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Department of Health and Human Services

Centers for Medicare & Medicaid Services

**42 CFR Parts 413, 441, et al.
Medicare and Medicaid Programs;
Conditions for Coverage for Organ
Procurement Organizations (OPOs);
Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 441, 486 and 498

[CMS-3064-P]

RIN: 0938-AK81

Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish new conditions for coverage for organ procurement organizations (OPOs), including multiple new outcome and process performance measures based on donor potential and other related factors in each service area of qualified OPOs. We are proposing new standards with the goal of improving OPO performance and increasing organ donation.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 5, 2005.

ADDRESSES: In commenting, please refer to file code CMS-3064-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates please):

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3064-P, P.O. Box 8015, Baltimore, MD 21244-8015.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your

arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marcia Newton, (410) 786-5265. Diane Corning, (410) 786-8486.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-3064-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. Key Statutory Provisions

The Organ Procurement Organization Certification Act of 2000 (section 701 of Pub. L. 106-505) and section 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (Pub. L. 106-554) contain identical provisions that amended section 371(b)(1) of the Public Health Service (PHS) Act (42 U.S.C. 273(b)(1)). The legislation directs the Secretary to establish regulations that include four major requirements. These are to:

1. Increase the re-certification cycle for OPOs from 2 to at least 4 years.

2. Establish outcome and process performance measures based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified OPOs.

3. Establish multiple outcome measures.

4. Establish a process for OPOs to appeal a de-certification on substantive and procedural grounds.

The re-certification cycle was increased from 2 years to 4 years through an interim final rule with comment (December 28, 2001, 66 FR 67109), "Emergency Re-certification for Coverage for Organ Procurement Organizations (OPOs)." The interim final rule re-certified all 59 OPOs until December 31, 2005 and extended their agreements with us until July 31, 2006. Thus, the re-certification cycle set forth in the interim final rule satisfies the first of the new criteria (that is, certification not more frequently than once every 4 years.) Our proposed rule addresses the remaining three requirements.

Section 1138 of the Social Security Act (the Act) (42 U.S.C. 1320b-8) provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be reimbursed in hospitals and critical access hospitals under the Medicare or Medicaid programs. Section 1138(b) of the Act also specifies that an OPO must operate under a grant made under section 371(a) of the PHS Act or must be certified or re-certified by the Secretary as meeting the standards to be a qualified OPO. Under these authorities, we previously established conditions for coverage for OPOs at 42 CFR 486.301, et seq. (May 2, 1996, 61 FR 19722).

Section 1102 of the Act gives the Secretary of Health and Human Services the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions with which he is charged under the Act. This section of

the Act gives the Secretary broad authority to establish requirements for OPOs that are necessary for the efficient administration of the Medicare program.

B. Why We Are Proposing New OPO Regulations

OPOs are government contractors that play a crucial role in ensuring that scarce transplantable human organs are provided to seriously ill patients suffering from end-stage organ failure. OPOs are responsible for identifying potential organ donors, informing families about their donation options, obtaining consent to donation, screening potential donors for infectious disease, clinically managing potential organ donors to maintain viability of their organs, placing the maximum number of organs possible with transplant centers, arranging for recovery, testing, and tissue typing of organs, and packaging and transporting organs to transplant hospitals. Clearly, OPO performance is one of the most critical elements of the nation's organ transplantation system. An OPO that is effective in procuring organs and delivering them safely to transplant centers will save more lives than an ineffective OPO. Therefore, under the broad authority in the statute, the Secretary has established performance standards for OPOs so that they excel in their critical mission.

The need for organ donors is acute and growing rapidly. While medical advances have made transplantation a viable treatment option for many patients suffering from end-stage organ failure, the supply of organs has not kept pace with the number of patients who need them. Since 1996 when the current OPO regulations went into effect through the end of 2002, the number of patients waiting for organs increased by nearly 60 percent to more than 80,792, while the number of deceased donors grew by only 14 percent. As of June 23, 2003, there were 82,049 patients waiting for a transplant.

Various studies, including those by the Harvard School of Public Health, the Partnership for Organ Donation, and the Association of Organ Procurement Organizations (AOPO), have estimated that approximately 10,500 to 22,000 deaths occurring in the United States every year could yield suitable donor organs. (C Christiansen, S Gortmaker, J William, et al: A Method for Estimating Solid Organ Donor Potential by Organ Procurement Region, *American Journal of Public Health*, Vol. 88, No. 22, November, 1998. E Sheey, S Conrad, L Brigham, et al: Estimating the Number of Potential Organ Donors in the United States, *The New England Journal of Medicine*, 349:667-74, August 14, 2003.

E Guadagnoli, C Christiansen, C Beasley, *Potential Organ-Donor Supply and Efficiency of Organ Procurement Organizations*, Health Care Financing Review, Vol. 24, No. 24, Summer 2003.) However, there were only 6,182 deceased donors in 2002 and only 18,244 transplants resulting from those donations. Based on these estimates, OPOs are recovering organs from, at most, only a little more than half the number of potential donors per year.

The study published in *The New England Journal of Medicine* found that of all potential organ donors reported in the study, only 42 percent became donors. Of those families who were asked to donate, only 39 percent agreed, and 16 percent of families were never asked whether they would agree to donation. The study published in the Health Care Financing Review found that of all potential organ donors reported in the study, only 35 percent became donors.

Over the years, many research studies have analyzed factors that impact donation rates, including health professionals' attitudes toward donation, the setting in which requests for donation are made, and medical examiner prohibitions on donation. Recently, researchers have increasingly turned their attention to the best practices of OPOs whose service areas have high donation rates.

In April 2003, the Health Resources and Services Administration (HRSA) began an ongoing "Organ Donation Breakthrough Collaborative" to bring best practices in organ donation to OPOs and hospitals, particularly to hospitals identified as having the greatest number of potential donors. More than three-quarters of the 59 OPOs are participating in the Collaborative. By studying the practices of six of the best-performing OPOs, the Collaborative's researchers have already identified several best practices for OPOs, as well as strategies for implementing them. Many of the best practices and associated strategies are discussed throughout this preamble to provide guidance for OPOs in implementing the requirements of the proposed rule.

Our proposals would fundamentally change the existing OPO regulations to emphasize quality and continuous quality improvement. The changes would ensure that each OPO utilizes best practices to improve its efficiency, effectiveness, and quality. While the requirements in the proposed rule apply to all OPOs, we have specifically targeted the requirements toward OPOs that may not understand the value of incorporating best practices into the structure of their organizations. Thus,

our overall goal is to improve the functioning of poor performing OPOs, rather than simply to terminate them.

In April 2001, the Department of Health and Human Services (the Department) launched "The Secretary's Donation Initiative," a multi-pronged effort to increase all types of donation—blood, marrow, tissue, and organ. In his speech launching the Initiative, the Secretary noted, "The facts are just astounding. Someone dies every 96 minutes because there aren't enough organs to go around." The five initial key elements of the Initiative were the Workplace Partnership for Life, a new model donor card, a national forum on donor registries, a national gift of life medal, and a drivers' education donation curriculum. The Department promised that it would launch additional elements under the Initiative in the future. The Organ Donation Breakthrough Collaborative is the sixth key element of the Secretary's Initiative. The Secretary believes promulgation of the multiple outcome and process performance measures in this rule will improve OPO performance and, as a result, increase organ donation and transplantation in the United States.

B. Overview of Key Proposed Provisions

1. Appeals and Competition Processes

In the congressional findings associated with section 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (42 U.S.C. 219(a)(2)) Congress found that the process for OPO re-certification created a level of uncertainty among OPOs that interfered with their effectiveness in increasing organ donation. Therefore, Congress directed the Secretary to develop a process for OPOs to appeal a de-certification on substantive and procedural grounds. (See section 219(c)(3) codified at 42 U.S.C. 273(b)(1)(D)(ii)(iv).) Under this authority, we are proposing a streamlined appeals process, in which an OPO facing de-certification could appeal and receive a decision on its appeal before its service area is opened for competition from other OPOs. (See proposed § 486.314.)

To further reduce the level of uncertainty identified by Congress, we propose making certain changes in the current re-certification process. Although we would open every OPO's service area for competition at the end of every re-certification cycle as under the current regulations, we would: (1) Permit OPOs to compete for open areas only if they met certain specific objective criteria; (2) allow competition only for entire service areas; and (3) use

clear, objective criteria for determining which OPO would be designated for the service area (See proposed § 486.316.)

A more extensive discussion of our proposal for the appeals and competition processes, as well as a description of other competition processes on which we are requesting comments, can be found in this preamble under proposed "General Requirements."

2. Proposed Multiple Outcome Performance Measures

When we published the current OPO regulations in 1996, population was the only measure readily available to assess donor potential. Therefore, we promulgated regulations that judge an OPO's performance based on the population in its service area (for example, the number of donors per million population). Subsequently, we began to investigate alternative methods for assessing donor potential in order to develop new outcome measures based on the organ donation potential in each OPO's service area. This preamble contains a discussion of our analysis of these alternative methods, as well as an explanation of the method we propose—using potential donor data reported by OPOs to the Organ Procurement and Transplantation Network (OPTN) based on information from hospital referral calls to OPOs. A discussion of the proposed multiple outcome measures can be found in this preamble under "OPO Outcome Performance Measures." The proposed regulatory text can be found at § 486.318.

The proposed outcome measures would address two requirements of the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001. The first requirement calls for promulgation of

"outcome* * * performance measures that are based on empirical evidence obtained through reasonable efforts of organ donor potential and other related factors in each service area of qualified organ procurement organizations." The second requirement calls for the use of "multiple outcome measures as part of the certification process."

3. Proposed Multiple Process Performance Measures

In addition to proposing multiple outcome measures, the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 require the Secretary to propose "process performance measures that are based on empirical evidence obtained through reasonable efforts of organ

donor potential and other related factors in each service area of qualified organ procurement organizations." In the congressional findings associated with section 219 of the Conference Report accompanying the Consolidated Appropriations Act, 2001 (Pub. L. 106–554, 42 U.S.C. 219(a)(6)(B)), Congress urged us to "improve the overall certification process" by incorporating process as well as outcome performance measures. Congress noted that current OPO regulations do not permit consideration of outcome and process performance measures that "would more accurately reflect the relative capability and performance of each organ procurement organization."

Therefore, we propose to establish outcome and process performance-related measures based on factors that affect an OPO's ability to provide the maximum number of healthy organs to transplant centers. The purpose of these measures is to improve OPO performance and increase organ donation by ensuring that OPOs attain the highest possible level of effectiveness and quality. The process performance measures we propose would require OPOs to develop performance protocols, monitor their own performance continuously, and make changes to improve the quality of their organizations.

The proposed new process performance measures are based on empirical evidence of organ donor potential and other related factors in each OPO service area derived from three bodies of knowledge: (1) Research into best practices in organ donation, (2) information about methods of maximizing organ donation based on our work with OPOs, and (3) accepted standards of practice and quality improvement strategies used by the larger health care community.

A review of the literature on best practices in organ donation provides empirical evidence that certain characteristics are common to successful OPOs. These characteristics include experienced leadership; efficient mechanisms for tracking activity; excellent communication with transplant hospitals; timely, on-site response to donor referrals; adequate experienced staff; data-driven decision making; in-hospital coordinators; and targeted hospital development programs. We have incorporated findings from the literature into the proposed process performance measures. Discussions and citations of individual studies can be found in this preamble in "Organ Procurement Organization Process Performance Measures."

Our experience with top-performing OPOs supports the validity of the literature on best practices. In 1998, we developed four "OPO Coordinator" positions in the four CMS Regional Consortia (Midwest, West, South, and Northeast). The OPO Coordinator positions are unique; OPOs are the only Medicare providers or suppliers that have our staff assigned to work with them on an ongoing basis to improve their quality and outcomes. The Coordinators sponsor seminars, conduct conferences and workshops, provide education for OPO staffs, conduct site visits, meet with OPO directors and hospital development staffs, recommend interventions to increase OPO efficiency and quality, analyze OPO's voluntary quality improvement efforts, and act as liaisons between OPOs and hospitals and between OPOs and tissue banks to resolve problems and promote cooperation. (We would note that for ease of use, the term "tissue bank" when used in this preamble and in the proposed regulations text refers to all types of tissue banks, including those that recover only corneas and eyes, and the word "tissues" refers to all types of tissues, including corneas and eyes.)

The proposed process performance measures are based heavily on the Coordinators' extensive experience with all 59 OPOs. The Coordinators' experience with and knowledge about OPOs provide much of the empirical evidence that has enabled us to develop proposed process performance measures targeted specifically toward increasing OPO performance and quality.

As stated earlier, some of the proposed requirements are based on other factors such as accepted standards of practice for all health care organizations. For example, proposed § 486.344 would require OPOs to use accepted standards of practice for testing donors to prevent transmission of the human immunodeficiency virus (HIV) and other infectious diseases. Proposed § 486.348 is based on quality assessment and performance improvement (QAPI) programs that have been embraced by the health care community and that have been shown to increase quality and outcomes of care.

