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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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**PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION
NETWORK**

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Authority: Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); Sections 1102, 1106, 1138 and 1872 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b-8 and 1395ii).

§Sec. 121.1 Applicability.

(a) The provisions of this part apply to the operation of the Organ Procurement and Transplantation Network (OPTN) and to the Scientific Registry.

(b) In accordance with Section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of that Act, and organ procurement organizations

designated under Section 1138(b)(1)(F) of the Social Security Act, are subject to the requirements of this part.

§Sec. 121.2 Definitions.

As used in this part—Act means the Public Health Service Act, as amended. Designated transplant program means a transplant program that has been found to meet the requirements of Sec. 121.9.

Family member means a family member of a transplant candidate, transplant recipient, or organ donor.

National list means the OPTN computer-based list of transplant candidates nationwide.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the national list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ means a human kidney, liver, heart, lung, or pancreas, and for purposes of the Scientific Registry, the term also includes bone marrow.

Organ donor means a human being who is the source of an organ for transplantation into another human being.

Organ procurement organization or OPO means an entity so designated by the Secretary under Section 1138(b) of the Social Security Act. Organ procurement and transplantation network or OPTN means the network established pursuant to Section 372 of the Act.

Potential transplant recipient or potential recipient means a transplant candidate who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered.

Scientific Registry means the registry of information on transplant recipients established pursuant to Section 373 of the Act.

Secretary means the Secretary of Health and Human Services and any official of the Department of Health and Human Services to whom the authority involved has been delegated.

Transplant candidate means an individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the national list by the individual's transplant program.

Transplant hospital means a hospital in which organ transplants are performed.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ. Transplant recipient means a person who has received an organ transplant. Transplant surgeon means a physician who provides surgical care and treatment to transplant recipients.

§Sec. 121.3 The OPTN.

(a) Composition of the Board. (1) The OPTN shall establish a Board of Directors of whatever size the OPTN determines appropriate, provided that it includes at least the following members: (i) Six members representing the following categories (two members from each category):

- (A) Transplant coordinators;
- (B) Organ procurement organizations;
- (C) Histocompatibility experts;

(ii) Eight individuals representing transplant candidates, transplant recipients, organ donors, and family members;

(iii) Ten members from the following categories (two members each):

- (A) Transplant surgeons;
- (B) Transplant physicians;
- (C) Transplant hospitals;
- (D) Voluntary health associations; and

(E) Other experts from related fields including medical examiners, hospital administration, or donor hospital personnel in such fields as trauma, emergency medical services, critical care, neurology, or neurosurgery; and

(iv) Six members from the general public from fields such as behavioral science, computer science, economics, ethics, health care financing, law, policy analysis, sociology, statistics, or theology. These members need not have technical expertise in organ donation or allocation.

(2) None of the members who are transplant recipients, transplant candidates, organ donors, family members, or general public members under paragraph (a)(1) of this section shall be employees of, or have a similar relationship with, the categories of members listed in paragraph (a)(1)(i) or paragraph (a)(1)(iii) or the OPTN.

(3) The Board of Directors shall include:

(i) Individuals representing the diversity of the population of transplant candidates and recipients served by the OPTN, including, to the extent practicable, minority and gender representation reflecting the population of potential transplant candidates served by the OPTN;

(ii) No more than 50 percent transplant surgeons or transplant physicians; and

(iii) At least 25 percent transplant candidates, transplant recipients, organ donors, and family members.

(4) Individuals on the Board shall be elected for a two-year term.

(b) Duties of the OPTN Board of Directors. (1) Executive Committee. The Board of Directors shall elect an Executive Committee from the membership of the Board. The Executive Committee shall include at least one member who is a transplant candidate, transplant recipient, organ donor, or family member;

one general public member, one OPO representative, and not more than 50 percent transplant surgeons and transplant physicians.

(2) Executive Director. The Board of Directors shall appoint an Executive Director of the OPTN. The Executive Director may be reappointed upon the Board's determination that the responsibilities of this position have been accomplished successfully.

(3) Committees. The Board of Directors shall establish such other committees as are necessary to perform the duties of the OPTN. Committees established by the Board of Directors shall include:

(i) Representation by transplant coordinators, organ procurement organizations, and transplant hospitals, and at least one transplant candidate, transplant recipient, organ donor, or family member; and

(ii) to the extent practicable, minority and gender representation reflecting the diversity of the population of potential transplant candidates served by the OPTN.

