to organ recovery;
   (5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.

(g) Organ allocation. The OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(h) Organ placement. The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

§ 486.346 Condition: Organ preparation and transport.

(a) The OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO must ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(b) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor’s management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. Two individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.

(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.

(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor’s blood type.

§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, including services
provided under contract or arrangement.

(a) Standard: Components of a QAPI program. The OPO’s QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) Standard: Death record reviews. As part of its ongoing QAPI efforts, an OPO must conduct at least monthly death record reviews in every Medicare and Medicaid participating hospital in its service area that has a Level I or Level II trauma center or 150 or more beds, a ventilator, and an intensive care unit (unless the hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals. When missed opportunities for donation are identified, the OPO must implement actions to improve performance.

(c) Standard: Adverse events. (1) An OPO must establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process. (2) The OPO must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO’s policies and practices to prevent repeat incidents.