Therefore, the process performance measures we propose would satisfy the second requirement in the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 for the Secretary to propose process performance measures "based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in

each OPO's service area." These include the following proposed requirements for OPOs:

- Have agreements with hospitals and critical access hospitals that address responsibilities in regard to the requirements for hospitals at § 482.45 and for critical access hospitals at § 485.643. (§ 486.322.)

- Maintain sufficient qualified staff (either from the OPO or under contract or arrangement) to accomplish a number of different objectives, including screening referral calls for donor potential, assessment of potential donors for medical suitability, requesting consent, maintaining donors, placing organs, overseeing organ recovery, performing death record reviews, and conducting QAPI activities. (§ 486.326.)

- Ensure that organ recovery personnel are qualified and trained. (§ 486.326.)

- Provide education, training, and performance evaluations for OPO staff. (§ 486.326.)

- Obtain informed consent for organ and tissue donation. (§ 486.342.)

- Develop and follow protocols for donor evaluation and management and organ placement and recovery. (§ 486.344.)

- Have a medical director who is responsible for implementation of these protocols, as well as oversight management of potential donors. (§ 486.326.)

- Arrange for screening and testing of the donor for infectious disease and testing and tissue typing of organs by a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1998. (§ 486.344 and § 486.346.)

- Collaborate with transplant programs and have protocols defining OPO and transplant hospital roles and responsibilities for donor evaluation, donor management, organ recovery, and organ placement. (§ 486.344.)

- Document recipient information, including blood type and position on the wait list, before organ recovery. (§ 486.344.)

- Develop and follow a protocol for packaging, labeling, handling, and shipping organs. (§ 486.346.)

- Establish a comprehensive, data-driven, QAPI program designed to monitor and evaluate performance of all donation services. (§ 486.348.)

- Perform death record reviews in hospitals with level I or level II trauma centers or 150 or more beds. (§ 486.348.)

In addition, we propose a number of other requirements based on the Secretary's authority under section 1102 of the Act to establish requirements

necessary for the efficient administration of the Medicare program. These requirements generally are related to (1) administrative matters (because efficient administration by Medicare contractors such as OPOs supports efficient administration of the Medicare program); (2) OPOs' relationships with Medicare donor and transplant hospitals; and (3) data collection, management, and reporting (because OPO data are needed by other Medicare entities, by other agencies within the Department, and by us for the certification of OPOs.) These proposed requirements include:

- Participation in the Organ Procurement and Transplantation Network. (§ 486.320.)

- Designated requestor training for hospital staffs. (§ 486.322.)

- Legal authority of a governing body for management and provision of OPO services and development and implementation of policies and procedures for administration of the OPO, the OPO's QAPI program, and services furnished under contract or arrangement. (§ 486.324.)

- Conflict of interest policies for the governing body, OPO directors, medical directors, senior management, and procurement coordinators. (§ 486.324 and § 486.326.)

- Credentialing records for organ recovery personnel. (§ 486.326.)

- Hospital-specific organ donation and transplantation data reported to Secretary and public. (§ 486.328.)

- Information management, including donor and transplant recipient information, data retention, and format of records. (§ 486.330.)

- A system to allocate donated organs that is consistent with the rules and requirements of the OPTN. (§ 486.344.)

- Investigation, analysis, and reporting of adverse events to us. (§ 486.348.)

Some of the proposed process performance measurements have a dual role in that they both satisfy the requirements of the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 and are based on the Secretary's authority under section 1102 of the Act. For example, the requirement for OPOs to provide designated requestor training for hospitals can be linked to the Organ Procurement Organization Certification Act of 2000 and section 219 of the Consolidated Appropriations Act, 2001 because the requirement is based on empirical evidence that shows improved consent rates when the OPO and hospital collaborate in requesting consent. (Note that factors in each

OPO's service area, such as the OPO's relationship with its hospitals, would determine whether hospitals would request, and OPOs would need to provide, designated requestor training). This proposed requirement also is necessary to the effective and efficient administration of the Medicare and Medicaid programs because under 42 CFR § 482.45, hospitals must ensure that individuals who discuss donation with families of potential organ donors are trained in a course offered or approved by the OPO.

Finally, section 1138(b)(1)(A) of the Act requires an OPO to be a "qualified" OPO as described in section 371(b) of the PHS Act. A number of the requirements we propose (for example, arrangements to cooperate with tissue banks and membership composition and authority of OPO boards) are based on requirements for qualified OPOs under the PHS Act. (See § 486.322 and § 486.324.) Proposed requirements that relate to the PHS Act are noted in the broader discussion in this preamble under "Proposed Process Performance Measures and Other Requirements."

II. Provisions of the Proposed Regulations

For the reasons discussed above, we propose to reorganize and revise 42 CFR part 486, subpart G. Following is a discussion of the specific requirements contained in the proposed conditions.

Proposed General Requirements

Basis and Scope (Proposed § 486.301)

Section 486.301 (Basis and scope) would remain unchanged from the existing regulations except that we would add a reference to § 1102 of the Act, and we would add the term, "non-renewal" to § 486.301(b)(3) to clarify that the scope includes non-renewal of agreements.

Definitions (Proposed § 486.302)

To reflect organizational changes in the regulations text, to remove obsolete material, and to provide further clarity to the regulations, we propose several amendments and additions to the definitions.

We propose amending the definition for "certification" to mean a Secretarial determination that an OPO meets (or has met) the requirements at 42 CFR 486.303 and is eligible for designation if it meets the additional requirements for designation.

We propose amending the definition of "designation" to clarify that designation is the process of assigning geographic service areas to OPOs. Once an OPO is certified and assigned a

geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under § 1138(b)(1)(F) of the Act.

We propose amending the definition of “entire metropolitan statistical area” to state that we do not recognize consolidated metropolitan statistical areas (CMSAs) when making service area determinations.

We propose amending the definition of “organ” to clarify that the definition includes multivisceral organs only when they are transplanted with an intestine.

We propose eliminating “potential donor” and replacing it with “organ donor potential.” The definition of “potential donor” in the current regulations refers to causes and conditions of death that are “generally acceptable” for donation of at least one solid organ.” In our definition for “organ donor potential,” we would include specific parameters for the cause and conditions of death that indicate medical suitability for organ donation. These parameters are discussed in this preamble under “Proposed OPO Outcome Measures,” section C3. We are particularly interested in public comments on this proposed definition.

We propose replacing “transplant center” with “transplant hospital” and have standardized the use of “transplant hospital” throughout this proposed regulation. A transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.

Additionally, we propose adding definitions for “adverse event,” “agreement cycle,” “death record review,” “de-certification,” “designated requestor,” “donor,” “donor document,” “potential donor denominator,” and “re-certification cycle.”

We propose a definition for “adverse event” because we propose requiring an OPO to report those events to us so that we can monitor the OPO’s response to the adverse event. An adverse event would mean an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.

We propose definitions for “agreement cycle” and “re-certification cycle” to clarify the difference between the two. The 4-year CMS/OPO agreement cycle runs from August 1 through July 31, unless it is extended

according to § 486.314. The 4-year re-certification cycle is based on the calendar year.

We have included a proposed definition for “death record review” because we would require OPOs to perform death record reviews as part of their QAPI programs.

We have included a definition for “de-certification” to explain that de-certification follows our determination that an OPO no longer meets one or more conditions for coverage (including, the outcome measures at § 486.318 and the process performance measures and other requirements) or no longer meets the requirements for certification or designation. If an OPO’s agreement with us is terminated or is not renewed, the OPO is de-certified.

We propose adding a definition for “designated requestor” to explain the role of designated requestors in the donation process. We propose a definition for “donor” to ensure that OPOs’ reporting of donor data is standardized. (The definition of “donor” is not intended to limit acceptable donors.)

We are proposing a definition for “donor document” because we would require OPOs to ensure that, in the absence of a donor document, the individual or individuals with responsibility to make the donation decision are informed of their option to donate organs or tissues or to decline to donate.

We propose adding “potential donor denominator” to the definitions because we would use this term for the potential donor data OPOs would report to the OPTN. Those data would be used as the basis for the multiple outcome measures.

These definitions, as we propose to add or revise them, are contained in the regulatory text section at the end of this document.

Requirements for Certification and Designation

[If you choose to comment on this section, please include the caption “Certification and Designation Requirements” at the beginning of your comments.]

Requirements for Certification (Proposed § 486.303)

The current regulations do not make a clear distinction between the requirements necessary for certification and the requirements necessary for designation, nor do they specify that an OPO must be certified before it is designated for a service area. Therefore, we propose adding a new section to

specify the requirements an OPO must meet to be certified.

Following are the proposed requirements. After each proposed requirement, we have listed the location of the requirement in the statute or in current regulations. To be certified, an OPO must:

(1) Have received a grant under 42 U.S.C. 273(a).

(2) Be a non-profit entity that is exempt from Federal income taxation under § 501 of the Internal Revenue Code of 1986. (See § 486.306(a).)

(3) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals. (See § 486.306(b).)

(4) Have an agreement with the Secretary to be reimbursed under title XVIII for the procurement of kidneys. (See section 371(b)(1)(C) of the PHS Act.)

(5) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005. (See § 486.301(b)(4).)

(6) Have procedures to obtain payment for non-renal organs provided to transplant centers. (See § 273(b)(1)(E).)

(7) Agree to enter into an agreement with any hospital in the OPO’s service area, including a transplant hospital, that requests an agreement. (See 486.304(b)(8).)

(8) Meet or have met the conditions for coverage, including the outcome measures and the process performance measures and other requirements. (See § 486.314. This section states that an OPO’s agreement with CMS may be terminated if the OPO does not meet the two conditions for coverage in the current regulations, as well as the requirements for qualifications for designation found in § 486.306.)

We propose that these threshold requirements for certification must be met before an OPO can be designated, pursuant to our proposed § 486.304.

Requirements for Designation (Proposed § 486.304)

Provisions regarding general requirements for designation as an OPO currently found in § 486.304 (“General requirements”) and requirements at § 486.306 (“Qualifications for designation as an OPO”) would be reorganized. Some requirements found in current § 486.304 have been moved to proposed § 486.303. Other requirements judged to be burdensome or unnecessary have been removed. For example, we would no longer require

OPOs to submit a written application for designation.

Most requirements in the current § 486.306 would be incorporated into other sections of the proposed rule. Specifically, requirements for OPO advisory boards and boards of directors have been moved to proposed § 486.324 (“Administration and governing body”). Requirements for agreements with hospitals, critical access hospitals, and tissue banks can be found in proposed § 486.322 (Relationships with hospitals, critical access hospitals, and tissue banks). Requirements for testing of donors and organs can be found in both proposed § 486.344 (Donor evaluation and management and organ placement and recovery) and proposed § 486.346 (Organ preparation and transport). Requirements for data reporting have been moved to proposed § 486.328 (Reporting of data), and requirements for protecting privacy of data can be found in proposed § 486.330 (Information management). Finally, requirements for professional education can be found in § 486.326 (Human resources). Our rationale for these proposed changes is addressed later in this preamble in our discussion of the individual sections.

In addition, we propose requiring OPOs to file a cost report within 5 months following the end of the fiscal year, rather than the current 3 months. This would conform the OPO regulations to § 413.24(f).

OPO Service Area Size Designation and Documentation Requirements (Proposed § 486.306)

The requirements contained in this section would be re-designated from the current § 486.307, and many requirements would remain unchanged. We would no longer require OPOs to provide population data to us since population would no longer be used as a basis for OPO certification.

We propose retaining the requirement that an OPO must procure organs from an average of at least 24 donors per calendar year. We believe it is important to retain this requirement to assure that each OPO has “a defined service area of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs* * *” as Congress intended. (See section 371(b)(1)(F) of the PHS Act.) In addition, we would change the current requirement for an average of 24 donors per calendar year in the 2 years before the year of re-designation to a requirement for an average of 24 donors per calendar year in the 4 years before the year of re-designation because the

re-certification cycle has been increased from 2 years to 4 years.

However, we would no longer permit exceptions to the 24-donor per year rule, including the exception for an OPO that serves an entire state. (See § 486.307(d)(2)(ii).) When the current regulations were published in 1996, the average OPO recovered 77 donors per year. Because of a decrease in the number of OPOs and an increase in the number of donors recovered nationwide, the average OPO procured approximately 100 donors in 2002. Therefore, we believe that an OPO procuring fewer than 96 donors in a 4-year period is too small to operate efficiently and effectively.

We propose removing language from the current regulations that refers to new entities or organizations becoming OPOs. Section 371(a) of the PHS Act provides authority for the Secretary to make grants to qualified OPOs that are described in subsection (b). However, given the provision in (b)(1)(D) added by the OPO Certification Act of 2000 (“notwithstanding any other provision of law, has met the requirements of this section and has been certified or re-certified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization* * *”), it appears impossible for the Secretary to give a grant to an organization that was not one of the 59 OPOs that was certified by the Secretary as meeting the performance standards in the 4-year period before January 1, 2000.

