§ 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 for every donor and transplant beneficiary and develop and follow procedures to ensure the confidentiality and security of the information.

(a) Donor information. The OPO must maintain a record for every donor. The record must include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information.

(b) Disposition of organs. The OPO must maintain records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant beneficiaries.

(c) Data retention. Donor and transplant beneficiary records must be maintained in a human readable and reproducible paper or electronic format for 7 years.

(d) Format of records. The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a
successor OPO. Records and data subject to this requirement include donor and transplant beneficiary records and procedural manuals and other materials used in conducting OPO operations.

§ 486.342 Condition: Requesting consent.
An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.

(a) An OPO must have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following:

(1) A list of the organs and/or tissues that may be recovered.
(2) The most likely uses for the donated organs or tissues.
(3) A description of the screening and recovery processes.
(4) Information about the organizations that will recover, process, and distribute the tissue.
(5) Information regarding access to and release of the donor’s medical records.
(6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor’s body.
(7) Contact information for individual(s) with questions or concerns.
(8) A copy of the signed consent form if a donation is made.

(b) If an OPO does not request consent to donation because a potential donor consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential donor’s State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.
The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

(a) Potential donor protocol management. (1) The medical director is responsible for ensuring that potential donor evaluation and management protocols are implemented correctly and appropriately to ensure that potential donors are thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

(2) The OPO must implement a system that ensures that a qualified physician or other qualified individual is available to assist in the medical management of a potential donor when the surgeon on call is unavailable.

(b) Potential donor evaluation. The OPO must do the following:

(1) Verify that death has been pronounced according to applicable local, State, and Federal laws.
(2) Determine whether there are conditions that may influence donor acceptance.
(3) If possible, obtain the potential donor’s medical and social history.
(4) Review the potential donor’s medical chart and perform a physical examination of the donor.
(5) Obtain the potential donor’s vital signs and perform all pertinent tests.

(c) Testing. The OPO must do the following:

(1) Arrange for screening and testing of the potential donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus.

(2) Ensure that screening and testing of the potential donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(3) Ensure that the potential donor’s blood is typed using two separate blood samples.

(4) Document potential donor’s record with all test results, including blood type, before organ recovery.