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Organ Procurement and Transplantation Network (OPTN): [Correspondence] [2]

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REGULATION TEXT

Accordingly, 42 CFR Part 121 is added to Subchapter K to read as follows:

Part 121-Organ Procurement and Transplantation Network

Sec.

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).

§ 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.

§ 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 § 121.9.

"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.

"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 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 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.

§ 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 members as follows:

(i) six members from, and selected by, the association(s) representing the following categories (two members from each category):

(A) transplant coordinators;

(B) organ procurement organizations;

(C) histocompatibility experts;

(ii) eight individuals from, and selected by, eight national associations representing transplant patients and candidates, and donor family members (one member from each association);

(iii) ten members elected by a majority vote of the voting OPTN membership, 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 elected by a majority vote of the voting OPTN membership 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 representing transplant patients and candidates or general public members under paragraph (a) shall be employees of institutions that earn substantial revenues from performing transplantation or donation services, or shall individually receive substantial emoluments from such institutions or from the OPTN itself.

(3) The Board of Directors shall include:

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

(ii) no more than 50 percent transplant surgeons, transplant physicians, and employees of transplant hospitals or organ procurement organizations; and

(iii) a reasonable portion of transplant candidates or recipients or individuals who are family members of transplant candidates, recipients or organ donors.

(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 transplant candidate or recipient or individual who is part of the family of a transplant candidate or recipient or organ donor, one transplant patient or candidate member, one general public member, one OPO representative, and not more than 50 percent transplant surgeons, transplant physicians, or employees of transplant hospitals or organ procurement organizations.

(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, transplant candidates or recipients or individuals who are part of the families of transplant candidates or recipients or organ donors, organ procurement organizations, and transplant hospitals; and

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

(4) The Board of Directors shall develop and propose policies for the equitable allocation of organs, as described in § 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 in writing 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 provide to the OPTN documentation which demonstrates interest in the fields of organ donation or transplantation.

(3) The OPTN shall, within a reasonable time not to exceed 90 days, accept as members entities or individuals described in paragraph (c)(1)(iii) of this Section.

(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 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 (insert date of publication), 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 (insert date of publication), 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.

§ 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 human donor organs in accordance

with § 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 a reasonable 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 § 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 OPTN Board of Directors shall inform the OPTN membership of upcoming Board meetings, 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.

(c) 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 the 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. 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. The revised policy developed by the Board of Directors of the OPTN shall be consistent with the comments and directions of the Secretary. If the OPTN does not revise the policy in a timely manner or in accordance with the organ allocation goals of § 121.8, or if the Secretary otherwise disagrees with its content, the Secretary may issue a new or revised policy on that subject that the OPTN must implement.

(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 keep them current with scientific and technological advances.

§ 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 all transplant candidates are placed on the national list as soon as they are determined to be candidates for transplantation. The OPTN shall from time to time 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 or disapprove the amount of the fee within a reasonable time of receiving the OPTN's submission.

§ 121.6 Organ procurement. The suitability of organs donated for transplantation shall be determined as follows:

(a) Tests. An OPO 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 potential donors 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.

§ 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 § 121.8.

(3) When a donor or donor organ does not meet a transplant program's donor acceptance criteria, as established under § 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 § 121.8 and implemented under § 121.4.

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

(3) An organ offer is made by the OPO which procured the organ 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 hospital shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe. A transplant hospital shall document and provide to the OPO with which it is affiliated and to the OPTN the reasons for refusal.

(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.

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

(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 hospital 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 hospital shall notify the OPTN and donating OPO of the circumstances justifying each such action within such time as the OPTN may prescribe.

§ 121.8 Allocation of organs.

(a) Policy development: Goals and Performance Indicators. The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process under § 121.4, organ-specific policies (including combinations of organs, such as for heart-lung transplants) for the equitable allocation of human cadaveric organs among potential recipients. Such policies shall be designed to achieve substantial and continuing progress in attaining the goals in paragraphs (1), (2), and (3) below, while meeting the requirements of paragraphs (4) and (5) below:

(1) Minimum listing criteria for including potential transplant recipients 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) Potential transplant recipients 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 designed and implemented:

(i) to allocate organs among potential recipients in order of decreasing 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 hospital variance in the performance indicator "waiting time in status" shall be as small as can reasonably be achieved, consistent with paragraph (a)(3)(ii);

(ii) to avoid futile transplantation, to avoid wasting organs through excessive time spent in placement and transportation, to avoid wastage of organs through failure to assess characteristics of the immune system or physical characteristics and conditions of potential recipients that make it unlikely that they can accept an organ successfully, to avoid inefficient management of organ placement, and to avoid preventing the exercise of sound medical judgment as applied to individual patients.

(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 subparagraph (v) below, 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;

(iv) timely report data to the Secretary on performance by organ and status category, including as appropriate 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 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.

(v) report data using such performance measures as the Secretary may determine, including but not limited to inter-transplant program variation in waiting time in status, total life years pre- and post-transplant, patient and graft survival rates following transplantation, number of patients misclassified by status or mis-listed, and number of patients who die waiting for a transplant.

(5) Transition.

(i) General. When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures to treat people on the national list and awaiting transplantation prior to the date of publication of the regulation 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 the effective date of the revised policies 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 shall, upon developing improved allocation policies and associated performance indicators, promptly transmit them to the Secretary for review. Such transmittals shall include such supporting material, including the results of model-based computer simulations, as necessary to understand the likely effects of policy changes and to demonstrate that the proposed policies comply with the goals 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 (insert date one year after the publication of this regulation) transmit initial revised policies to meet the goals and performance indicators of § 121.8 (a) together with supporting documentation to the Secretary for review in accordance with § 121.4.

(2) No later than (insert date 90 days after publication date of this regulation) the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the goals and performance indicators of § 121.8 (a) to the Secretary for review in accordance with § 121.4.

(d) Variances. The OPTN may develop variances and other deviations from OPTN policies that test methods of improving allocation, consistent with the performance goals. All such experimental standards shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Existing and future variances may be appealed to the Secretary under the procedures of § 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.

§ 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 HHS for reimbursement under Medicare and Medicaid; or

(2) be an organ transplant program 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 § 121.4;

(iii) has on site a transplant physician qualified in accordance with policies developed under § 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 facilities required for monitoring immunosuppressive drugs; and

(vii) makes available psychiatric and social support services for transplant candidates, 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 § 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 § 121.9(a)(1), (2), or (3).

(c) The OPTN shall, within a reasonable time not to exceed 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.

§ 121.10 Review and evaluation.

(a) Review and evaluation by the Secretary. The Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant hospitals 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 § 121.3(c) for membership in the OPTN;

(ii) reviewing applications submitted under § 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 hospitals, 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 schedule 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. The OPTN shall also report to the Secretary within 14 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 this part, and shall provide any recommendations for appropriate action by the Secretary. Appropriate action may include removal of designation as a transplant program under § 121.9, 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.

§ 121.11 Record maintenance and reporting requirement.

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

(1) OPTN

(i) The OPTN shall maintain and operate an automated system for managing information about organ transplant candidates, recipients, and donors, including a computerized national list of individuals waiting for transplants.

(ii) The OPTN shall maintain records of all transplant candidates, all organ donors and all transplant recipients.

(iii) The OPTN shall operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested.

