

(3) The OPO must provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation.

(c) *Standard: Education, training, and performance evaluation.* The OPO must provide its staff with the education, training, and supervision necessary to furnish required services. Training must include but is not limited to performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. OPOs must evaluate the performance of their staffs and provide training, as needed, to improve individual and overall staff performance and effectiveness.

(d) *Standard: Medical director.* The OPO's medical director is a physician licensed in at least one of the States or territories within the OPO's service area or as required by State or territory law or by the jurisdiction in which the OPO is located. The medical director is responsible for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

**§ 486.328 Condition: Reporting of data.**

(a) An OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Beneficiaries, and DHHS, as requested by the Secretary. The data may include, but are not limited to:

- (1) Number of hospital deaths;
- (2) Results of death record reviews;
- (3) Number and timeliness of referral calls from hospitals;
- (4) Number of eligible deaths;
- (5) Data related to non-recovery of organs;
- (6) Data about consents for donation;
- (7) Number of eligible donors;
- (8) Number of organs recovered, by type of organ; and

(9) Number of organs transplanted, by type of organ.

(b) An OPO must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.

(c) Data to be used for OPO re-certification purposes must be reported to the OPTN and must include data for all deaths in all hospitals and critical access hospitals in the OPO's donation service area, unless a hospital or critical access hospital has been granted a waiver to work with a different OPO.

(d) Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the error is identified.

(e) For the purpose of determining the information to be collected under paragraph (a) of this section, the following definitions apply:

(1) *Kidneys procured.* Each kidney recovered will be counted individually. En bloc kidneys recovered will count as two kidneys procured.

(2) *Kidneys transplanted.* Each kidney transplanted will be counted individually. En bloc kidney transplants will be counted as two kidneys transplanted.

(3) *Extra-renal organs procured.* Each organ recovered is counted individually.

(4) *Extra-renal organs transplanted.* Each organ or part thereof transplanted will be counted individually. For example, a single liver is counted as one organ procured and each portion that is transplanted will count as one transplant. Further, a heart and double lung transplant will be counted as three organs transplanted. A kidney/pancreas transplant will count as one kidney transplanted and one extra-renal organ transplanted.

**§ 486.330 Condition: Information management.**

An OPO must establish and use an electronic information management system to maintain the required medical, social and identifying information