(4) The Board of Directors shall develop and propose policies for the equitable allocation of organs, as described in Sec. 121.8.

(c) Membership of the OPTN. (1) The OPTN shall admit and retain as members the following:

(i) All organ procurement organizations;

(ii) Transplant hospitals participating in the Medicare or Medicaid programs; and

(iii) Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation.

(2) To apply for membership in the OPTN:

(i) An OPO shall provide to the OPTN the name and address of the OPO, and the latest year of designation under section 1138(b) of the Social Security Act;

(ii) A transplant hospital shall provide to the OPTN the name and address of the hospital, a list of its transplant programs by type of organ; and

(iii) Any other organization, institution, or individual eligible under paragraph (c)(1)(iii) of this section shall demonstrate to the OPTN an interest in the fields of organ donation or transplantation.

(3) The OPTN shall accept or reject as members entities or individuals described in paragraph (c)(1)(iii) of this section within 90 days.

(4) Applicants rejected for membership in the OPTN may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(i) Deny the appeal; or

(ii) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

(d) Corporate Status of the OPTN. (1) The OPTN shall be a private, not-for-profit entity.

(2) The requirements of this section do not apply to any parent, sponsoring, or affiliated organization of the OPTN, or to any activities of the contracting organization that are not integral to the operation of the OPTN. Such an organization is free to establish its own corporate procedures.

(3) No OPTN member is required to become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN, to comply with the by-laws of any such organization, or to assume any corporate duties or obligations of any such organization.

(e) Effective date. The organization designated by the Secretary as the OPTN shall have six months from July 1, 1998, or six months from its initial designation as the OPTN, whichever is later, to meet the board composition requirements of paragraph (a) of this section. The organization designated by the Secretary as the OPTN shall have six months from July 1, 1998, or six months from initial designation as the OPTN, whichever is later, to meet any other requirements of this section, except that the Secretary may extend such period for good cause.

§Sec. 121.4 OPTN policies: Secretarial review and appeals.

(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:

(1) Policies for the equitable allocation of cadaveric organs in accordance with Sec. 121.8;

(2) Policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;

(3) Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:

(i) Ensuring that patients in need of a transplant are listed without regard to ability to pay or source of payment;

(ii) Procedures for transplant hospitals to make reasonable efforts to make available from their own resources, or obtain from other sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;

(iii) Recommendations to private and public payers and service providers on ways to improve coverage of organ transplantation and necessary follow-up care; and

(iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;

(4) Policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by Sec. 121.9;

(5) Policies for nominating officers and members of the Board of Directors; and

(6) Policies on such other matters as the Secretary directs.

(b) The Board of Directors shall:

(1) Provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN; and

(2) Provide, at least 30 days prior to their proposed implementation, proposed policies to the Secretary, who may provide comments and/or objections within a reasonable time, or may publish the policies in the Federal Register to obtain comments from the public. The Board of Directors shall indicate which of the proposed policies it recommends be enforceable under Sec. 121.10. If the Secretary seeks public comments, these comments will be considered and may affect subsequent response to the OPTN. The OPTN shall take into account any comments the Secretary may provide. If the Secretary objects to a policy, the OPTN may be directed to revise the policy consistent with the Secretary's direction. If the OPTN does not revise the policy in a timely manner or if the Secretary otherwise disagrees with its content, the Secretary may take such other action as the Secretary determines appropriate.

(c) The OPTN Board of Directors shall provide the membership and the Secretary with copies of the policies as they are adopted, and make them available to the public upon request. The Secretary will publish lists of these documents in the Federal Register, indicating which ones are subject to the special compliance requirements and potential sanctions of section 1138 of the Social Security Act. The OPTN shall also continuously maintain OPTN policies for public access on the Internet, including current and proposed policies.

(d) The OPTN, or its members, or other individuals, or entities objecting to policies developed by the OPTN or the Secretary may submit appeals to the Secretary in writing. Any such appeal shall include a statement of the basis for the appeal. The Secretary will seek the comments of the OPTN on the issues raised in the appeal of an OPTN-developed policy. Policies remain in effect during the appeal. The Secretary may:

(1) Deny the appeal;

(2) Direct the OPTN to revise the policies consistent with the Secretary's response to the appeal, or

(3) Take such other action as the Secretary determines appropriate.

(e) The OPTN shall implement policies and:

(1) Provide information to OPTN members about these policies and the rationale for them.

(2) Update policies developed in accordance with this section to accommodate scientific and technological advances.