(iv) In making information available, the OPTN shall provide copies of such manuals, forms, flow charts, operating instructions, or other explanatory materials as will enable recipients to understand, interpret, and use the information accurately and efficiently.

(2) Organ procurement organizations and transplant hospitals-

(i) Maintenance of records. All OPOs and transplant hospitals 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.

(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 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 so as to facilitate use by both lay persons and professional users. These data shall be updated no less frequently than every three 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 three 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 three 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 resources permit, or as directed by the Secretary. The OPTN 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, to assess individual transplant programs, or for other purposes. The OPTN may impose reasonable charges for the separable costs of responding to such requests. 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.

(3) The Scientific Registry shall provide to the Secretary such data as the Secretary may specify.

(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 hospitals, 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.

§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 and other policies of the OPTN

that have been approved by the Secretary under this Part.

NewsFlash WHAT'S HAPPENING NOW

WASHINGTON THE FULL STORY

# Big difference between best and worst in organ banks



**By LAURA MECKLER**
**The Associated Press**
**09/08/98 2:26 AM Eastern**

WASHINGTON (AP) -- More than 4,000 people die each year waiting for new hearts, livers, lungs and kidneys, but thousands more transplants could occur if not for wide disparities among the organ banks that find donors and match them with patients.

The nation's best organ banks move four times as many organs from the dead to the living as the worst, according to an Associated Press computer analysis.

As the government struggles to find the fairest way to allocate scarce replacement organs, that discrepancy helps explain why patients in certain parts of the United States stand a much better chance at getting the transplants they need.



Interviews with organ banks across the country suggest a program's ability to work with local hospitals accounts for much of the difference. Others appear to be hampered by ethnic minorities who are more reluctant to donate or a preponderance of illness that precludes donation, such as AIDS.

But no one is certain why some programs do so much better.

"You'd like to take the top 10 and clone them," said Coralyn Colliday at the Department of Health and Human Services.

Sixty-three organ banks cover the country, handling the intense, behind-the-scenes work essential for transplants to succeed.

They talk with grieving families, often moments after death. When families say yes, they match those donors with recipients and make the needed dozens of arrangements.

Some do it much better: In upper Wisconsin, there were 146 organ transplants for every 1,000 deaths in a year; in Mississippi, only 18.

The AP analysis of 1996 and 1997 data also suggested:

--Two thousand more transplants could be done each year if each

below-average organ bank brought its performance up to the median. Half the programs perform above the median, half below.

--If every organ bank performed like the top 10, there would be 14,600 more transplants each year -- a huge increase over the 17,000 now done each year.

Over the last two decades, transplant techniques have improved and more hospitals have created programs.

But donation has not kept pace. Ten years ago, the list of people waiting for transplants was four times as long as the list of donors. By 1996, it was nine times as long.

Today, 57,839 people are waiting.

Waits are much longer in some parts of the country, often because a strong program attracts patients from elsewhere. Lists also get longer when there are fewer local donors.

That has prompted a debate over the best way to allocate the organs available. The Department of Health and Human Services wants an overhaul of the geographic-based system that now offers organs to local patients first, even if someone farther away is sicker.

HHS now requires hospitals to report all deaths to organ banks in hopes of finding more donors. And the government also is trying to increase donation, sponsoring a conference to share information about what works.

But federal officials do little to highlight the differences among organ banks, beyond assuring that they meet minimum criteria. And they have rarely suggested that communities that fail to donate organs -- or the organ banks that serve them -- are partly to blame for long waits.

The best organ banks work well with hospitals and have clear procedures for identifying donors and talking with families.

But in places where transplant rates hover near the bottom -- Mississippi, the upper Northwest, Buffalo, N.Y., and New York City -- organ banks say they miss many potential donors because hospitals do not notify them.

The Buffalo bank estimates 25 percent of potential donors are never referred, and another 25 percent are referred too late -- the patient has been taken off a ventilator, for instance, allowing organs to deteriorate. New York City officials think they miss half.

"Sometimes they report (potential donors) early but they won't let us come on site," said Denise Payne, who heads the New York Organ Donor Network, which serves New York City and ranked No. 58. "They feel it's too early and don't want us there."

In contrast, most high-performing organ banks say it's critical to get to the hospital early and put logistics in place, in case a family consents.

Most stress the importance of waiting to talk with families about donation until they understand their loved one is dead. By contrast, low performers have trouble getting doctors to deliver the bad news about death and ask about donation in separate conversations.

"The family needs time to accept the grief," said John Wingate of Minneapolis' LifeSource, the No. 2 organ bank.

And excellent programs usually have top-notch ways to communicate with donor families after transplants.

In Wisconsin, counselors call families on the anniversaries of donors' death and on birthdays, just to see how they're doing.

But organ banks have less control over other factors.

In New York City, a higher proportion of AIDS deaths means fewer people are medically eligible to donate organs.

And low-performing banks almost uniformly point to an ethnic group wary of donation: blacks in Georgia and New York City, Mexican-Americans in south Texas, Filipinos in Hawaii, Native Americans in the Northwest.

"The Asian community still has some strong cultural ties to the ancestral belief that the body needs to be fully intact in order for the soul to rest peacefully," said Jill Steinhaus of LifeCenter Northwest in Washington state.

But demographics cannot explain all differences. In Los Angeles, one bank ranked No. 4 while another performed so poorly the government is shutting it down.

Still, three of the top five banks serve the neighboring states of Wisconsin, Minnesota and the Dakotas.

Lori Shinstine, of the University of Wisconsin, which runs the No. 1 organ bank, gave some of the credit to what she called a spirit of generosity that helps recruit donors.

"We live in a community where people are willing to help each other."

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Please send any questions or comments to newsflash@nj.com.

**September 7, 1998**

# Organ Banks Evaluated

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

**Filed at 2:29 p.m. EDT**

**By The Associated Press**

Best organ banks, and the average number of transplants they enabled in 1996 and 1997 per 1,000 deaths:

University of Wisconsin, Madison, Wis., 146.01

LifeSource, St. Paul, Minn., 99.94

Intermountain Organ Recovery Systems, Salt Lake City, 97.60

Southern California Organ Procurement Center, Los Angeles, 95.15

Wisconsin Donor Network, Milwaukee, 93.43

Organ and Tissue Center of Southern California, San Diego, 85.26

Washington Regional Transplant Consortium, Washington, D.C., 82.59

Lifeline of Ohio, Columbus, Ohio, 78.79

LifeLink of Florida, Tampa, Fla., 75.48

Donor Alliance, Denver, 74.74

TransLife, Orlando, Fla., 71.88

NorthEast OPO, Hartford, Conn., 71.23

Pacific Northwest Transplant Bank, Portland, Ore., 70.76

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**Worst organ banks, and the average number of transplants they enabled in 1996 and 1997 per 1,000 deaths:**

**Mississippi Organ Recovery Agency, Jackson, Miss., 17.80**

**Regional Organ Procurement Agency of Southern California, Los Angeles, 25.26**

**New York Organ Donor Network, New York City, 25.40**

**LifeLink of Puerto Rico, 29.5**

**Upstate New York Transplant Services, Buffalo, N.Y., 33.10**

**South Carolina Organ Procurement Agency, Charleston, S.C., 34.27**

**Organ Donor Center of Hawaii, Honolulu, 34.30**

**Carolina LifeCare, Winston-Salem, N.C., 35.29**

**Nevada Donor Network, Las Vegas, Nev., 37.80**

**Virginia's Organ Procurement Agency, Midlothian, Va., 37.94**

**New Jersey Organ & Tissue Sharing Network, Springfield, N.J., 38.59**

**New Mexico Donor Services, Albuquerque, N.M., 38.90**

**September 7, 1998**

# List of Organ Procurement Groups

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

**Filed at 2:02 p.m. EDT**

**By The Associated Press**

Here is a list of organ procurement organizations and the number of transplants enabled per 1,000 deaths. The figure is an average of two years, 1996 and 1997. The list also includes the location of each group's headquarters and a description of its territory.