Therefore, we propose removing the language at § 486.307(d)(2)(iv) that requires an entity to show that it can procure organs from at least 50 potential donors per year if it was not previously designated as an OPO. We also propose removing references related to designation of or requirements for entities or organizations that are not currently OPOs

Additionally, we would remove obsolete service area size standards for periods during 1996 and before. We would change the current requirement for submission of information about acute care hospitals that have an operating room and the equipment and personnel to retrieve organs to submission of information about hospitals that have both a ventilator and an operating room, since we propose requiring OPOs to have agreements with 95 percent of those hospitals. (See discussion in this preamble of § 486.322, Relationships with hospitals, critical access hospitals, and tissue banks). Finally, we would increase the designation period from 2 years to 4

years to conform the designation period to the re-certification cycle.

Designation of One OPO for Each Service Area (Proposed § 486.308)

Requirements for the designation of one OPO for each service area would be moved from § 486.316 to proposed § 486.308. Many requirements would remain unchanged. However, we propose replacing the “tie-breaker criteria” used to designate an OPO when two or more OPOs apply for the same area with new criteria found in proposed § 486.316 (“Re-certification and competition processes”). (See discussion of proposed § 486.316 in this preamble for a discussion of the proposed criteria.)

Changes in Ownership or Service Area (Proposed § 486.310)

The requirements for an OPO changing ownership or changing its service area found in § 486.318 would be moved to proposed § 486.310. Many requirements would remain unchanged. However, we propose requiring certain additional information if there is a change in ownership of an OPO. The OPO would be required to provide information specific to the board structure of the new organization to ensure that all required representatives are included. In addition, the OPO would be required to submit operating budgets, financial information, and other written documentation we determine to be necessary for designation to ensure that the OPO continues to meet the requirements for designation.

De-Certification (Proposed § 486.312)

[If you choose to comment on this section, please include the caption “De-certification” at the beginning of your comments.]

Many of the requirements contained in § 486.325 (“Termination of agreement with CMS”) would be moved to proposed § 486.312, but the title of the section would be changed to “De-certification,” to reflect the fact that if an OPO’s agreement with us ends (whether through voluntary or involuntary termination or non-renewal of the OPO’s agreement), we would de-certify the OPO.

The paragraph titled “Voluntary termination” would remain substantially unchanged, but the paragraph would be renamed “De-certification due to voluntary termination of agreement.” Additionally, we would add language to indicate that we would de-certify the OPO as of the effective date of the voluntary termination. The paragraph

titled "Involuntary termination" also would remain substantially unchanged, but the paragraph would be renamed "De-certification due to involuntary termination of agreement."

Additionally, we propose adding language to indicate that we would de-certify the OPO as of the effective date of the involuntary termination.

We propose adding a paragraph titled, "De-certification due to non-renewal of agreement," which states that we will not renew an OPO's agreement if the OPO fails to meet the outcome measures at § 486.318 based on data from the most recent re-certification cycle or if the OPO is no longer designated for the service area. In that case, we would de-certify the OPO as of the ending date of the agreement. We propose removing the paragraph titled, "Appeal right," because we propose a new appeals process in § 486.314.

In proposed § 486.312(d), we have retained our general policy of providing an OPO with at least 90 days notice before a de-certification would be effective. However, we propose that in cases of urgent need, notice of de-certification would be given at least three days before de-certification. We expect that cases where an OPO would need to be replaced based on urgent need would be extremely rare. Nevertheless, in unusual circumstances, this expedited time frame may be necessary to protect the public health. The notice to the OPO would specifically state the reason for de-certification and the effective date. We propose changing the title of the paragraph, "Effects of termination" to "Effects of de-certification." We propose retaining the paragraph, "Public Notice," but we would add language that states we would give public notice of involuntary termination or non-renewal of agreement in local newspapers in the OPO's service area.

Finally, we propose eliminating the paragraph, "Reinstatement" because our proposed appeals process sets forth the process we would use for an OPO whose de-certification was reversed by a CMS hearing officer. If a hearing officer upheld a de-certification, we would not voluntarily reinstate the de-certified OPO. Thus the current language regarding reinstatement would no longer be needed.

Appeals (Proposed § 486.314)

[If you choose to comment on this section, please include the caption "Appeals" at the beginning of your comments.]

Under existing regulations, an agreement with an OPO could be involuntarily terminated for failure to

meet the conditions for coverage, and any resulting appeals were governed by regulations at 42 CFR part 498. If an OPO failed the outcome performance standards set forth in 486.310, we de-certified the OPO as of August 1 of the year following the end of the re-certification cycle. Although the OPO was given the right to appeal under part 498, it was not possible to complete the appeals process prior to expiration of our agreement with the OPO on August 1. Therefore, we opened the OPO's service area to competition from other OPOs as soon as the OPO was notified about the de-certification. The existing time frame generally did not permit a decision to be made on an appeal prior to a successor OPO taking over the service area when the de-certified OPO's agreement with us expired on August 1. In order to resolve this problem, we propose to make changes to the appeals process and alter the timing of the competition. Specifically, we would: (1) Delay competition until an appeal is completed; (2) expedite appeals by using a CMS hearing officer; and (3) extend an OPO's agreement beyond August 1 if necessary.

In the OPO Certification Act of 2000, Congress specified that we must propose a process whereby an OPO could appeal a de-certification on substantive or procedural grounds. (See section 273(b)(D)(ii)(IV).) Therefore, we are proposing a process whereby an OPO facing de-certification due to involuntary termination or non-renewal of its agreement with us would be able to appeal the de-certification on substantive or procedural grounds and receive a decision on its appeal before its service area was opened for competition from other OPOs. We believe the proposed appeals process would be both fair and expeditious.

An OPO would have 30 calendar days from the date on the notice of de-certification to submit an appeal to a CMS hearing officer. In the appeal, the OPO would be given the opportunity to submit evidence to show why it should not be de-certified. Appeals could be based on substantive and/or procedural grounds. Within 2 weeks of receipt of the OPO's appeal, the CMS hearing officer would schedule a hearing. The hearing officer would issue notice of his or her decision to the OPO by certified mail within 2 weeks following the date of the hearing.

In making an appeal on substantive grounds, an OPO could submit evidence of factors that negatively impacted organ donation in its service area and prevented it from meeting the outcome or process performance measures or other requirements. For example, an

OPO might have evidence that its ability to obtain consent from families of potential donors was adversely affected by certain demographic factors in its service area, such as the presence of a significant number of citizens whose race, ethnicity, religion, or educational level may be associated with lower rates of consent to organ donation. As another example, an OPO might have evidence that its ability to recover and transport organs to transplant centers while they are still viable for transplantation was hampered by the remote location of many of its donor hospitals.

Since most OPOs have some factors in their service areas that work against organ donation, the failing OPO would need to demonstrate not only the specific factors that affected its ability to meet the outcome measures but also what it did to attempt to ameliorate the factors. For example, if an OPO provided data to show that it has a high minority population that historically has had a lower rate of consent to donation, the OPO would have to demonstrate what it did to address the situation (such as conducting targeted public education) and whether these efforts were successful.

Evidence submitted by an OPO about substantive factors could include, but would not be limited to, research studies, demographic studies, data from the OPO's QAPI program, and information on the OPO's public and professional education and hospital development activities.

In making an appeal on procedural grounds, an OPO could, for example, provide evidence that incorrect data were used by us to determine whether the OPO met the outcome measures.

We propose that if the hearing officer reversed our determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, we would not de-certify the OPO. An OPO that was successful in its appeal would have a right to compete for this service area for the next cycle.

If the de-certification determination was upheld by the hearing officer, Medicare and Medicaid payment would not be made for organ procurement services the OPO furnished on or after the effective date of de-certification. The unsuccessful OPO would not be permitted to compete for the service area, or any other service area.

As stated earlier, OPOs currently have the right to appeal a de-certification under part 498, which sets forth procedures for providers and suppliers to appeal decisions that affect participation in the Medicare program. Since this proposed rule includes an appeals process for OPOs that is

separate from the part 498 process, we propose that if a hearing officer denied an OPO's appeal, the OPO would have no further administrative appeal rights. Thus, we propose removing OPOs from the definition of suppliers found at § 498.2.

However, we note that section 901 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) defines the term "supplier" to mean "unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title [title XVIII]." Nevertheless, the unique nature of OPOs and their special role in the Medicare program distinguishes them from other suppliers. Typically, suppliers furnish medical items and services directly to Medicare beneficiaries and obtain direct payment for Medicare-covered items and services from a Medicare carrier. A supplier may furnish one or more of the health care items included within the definition of "medical and other health services" that are defined in section 1861(s) of the Act and are included in the scope of the part B program. (See section 1832 of the Act.) Many suppliers do not have a formal participation agreement with the Secretary. (See section 1842(h) of the Act.) In contrast, an OPO is required to have an agreement with the Secretary. (See 42 U.S.C 273(b)(1)(C).) Moreover, many, if not most, organ donors are not Medicare beneficiaries, and many organs recovered by OPOs are not transplanted into Medicare beneficiaries.

Given this framework, and to ensure that Medicare pays appropriately for its share of organ acquisition costs, OPOs have payment rules and methodologies that differ from the payment rules and methodologies used for other suppliers. (See, for example, 42 CFR § 413.200.) Among other differences, organ acquisition costs are not paid directly by a carrier to an OPO. Instead, the OPO is paid by the transplant hospital, subject to later adjustment (see 42 CFR 413.200(c)(iv)), and Medicare pays the transplant hospital for the organ acquisition costs. If necessary, Medicare payment to the OPO is adjusted after it files its yearly cost report; for example, if the OPO's costs to recover organs exceeded the payments it received for the organs, Medicare covers the additional costs, based on the percentage of organs that were recovered and transplanted into Medicare beneficiaries. However, for purposes of the adjustment, all organs provided by the OPO to Medicare-approved transplant centers are

considered to be organs that were transplanted into Medicare beneficiaries. Since approximately 64 percent to 74 percent of extra-renal organ transplant centers and approximately 100 percent of kidney transplant centers are Medicare approved, the Medicare program reimburses OPOs for their excess costs for most of the organs they recover. Thus, the legal relationship between an OPO and the Medicare program is different from other "suppliers" and reflects important statutory differences.

The MMA also requires the Secretary to establish in regulations a provider and supplier enrollment process that includes an appeals process. Section 936 of MMA states that suppliers "whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection [1866](h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary. Although the appeals process we propose for OPOs differs from the MMA appeals process, it specifically addresses the congressional findings associated with the OPO Certification Act of 2000 that the uncertainty of the current re-certification interferes with the effectiveness of OPOs in raising the level of donation. This alternative appeals process is necessary because there is a limited time period from the date that the outcome performance measure data are available to the date when the OPO contract cycle ends. Therefore, to achieve the goals of the 2000 legislation, including providing an equitable process for appeals, OPO appeals must be expedited and completed before a replacement OPO is named in order to avoid disruption in organ procurement.

Under our proposed rule, if the hearing officer upheld a de-certification determination, we would open the OPO's service area for competition from other OPOs. The de-certified OPO would not be permitted to compete for the open area, and in most cases, the de-certification would be effective as of the ending date of the OPO's agreement with us.

However, if the appeals process did not leave sufficient time for us to conduct a competition process for the open area and provide for a smooth transition of the service area to the successor OPO, we could, at our discretion, extend the OPO's agreement with us for a period of time not to exceed an additional 60 days.

We believe the appeals process we propose fully satisfies the statutory

requirement to provide a process for an OPO to appeal a de-certification on substantive and procedural grounds. Although the process is streamlined to allow an OPO to receive a decision on its appeal before the effective date of the de-certification and before its service area being opened for competition, it allows ample time for the OPO to prepare and present evidence of the substantive or procedural basis for its appeal. Furthermore, the process allows sufficient time for a hearing officer to consider the evidence and make a fair decision that affords all of the process that is due to the OPO, while safeguarding our ability to remove and replace an OPO that has not performed well.

Re-Certification and Competition Processes (Proposed § 486.316)

[If you choose to comment on this section, please include the caption "Re-certification and competition" at the beginning of your comments.]

Congress stated in the congressional findings associated with section 219 of the Consolidated Appropriations Act, 2001 that the OPO re-certification process "created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of donation." Under existing regulations at § 486.310 and § 486.316, the service area of every OPO was opened for competition at the conclusion of every re-certification cycle, regardless of whether the OPO met the outcome performance standards for the prior re-certification cycle. Any OPO that met the performance standards for the prior re-certification cycle was eligible to compete for an open service area or a portion of an open service area.

Under existing OPO regulations, an OPO that failed to meet the outcome measures would lose its service area and be de-certified. Its service area would be opened for competition from all OPOs that met the outcome performance standards. If no OPO that met the outcome performance standards was willing to accept responsibility for the service area, the OPO that failed the outcome performance measures would be re-designated for the service area if it submitted an acceptable corrective action plan to us.

Under existing regulations, if more than one OPO that met the performance standards wanted to take over the service area or part of the service area of another OPO, we used six "tiebreaker" criteria to determine which OPO should be awarded the service area. The tiebreakers were: (1) Prior performance, including the previous

year's experience in terms of the number of organs retrieved and wasted and the average cost per organ; (2) actual number of donors compared to the number of potential donors; (3) the nature of relationships and degree of involvement with hospitals in the organization's service area; (4) bed capacity associated with the hospitals with which the organizations have a working relationship; (5) willingness and ability to place organs within the service area; and (6) proximity of the organization to the donor hospitals.