§Sec. 121.5 Listing requirements.

(a) A transplant hospital which is an OPTN member may list individuals only for a designated transplant program.

(b) Transplant hospitals shall assure that individuals are placed on the national list as soon as they are determined to be candidates for transplantation. The OPTN shall advise transplant hospitals of the information needed for such listing.

(c) An OPTN member shall pay a registration fee to the OPTN for each transplant candidate it places on the national list. The amount of such fee shall be determined by the OPTN with the approval of the Secretary. No less often than annually, and whether or not a change is proposed, the OPTN shall submit to the Secretary a statement of its proposed registration fee, together with such supporting information as the Secretary finds necessary to determine the reasonableness or adequacy of the fee schedule and projected revenues. This submission is due at least three months before the beginning of the OPTN's fiscal year. The Secretary will approve, modify, or disapprove the amount of the fee within a reasonable time of receiving the OPTN's submission.

§Sec. 121.6 Organ procurement.

The suitability of organs donated for transplantation shall be determined as follows:

(a) Tests. An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.

(b) HIV. Organs from individuals known to be infected with human immunodeficiency virus shall not be procured for transplantation.

(c) Acceptance criteria. Transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.

§Sec. 121.7 Identification of organ recipient.

(a) List of potential transplant recipients. (1) An OPTN member procuring an organ shall operate the OPTN computer match program within such time as the OPTN may prescribe to identify and rank potential recipients for each cadaveric organ procured.

(2) The rank order of potential recipients shall be determined for each cadaveric organ using the organ-specific allocation criteria established in accordance with Sec. 121.8.

(3) When a donor or donor organ does not meet a transplant program' donor acceptance criteria, as established under Sec. 121.6(c), transplant candidates of that program shall not be ranked among potential recipients of that organ and shall not appear on a roster of potential recipients of that organ.

(b) Offer of organ for potential recipients. (1) Organs shall be offered for potential recipients in accordance with policies developed under Sec. 121.8 and implemented under Sec. 121.4.

(2) Organs may be offered only to potential recipients listed with transplant programs having designated transplant programs of the same type as the organ procured.

(3) An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital.

(4) A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe. A transplant program shall document and provide to the OPO and to the OPTN the reasons for refusal and shall maintain this document for one year.

(c) Transportation of organ to potential recipient. (1) Transportation. The OPTN member that procures a donated organ shall arrange for transportation of the organ to the transplant hospital.

(2) Documentation. The OPTN member that is transporting an organ shall assure that it is accompanied by written documentation of activities conducted to determine the suitability of the organ donor and shall maintain this document for one year.

(3) Packaging. The OPTN member that is transporting an organ shall assure that it is packaged in a manner that is designed to maintain the viability of the organ.

(d) Receipt of an organ. Upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with the transplant. In the event that an organ is not transplanted into the potential recipient, the OPO which has a written agreement with the transplant hospital must offer the organ for another potential recipient in accordance with paragraph (b) of this section.

(e) Wastage. Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN and the OPO which made the organ offer of the circumstances justifying each such action within such time as the OPTN may prescribe.

§Sec. 121.8 Allocation of organs.

(a) Policy development. The Board of Directors established under Sec. 121.3 shall develop, in accordance with the policy development process under Sec. 121.4, organ-specific policies (including combinations of organs, such as for heart-lung transplants) for the equitable allocation of cadaveric organs among potential recipients. Such policies shall meet the requirements in paragraphs (a)(1), (2), (3), (4), and (5) of this section. Such policies shall be reviewed periodically and revised as appropriate.

(1) Minimum listing criteria for including transplant candidates on the national list shall be standardized and, to the extent possible, shall contain explicit thresholds for listing a patient and be expressed through objective and measurable medical criteria.

(2) Transplant candidates shall be grouped by status categories ordered from most to least medically urgent, with a sufficient number of categories to avoid grouping together persons with substantially different medical urgency. Criteria for status designations shall contain explicit thresholds for differentiating among patients and shall be expressed, to the extent possible, through objective and measurable medical criteria.

(3) Organ allocation policies and procedures shall be in accordance with sound medical judgment and shall be designed and implemented: (i) To allocate organs among transplant candidates in order of decreasing medical urgency status, with waiting time in status used to break ties within status groups. Neither place of residence nor place of listing shall be a major determinant of access to a transplant. For each status category, inter-transplant program variance in the performance indicator waiting time in status shall be as small as can reasonably be achieved, consistent with paragraph (a)(3)(ii) of this section. Priority shall be given to reducing the waiting time variance in the most medically urgent status categories before reducing the waiting time variance in less urgent status categories, if equivalent reductions cannot be achieved in all status categories; and

(ii) To avoid futile transplantation, to avoid wasting organs, and to promote efficient management of organ placement.