Institutions with higher numbers enabled more transplants, potentially saving more lives:

1. University of Wisconsin, 146.01

Madison, Wis.; Wisconsin except area surrounding Milwaukee

2. LifeSource, 99.94

St. Paul., Minn.; Minnesota, North Dakota, South Dakota, two counties in Wisconsin

3. Intermountain Organ Recovery Systems, 97.60

Salt Lake City; Utah, southern Idaho, southwest Wyoming

4. Southern California Organ Procurement Center, 95.15

Los Angeles; part of the Los Angeles area

5. Wisconsin Donor Network, 93.43

Milwaukee; 11 counties in eastern Wisconsin

6. Organ and Tissue Center of Southern California, 85.26

San Diego; Imperial and San Diego counties

7. Washington Regional Transplant Consortium, 82.59

Washington, D.C.; Washington plus Maryland and Virginia suburbs

8. Lifeline of Ohio, 78.79

Columbus, Ohio; Columbus, Mansfield, southeast Ohio, part of West Virginia

9. LifeLink of Florida, 75.48

Tampa, Fla.; Tampa area

10. Donor Alliance, 74.74

Denver; Colorado, most of Wyoming

11. TransLife, 71.88

Orlando, Fla.; Orlando area

12. NorthEast OPO, 71.23

Hartford, Conn.; most of Connecticut, western Massachusetts

13. Pacific Northwest Transplant Bank, 70.76

Portland, Ore.; Oregon, parts of Washington and Idaho

14. Golden State Donor Services, 65.84

Sacramento, Calif.; nine California counties

15. Iowa Statewide OPO, 65.66

Iowa City, Iowa; most of Iowa, one Nebraska county

16. LifeLink of Georgia, 64.90

Atlanta; most of Georgia, two counties in South Carolina

17. Delaware Valley Transplant Program, 63.57

Philadelphia; Delaware, eastern Pennsylvania and part of New Jersey

18. Kentucky Organ Donor Affiliates, 62.13

Louisville, Ky.; most of Kentucky, small parts of Indiana, Ohio and West Virginia

19. Nebraska Organ Retrieval System, 61.94

Omaha, Neb.; most of Nebraska, one Iowa county

20. California Transplant Donor Network, 60.25

San Francisco; 40 counties in California

21. Center for Organ Recovery and Education, 59.60

Pittsburgh; western Pennsylvania, part of West Virginia

22. Southwest Transplant Alliance, 57.02

Dallas; 90 Texas counties mostly in northeast

23. Mid-America Transplant Services, 55.82

St. Louis; eastern Missouri, southern Illinois, small part of Arkansas

24. University of Florida, 55.58

Gainesville, Fla.; northern Florida

25. Tennessee Donor Services, 54.28

Nashville; most of Tennessee, small parts of Georgia and Kentucky

26. Life Gift Organ Donation Center, 51.72

Houston; 108 Texas counties mostly in northwest

27. Midwest Organ Bank, 51.27

Westwood, Kan.; Kansas, western Missouri

28. Fingerlakes Donor Recovery Network, 50.27

Rochester, N.Y.; 19 New York counties

29. Ohio Valley LifeCenter, 50.09

Cincinnati; southwest Ohio, small parts of Indiana and Kentucky

30. LifeShare of the Carolinas, 49.89

Charlotte, N.C.; part of North Carolina, one county in South Carolina

31. LifeNet, 49.88

Virginia Beach, Va.; eastern Virginia

32. Donor Network of Arizona, 49.58

Phoenix; most of Arizona

33. Regional Organ Bank of Illinois, 49.25

Chicago; most of Illinois, small parts of Indiana and Iowa

34. Indiana Organ Procurement Organization, 48.76

Indianapolis; most of Indiana, one county in Kentucky

35. Life Connection of Ohio, 48.33

Maumee, Ohio; western Ohio

36. South Texas Organ Bank, 47.93

San Antonio, Texas; 56 Texas counties in central, southern and eastern Texas

37. Life Resources, 47.08

Johnson City, Tenn.; southwest Virginia and northeast Tennessee

38. Center for Donation and Transplant, 46.97

Albany, N.Y.; 23 New York counties, one Vermont county

39. Alabama Organ Center, 46.86

Birmingham, Ala.; Alabama and three Georgia counties

40. Arkansas Regional Organ Recovery Agency, 46.29

Little Rock, Ark.; most of Arkansas

41. University of Miami Organ Procurement Agency, 45.32

Miami; southern Florida

42. LifeBanc, 43.69

Cleveland; northeast Ohio

43. Mid-South Transplant Foundation, 43.39

Memphis, Tenn.; parts of Tennessee, Arkansas and Mississippi

44. LifeLink of Southwest Florida, 43.25

Tampa, Fla.; Fort Myers area

45. New England Organ Bank, 42.08

Newton, Mass.; Rhode Island, Maine, New Hamshire, most of Vermont, most of Massachusetts, New Haven area of Connecticut

46. Transplant Resource Center of Maryland, 41.83

Baltimore; Maryland except D.C. suburbs, one West Virginia country

47. Carolina Organ Procurement Agency, 41.61

Greenville, N.C.; eastern North Carolina, two counties in Virginia

48. Transplantation Society of Michigan, 41.55

Ann Arbor, Mich.; Michigan

49. Louisiana Organ Procurement Agency, 41.09

Metarie, La.; Louisiana

50. New Mexico Donor Program, 38.90

Albuquerque, N.M.; New Mexico

51. New Jersey Organ & Tissue Sharing Network, 38.59

Springfield, N.J.; most of New Jersey

52. Virginia's Organ Procurement Agency, 37.94

Midlothian, Va.; western Virginia

53. Nevada Donor Network, 37.80

Las Vegas, Nev.; Nevada, one Arizona county

54. Carolina LifeCare, 35.29

Winston-Salem, N.C.; western North Carolina

55. Organ Donor Center of Hawaii, 34.30

Honolulu; Hawaii

56. South Carolina Organ Procurement Agency, 34.27

Charleston, S.C.; most of South Carolina

57. Upstate New York Transplant Services, 33.10

Buffalo, N.Y.; seven New York counties

58. New York Organ Donor Network, 25.40

New York City; New York City area, Long Island

59. Regional Organ Procurement Agency of Southern California, 25.26

Los Angeles; part of the Los Angeles area

60. Mississippi Organ Recovery Agency, 17.80

Jackson, Miss.; most of Mississippi

61. LifeLink of Puerto Rico, 29.5

Guaynabo, P.R.; Puerto Rico and American Virgin islands

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Note:

Two organ procurement agencies are not included in this ranking because data was unavailable on the number of deaths in the area, making a calculation of transplants per death impossible.