As stated earlier in this preamble, we propose opening every OPO's service area for competition at the end of every re-certification cycle as we did under the existing regulations. However, we are proposing certain limitations that we believe would address the uncertainty

in the re-certification process that was noted by Congress. The limitations would ensure that: (1) The process can be completed expeditiously; (2) disruptions to service areas will be minimized; and (3) an OPO may compete for an open area only if it is likely to be able to improve organ donation in the service area.

The proposed competition process would differ somewhat, depending upon whether a service area was opened for competition because the incumbent OPO was de-certified or because of the wider competition process taking place at the end of a re-certification cycle.

First, we would permit OPOs to compete for open areas only if they met certain specific objective criteria. These criteria would vary, depending upon whether the incumbent OPO was or was

not de-certified. Second, we would allow competition only for entire service areas. A service area could be divided only if the incumbent OPO was de-certified and no OPO wanted to accept responsibility for the service area. In such case, we could, at our discretion, choose a single OPO to take over the service area or adjust the service area boundaries of two contiguous OPOs to incorporate the open area. Finally, we are proposing to use specific clear, objective criteria for determining which OPO would be selected for a service area.

The chart below shows how the process would differ. Following the chart is a more detailed explanation of our proposal.

Incumbent OPO decertified?	Incumbent OPO permitted to compete?	Can service area be divided?	Criteria OPOs must meet to compete for open area	Criteria CMS uses to choose OPO
Yes	No	Yes, at discretion of CMS.	4 out of 5 outcome performance measures at or above the mean.	Acceptable plan to increase organ donation in open area.
No	Yes	No	4 out of 5 outcome performance measures at or above the mean. Conversion rate (actual donors as a percentage of potential donors) at least 15 percentage points higher than incumbent's conversion rate.	Acceptable plan to increase organ donation in open area.

Competition When OPO Has Been De-Certified

We propose that if we notify an OPO that it will be de-certified because its agreement will be terminated or will not be renewed and the OPO does not appeal within the time frame specified in § 486.314(a) or the OPO appeals but the de-certification is upheld (see § 486.314(c)), we would open the OPO's service area for competition from other OPOs. An OPO's service area would not be opened for competition until the conclusion of the proposed appeals process.

Only OPOs that meet 4 out of 5 outcome performance measures at or above the mean for the preceding re-certification cycle would be eligible to compete for the open service area of a de-certified OPO. The de-certified OPO would not be permitted to compete for its service area, or any other service area. Competing OPOs would be permitted to compete only for the entire service area.

By requiring an OPO to have attained the mean or greater in 4 out of the 5 outcome performance measures in order to compete for the open area of a de-certified OPO, we would limit competition to OPOs that have performed significantly better than the

failing OPO. That is, the overall performance of an OPO that meets 4 out of 5 outcome performance measures at or above the mean would be, at the least, approximately 25 percentage points higher overall than the performance of an OPO that is de-certified because it did not meet 4 out of 5 outcome performance measures at 75 percent of the mean. We propose establishing the threshold at 100 percent of the mean for 4 out of 5 outcome performance measures because we believe that an OPO whose performance is at or above the mean would have the expertise needed to take over a failing OPO's service area and improve organ donation.

OPOs would be permitted to compete only for entire service areas. We have found that permitting competition for partial service areas provides an incentive for OPOs to attempt to "raid" portions of neighboring service areas for purely business reasons, with no regard to whether the OPO can increase organ donation in those areas. For example, an OPO may wish to take over counties in a neighboring service area where hospitals demonstrate high conversion rates, which would improve the competing OPO's overall outcome performance measures but lead to no

actual increase in organ donation. An OPO with a tissue bank may want a section of another OPO's service area that has particularly high tissue donation potential in hopes of expanding its tissue bank into the area. Because of the problems created by allowing competition for partial service areas, we believe it is critically important to require OPOs to compete for entire service areas.

If no OPO applied to compete for the service area of a de-certified OPO, we could select a single OPO to take over the entire open area or adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS would select an OPO based on the OPO's success in meeting the process performance standards during the preceding re-certification cycle

Competition When OPO Has Not Been De-Certified

We propose that all OPO service areas would be opened for competition at the end of every re-certification cycle. Once we determined that an OPO met the outcome measures at § 486.318 for the previous re-certification cycle and was found to be in compliance with the process performance measures and other requirements at §§ 486.320

through 486.348, CMS would open the OPO's service area for competition from other OPOs.

To compete for open areas, OPOs would be required to meet certain criteria based on data from the preceding re-certification cycle. An OPO would be required to meet the following: (1) 4 out of 5 outcome performance measures at or above the mean; and (2) a conversion rate of potential donors to actual donors at least 15 percentage points higher than the conversion rate of the OPO currently designated for the service area. (The conversion rate is the first of the five outcome performance measures.) OPOs would be required to compete for an entire service area. The incumbent OPO would be permitted to compete for its own service area.

To illustrate how this process would work, we provide the following example:

OPO A's service area is opened for competition. The OPO met 4 out of 5 outcome performance measures at or above the mean for the preceding re-certification cycle. Its conversion rate was 109 percent of the mean. A survey of the OPO determined that it met all process performance measures. Two OPOs would like to compete for OPO A's service area. Both OPOs met 4 out of 5 outcome performance measures at or above the mean and both met all process performance measures. OPO B's conversion rate was 117 percent of the mean, and OPO C's conversion rate was 125 percent of the mean. OPO C is permitted to compete for OPO A's open area because its conversion rate is 16 percentage points higher than OPO A's conversion rate. OPO B is not permitted to compete for the open service area because its conversion rate is only 8 percentage points higher than OPO A's conversion rate. In selecting an OPO for the service area, we would consider each OPO's success in meeting the process performance measures during the prior re-certification cycle, as well as submission of an acceptable plan to increase organ donation in the open service area.

We propose that an acceptable plan would, at a minimum: (1) Be based on the competing OPO's experience in its own service area; (2) include an analysis of existing barriers to increasing organ donation in the open area, both internal (for example, high staff turnover) and external (for example, language barriers due to a high number of recent immigrants in the OPO's service area); and (3) provide a detailed description of specific activities and interventions for increasing organ donation in the open area. An OPO's plan to increase organ

donation in the open service area would be used by us to assist in identifying the most effective organization to maximize organ donation in the open area.

Given the constraints imposed by geography, as well as the variation in OPO performance, resources, and ability, we believe the process we propose would result in the selection of the OPO or OPOs most likely to improve organ donation rates in an open area.

As stated earlier in this preamble, we expect that our proposal would permit the competition process to be completed expeditiously. Agreements expire on July 31 of the year following the end of the re-certification cycle (for example, the current re-certification cycle ends December 31, 2005, and our agreements with OPOs expire July 31, 2006), giving us only 7 months to complete the many steps necessary to re-certify OPOs and renew their agreements with CMS. To reduce the uncertainty in the re-certification process identified by Congress, it is important that the competition process be completed as quickly as possible so that OPOs know whether they will retain their service areas for an additional 4 years.

We expect that the OPTN and SRTR will need a minimum of 2 months to finalize the OPO outcome performance measure data after the close of a re-certification cycle on December 31. This would leave at most 5 months for us to analyze the data, determine whether each OPO met or did not meet the requirements for re-certification, notify OPOs of their status, open service areas for competition, provide sufficient opportunity for OPOs competing for a service area (including the incumbent OPO) to develop and submit a plan to increase organ donation, review plans, designate an OPO for each service area that is under competition, notify OPOs of their status, and conduct transitional activities, as needed.

We believe that our proposed process would facilitate the timely completion of the competition for three reasons: (1) The process we propose is simple and straightforward; (2) the requirements we propose for OPOs to compete for an open area are unambiguous and, therefore, unlikely to lead to misunderstandings that could impede the process; and (3) the requirements for competition, as well as the prohibition against dividing service areas, would act to limit the number of OPOs permitted to or interested in competing for open areas.

We propose opening all OPO service areas at the end of every re-certification cycle because we believe that healthy competition between OPOs can lead to improvements in quality and outcomes,

as long as there are strict criteria for selecting the OPOs that are permitted to compete for open areas.

We have found that completely unrestrained competition for OPO service areas can damage collaborative relationships, impede sharing of best practices across OPOs, and, as a result, degrade OPO quality. As a consequence of the Breakthrough Collaborative, OPOs have forged an impressive number of collaborative relationships. OPOs are eagerly sharing best practices and providing assistance to fellow OPOs in solving problems and reducing barriers to donation. For the first time, many OPOs are seeing themselves not just as individual businesses but as participants in a widespread campaign to save lives by increasing organ donation. We believe it is critical that the competition process we use to re-certify OPOs does not damage these collaborative relationships. Therefore, we are requesting comments on the following competition options.

One option would be a highly restricted competition process in which only service areas of OPOs that did not meet the conditions for coverage (that is, the outcome performance measures at § 486.318 or the process performance measures and other requirements at §§ 486.320 through 486.348) would be opened for competition. Any OPO that met the conditions for coverage would be re-certified, re-designated for its service area, and its agreement with CMS would be renewed for another 4 years. This competition process would considerably reduce the uncertainty in the re-certification process that was identified by Congress. However, this process would nearly eliminate desirable competition that we believe can create an incentive for OPOs to perform optimally.

We are soliciting comments on variations of the proposed limited competition process for OPOs whose service areas would be opened for competition at the end of a re-certification cycle (with the exception of OPOs whose service areas would be opened due to de-certification). Under these options, all service areas would be opened for competition, but the criteria OPOs would be required to meet to compete for open areas would differ. Under alternative one, an OPO would be permitted to compete for an open area if its conversion rate was a least 15 percentage points higher than the conversion rate of the OPO currently designated for the service area. This alternative would not require that an OPO meet a minimum outcome performance measure standard. It would allow more OPOs to compete for

open areas. However, this alternative would allow OPOs whose performance is below the mean to compete for open areas.

Alternative two is a limited competition process similar to the one we propose in this proposed rule, except that a competing OPO would be required to meet 120 percent of the mean, rather than 100 percent of the mean, for 4 out of 5 outcome performance measures. Under this alternative, an OPO still would be required to have a conversion rate at least 15 percentage points higher than the conversion rate of the OPO designated for the service area. It is likely that very few OPOs would be able to compete for open areas under this competition process, but the strict criteria would ensure that only the very best OPOs could compete for open areas.

We believe that the limited competition process we propose, if implemented, would encourage healthy competition that improves OPO quality and functioning and would lead to increased organ donation and transplantation. We are requesting comments on the proposed and alternative forms of competition in this proposed rule. Specifically, we are requesting comments regarding the effect of competition on increasing organ donation, especially in service areas of poorly-performing OPOs, and on the collaborative relationship among OPOs.

Proposed OPO Outcome Measures

[If you choose to comment on this section, please include the caption "Outcome Measures" at the beginning of your comments.]

Condition: Outcome Measures
(Proposed § 486.318)

A. Current Outcome Performance Standards

Currently, five quantitative performance standards are used in evaluating OPO performance: number of donors, kidneys procured, kidneys transplanted, extra-renal organs procured, and extra-renal organs transplanted. Each of these outcome performance standards is calculated per million population, and OPOs are ranked accordingly. An OPO must be at or above 75 percent of the national mean for at least 4 out of 5 performance standards in order to be re-certified.

Congress directed that our new regulations include multiple outcome measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and

other related factors in each OPO's service area. Many factors can affect the number of potential donors in a service area, such as a large elderly population, a low motor vehicle accident rate, or a high incidence of the Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS). These factors are likely to reduce the number of potential organ donors, whereas factors such as a high homicide rate or a high motor vehicle accident rate are likely to increase the number of potential donors.

B. Evaluation of Alternative Methods for Determining Organ Donor Potential

In a 1997 report, "Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance," the U.S. General Accounting Office (GAO) explored options for assessing OPO performance and recommended that CMS consider developing new outcome measures based on the number of potential donors in an OPO's service area. The report discusses the feasibility of replacing population with: (1) The number of deaths in an OPO's service area; (2) the number of deaths adjusted for age and cause of death; (3) an estimate of the number of potential donors in an OPO's service area determined by statistical modeling; or (4) the number of potential donors determined by death record reviews.

The GAO report noted that both the number of deaths and the number of deaths adjusted for age and cause of death are a better indicator of the number of potential donors than population because they eliminate a large portion of the population that an OPO cannot consider for organ donation. However, the GAO pointed out that there are significant drawbacks to using either deaths or deaths adjusted for age and cause of death, including lack of timely data and the inability to identify those deaths suitable for use in organ donation. For example, although the National Center for Health Statistics (NCHS) collects death data from States, Oklahoma, and Puerto Rico do not report their deaths, and there is an 18 to 24 month lag in the availability of death data from the NCHS.