(4) The OPTN shall:

(i) Develop mechanisms to promote and review compliance with each of these goals;

(ii) Develop performance indicators to facilitate assessment of how well current and proposed policies will accomplish these goals;

(iii) Use performance indicators, including indicators described in paragraph (a) 4)(iv) of this section, to establish baseline data on how closely the results of current policies approach these goals and to establish the projected amount of improvement to result from proposed policies; and

(iv) Timely report data to the Secretary on performance by organ and status category, including program-specific data, OPO-specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the nation as a whole, and such other geographic areas as the Secretary may designate. Such data shall include inter-transplant program variation in waiting time in status, total life years pre- and post-transplant, patient and graft survival rates following transplantation, patients misclassified by status, and number of patients who die waiting for a transplant. Such data shall cover such intervals of time, and be presented using confidence intervals or other measures of variance, as appropriate to avoid spurious results or erroneous interpretation due to small numbers of patients covered.

(5) Transition. (i) General. When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the national list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

(ii) Special rule for initial revision of liver allocation policies. When the OPTN transmits to the Secretary its initial revision of the liver allocation policies, as directed by paragraph (c)(2) of this section, it shall include transition procedures that, to the extent feasible, treat each individual on the national list and awaiting transplantation on April 2, 1998, no less favorably than he or she would have been treated had the revised liver allocation policies not become effective. These transition procedures may be limited in duration or applied only to individuals with greater than average medical urgency if this would significantly improve administration of the list or if such limitations would be applied only after accommodating a substantial preponderance of those disadvantaged by the change in the policies.

(b) Secretarial review of policies and performance indicators. The OPTN's transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures of paragraph (a) of this section.

(c) Deadlines for initial reviews. (1) The OPTN shall conduct an initial review of existing allocation policies and, except as provided in paragraph (c)(2) of this section, no later than July 1, 1999, transmit initial revised policies to meet the requirements of Sec. 121.8 (a), together with supporting documentation to the Secretary for review in accordance with Sec. 121.4.

(2) No later than August 31, 1998, the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the requirements

of Sec. 121.8 (a) to the Secretary for review in accordance with Sec. 121.4. The OPTN may transmit these materials without seeking further public comment under Sec. 121.4(b) or (c).

(d) Variances. The OPTN may develop experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time-limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of Sec. 121.4.

(e) Directed donation. Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation.

§Sec. 121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare and Medicaid; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under Sec. 121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under Sec. 121.4;

(iv) Has available operating and recovery room resources, intensive care resources and surgical beds, and transplant program personnel;

(v) Shows evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and immunogenetics and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support;

(vi) Has immediate access to microbiology, clinical chemistry, histocompatibility testing, radiology, and blood banking services, as well as the capacity to monitor treatment with immunosuppressive drugs; and

(vii) Makes available psychiatric and social support services for transplant candidates, transplant recipients and their families; or

(3) Be a transplant program in a Department of Veterans Affairs hospital which is a Dean's Committee hospital which shares a common university-based transplant team of a transplant program which meets the requirements of Sec. 121.9(a) (1) or (2).

(b) To apply to be a designated transplant program, transplant programs shall provide to the OPTN such documents as the OPTN may require which show that they meet the requirements of Sec. 121.9(a) (1), (2), or (3).

(c) The OPTN shall, within 90 days, accept or reject applications to be a designated transplant program.

(d) Applicants rejected for designation may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(1) Deny the appeal; or

(2) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

§Sec. 121.10 Reviews, evaluation, and enforcement.

(a) Review and evaluation by the Secretary. The Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant programs which the Secretary deems necessary to carry out her/his responsibilities under the Public Health Service Act and the Social Security Act.

(b) Review and evaluation by the OPTN. (1) The OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of:

(i) Reviewing applications submitted under Sec. 121.3(c) for membership in the OPTN;

(ii) Reviewing applications submitted under Sec. 121.9(b) to be a designated transplant program; and

(iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies.

(2) Upon the approval of the Secretary, the OPTN shall furnish review plans and procedures, including survey instruments and a description of data systems, to each member OPO and transplant hospital. The OPTN shall furnish any revisions of these documents to member OPOs and hospitals, after approval by the Secretary, prior to their implementation.