The Oklahoma Organ Sharing Network in Oklahoma City is not included because the state does not report death data to the Centers for Disease Control and Prevention.

LifeCenter Northwest, which covers Alaska, Montana and most of Washington, is not included because it is a product of two organ banks that recently merged. There is no reliable death data for the new entity.

It is, however, possible to calculate the number of transplants performed for every 1 million people living in these area. This is the standard that the government uses to judge organ banks.

Using the population standard, the Oklahoma Organ Sharing Network, which covers the state of Oklahoma, ranked No. 52 out of 63 organ banks. It performed an average of 54.46 transplants per year in 1996 and 1997 for every 1 million people.

LifeCenter ranked No. 56, performing 52.65 transplants for every 1 million people.

Melissa
F 69Φ-5673

Here i

**caplan @ mail.med.upenn.edu**
12/11/97 11:14:32 PM

Record Type: Record

To: jmande

cc:

Subject: cannot get there on monday at 11 but here is a statement--edit away and send it back

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Organ and tissue donation in the United States rely on the voluntarism, generosity, compassion and altruism of the American people. As a nation we owe it to those who desperately need transplants to do everything we can to insure that ~~the~~ every American understands that the need is great, they have the power to help those in need and that the opportunity is presented to them to do so. That is why I am so pleased and enthusiastic that Vice President Gore has chosen to reiterate this nation's committment to do all that it can to help those disabled or dying as a result of diseases and disorders by announcing new initiatives aimed at maintaining and enhancing the availability of human organs and tissues for transplantation.

The transplant community has had no better friend than Al Gore. He has been a staunch advocate for patients seeking transplants, their families and friends. When, more then a decade ago, he was in the House of Representatives he became concerned about the plight of those seeking transplants. Al took the lead in making sure that the transplant community understood the importance of insuring that the distribution of freely donated organs and tissues be fair and equitable. He read and reflected on the idea of a then much younger bioethics professor to promote legislation requiring that every family that has suffered a death be made aware of the option of organ and tissue donation by a properly trained health care professional. He moved this idea forward and saw to it, when he himself moved on to the United States Senate, that Federal law guarantees that the offer of organ and tissue donation become a routine and widely accepted part of the process of coping with the tragedy of the loss of a loved one. The committment to doing everything possible to help those in need of transplants has continued throughout his tenure as Vice President.

I have been studying and wrestling with the subject of organ and tissue donation for many, many years. I remain more convinced then ever that the keys to maintaining and increasing the supply of cadaver organs and tissues available in this country is to insure that the public understands the importance of serving as organ and tissue donors, has every opportunity to donate, and that those who seek the altruism of the American people when death occurs are properly trained, experienced and sensitive to individual emotions, values and sensitivities about the loss of a loved one. The policies and partnerships announced today by the Vice President well serve these ends.

I want to offer my full support for the Vice President's initiatives. I want to congratulate him for continuing to strive to improve this nation's performance in helping those who need transplants. And I want to thank him for his unwavering determination to do what is necessary to insure that organ and tissue donation in this country reflect the core values of choice, altruism, and voluntarism.

THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FEB 24 1998

NOTE TO CHRIS JENNINGS

As we discussed, here are several upcoming opportunities for the President and Vice President to participate in follow-up activities for the National Organ and Tissue Donation Initiative. These activities would be linked to National Organ and Tissue Donor Awareness Week, April 19-25. I look forward to discussing these opportunities with you at your earliest convenience.

## I. CBS TV movie *Nicholas' Gift*

A. Advance screening of *Nicholas' Gift*: An invitation-only screening of this movie during the week of April 19 provides the opportunity to both recognize and encourage commitments by major corporations to promoting organ and tissue donation among their employees, as the Vice President challenged them to do when he announced the new federal employee education effort. *Nicholas' Gift*, starring Jamie Lee Curtis and Alan Bates, dramatizes the story of Reg and Maggie Green, a California couple who inspired a major increase in donation in Italy when they donated their seven-year-old son's organs after he had been shot in the head by highway bandits while on a family vacation in 1994. Seven children and adults received Nicholas' organs and tissues. The movie will air on CBS on Sunday, May 3 at 9:00 p.m. with an expected audience of 30 million viewers. Screening participants would include senior corporate officials, Congressional members, ambassadors from Italy and Japan, Jamie Lee Curtis, and Reg and Maggie Green

B. Public service announcement (PSA): The producers of Nicholas' Gift and Jamie Lee Curtis have expressed their desire for the President or Vice President to appear with Ms. Curtis in a 15-second PSA to air with *Nicholas' Gift*. The PSA would include a toll-free hotline (1-800-355-SHARE) for callers to receive a free brochure and donor card and HHS' Web site (www.organdonor.gov).

## II. Federal Employee Education Campaign

A. Memorandum to all federal agency heads: A memorandum from the President or Vice President would galvanize the federal agencies to participate in this new effort. A *Federal Kit* with implementation materials, including donation messages for pay slips, would be included with the memorandum. A draft memorandum is attached.

B. Satellite broadcast to all federal employees: A 30-second pre-taped message by the President or Vice President could be included in a 5-7 minute video on donation to be broadcast to all federal employees via satellite on April 1. The video, to be produced with Media Technologies, will air during a 90-minute OPM broadcast on "leaving the federal government." The video would be disseminated to federal agencies for later use.

Kevin Thurm

Attachment

# DRAFT

MEMORANDUM TO HEADS OF DEPARTMENTS AND INDEPENDENT AGENCIES

From: President Clinton or Vice President Gore

Subject: Organ and Tissue Donation

Last December, Vice President Al Gore and Health and Human Services Secretary Donna E. Shalala launched the National Organ and Tissue Donation Initiative. This initiative includes a new effort by the Federal government to increase awareness of organ and tissue donation among Federal employees. As we approach National Organ and Tissue Donor Awareness Week, April 19 - 25, I ask for your commitment in making Federal employees more aware of how they can become potential donors, bringing hope to those in desperate need of life-saving assistance.

Despite medical advances in transplantation and widespread support for donation, thousands of opportunities to donate and save lives are missed each year, often because families do not know about the wishes of their loved ones or because families are not asked to donate. Through a broad national partnership of public, private, and voluntary organizations, the National Organ and Tissue Donation Initiative aims to educate and inspire more individuals and families to make personal decisions about donation; to indicate their decisions on donor cards, driver's licenses, wills or living wills; to discuss their donation decisions with family members; and to say yes when asked to donate. Even with a signed donor card or other document, next-of-kin are asked to provide consent for donation.

The decision to become a potential donor is, of course, a private one. With proper information, however, employees and their families will be in a better position to make informed decisions. To implement employee education efforts, we are sending your Director of Personnel information that can be used to inform employees about organ and tissue donation, including donation messages for employee pay slips. A copy of this information is enclosed. Employees who want more information and a donor card also may contact the initiative's toll-free hotline (1-888-90-SHARE) or Web site (www.organdonor.gov).

Thank you for your support in this effort to provide Federal employees the opportunity to demonstrate their generosity and their commitment to the welfare of this Nation. Together, we can answer the hopes of many more Americans waiting for a second chance at life.