The GAO recommended that CMS investigate the development of two different models for estimating the number of potential donors in an OPO service area. One of these models was developed by the Harvard School of Public Health and the Partnership for Organ Donation, and the other was developed under the auspices of the AOPO. Although death record reviews are acknowledged to be the "gold

standard" for estimating the number of potential organ donors (as long as they are conducted with a standardized protocol by uniformly trained reviewers), they are, as the GAO noted, relatively labor intensive, time consuming, and expensive. Therefore, CMS concurred with GAO's recommendation to investigate alternatives for determining donor potential.

1. Regression Models for Estimating Donor Potential

Harvard and the Partnership for Organ Donation developed their model based on their 1993 study of 89 hospitals in 3 OPO service areas, using regression analysis to test hospital characteristics as predictors of the number of potential organ donors. Their analysis demonstrated that four hospital characteristics used together could be used to predict organ donation potential: Number of staffed beds, trauma center certification, medical school affiliation, and Medicare case-mix index (a measure of the complexity of cases treated in the hospital). The model was validated using death record reviews, and a study was conducted to verify the accuracy of the death record reviews (an interrater reliability study). The results of the study were published in the "American Journal of Public Health" in November 1998. (C Christiansen, S Gortmaker, J William, *et al.*: A Method for Estimating Solid Organ Donor Potential by Organ Procurement Region, American Journal of Public Health, Vol. 88, No. 22, November, 1998.)

Like the Harvard/Partnership model, the AOPO model was developed using regression analysis to test the validity of various hospital characteristics as predictors of donor potential. The AOPO model estimates the number of potential donors based on three factors: Whether the hospital has neurosurgery services; whether it has an emergency room; and whether it is a non-profit or for-profit entity. AOPO developed its model based on death record reviews in hospitals in 16 OPO service areas. (The study began with 30 OPOs, but 14 furnished incomplete data and their data were not included in many of the analyses AOPO used to develop its model.) An interrater reliability study to determine the accuracy of the OPOs' death record reviews has not been conducted.

In 1999, we contracted with the Harvard School of Public Health to apply the Harvard/Partnership model in all OPOs nationwide. In 2000, after receiving Harvard's results, we compared the number of potential

donors estimated by the Harvard model with the number of potential donors estimated by the AOPO model. (Both Harvard and AOPO used 1998 data.) We also compared the number of potential donors estimated by the two models in the 16 OPOs included in the AOPO study with the results from reviews of 1998 death records in those 16 OPOs' service areas conducted as part of the AOPO study. (Although AOPO has not conducted an interrater reliability study to verify the accuracy of the death record reviews, for purposes of this analysis, we assumed AOPO's death record reviews accurately estimated the number of potential donors in each OPO's service area during 1998.)

When compared to the number of potential donors determined by AOPO through death record reviews, neither the Harvard model nor the AOPO model consistently predicted the number of potential donors in individual OPO service areas. In AOPO's study of 16 OPOs, estimates ranged from 18.6 percent lower than the number of potential donors determined by death record reviews to an estimate that was 47.7 percent higher than the number of potential donors determined by death record reviews. The Harvard model's estimates ranged from 14.3 percent lower to 184 percent higher.

The failure of the two models to accurately estimate the number of potential donors may be due to many factors, including the accuracy (or inaccuracy) of information about hospital characteristics obtained by the researchers from a variety of sources, such as interviews with hospital staffs and American Hospital Association (AHA) data. Additionally, there were differences in criteria for hospitals' inclusion in the study between the original Harvard study and the CMS-contracted study, as well as differences between those studies and the AOPO study.

However, the primary reason the models produced such imprecise estimates is that they are based on regression analysis. Regression analysis is a method for estimating the statistical association between a group of independent (or predictor) variables and a dependent (or outcome) variable. Regression analysis can be used to test a hypothesis by determining how a change in one or more of the independent variables affects the value of the dependent variable. Both the Harvard and AOPO researchers tested the effect of a variety of hospital characteristics, such as number of full time equivalent positions (an independent variable) on the number of

potential donors in a hospital (the dependent variable).

The development of a regression model involves: (1) Initial selection of variables that are believed to have predictive potential; (2) collecting and organizing the data on the chosen variables; (3) testing the correlation between the variables; (4) choosing independent variables with a low degree of correlation between themselves and a high degree of correlation with the dependent variable; and (5) validating the results against results obtained through a previously tested method (for example, through death record reviews). The objective is to develop a model that uses the least amount of independent variables necessary to have the greatest amount of predictive capability and which uses data that can be updated routinely from existing sources, such as AHA data. However, the model cannot be used indefinitely without revalidation to determine whether the independent variables remain predictive. Thus, in order to use the Harvard and AOPO regression models for certification purposes, they would have to be revalidated periodically using death record reviews.

Since they are based on regression analysis, both models produce an estimate of potential donors with a range (plus or minus) within which, statistically, there is a 95 percent probability that the true number of potential donors lies. This range is called the "confidence interval." The range of the confidence interval is determined as illustrated in the following example. If the number of potential donors based on regression analysis is determined to be 100 and the confidence interval is 46, the range of the confidence interval is calculated by subtracting one half of the confidence interval from the number of potential donors (that is, one half of 46 is subtracted from 100 ($100-23=77$)) and adding one half of the confidence interval to the number of potential donors (that is, one half of 46 is added to 100 ($100+23=123$)). Thus, the range of the confidence interval in this example would be between 77 and 123, and one could be 95 percent certain that the number of potential donors was between 77 and 123.

The wider the confidence interval, the less certainty there is that the model works well as an estimate of the number of potential donors in a particular OPO's service area. Large intervals generally occur in OPO service areas with a small number of estimated potential donors or a small number of hospitals. In fact, Harvard has stated it does not believe its model produced an accurate estimate of

the number of potential donors in eight OPO service areas that have only a small number of hospitals.

As an example, Harvard estimated that one small OPO had 96 potential donors in 1998, with a confidence interval width of 120; that is, one can be 95 percent confident that the actual number of potential donors was between 36 and 156. Similarly, AOPO estimated that a small OPO had 57 potential donors with a confidence interval width of 82; that is, one can be 95 percent confident that the actual number of potential donors was between 16 and 98. Obviously, it would be problematic to use estimates with such large confidence intervals for certifying OPOs.

However, even for large OPOs, the two models produce ranges that are unacceptably large for certification purposes. One of the largest of the 16 OPOs in the AOPO study was estimated to have 395 potential donors with an interval width of 93, that is, one can be 95 percent certain that the number of potential donors was between 349 and 442. Harvard estimated that the same OPO had 740 potential donors, with an interval width of 312, that is, one can be 95 percent certain that the number of potential donors was between 583 and 896.

Overall, the Harvard model estimates a much larger number of potential donors than the AOPO model for most individual OPO service areas. The Harvard model also estimates a much larger pool of donors nationwide than the AOPO model—11,700 to 21,800 potential organ donors annually to AOPO's 11,000 to 14,000 potential donors annually. It is certainly possible to debate the reasons for the disparities in estimates between the two models (both nationwide and in individual service areas). For example, the Harvard model was tested and validated in only 3 OPO service areas, whereas the AOPO model was tested and validated in 16 and, thus, may be more accurate. However, regardless of the reason for the difference in estimates of the number of potential donors between the two models, the central fact remains that they are unreliable estimates and, therefore, unacceptable for OPO certification purposes.

To demonstrate the effect of using those estimates to rate an OPO's performance, we can look at the large OPO that was estimated by the AOPO study to have 395 potential donors and use a hypothetical example to suppose that in 1998 the OPO had 180 donors, or a conversion rate (that is, the number of donors from whom organs are recovered for the purpose of

transplantation as a percentage of the number of potential donors) of approximately 46 percent. (The average conversion rate for the 16 OPOs in the AOPO study was 50 percent.) If, however, the OPO's actual number of potential donors was at the bottom of the confidence interval (349), its conversion rate was actually an above-average 52 percent, but if the actual number of potential donors was at the top of the confidence interval (442), its conversion rate was only 41 percent, which is well below average.

For smaller OPOs, the effect of the confidence interval is much greater, and could result in re-certification of a poor OPO or de-certification of a good OPO. For example, if we look at the small OPO estimated by AOPO to have 57 potential donors (with a confidence interval between 16 and 98 potential donors) and use a hypothetical example to suppose that it had 12 donors, its conversion rate based on its estimated potential of 57 donors is an abysmal 21 percent, and the OPO would very likely be de-certified. If the OPO's potential were at the top of the confidence interval (98 potential donors), the OPO looks even worse—with a conversion rate of only 12 percent. However, if the OPO's potential were at the bottom of the confidence interval (16 potential donors), its conversion rate would be an impressive 75 percent, and the OPO would be considered a top performer.

Our analysis of the Harvard and AOPO data showed that in some cases, as would be expected, the number of potential donors as determined by AOPO's 1998 death record reviews fell outside the confidence interval predicted by both models. Consider the example of one OPO estimated to have 192 potential donors using the AOPO model (confidence interval 152–232) and 197 potential donors using the Harvard model (confidence interval 135–259). According to AOPO's death record reviews, the OPO's actual number of potential donors was 130. Using a hypothetical example, we can suppose that the OPO had 65 donors in 1998. Thus, its conversion rate based on the AOPO death record reviews would have been 50 percent—average according to the AOPO study of 16 OPOs. However, according to the AOPO model, the OPO's conversion rate would have been only 34 percent; and according to the Harvard model, its conversion rate would have been 33 percent. With a threshold for re-certification established at 75 percent of the mean 50 percent conversion rate (37.5 percent), the OPO could have faced de-certification.

2. AOPO Recommendations

The AOPO has long been a champion of replacing population-based outcome performance standards with measures based on the number of potential donors. The goal of AOPO's death record review study was to find an alternative to population that would be a reasonably accurate measure of the number of potential donors. However, in a series of meetings with us to discuss the results of its death record review study, the AOPO did not recommend using either the AOPO or the Harvard methodologies to estimate donor potential in individual OPO service areas.

Instead, in written proposals to us dated February 28, 2001 and April 25, 2001, the AOPO recommended outcome measures based on both population and the number of potential donors as determined by death record reviews. AOPO's recommended outcome measures would consist of a two-tiered system for OPO certification that would rely on population in the first tier and, for OPOs that failed the first-tier measures, the number of potential donors determined by death record reviews in the second tier.

The AOPO recommended that we retain the 5 factors currently used to measure OPO performance, that is, donors, kidneys procured, kidneys transplanted, extra-renal organs procured, and extra-renal organs transplanted. They recommended that: (a) In the first tier, OPOs be screened using the current population-based performance standards, that is, OPOs would have to meet 4 out of the 5 current performance standards at 75 percent of the mean (2 performance standards at 50 percent of the mean for OPOs operating exclusively in non-contiguous States or territories) to pass the first tier; (b) an OPO not meeting the first-tier outcome measures be required by us to submit data for all deaths occurring in hospitals in its service area with 150 beds or more; (c) OPOs be re-certified if their death record review data indicated a conversion rate of at least 50 percent of the national mean conversion rate found in the AOPO study of 30 OPOs (including the 14 OPOs that furnished incomplete data); and (d) the national conversion rate be updated every 4 to 5 years.

C. Outcome Measures

1. Problems With Two-Tier Assessment

AOPO's recommended two-tier process relies primarily on population-based measures. In fact, the first tier is identical to the existing performance standards, and few, if any, OPOs would

be assessed using second-tier measures based on death record reviews.

AOPO has criticized the current population-based performance standards because they fail to take into account factors that negatively impact the number of potential donors in an individual OPO's service area, such as high rates of HIV/AIDS and low motor vehicle accident and homicide rates. They argue that population-based measures cause some good OPOs to look like poor performers. However, the reverse is also true—factors in some OPO service areas, such as low rates of HIV/AIDS and high motor vehicle accident and homicide rates, may create a relatively high donor potential, making OPOs whose actual performance is below average look like good performers.

The implications of this are clear. The two-tier method might prevent de-certification of good OPOs by giving OPOs that may be disadvantaged by population-based measures an opportunity to prove they are good performers by submitting results from death record reviews. However, the two-tier method would not prevent re-certification of poorly performing OPOs that may appear to be good performers using population-based measures.

In the congressional findings associated with section 219 of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554), Congress directed the Secretary to develop measures that “accurately measure performance differences among the organ procurement organizations.” We do not believe a two-tier method with the first tier based on population is a reliably accurate methodology for assessing OPO performance, and we do not believe re-certification of OPOs should be based on an inaccurate methodology. Furthermore, we believe it is incumbent upon the agency, as both a prudent purchaser of health care services and a guardian of the organ donation system in the United States, to propose an accurate measure of OPO performance “based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations,” as Congress clearly intended in 42 U.S.C. 273(b)(1)(D)(ii). Such a measure should enable the Secretary and the public to distinguish between good OPOs and poor OPOs.

In addition to its reliance on population-based measures in the first tier, another drawback of the two-tier process proposed by AOPO is that in order to use death record review results in the second tier, we initially would

need to calculate a national conversion rate to which OPOs could be compared and then recalculate the conversion rate periodically—probably every 4 to 5 years. AOPO has suggested that we determine the national conversion rate through a sample of death records from hospitals throughout the United States. We believe this process would go far beyond the “reasonable effort” Congress envisioned for determining donor potential.