(3) At the request of the Secretary, the OPTN shall conduct special reviews of OPOs and transplant programs, where the Secretary has reason to believe that such entities may not be in compliance with these rules or OPTN policies or may be acting in a manner which poses a risk to the health of patients or to public safety. The OPTN shall conduct these reviews in accordance with such schedules as the Secretary specifies and shall make periodic reports to the Secretary of progress on such reviews and on other reviews conducted under the requirements of this paragraph.

(4) The OPTN shall notify the Secretary in a manner prescribed by the Secretary within 3 days of all committee and Board of Directors meetings in

which transplant hospital and OPO compliance with these regulations or OPTN policies is considered.

(c) Enforcement of OPTN rules. (1) OPTN recommendations. The Board of Directors shall advise the Secretary of the results of any reviews and evaluations conducted under paragraph (b)(1)(iii) or paragraph (b)(3) of this section which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary. Appropriate action may include removal of designation as a transplant program under Sec. 121.9, termination of a transplant hospital's participation in Medicare or Medicaid, termination of a transplant hospital's reimbursement under Medicare and Medicaid, or termination of an OPO's reimbursement under Medicare and Medicaid, if the noncompliance is with a policy designated by the Secretary as covered by section 1138 of the Social Security Act.

(2) Secretary's action on recommendations. Upon the Secretary's review of the Board of Directors' recommendations, the Secretary may:

- (i) Request further information from the Board of Directors or the alleged violator, or both;
- (ii) Decline to accept the recommendation;
- (iii) Accept the recommendation, and notify the alleged violator of the Secretary's decision; or
- (iv) Take such other action as the Secretary deems necessary.

§Sec. 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 national 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.

(b) Reporting requirements. (1) The OPTN and the Scientific Registry, as appropriate, shall:

(i) In addition to special reports which the Secretary may require, submit to the Secretary a report not less than once every fiscal year on a schedule prescribed by the Secretary. The report shall include the following information in a form prescribed by the Secretary:

(A) Information that the Secretary prescribes as necessary to assess the effectiveness of the Nation's organ donation, procurement, and transplantation system;

(B) Information that the Secretary deems necessary for the report to Congress required by Section 376 of the Act; and,

(C) Any other information that the Secretary prescribes.

(ii) Provide to the Scientific Registry data on transplant candidates and recipients, and other information that the Secretary deems appropriate. The information shall be provided in the form and on the schedule prescribed by the Secretary;

(iii) Provide to the Secretary any data that the Secretary requests;

(iv) Make available to the public timely and accurate program-specific information on the performance of transplant programs. This shall include free dissemination over the Internet, and shall be presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently. These data shall be updated no less frequently than every six months and shall include three-month, one-year, three-year and five-year graft and patient survival rates, both actual and statistically expected, and shall be presented no more than six months later than the period to which they apply. Data presented shall include confidence intervals or other measures that provide information on the extent to which chance may influence transplant program-specific results. Such data shall also include such other cost or performance information as the Secretary may specify, including but not limited to transplant program-specific information on waiting time within medical status, organ wastage, and refusal of organ offers. These data shall also be presented no more than six months later than the period to which they apply;

(v) Respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary. The OPTN or the Scientific Registry may impose reasonable charges for the separable costs of responding to such requests. Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such

data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed. All requests shall be processed expeditiously, with data normally made available within 30 days from the date of request;

(vi) Respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes. The OPTN or Scientific Registry may impose charges for the separable costs of responding to such requests. An estimate of such charges shall be provided to the requester before processing the request. All requests should be processed expeditiously, with data normally made available within 30 days from the date of request; and

(vii) Provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member.

(2) An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs, transplant program performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital.

(c) Public access to data. The Secretary may release to the public information collected under this section when the Secretary determines that the public interest will be served by such release. The information which may be released includes, but is not limited to, information on the comparative costs and patient outcomes at each transplant program affiliated with the OPTN, transplant program personnel, information regarding instances in which transplant programs refuse offers of organs to their patients, information regarding characteristics of individual transplant programs, information regarding waiting time at individual transplant programs, and such other data as the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation.

§Sec. 121.12 Preemption.

No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that would restrict in any way the ability of any transplant hospital, OPO, or other party to comply with organ allocation policies of the OPTN or other policies of the OPTN that have been approved by the Secretary under this part.

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