Enclosure

March 25, 1998

# Patients' Lives on the Line in Battle Over Transplants

**Related Articles**

- U.S. to Overhaul Donor-Organ Distribution Method (Feb. 27)
- Journal: Brazil Faces Controversy Over Organ Donor Law (Jan. 15)
- Muslim Leader Approves of Donating Organs (May 21, 1997)

By SHERYL GAY STOLBERG

ASHINGTON -- For two years and one month, Mindy Ervin has waited in uneasy limbo for a new liver. Too well to be ushered to the top of the transplant list, yet so sick that she has already planned her own funeral, she spends most of her time in bed, hoping the telephone will ring with news of an available organ.

A former nurse who suffers a rare autoimmune disease, Mrs. Ervin, of Portsmouth, R.I., lives in the region with the nation's longest wait for livers. She cannot have her transplant in Florida or South Carolina, where waiting times are shorter; her insurance company will not permit it. Five weeks ago, she endured a devastating false alarm. She dashed to the New England Medical Center in Boston for the long-awaited operation, only to learn the next morning that the donated organ was unsuitable.

"I told my husband, 'This is not living,' " said Mrs. Ervin, adding that she no longer expects to see her 37th birthday in July. "I'm just existing, waiting for it to happen, and nobody can tell me if it is going to happen. Emotionally, I don't know how much longer I can hang on."

Now the Ervins must contend with an additional uncertainty: The Clinton administration is about to dismantle the regional system for distributing donated organs and replace it with a national list in which the sickest patients would get priority. In a recent letter to 89 members of Congress, Donna E. Shalala, the secretary of health and human services, sketched her proposal, saying the change would even out waiting times across the country and insure that very sick people do not die waiting while those who are less acutely ill receive

transplants.

But Dr. Shalala's plan, which is expected to be codified as a federal regulation this month, has done little to ease the minds of patients like Mrs. Ervin and even less to settle the Solomon-like debate about how organs -- and in particular livers, which are in extremely short supply -- should be distributed. Rather, it has exposed a nasty political and economic fight between large and small transplant centers, each vying for its share of the lucrative transplant business, in which an operation can cost $250,000.

Surgeons who trained side-by-side are accusing one another of putting money ahead of patients' interests. The fight is so venomous that Dr. John Fung, chief of liver transplant surgery at the University of Pittsburgh Medical Center and an outspoken opponent of the current system, complained that he has been "blackballed from administrative positions" in scientific societies by doctors who disagreed with him.

Small transplant centers, fearing that a national list could put them out of business, have argued that a national list would concentrate organs in big cities, hurting poor patients, especially minorities, who do not have the means to travel. Big hospitals have complained that their smaller counterparts are trying to hoard organs for patients who are not desperate.

In Washington, the lobbying is as intense as if the fight were over a tax bill. The Pittsburgh hospital, which pioneered liver transplants, has retained a Little Rock, Ark., lawyer who represents President Clinton to press its case that the regional system should be scrapped. A coalition of mid-size medical centers, including the University of Cincinnati, Vanderbilt University and a doctors' group from the Medical University of South Carolina, is fighting back with its own big-gun lobbyists.

"I wish we were having an open-ended debate about what's fair," lamented Dr. Arthur Caplan, a bioethicist and the author of "Am I My Brother's Keeper," (Indiana University Press, 1998), a book about liver transplants. "Unfortunately, what I suspect we are seeing is a political squabble among transplant centers about what's in their interest."

Caught in the middle of this fracas are patients like Mindy Ervin, who said she has no idea how the rules would affect her. With more than 10,000 people waiting for a liver and only 4,000 livers available each year, she noted, "some of us are going to die." The question that is dividing transplant surgeons and patients is what system will make the best use of donated organs and save the most lives.

"It's among the thorniest issues I've dealt with here," said one official at the Health and Human Services Department who is involved with the proposed rules and who spoke on condition of anonymity. "A lot of things we do involve people's lives, but changing the system of distributing organs alters who lives and who dies, or how long you live and when you die."

While a sickest-first national policy might seem to make the most sense, some experts, including Caplan, say it may not be the best use of organs. Sicker people are more likely to die after their transplants, or to need second and even third transplants. The problem is especially acute with liver patients; unlike people in kidney failure, they cannot be kept alive through dialysis or other medical means.

"It's as if we were in a lifeboat," Caplan said, "and instead of trying to figure out how many of us might survive a shortage of food and water, we said, 'Let's pick the people who are closest to dead and save them.' "

At the same time, projections of how the new policy would affect patients conflict. An analysis performed for the Pittsburgh hospital by CONSAD Research Corporation found that Dr. Shalala's proposal would save as many as 200 lives a year by offering organs to people who would not otherwise get them.

But a competing study by the United Network for Organ Sharing, the nonprofit organization that runs the distribution system, found that Dr. Shalala's plan would result in 761 additional repeat transplants each year, and that the overall survival rate after transplants would drop from 75 percent to 68 percent.

"Do we want to transplant the sickest patients first, or the most people possible?" asked Walter Graham, the network's executive director, who favors keeping the current system. "Those are two conflicting objectives. Our answer is that you want to do both, but you can't do both."

So vexing is this issue that the attempt to draft new rules has languished in the bureaucracy since 1989, five years after the passage of the National Organ Transplant Act. The law spawned the organ sharing network, a collection of 63 independent organizations that procure organs in their local areas and assign them to hospitals.

The network's distribution plan works this way: Patients are given a rank of one, two or three, depending on the severity of their illness. When an organ becomes available, it is offered to people in the area, starting with the sickest. If there are no local patients, the organ is offered regionally, then nationally.

But donation patterns, as well as waiting lists, vary greatly throughout the nation's 11 regions. In New England, for instance, the wait for a liver is roughly two years, five times as long as in the Southeast.

In 1996, Dr. Shalala noted in her letter, more than half the livers used locally were given to patients who were well enough to be at home. Yet that same year, nearly 400 of the 953 patients who died while awaiting transplants died in the hospital.

With competition for organs fierce, many patients "game the system," said Dr. Caplan, the bioethicist. Some sign up at more than one transplant center, which is permitted under the network rules. Others switch to a hospital where the wait

is short.

That is not an option for Mrs. Ervin, whose husband works in a boat yard painting yachts. "People tell us, 'List down in Florida, the wait is shorter,' " Michael Ervin said, "But we don't have the money, and our insurance won't pay for it."

Mistrust among doctors and patients runs deep. Goldsby Margiotta, a Virginia woman who has been waiting three years for a liver, said she stopped going to a patient support group when the husband of another transplant candidate began calling her home with prying questions. "He thought I was some kind of interloper trying to get his wife's liver," she said.

To complicate matters, the lists are fluid, with patients' ranks changing constantly depending on the state of their health. "Everybody just thinks you put your name on this big list and when your number comes up they call you," Mrs. Ervin said. "It's not like that at all. People constantly ask me, 'What number are you?' I have no idea."

The high demand is, in a sense, testimony to the success of transplant medicine, particularly liver transplants. Nearly every liver transplant surgeon in the United States has trained at the University of Pittsburgh, or trained under someone who has. Over the past decade, the Pittsburgh-trained surgeons fanned out across the United States, starting programs at local hospitals.