Furthermore, in order to have the national conversion rate available to us shortly after the close of a re-certification cycle, a national sample would have to be calculated well in advance of the end of the re-certification cycle to allow us sufficient time to find a contractor and to allow the contractor sufficient time to design and conduct a study and analyze the results. However, if all OPOs passed the first tier at the conclusion of the re-certification cycle, CMS would have no need of the national conversion rate that it had obtained. We believe there is a simpler, more accurate, and more reliable method of measuring an OPO’s performance according to its donor potential.

2. OPTN Data as Alternative Data Source

We propose eliminating the use of population-based standards and, instead, basing outcome measures entirely on organ donor potential. Organ donor potential (that is, the number of potential organ donors) would be determined by data reported by OPOs to the OPTN, based primarily on referral calls the OPOs receive from hospitals. We believe this system would be simple, straightforward, and easy for OPOs and the public to understand. Furthermore, the OPOs already report data on organ donor potential to the OPTN.

OPOs report certain data elements to the OPTN whenever they query the OPTN’s system to find a match for a potential donor, and the OPTN has a sophisticated system in place to capture this information electronically. As part of its efforts to monitor the impact of the hospital CoP (condition of participation) for organ, tissue, and eye procurement), the Health Resources and Services Administration (HRSA) asked the OPTN in 2001 to begin collecting additional, hospital-specific data from OPOs, including the number of referral calls OPOs receive from hospitals reporting deaths and imminent deaths, the number of referrals meeting organ donor eligibility criteria (that is, the number of potential donors), and the number of consents obtained on referrals meeting

organ donor eligibility criteria. Data are reported monthly for deaths occurring during the previous month. The data are obtained by the OPOs from referral calls hospitals and critical access hospitals are required to make to OPOs by the hospital CoP (see §§ 482.45 and 485.643) and are supplemented by data gathered by OPOs onsite at their hospitals. OPOs began reporting the data to the OPTN in September 2001.

In the first few months of the data collection, HRSA and the OPTN found many instances of incomplete data reporting by the OPOs, particularly the number of deaths and imminent deaths. However, the completeness of these data is improving. OPOs reported approximately 900,000 deaths and imminent deaths in 2002 (a known undercount), which is not far from the 982,914 inpatient hospital deaths reported by the National Center for Health Statistics for 2000. The number of potential donors reported by OPOs (termed “eligible deaths” by the OPTN and SRTR) for 2002 is consistent with estimates of the annual number of potential donors made by the organ donation community. HRSA and the OPTN continue to work with OPOs to further improve the database. We expect that if these data are used for certification purposes, the completeness of the data will approach 100 percent.

To assess the accuracy of the data OPOs are reporting to the OPTN, the SRTR recently analyzed the ability of “eligible deaths” data to predict the actual number of donors. They compared “eligible deaths,” as well as the number of potential donors estimated by the Harvard model with the actual number of donors. The researchers found “eligible deaths” to be substantially more predictive of actual donors. The SRTR noted that more complete data reporting by OPOs to the OPTN will improve the reliability of the data. (“New Methods for Estimating Total Potential (Organ) Donors in the U.S.” J McGowan, M Guidinger, R Pietroski, D Gaylin, A Ojo, *et al.* Abstract presented at American Transplantation Congress meeting, Washington DC, May 30–June 4, 2003.)

3. Standardized Definition of Organ Donor Potential

Our proposed definition is based on patient age, cause of death, and co-morbid conditions that contraindicate donation. We would use the following definition of “organ donor potential”: the number of patients whose age is 70 or less meeting death by neurological criteria, based on generally accepted practice parameters for determining

brain death, who do not have any of the following clinical indications:

- Tuberculosis.
- Creutzfeldt-Jacob disease or any other prion-induced disease.
- Viral septicemia.
- Rabies.
- Reactive hepatitis B surface antigen.
- Any retro virus infection.
- Active malignant neoplasms, except primary central nervous system tumors and basal cell and squamous cell carcinomas.
- Aplastic anemia.
- Agranulocytosis.
- Active viral and systemic fungal infections.
- Gangrene of bowel.
- Extreme prematurity.
- Positive serological or viral culture findings for HIV.
- Chagas Disease.

Although the upper age limit for donation continues to rise as OPOs and transplant programs become increasingly willing to consider recovering and transplanting “expanded criteria” organs, almost all organs come from donors younger than 70. Therefore, we propose limiting the definition of “organ donor potential” to donors of age 70 and below. We propose limiting the definition to include only deaths from neurological causes (that is, brain death) rather than including non-heartbeating donation (also called donation after cardiac death (DCD)). Although DCD is becoming more common, it remains the exception; in 2000, there were only 119 non-heartbeating donors, and in 2001, there were only 167. We are proposing rule-out criteria that are generally accepted by the organ donation and transplantation community as precluding organ donation because these co-morbid conditions render an individual medically unsuitable for organ donation. However, we are specifically requesting public comments regarding our proposed definition.

We propose using a specific term, “potential donor denominator,” for the data on organ donor potential OPOs would report to the OPTN. The potential donor denominator would indicate the number of individuals in an OPO’s service area who meet the criteria for organ donor potential, as defined by regulations. The term “potential donor denominator” would differentiate the data OPOs would report to the OPTN from data based on other definitions of “potential donor” or “organ donor potential” used in the OPO community.

Because definitions vary among OPOs, the universe of potential donors we would use for OPO certification could be different from that used by some OPOs. For example, an OPO that

has liberal donor criteria (perhaps including recovery of non-heartbeating donors) would consider itself to have a larger number of potential donors than the number it reports to the OPTN for the "potential donor denominator." In these instances, OPOs would be able to exceed 100 percent of the standard. Conversely, an OPO with conservative donor criteria would consider itself to have a smaller number of potential donors than the number it reports to the OPTN.

Determining whether organs should be recovered and transplanted is a medical decision; therefore, our proposed definition is not intended to limit the donors or organs an OPO recovers for transplantation. We are aware that many OPOs are successfully recovering transplantable organs from donors that do not fall within our proposed definition.

4. OPTN Data

In outlining the limitations of the current re-certification process, Congress noted that outcome and process performance measures should be considered that would "more accurately reflect the relative capability and performance of each organ procurement organization." We believe that basing multiple outcome measures on potential donor denominator data reported to the OPTN, as we propose, would give us, each OPO, the organ donation and transplantation community, and the public a clear picture of OPO capability and performance and eliminate possible inaccuracies and inconsistencies associated with current population-based standards.

Using potential donor denominator data reported to the OPTN would have additional significant advantages. Congress required the Secretary to propose standards based on "empirical evidence, obtained through reasonable efforts" of organ donor potential. Thus, we believe that Congress expected that the outcome measures data would be verifiable and that the processes used to obtain and verify the data would be practical and sensible.

The SRTR has developed a methodology that is being used to validate the data OPOs report to the OPTN. The methodology is based on readily available data on hospital bed size and other factors, as well as hospital death data obtained from the National Center for Health Statistics. If data reported by an OPO appear to be incorrect, the SRTR performs further analysis, and the data is corrected if necessary. We are confident that the use of this methodology would ensure that

the data used for OPO certification are accurate.

OPTN data also would be verified by hospital surveyors when they review data on hospital deaths and hospital death records to verify hospital and critical access hospital compliance with the CoPs. In addition, since we propose requiring OPOs to publish hospital-specific organ donation data annually (see proposed § 486.328), hospitals could verify their own data to ensure OPOs are reporting data accurately to the OPTN. Certainly, using OPTN data would be both sensible and practical because the OPTN already has a system in place to collect and verify the data, and all 59 OPOs have the capability to report the data electronically.

5. Death Record Reviews as Alternative Data Source

Because death record reviews are considered by the OPO community to be the "gold standard" for estimating the number of potential donors in a hospital, we considered proposing outcome measures based entirely on data derived from OPOs' reviews of hospital death records. GAO gave serious consideration in its 1997 report to the use of death record reviews performed by OPOs to determine the number of potential donors for OPO certification. However, there are a number of disadvantages to basing certification on death record review data. In fact, the GAO report noted drawbacks to using OPO-conducted death record reviews, including the cost of the reviews and the challenge of maintaining consistency in the reviews.

Maintaining consistency in performing death record reviews for certification purposes would be difficult, because we would have to ensure that all 59 OPOs performed the reviews in the same manner. This would require development of a standardized protocol for the reviews, as well as ongoing, nationwide training for OPOs in hospital selection, sampling, record review, and reporting. Furthermore, it would be difficult for many OPOs to complete death record reviews for the final year of the re-certification cycle in time for us to use the data for re-certification. (Note that while we propose requiring all OPOs to perform death record reviews as part of their QAPI programs (see proposed § 486.348), death record reviews performed by OPOs for their own purposes would not require standardization across OPOs because the reviews would be performed solely to provide data for quality improvement for each individual OPO.)

Therefore, in weighing the two methods of determining the number of potential donors (data reported by hospitals to OPOs and by OPOs to the OPTN or death record reviews performed by OPOs), we believe that using OPTN data most clearly fulfills Congress's intention in requiring promulgation of measures based on "empirical evidence, obtained through reasonable efforts." OPTN data would provide an accurate measure of organ donor potential and OPO performance, and using OPTN data would be simple and straightforward because a system is already in place to report, capture, and disseminate the data.

We propose that potential donor denominator data reported to the OPTN to be used for OPO re-certification include data for all deaths that occur in Medicare and Medicaid participating hospitals in an OPO's service area, unless a hospital has received a waiver to work with a different OPO. At present, OPOs are reporting data to the OPTN within 30 days of the end of the month in which a death occurred, and we propose requiring that OPOs continue to report their data within this time frame. We believe this provides adequate time for OPOs to report data, while ensuring that data will be available to us when needed for certification purposes. (This proposal can be found in the proposed condition for reporting of data at § 486.328(b).)

To ensure accuracy, OPOs would need to report the potential donor denominator data consistently, adhering strictly to the criteria in the proposed definition for organ donor potential. Reporting the data "consistently" means that if the OPO determined at any time, from the referral of a patient by a hospital through recovery and testing of the patient's organs, that the patient met any of the rule-out criteria listed in the definition, the patient would be eliminated as a potential donor and would not be reported to the OPTN under this regulation. If an OPO determined through death record reviews or other means that the potential donor denominator data it reported to the OPTN was incorrect, the OPO would be required to report the corrected data to the OPTN within 30 days of the end of the month in which the mistake is identified. (This proposed requirement can be found in the proposed condition for information management at § 486.328(b).)

However, while we propose basing OPO outcome measures on the number of potential donors as evidenced by OPTN data, we are specifically requesting comments on the feasibility of basing OPO outcome measures on the

number of potential donors as determined by death record reviews.

6. Outcome Performance Standards and Thresholds

With the exception of OPOs operating exclusively in non-contiguous U.S. States, territories, possessions, or commonwealths, we propose an OPO certification threshold of 75 percent of the national mean for 4 out of 5 of the following outcome measures, averaged over the 4 calendar years before the year of re-certification: (1) Donors as a percentage of the potential donor denominator; (2) number of kidneys procured, as a percentage of the potential donor denominator; (3) number of kidneys transplanted, as a percentage of the potential donor denominator; (4) number of extra-renal organs procured, as a percentage of the potential donor denominator; and (5) number of extra-renal organs transplanted, as a percentage of the potential donor denominator.

These five OPO performance factors are the same as those used in the current outcome performance standards. However, the outcome performance measures we propose would be based on the organ donor potential in an OPO's service area, rather than the population in the service area. We are proposing the same performance factors because they represent the totality of what an OPO does—from identifying and managing potential donors through ensuring delivery of healthy organs to hospitals for transplantation.

An OPO operating exclusively in non-contiguous States, territories, possessions, or commonwealths would be required to meet the following outcome measures at 50 percent or more of the national mean, averaged over the 4 calendar years before the year of re-certification: (1) Number of kidneys procured, as a percentage of the potential donor denominator; and (2) number of kidneys transplanted, as a percentage of the potential donor denominator. As in the current regulations, OPOs operating in non-contiguous areas would be required to meet measures only for kidneys procured and kidneys transplanted because there are few extra-renal transplant programs located in non-contiguous areas and because the permissible cold ischemic time for extra-renal organs is shorter than that for kidneys, making shipment of extra-renal organs to the continental U.S. for transplantation problematic.

We believe all 5 proposed outcome measures are critical for assessing performance of OPOs located in the continental United States because, taken

together, they reflect the entire spectrum of the donation process for which those OPOs are responsible. Furthermore, although it is true that organs recovered by an OPO for transplantation sometimes are discarded (or used for research instead of transplantation) for reasons beyond the control of the OPO, OPOs are responsible for the majority of functions that determine whether an organ is transplanted (for example testing, recovery of the organ, packaging, and transport). Nevertheless, since there is some disagreement in the OPO community on this issue, we are specifically requesting public comments on the need for each of the five measures.

