
42 C.F.R. § 121.11

Record maintenance and reporting requirements.

(a) *Record maintenance.* Records shall be maintained and made available subject to OPTN policies and applicable limitations based on personal privacy as follows:

(1) The OPTN and the Scientific Registry, as appropriate, shall:

(i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;

(ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;

(iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and

(iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.

(2) *Organ procurement organizations and transplant programs*—(i) *Maintenance of records.* All OPOs and transplant programs shall maintain such records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related matters as the Secretary deems necessary to carry out her/his responsibilities under the Act. The OPO or transplant program shall maintain these records for seven years.

(ii) *Access to facilities and records.* OPOs and transplant hospitals shall permit the Secretary and the Comptroller General, or their designees, to inspect facilities and records pertaining to any aspect of services performed related to organ donation and transplantation.

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