In 1990, there were an estimated 50 liver transplant programs in the country; today, there are 120. As the number of programs grew, the number of operations performed in Pittsburgh declined by more than half, from 569 in 1990 to 230 last year, according to Dr. Roger Evans, a health policy analyst at the Mayo Clinic in Rochester, Minn., who studies organ allocation. "In the end," he said, "Pittsburgh created its own competition."

In 1991, the organ sharing network made a crucial change in its distribution policy that set the stage for the current dispute. Earlier, patients facing imminent death had priority for organs, no matter where they lived. When that provision was eliminated, the number of patients dying on Pittsburgh waiting list ballooned, said Dr. Fung, the hospital's liver transplant chief.

In 1993, after pressing unsuccessfully for the organ network to rescind the rule change, Pittsburgh officials turned to the government, which by that time was considering setting standards for organ allocation. They enlisted David Matter, a Pittsburgh real estate developer and college friend of President Clinton, to raise the issue at the White House. Matter said he wrote and talked to the president several times. And Pittsburgh hired a Little Rock lawyer, John R. Tisdale, who said last week that he was encouraged to see Dr. Shalala "leaning in our direction."

Also encouraged were transplant surgeons at the University of Nebraska, University of California at San Francisco and other large hospitals, including Mt. Sinai Medical Medical Center in New York. Dr. Charles Miller, Mt. Sinai's

director of transplantation, said the current system is so Balkanized that a patient in his intensive care unit might be denied a liver that goes to someone waiting at home in Ft. Lee, New Jersey, just across the Hudson River.

But officials of the organ sharing network are not going to abandon their policy without a fight. They have hired their own lobbyist and hinted at a lawsuit, saying the government has no right to impose rules. "Where does all this come from?" asked Graham, the executive director. "The only answer I can come up with is that it came as a result of political influence."

Graham contends the current system encourages organ donation, because donors want to know that their organs will help their neighbors, a view Miller describes as "beyond bunk." Doctors from smaller transplant centers, however, agree with Graham. They say liver transplant candidates are dying across the country and that replacing the regional system will do nothing more than change where people die.

"This national sharing plan is not going to bring organs to Cincinnati," complained Dr. Douglas Hanto, director of the adult liver transplant program at the University of Cincinnati. "What will happen is, livers will be taken from Ohio and sent to Pittsburgh. I think Pittsburgh is just flat out very interested in their own program."

To which Fung, the Pittsburgh surgeon, retorted: "Call Doug Hanto back. Ask him what I did for him three or four years ago when he had a very sick patient in Ohio. Ask him if I sent him a liver from Pittsburgh. We are willing to live and abide by the rules."

As the debate rages, Congress is considering jumping in. Sen. William Frist, a Tennessee Republican and heart surgeon who practiced at Vanderbilt University, said he would consider holding hearings once the final regulations are announced. He said he is particularly concerned that a national policy would deny access to poor patients who cannot travel.

"The secretary cannot play doctor," Frist said. For her part, Dr. Shalalasaid in her letter that she does not intend to "interfere in the practice of medicine;" she simply expects the organ sharing network to devise new rules to meet the government's standards.

As for patients, they can do little more than wait. Mrs. Ervin's transplant surgeon, Dr. Richard Rohrer, chief of the division of transplant surgery at New England Medical Center, is optimistic about her prospects. Though her blood type is AB, the least-common type, she could accept an organ from any blood donor group. "She has escape channels that other patients don't," Rohrer said.

But his patient is frightened and feels herself growing weaker. She is nauseated, jaundiced and has not eaten solid food for weeks. Because her disease has destroyed her immune system, she rarely leaves the house, for fear of catching a cold. The weeks since her false alarm have been especially tough.

"I hope I get the call again," she said. "But I hope it comes before I'm so ill that I won't be able to survive the surgery. That's my biggest fear. Will it come soon enough?"



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# ORGAN DONATION

# Assessing Performance of Organ Procurement Organizations

Statement for the Record by Bernice Steinhardt, Director
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GAO/T-HEHS-98-131

# Organ Donation: Assessing Performance of Organ Procurement Organizations

Mr. Chairman and Members of the Subcommittee:

We are pleased to contribute this statement for the record as part of the Subcommittee's review of issues concerning organ donation. Our comments will focus on the current standard for assessing the effectiveness of organ procurement organizations and alternatives to this standard.

Advancements in organ transplant technology have increased the number of patients who could benefit from such transplants. The supply of organs, however, has not kept pace with the growing number of transplant candidates, continuing to widen the gap between transplant demand and organ supply. With the passage in 1984 of the National Organ Transplant Act, the Congress sought to increase the organ supply. To some extent, this has succeeded: the number of cadaveric[1] organ donors increased 33 percent between 1988 and 1996—from 4,083 to 5,416—and the number of organs transplanted from cadaveric donors rose from 10,964 to 16,802 in the same period. Nevertheless, the organ supply has not kept pace with demand, and over 54,000 patients are now on the waiting list for a transplant.

The Department of Health and Human Services (HHS) has just published a new regulation to change the allocation of organs from what is now a largely regional approach to a more national approach.[2] Under current policies, matching organs are usually made available to all listed patients in a local organ procurement area before they are made available to other patients. Today we will discuss a key element of the current system, the local organ procurement organizations (OPO), rather than the impact of the change in policy.

To help the Congress better understand the operation of the organ allocation and procurement system, we have issued several reports over the last few years examining the equity of organ allocation decisions, variations in patient waiting times, and the lack of adequate measures to assess organ procurement effectiveness.[3] Most recently, in November 1997, we reported on our examination of the approaches for

[1]Some patients receive organs, particularly kidneys, from living donors. In 1996, 3,524 people donated organs.

[2]63 Federal Register 16296 et seq., Apr. 2, 1998 (to be codified at 42 CFR Part 121).

[3]Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs (GAO/HRD-93-56, Apr. 22, 1993) and Impact of Organ Allocation Variances (GAO/HEHS-95-203R, July 31, 1995).

assessing the effectiveness of OPOs in increasing the organ supply.[4] Our statement will focus on this most recent work, in which we examined (1) whether the current standard for assessing OPOs' effectiveness appropriately measures the extent to which OPOs are maximizing their ability to identify, procure, and transplant organs and tissue and (2) alternatives to the current standard that could be more effective.

OPOs play a crucial role in procuring and allocating organs.[5] They provide all the services necessary in a geographical region for coordinating the identification of potential donors, requests for donation, and recovery and transport of organs. OPOs work with the medical community and the public through professional education and public awareness efforts to encourage cooperation in and acceptance of organ donation. Although they have similar responsibilities, OPOs vary widely in the geographic size and demographic composition of their service areas as well as in number of hospitals, transplant centers, and patients served. The Health Care Financing Administration (HCFA) administers section 1138 of the Social Security Act,[6] which requires, among other things, that the Secretary of HHS designate one OPO per service area and that OPOs meet standards and qualifications to receive payment from Medicare and Medicaid. Section 371(b)(3)(B) of the Public Health Service Act[7] provides that an OPO should "conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors."

HCFA regulations set performance standards for OPOs.[8] These standards assess OPOs according to their achieving numerical goals per million population in their service areas in five categories: (1) organ donors; (2) kidneys recovered; (3) kidneys transplanted; (4) extrarenal organs, that is, hearts, livers, pancreata, and lungs recovered; and (5) extrarenal organs transplanted. HCFA assesses OPOs' adherence to the standards and qualifications every 2 years. Each OPO must meet numerical goals in four of the five categories to be recertified by HCFA as the OPO for a particular area

[4]Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance (GAO/HEHS-98-26, Nov. 26, 1997).