Under current regulations, OPOs report outcome performance data to us only for pancreata procured for whole organ transplantation. However, legislation enacted on October 25, 2004 (Pub. L. 108-362) which amends section 371 of the PHS Act, requires that pancreata recovered and used for islet cell transplantation or for research be counted for purposes of OPO certification and re-certification. Therefore, when compiling outcomes performance measures data and utilizing the data for re-certification of OPOs, we will include pancreata recovered and used for islet cell transplantation or for research under the category of extra-renal organs, along with pancreata recovered and used for whole organ transplantation. Also, because researchers and OPOs have suggested that we encourage OPOs to recover other organs for research purposes, we invite comment on whether all organs recovered for research should be included in the outcome measures.

When the current outcome performance standards were established, we deliberately set the threshold for re-certification at a point we thought would prevent de-certification of good OPOs based on what may have been imprecise population-based performance standards. It would seem logical that along with adopting more precise outcome measures, we would raise the threshold for re-certification. However, since measures based on a potential donor denominator have never been used for OPO certification, we are somewhat reluctant to propose a change in the threshold for re-certification that might result in the de-certification of many OPOs. Nevertheless, we are specifically requesting public comment on the following three issues: (1) Whether OPOs located in the continental U.S. should be required to meet more (or less) than 75 percent of

the national mean and, if so, the appropriate percentage threshold; (2) whether OPOs operating in non-contiguous states or territories should be required to meet more (or less) than 50 percent of the national mean; and (3) whether OPOs located in the continental U.S. should be required to meet all 5 (instead of just 4) measures.

OPO Process Performance Measures

Condition: Participation in Organ Procurement and Transplantation Network (Proposed § 486.320)

Current OPO regulations at § 486.308 require OPOs to be members of and abide by the rules of the OPTN, and we propose to retain this requirement. However, we propose eliminating the requirement for an OPO to become an OPTN member before becoming designated by us because the OPTN requires an OPO to furnish information demonstrating designation by us to become a member of the OPTN. (See 42 CFR 121.3(b)(2).) Therefore, we propose that only after being designated would an OPO be required to be a member of the OPTN. In addition, we propose to eliminate the requirement that OPOs have a written agreement with the OPTN because a written agreement is not part of the OPTN membership process.

Condition: Relationships With Hospitals, Critical Access Hospitals, and Tissue Banks (Proposed § 486.322)

[If you choose to comment on this section, please include the caption "Relationships with hospitals" or "Relationships with tissue banks" at the beginning of your comments as appropriate.]

Good relationships between OPOs and organizations involved in the donation process often result in more efficient operations, such as shared referral lines for hospitals to use when calling about deaths and collaboration between OPOs and tissue banks in training hospital designated requestors. Furthermore, collaboration and cooperation between donation organizations promotes a positive public opinion about donation.

All six OPOs whose practices were studied for the Organ Donation Breakthrough Collaborative have strong collaborative relationships with their hospitals. Donor Alliance in Colorado has 6 full-time "donation consultants," who are liaisons to the 100 hospitals in the OPO's service area and provide professional education and feedback. In-house coordinators from LifeGift Organ Donation Center in Houston meet regularly with hospital medical staff to

review organ donation cases. The University of Wisconsin OPO “views hospital staff as an extension of OPO staff, contributing to the achievement of OPO goals.” Their OPO staff encourage physicians, nurses, and pastoral care staff to participate in the donation process and provide support and guidance.

Collaboration between OPOs and hospitals is absolutely critical to the donation process. Good relationships encourage cooperation from hospital staffs in making referrals of potential donors timely, supporting OPOs in discussing donation with families (or acting as designated requestors), and providing support services for management of potential donors. We expect that the requirements we propose will increase communication and cooperation between OPOs and the hospitals in their service areas.

The current regulations at § 486.306(g) require OPOs to have a working relationship with at least 75 percent of the Medicare and Medicaid participating hospitals in their service areas that have an operating room and the equipment and personnel for retrieving organs. Regulations at § 486.304(b)(8) require OPOs to have a working relationship with any hospital in the service area, including a transplant hospital that requests a working relationship. Furthermore, the hospital and critical access hospital CoPs for organ, tissue, and eye procurement require all Medicare and Medicaid participating hospitals and critical access hospitals to have and implement an agreement with an OPO designated under part 486 that includes a protocol for referral of all deaths and imminent deaths. (See §§ 482.45 and 485.643.)

We considered proposing a rule that would require an OPO to have an agreement with every hospital and critical access hospital in its service area (unless a hospital had a waiver to work with a different OPO) to ensure that OPOs do not overlook a single potential donor. However, the PHS Act requires only that an OPO have agreements with a “substantial majority” of hospitals in its service area that have facilities for organ donation.

Therefore, we propose maximizing the number of hospitals with which OPOs have agreements (consistent with the PHS Act) by requiring OPOs to have agreements with 95 percent of the hospitals and critical access hospitals in their service areas that have both a ventilator and an operating room. (Note: If a hospital received a waiver from us to work with another OPO, the hospital would not be counted as part of the

OPO’s service area.) Since it is necessary for a hospital to have a ventilator to maintain a potential donor and an operating room for recovery of organs, we believe a requirement for OPOs to have agreements with 95 percent of hospitals and critical access hospitals with a ventilator and an operating room would capture a “substantial majority” of hospitals with facilities for organ donation.

Our OPO Coordinators have found that most OPOs ask their hospitals to sign a “generic” agreement that does not address each entity’s role in the donation process and does not define key terms, such as “imminent death” and “timely referral.” This lack of specificity can lead to problems; for example, disagreement between an OPO and hospital about their respective roles in discussing donation with families, differing viewpoints of OPO staff and hospital physicians regarding what constitutes “imminent death,” or disagreements between an OPO and hospital about the appropriate timing of referrals to the OPO. However, the Coordinators have observed that where OPOs network with their hospitals to clearly define roles and responsibilities for the donation process, referral rates are higher.

Therefore, to avoid problems, promote collaboration, and assure that OPOs’ agreements with their hospitals support the overall goal of maximizing organ donation and transplantation, we propose requiring that OPOs’ agreements with hospitals and critical access hospitals must describe the responsibilities of both the OPO and the hospital in regard to the hospital requirements at §§ 482.45 or 485.643, as appropriate, (for example, how referrals will be made and how collaboration in reviewing death records will occur) and specify the meaning of the terms, “timely referral” and “imminent death.”

One of our proposals for OPOs’ relationships with their hospitals is based on observations made by the Office of the Inspector General (OIG) in its August 2000 report on the hospital CoP. The OIG noted that although research shows that collaboration between OPOs and hospitals in approaching families about organ donation yields the highest consent rates, the OIG found that 23 out of 61 OPOs had not provided any training to hospital staffs. Only 22 OPOs had trained designated requestors in more than 10 percent of the hospitals in their service areas. (A “designated requestor” under the hospital CoP is an individual who has been trained in a course offered or approved by the OPO to discuss

donation with families of potential donors. See § 482.45(a)(3).)

The OIG estimated that 70 percent of hospitals had been offered designated requestor training by their OPOs; however, staff in only 44 percent of hospitals had been trained. The OIG suggested this could be due to “a number of practices that indicate OPO resistance to training and using hospital staff as designated requestors.” They noted that some OPOs make it difficult for hospital staffs to attend training (for example, holding training sessions several hundred miles away from hospitals), and other OPOs establish programs that lack the flexibility to respond to the needs of various types of hospitals and individuals.

Although CMS intended the designated requestor requirement in the hospital CoP to lead to more collaboration between OPOs and hospitals and increased hospital involvement in the donation process, the OIG commented that the requirement may have had the opposite effect. That is, since OPOs are reluctant to train hospital staffs and to involve them in the donation process, some hospitals are allowing OPOs to take over the entire donation process.

Nevertheless, in some OPO service areas, the OPO handles most or all requests for donation, and consent rates are good. In other areas, hospitals cannot spare staff to attend designated requestor training, and the hospital and critical access hospital CoPs makes it clear that the hospital, not the OPO, has the right to decide whether an OPO representative or a hospital designated requestor will offer the option of donation. Based on these facts, we do not believe it would be advisable to require every OPO to provide designated requestor training in every hospital and critical access hospital in its service area. Instead, we propose requiring OPOs to offer designated requestor training on at least an annual basis for hospital and critical access hospital staffs. We propose that training be offered at least annually because most hospital staff do not discuss donation with families frequently enough to maintain their proficiency unless they receive periodic training.

We urge OPOs to encourage designated requestor training so that hospital staff can support and collaborate with OPO staff in the donation process. We applaud the efforts of OPOs like LifeLine of Ohio that actively promote designated requestor training in hospitals. In its “Quest for Excellence” in educating hospitals, LifeLine made it possible for staff in those hospitals to earn free

continuing education credits by completing designated requestor training, either in the hospital or via the Internet. In the University of Wisconsin OPO service area, hospital staff are the primary requestors. OPO staff conducts a designated requestor training program and ongoing training and case reviews at hospitals to educate hospital staff about all aspects of organ donation, including case management.

Before the CoP, hospitals called tissue banks about potential tissue donors and called OPOs about potential organ donors. However, the hospital CoP at § 482.45 and critical access hospital CoP at § 485.643 require hospitals and critical access hospitals to refer all deaths and imminent deaths (rather than just potential organ donors) to an OPO. The hospital and critical access hospital CoPs state that in the absence of alternative arrangements between a hospital and a tissue bank, the OPO will determine suitability for tissue donation. However, after the hospital CoP went into effect in August 1998, very few hospitals were willing to have "alternative arrangements" that would have required them to call tissue banks about potential tissue donors in addition to calling an OPO about every death. Thus, in most areas of the country, OPOs became the "gatekeepers" for information about potential tissue donors. Since many OPOs are in the tissue banking business, the OPOs' gatekeeper position created some tension between a few OPOs and the independent tissue banks in their service areas.

We have received complaints both from tissue banks and OPOs. Tissue banks have charged that OPOs fail to notify them about potential tissue donors in a timely manner, charge unreasonable referral fees for notifying them of potential donors, refuse to allow tissue banks to participate in designated requestor training sessions OPOs provide to hospitals, or refuse to use the tissue banks' screening and notification protocols when referring donors.

For their part, OPOs have complained that some tissue banks have paid no referral fees since the hospital CoP went into effect in August 1998. (We require OPOs to charge tissue banks for their costs in making referrals so that the costs are not passed on to the Medicare program. (See Medicare Provider Reimbursement Manual, section 2773.1)) In addition, some OPOs have charged that tissue banks do not respond timely to the referrals they receive, resulting in the loss of viable tissue. Since donor families and the public often regard all donation as organ donation, that loss of donation potential

in a donor for whom consent has already been obtained may reflect badly on the OPO, rather than the tissue bank.

Clearly, difficult relationships between OPOs and the tissue banks in their service areas waste valuable time and energy and distract OPOs from their mission of maximizing organ donation. Therefore, based on the Secretary's authority under section 1102 of the Act to establish requirements necessary for the efficient administration of the Medicare program, as well as the PHS Act requirement at section 371(b)(3)(I) for OPOs to "cooperate" with tissue banks to ensure all usable tissues are obtained, we are proposing requirements to ensure that OPOs maintain collaborative relationships with the tissue banks in their service areas. We believe the requirements we propose would serve to promote cooperation on the part of OPOs.

We propose to strengthen the current requirement for OPOs to cooperate with tissue banks in the retrieval, processing, preservation, storage, and distribution of tissues, as may be appropriate, to ensure that all usable tissues are obtained from potential donors. We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors:

- (1) Screening and referral of potential tissue donors;
- (2) Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and
- (3) The retrieval, processing, preservation, storage, and distribution of tissues.

An OPO would not be required to have an arrangement with a tissue bank unwilling to have an arrangement with the OPO. In such a situation, we would not consider the OPO to be out of compliance with the requirement.

It should be noted here that the goal of the Secretary's Donation Initiative is to increase all types of donation, including tissue, marrow, and blood donation. Therefore, although the purpose of this proposed rule is to increase organ donation, the Secretary has an interest in ensuring that OPOs act responsibly and collaboratively to further tissue donation in the United States.

Condition: Administration and Governing Body (§ 486.324)

[If you choose to comment on this section, please include the caption

"Administration and governing body" at the beginning of your comments.]

In the current regulations, requirements for OPO boards are found at § 486.306, which lists qualifications to be designated by us as an OPO. We propose creating a separate section for administration and governing body, which would contain the proposed requirements for membership composition and bylaws of OPO boards, as well as requirements for the governing body that would have legal authority and responsibility for the management and provision of OPO services.

Section 371(b)(1)(G) of the PHS Act (42 U.S.C. 273(b)(1)(G)) stipulates that a qualified OPO must have a board of directors or an advisory board that is composed of:

- Members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area;
- Members who represent the public residing in such area,
 - A physician with knowledge, experience, or skill in the field of histocompatibility;
 - A physician with knowledge or skill in the field of neurology; and
 - A surgeon from each transplant center in the OPO's service area with which the OPO has arrangements to coordinate its activities. (The surgeon must have practicing privileges in the represented transplant center and perform organ transplant surgery).

In addition, the PHS Act states the board has the authority to recommend policies for the procurement of organs and other functions (which are described below) and has no authority over any other activity of the OPO.