[5]OPOs are nonprofit private entities that facilitate the acquisition and distribution of organs.

[6]42 U.S.C. 1320b-8.

[7]42 U.S.C. 273(b)(3)(B).

[8]42 CFR Part 486, Subpart G.

and to receive Medicare and Medicaid payments.[9,10] Without HCFA certification, an OPO may not continue to operate. In 1996, HCFA assessed OPOs for the first time using the population-based standard with 1994 and 1995 procurement and transplant data.

Whether the HCFA population-based standard appropriately measures the extent to which OPOs are maximizing their ability to identify, procure, and transplant organs and tissue was the subject of our recent report. We determined the strengths and weaknesses of the current standard and identified and assessed alternatives to that standard.

In brief, HCFA's current performance standard does not accurately assess OPOs' ability to meet the goal of acquiring all usable organs because it is based on the total population, not the number of potential donors, within the OPOs' service areas. We identified two alternative performance measures that would better estimate the number of potential organ donors: measuring the rates of organ procurement and transplantation compared with either the number of deaths or the number of deaths adjusted for cause of death and age. Both these approaches have limitations, however, in data availability and accuracy. Two other methods for assessing OPO performance—medical records reviews and modeling—show promise because they could more accurately determine the number of potential donors. Because OPOs must meet the performance goals to continue to operate, approaches that more accurately differentiate between OPOs that achieve greater or lesser proportions of all possible donations in their service areas can help increase donations.

## Background

Although the number of donors is growing more slowly than the demand for organs, the number of donors has steadily increased since 1988. The major reason for this increase is because many more older people are becoming organ donors than in the past. Nearly two-thirds of cadaveric donors were between the ages of 18 and 49 in 1988, but by 1996 only about one-half of donors were in this age group. The proportion of donors aged 50 and older doubled from about 12 percent in 1988 to about 26 percent in 1996. Another reason for the increase in donors is because more minorities are consenting to donate organs. Between 1988 and 1996, the

[9]During the 1996 designation period only, HCFA redesignated OPOs that met numerical goals in three of the five categories and submitted an acceptable corrective action plan.

[10]According to HCFA regulations, certification or recertification refers to HCFA's determination that an entity meets the standards for a qualified OPO; designation or redesignation refers to HCFA's approval of an OPO to receive Medicare and Medicaid payments. These terms are usually used interchangeably.

percentage of organ donors who belonged to racial and ethnic minority groups increased from about 16 to 23 percent.

The organ donation process usually begins at a hospital when a patient is identified as a potential organ donor. Only those patients pronounced brain dead are considered for organ donation.[11,12] Most organ donors either die from nonaccidental injuries, such as a brain hemorrhage, or accidental injuries, such as a motor vehicle accident. Other causes of death that can result in organ donation include drowning, gunshot or stab wound, or asphyxiation.

Once a potential organ donor has been identified, a staff member of either the hospital or the OPO typically contacts the deceased's family, which then has the opportunity to donate the organs. If the family consents to donation, OPO staff coordinate the rest of the organ procurement activities, including recovering and preserving the organs and arranging for their transport to the hospital where the transplant will be performed.

One donor may provide organs to several different patients. Each cadaveric donor provides an average of three organs. In 1996, OPOs procured kidneys from 93 percent of organ donors and livers from 82 percent of them; other organs were procured at lower rates.

## Role of OPOs

The national system of 63 OPOs currently in operation coordinates the retrieval, preservation, transportation, and placement of organs. For Medicare and Medicaid payment purposes, HCFA certifies that an OPO meets certain criteria and designates it as the only OPO for a particular geographic area. OPOs must meet service area and other requirements. As of January 1, 1996, each OPO had to meet at least one of the following service area requirements:

1. It must include an entire state or official U.S. territory.

2. It must either procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation, or it must request and receive an exception to this requirement.

[11]States set the legal standard for determining death. "Brain death" is defined as the irreversible cessation of all functions of the entire brain, including the brain stem.

[12]Organs are recovered from a small number of donors declared dead by traditional cardiac death criteria. Some have termed these donors as "non-heartbeating."

3. If it operates exclusively in a noncontiguous U.S. state, territory, or commonwealth, the OPO must procure organs at the rate of 50 percent of the national average of all OPOs for both kidneys procured and transplanted per million population.

4. If it is a new entity, the OPO must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

In addition, an OPO must be a nonprofit entity and meet other requirements for the composition of its board, its accounting, its staff, and its procedures. To ensure the fair distribution and safety of organs, OPOs must have a system to equitably allocate organs to transplant patients. In addition, OPOs must arrange for appropriate tissue typing of organs and ensure that donor screening and testing for infectious diseases, including the human immunodeficiency virus, are performed.

OPOs use a variety of methods for increasing donation such as raising public awareness of organ donation and developing relationships with hospitals. The goal of public education is to promote the consent process, giving people the information they need to make decisions about organ and tissue donation and encouraging them to share their decisions with their families. Such public education campaigns include mass media advertising; presentations to schools, churches, civic organizations, and businesses; and informational displays in motor vehicle offices, city and town halls, public libraries, pharmacies, and physician and attorney offices.

In addition, education efforts help hospital staff clarify organ and tissue recovery policies to ensure that potential donors are consistently recognized and referred. OPOs also conduct hospital development activities to build strong relationships with service area hospitals to promote organ donation.

## Problems With the Current Standard

HCFA chose a population-based standard to assess OPO performance after considering the availability and cost to the OPOs of obtaining and analyzing various types of data. When HCFA first applied this standard in 1996, five OPOs were subject to action for failing to meet the standard. This resulted in two OPOs' service areas being taken over by adjacent OPOs, a portion of one OPO's service area being taken over by an adjacent OPO, and the merger of one OPO with another. The fifth OPO that failed the standard was

determined to be a new entity and not subject to meeting the performance standard.

A population-based standard, however, does not accurately assess OPO performance because OPO service areas consist of varying populations. Although potential organ donors share certain characteristics, including causes of death, absence of certain diseases, and being in a certain age group, OPO service area populations can differ greatly in these characteristics.

For example, motor vehicle accidents, the cause of death for about one-quarter of organ donors in 1994 and 1995, ranged from about 4.4 to about 17.9 per 100,000 population among the states and the District of Columbia. In addition, the rates of acquired immunodeficiency syndrome, a disease that eliminates someone for consideration as an organ donor, differ among the states and the District of Columbia—from 2.8 to 246.9 cases per 100,000 people in 1994. Furthermore, although most organ donors were between 18 and 64 years of age in 1994 and 1995, this age group constitutes from 56 to 66 percent of the population in different states. Thus, the number of potential organ donors can vary greatly for OPOs serving equally sized populations.

## Alternative Standards Could More Accurately Assess OPO Performance

We identified several performance measures as alternatives to the current population-based standard. The alternatives we examined included measuring organ procurement and transplantation compared with (1) the number of deaths, (2) the number of deaths adjusted for cause of death and age, (3) the number of potential donors based on medical records reviews, and (4) the number of potential donors based on modeling estimates in an OPO service area.

In developing its current OPO performance standard, HCFA considered using the number of service area deaths as the basis for assessing performance. Although some organs, typically kidneys, are obtained from living donors, OPOs recover organs from cadaveric donors. Therefore, the number of deaths in an OPO's service area more accurately reflects the number of an OPO's potential donors. In 1994, the United States had about 2.3 million deaths out of a population of about 260 million. Although using total deaths fails to consider other factors about and characteristics of potential donors, it would eliminate considering a portion of the population that an OPO clearly could not consider for organ donation.

HCFA also considered using an adjusted measure of deaths for the performance standard. Measuring OPO performance according to the number of service area deaths adjusted for cause of death and age more accurately reflects the number of potential donors than measuring performance according to the number of all service area deaths. The number of service area deaths adjusted for cause of death and age better estimates the number of potential donors because it accounts for the small subset of the deceased that may be suitable organ donation candidates. Adjusting for cause of death and limiting consideration to deaths of those under age 75, we found that in 1994 about 147,000, or 6 percent, of the 2.3 million U.S. deaths involved these causes of death or were of people in this age group. This estimate, however, is much larger than the estimates some have made of a national donor pool of from 5,000 to 29,000 people per year.

We found that both the death and adjusted-death measures have drawbacks that limit their usefulness, however, including lack of timely data and inability to identify those deaths suitable for use in organ donation. We ranked the OPOs, using 1994-95 OPO procurement and transplant data, according to the current population-based measure and these two alternative measures—number of deaths and adjusted deaths. Although three OPOs would not qualify for recertification under any of these measures, according to our review, the number of and which OPOs would not qualify vary depending on the measure used. More OPOs would have been subject to termination under either of these alternative measures.

HCFA did not consider two other methods for determining the number of potential donors—medical records reviews and modeling—that show promise for determining OPOs' ability to acquire all usable organs. Reviewing hospital medical records is the most accurate method of estimating the number of potential donors in an OPO's service area. A medical records review involves reviewing all deaths at a hospital with an in-depth examination of those meeting certain criteria. Reviewing the records of these patients reveals the patients' suitability for organ donation based on several factors, including cause of death, evidence of brain death, and contraindications for donation such as age and disease. Such reviews can identify that subset of deaths in which patients could have become organ donors—the true number of potential donors for an OPO service area.

Most OPOs do conduct medical records reviews but at varying levels of sophistication. For records reviews to be useful for assessing OPO performance, the reviews would have to be conducted consistently among OPOs and the results would need to be available for validation. Such reviews, however, are labor intensive and therefore expensive. Although most OPOs are conducting some form of medical records reviews and therefore already incurring the costs of these reviews, HCFA must consider its own and the OPOs' additional expense involved in standardizing such reviews. Other considerations include the extent to which the reviews would add to the cost of organs and whether these costs would outweigh the benefit of more accurately measuring the number of potential donors.

Another alternative, modeling, shows promise and would be less expensive than medical records reviews. At least one group is developing a modeling method using substitute measures to provide a valid measure for estimating the number of potential donors. The goal of this effort is to design an estimating procedure that will be relatively simple to execute, inexpensive, and valid. This approach uses information from hospitals in the OPO's service area on variables, such as total number of deaths, total staffed beds, Medicare case mix, medical school affiliation, and trauma center certification, to predict the number of potential donors. Using existing data would make this alternative less costly than medical records reviews; however, the accuracy of such a model has yet to be established. If the number of potential donors for an OPO can be reasonably predicted using a set of variables, this could eliminate concerns about the cost of implementing medical records reviews.

## Recommended Future Steps

HCFA believes its current standard identifies OPOs that are poor performers. When publishing its final rule, however, the agency stated that it was interested in any empirical research that would merit consideration for further refining its standard. The approaches we identified in our report merit HCFA's consideration.

More specifically, our report recommended that to better ensure that HCFA accurately assesses OPOs' organ procurement performance and that OPOs are maximizing the number of organs procured and transplanted, the Secretary of Health and Human Services direct HCFA to evaluate the ongoing development of methods for determining the number of potential donors for an OPO. These methods include medical records reviews and a model to estimate the number of potential donors. If HCFA determines that one or both of these methods can accurately estimate the number of

potential donors at a reasonable cost, it should choose one and begin assessing OPO performance accordingly.

HCFA has concurred with our recommendation. It has indicated that when the ongoing research on medical records reviews and modeling are complete and it receives the studies, it will review the results to determine if it can support a better performance standard.

HCFA's continuous monitoring of the developments in approaches to identifying potential organ donors is important. Because the demand for organs surpasses the supply, OPOs are required by law to conduct and participate in systematic efforts to acquire all usable organs from potential donors. As we have reported, unless HCFA measures OPO performance according to the number of potential donors, the agency cannot determine OPOs' effectiveness in acquiring organs.

# Editorial



March 30, 1998

## For Fairness in Organ Transplants

Secretary Donna Shalala of the Department of Health and Human Services wants to give gravely ill patients the same shot at a life-saving liver transplant whether they live in downtown Pittsburgh or rural Mississippi.

Survival, she rightly says, should not be an accident of geography. Yet the private organization that coordinates the organ transplant program for H.H.S. -- United Network for Organ Sharing -- rejects her sensible idea. Part of its objection flows from a seeming misunderstanding of Ms. Shalala's intention. But UNOS's resistance also reflects its defense of small transplant centers around the country whose autonomy and income would be undermined by the Secretary's plan.

About 4,000 Americans die each year because there are not enough donated livers, kidneys and other organs to go around. Under current rules, transplant centers get to use organs that are locally donated even if they could be better used elsewhere. Local control has led to severe mismatches between the number of patients needing transplants and the number of organs available, so that wait times are five times longer in some parts of the country than in others. Besides guaranteeing simple fairness, Ms. Shalala wants to minimize the ravages of rationing organs by sending them where they are most needed. She also wants a system that is less tilted in favor of the rich, who can afford to fly to wherever the wait is short.

Under her proposal, the poor can sit tight and be treated just as fast.

UNOS's fear is that Ms. Shalala's plan would reinstate a misguided policy that once directed donated organs to the sickest patients first. Such patients can be unlikely candidates to recover even with a transplant. UNOS wants donated organs also to go to patients who are most likely to survive, even if they are not the sickest or longest-waiting patients.

But officials at H.H.S. deny that they want to reverse UNOS's policy. All H.H.S. says it wants is a medically responsible way to diminish geographic disparities.

Indeed, Ms. Shalala has asked UNOS to design the new system, including national standards for placing and ranking patients on waiting lists for organ

transplants.

When parties cannot resolve simple misunderstandings, it is a safe bet that something beyond confusion lurks behind the word games. In this case, UNOS relentlessly defends the interests of transplant centers across the country that financially thrive by transplanting organs that are locally donated.

Under Ms. Shalala's proposal, some of these donated organs would be steered to large transplant centers with long waiting lists of gravely ill patients.

The best way to solve the problem of waiting lists is to eradicate organ shortages by persuading more Americans to donate organs at death. The next best answer is to manage the organ shortage wisely.

For that to happen, UNOS needs to suspend suspicion of Ms. Shalala's intentions and get on with the job of designing a sophisticated system for directing donated organs where they will do the most good.