The current regulations at § 486.306(f) require an OPO to have a board of directors or an advisory board. An OPO may have more than one board, but at least one board must be responsible for recommending policies relating to the donation, procurement, and distribution of organs and include the specific membership composition required by the PHS Act. (See section 371(b)(1)(H) (42 U.S.C. 273(b)(1)(H).)

We are proposing a similar requirement, in that an OPO may have as many individual boards as it chooses, but one of its boards must have the specific membership composition prescribed by the PHS Act and must operate under restraints similar to those prescribed by the PHS Act for that board. That is, the board would be limited to recommending policies relating to the donation, procurement, and distribution of organs, would serve

only in an advisory capacity, and could not also serve as the OPO's board of directors. For purposes of discussion in this preamble, we refer to this board as an advisory board. To ensure that the board's members remain in an advisory capacity as stipulated by the PHS Act, we propose that the board's members would be prohibited from serving on any other OPO board. We also would require OPOs to have bylaws for each of its boards to address potential conflicts of interest, length of terms, and criteria for selection and removal of members.

Note that there appears to be a cross-reference problem in the PHS Act related to the recommendations of the advisory board. The statute provides that the advisory board "has the authority to recommend policies for the procurement of organs and other functions described in (2). (See 42 U.S.C. 273(b)(1)(H)(ii).) Currently, section 371(b)(2) is directed to the Secretary and concerns rulemaking. It does not speak to policies where an advisory board's recommendations would be relevant for an OPO. We believe it is likely that Congress intended that the OPO obtain the recommendations of the advisory board on the functions that an OPO is required to perform and that are listed in section 273(b)(3). We are proposing that the advisory board make recommendations to the OPOs on the subjects discussed in section 273(b)(3) and that are specifically listed in proposed § 486.324(b) through (11). Even if there were not a cross-reference problem, we would propose that the advisory board make recommendations to the OPO on the topics identified in our proposed rules based on our authority at 42 U.S.C. 1102. The expertise of the board would provide a useful perspective on those issues, and the advisory board's recommendations would likely lead to more efficient and effective actions by the OPO in procuring organs, as well as better coordination with various business partners.

We propose including in the condition for administration and governing body, certain language from the PHS Act that specifies the types of policies this advisory board can recommend. We believe that it is worth restating these specific provisions, both because the philosophy behind them is important and because we do not believe all OPOs and OPO board members are aware of them.

The single OPO advisory board whose membership composition is mandated by the Act has the authority to recommend policies for the procurement of organs and other functions including: (1) Effective

agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation; (2) systematic efforts, including professional education, to acquire all usable organs from potential donors; (3) arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome; appropriate tissue typing of organs; a system for allocation of organs among transplant patients according to established medical criteria; transportation of organs to transplant hospitals; coordination of activities with transplant hospitals in the OPO's service area; participation in the OPTN; arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to ensure that all usable tissues are obtained from potential donors; annual evaluation of the effectiveness of the OPO in acquiring organs; and assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors. The PHS Act states that the OPO board "has no authority over any other activity of the organization." (See section 371(b)(1)(H)(iii) of the PHS Act (42 U.S.C. 273(b)(1)(H)(iii).)

It has come to our attention that some OPO boards with the membership composition stipulated by the PHS Act may do more than recommend policies. This is a matter of concern because some OPOs have told us that their boards prevent them from taking steps to adopt best practices because of the costs involved (for example, by refusing to approve the hiring of additional staff or implementation of protocols to provide better management of potential donors). Board members may be motivated by a desire to keep standard organ acquisition fees low for the transplant hospitals in their OPO's service area; however, the result may be that organ donation rates remain low as well. We would note that some OPOs have taken steps to address what they regard as the conflict of interest created by having a board heavily weighted with representatives of transplant centers. For example, New England Organ Bank (one of the high-performing OPOs studied in the Organ Donation

Breakthrough Collaborative) has balanced the representation on its board by adding members to its board who represent other hospitals and community interests. Donor alliance, another OPO studied by the Collaborative, has a 25-member community-based board that has "allowed considerable latitude for innovation and risk-taking."

By incorporating this language into our proposed regulations for OPOs, we are reminding OPOs and their boards that under the PHS Act, the OPO board whose membership composition is outlined in the PHS Act has specific limits placed on its authority.

Note that our proposed language differs from that of the PHS Act in some respects. Instead of "a system for allocating organs according to established medical criteria" we propose referencing "a system for allocating organs according to the rules and requirements of the OPTN," because the OPTN establishes the medical criteria used to allocate organs among transplant patients. (The term "rules and requirements of the OPTN" means those rules and requirements approved as enforceable by the Secretary.)

Both the PHS Act and the existing regulations require an OPO to have a tissue bank representative on its board. We propose requiring an OPO to have on its advisory board a tissue bank representative from a facility not affiliated with the OPO, unless the only tissue bank in the service area is affiliated with the OPO. (In other words, if the OPO operates a tissue bank, the OPO must include an independent tissue bank on the board that represents all independent tissue banks in the OPO's service area, unless there are no independent tissue banks in the OPO's service area.) These requirements presume that tissue bank representatives with these qualifications exist in an OPO's service area and would be willing to serve on the OPO's advisory board. If not, the OPO would not be considered out of compliance with this requirement.

Because of the "gatekeeper" role of OPOs in regard to potential tissue donors, we believe it is important for OPO boards to include representatives from tissue banks that are not affiliated with the OPO (unless, of course, the OPO has the only tissue bank in the service area) to ensure that tissue banks have some voice in the OPO policies that affect them and to encourage OPOs and tissue banks to work together on issues that affect both organizations.

Although the PHS Act specifies that hospital administrators must be

represented on an OPO's board of directors or advisory board, it does not specify whether donor or transplant hospital administrators should be represented. Since transplant hospitals are already well represented by the many transplant surgeons who serve on OPO boards, we strongly urge (but would not require) OPOs to include administrators from donor hospitals to provide input and foster collaboration between OPOs and their donor hospitals.

We have received suggestions that we require OPOs to include representatives from research facilities, donor family members, transplant recipients, coroners or medical examiners, social workers, and chaplains on their advisory boards. Although these are worthy suggestions, we are reluctant to require OPO advisory boards to accommodate all these interests, lest they become too large to operate effectively. Additionally, many OPOs already include some of these individuals on their boards to fulfill the requirement for members representing the public. Therefore, we are requesting comments on the advisability of requiring OPO boards to have those representatives.

Note that, for clarification purposes, we are proposing to change the current requirement for an OPO to have a transplant surgeon from each transplant center on its board to a requirement for an OPO to have a transplant surgeon from each transplant hospital on its advisory board. Although "transplant hospital" and "transplant center" are often used interchangeably, the term "transplant center" sometimes is used to refer to an individual transplant program (such as a heart transplant program or liver transplant program) within a hospital that performs transplants. Since some OPOs have more than a dozen transplant hospitals in their service areas, a requirement to have a transplant surgeon from each program within each hospital would lead to OPO advisory boards with an overwhelming number of members. Therefore, we believe it is advisable to change the language to clarify that even if a hospital has multiple transplant programs, the OPO need have only one transplant surgeon per transplant hospital or hospital system.

In addition, we propose requiring that the transplant surgeon who serves on the OPO board must have practicing privileges and perform transplants in the hospital he or she represents. This requirement would ensure the surgeon has a thorough knowledge of the needs of the transplant hospital and can

represent the hospital or hospital system adequately.

When selecting transplant surgeons for their advisory boards, OPOs should strive for representation of all organ types. That is, if an OPO's service area includes heart, liver, lung, pancreas, and kidney transplant programs, the OPO should include a surgeon who performs each type of transplant.

We are proposing to require that OPOs have a governing body (for example, a board of directors) that has full legal authority and responsibility for the management and provision of all services. We believe it is important for efficient operation of an OPO for authority to reside in a single body. The governing body would be responsible for developing and overseeing implementation of policies and procedures necessary for effective administration of the OPO, including fiscal operations, a QAPI program, and services furnished under contract or arrangement, including agreements for these services. We would require an OPO to have a procedure to address potential conflicts of interest for the governing body. In addition, we would require the governing body to appoint an individual to be responsible for day-to-day operation of the OPO. We are requesting public comment regarding the proposed requirement for a governing body, specifically, whether it would be appropriate for the legal authority and responsibility for the management and provision of all OPO services to lie with an individual, rather than a governing body.

We believe the requirements we propose would provide flexibility so that each OPO would be free to choose the most efficient and effective form of administration and governance to suit its own needs and to fulfill its mission of maximizing organ donation.

Condition: Human Resources (Proposed § 486.326)

[If you choose to comment on this section, please include the caption "Human resources" at the beginning of your comments.]

The current regulations at § 486.306(e) require an OPO to have "a director and such other staff, including an organ donation coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area." There are no additional human resources requirements in the current regulations.

We do not believe this single requirement is adequate to ensure that each OPO has a sufficient number of staff members with the proper skills to provide necessary services and to

maximize recovery of healthy organs for transplantation. Furthermore, both research studies (which are cited throughout our discussion of proposed § 486.326) and the experiences of our OPO Coordinators provide evidence that having a sufficient number of trained and qualified staff is positively associated with good outcomes, such as increases in organ donation. We also note that one of the best practices identified by the Organ Donation Breakthrough Collaborative is to "strive to recruit and retain highly motivated and skilled staff."

Thus, we are proposing human resources requirements that we believe are essential to the functioning of all OPOs. We propose that an OPO would be required to have a sufficient number of qualified staff to ensure that all usable organs are recovered and to provide all required services to the families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

OPOs would be required to ensure that all individuals who provide or supervise services, including services provided under contract or arrangement, are qualified to perform these duties.

In addition, we would require every OPO to develop and implement a written policy to address potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators. In 2002, we cited a Florida OPO whose procurement director owned a company that purchased organs from the OPO and sold them for research—a serious conflict of interest that led to the dismissal of OPO officials. We believe an OPO's conflict-of-interest policy should clearly delineate and prohibit those outside activities or affiliations that have the potential to impact an employee's ability to make impartial decisions that are in the best interests of both the OPO itself and the organ procurement and transplantation system in the United States.

Although the Medicare hospital regulations require hospitals to review credentials and grant clinical privileges to medical staff, it is difficult, if not impossible, for a donor hospital to credential and grant privileges to recovery surgeons and other members of recovery teams who are not members of the hospital's medical staff. Recovery surgeons and other recovery team members may recover organs in a particular donor hospital no more than once in a period of several years. Thus, their work is too limited to undergo effective review by the donor hospital for the granting of clinical privileges.

However, it is imperative that someone ensure recovery personnel are qualified to recover organs in a manner that preserves their viability for transplantation.

Therefore, we propose requiring OPOs to maintain credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO (for example, transplant surgeons from local transplant hospitals who frequently recover organs in the OPO's donor hospitals). In addition, we propose requiring OPOs to ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained. Note that we are not proposing a requirement for an OPO to maintain credentialing records for physicians and other practitioners if they do not routinely recover organs under contract or arrangement with the OPO (for example a transplant surgeon from a hospital outside the OPO's service area). In those circumstances, the OPO would be required only to verify that the transplant surgeon was qualified and trained. This could be accomplished by, for example, contacting the transplant hospital to confirm that the surgeon who will be recovering an organ at one of the OPO's hospitals is credentialed and has privileges at the transplant hospital.

Studies provide empirical evidence that sufficient staffing serves to maximize organ donation. For example, in a report on 12 years of experience at LifeGift Organ Donation Center in Texas, the report's authors commented that LifeGift's staff resources were "critical to its ability to sustain and increase donation." They noted that LifeGift in the 7-year period preceding publication of the report had an 80 percent growth in staff and a 61 percent increase in organ donors. (*T. Shafer, C Van Buren, C Andrews; Program Development and Routine Notification in a Large Independent OPO: A 12-year Review, Journal of Transplant Coordination, Vol. 9, No. 1, March, 1999.*)

A recent report on OPO best practices listed "timely, on-site response to potential donor referrals" as a key attribute of a successful OPO. (Preliminary results of a best practices study presented at tri-annual meeting of the South-Eastern Organ Procurement Foundation on September 14, 2000 by R. Randal Bollinger, MD, Ph.D. Chief of the Division of General Surgery, Duke University Medical Center. In addition to Dr. Bollinger, other study authors include Dennis Heinrichs, MBA, President, LifeLink Foundation; and

United Network for Organ Sharing (UNOS) staff members.) (Note that UNOS is the organization under contract with the Health Resources and Services Administration to operate the OPTN.)

The report on LifeGift's 12-year experience noted that "adequate, even 'deep' staffing levels allowed the OPO to respond in person within one hour of referral on every potential organ donor case." We do not propose mandating a 1-hour time frame because geographical and other differences in OPO service areas could make such a short time frame impossible to meet. Furthermore, some hospitals contact their OPOs very early in the donation process, which means it may not be necessary for OPO staff to arrive at the hospital within 1 hour. Clearly the ideal time frame is one in which the OPO arrives at the hospital early enough to ensure that all steps in the donation process can take place, and the desired outcome is the recovery of healthy organs.

Therefore, we propose requiring the OPO to provide sufficient coverage, either by its own staff or under contract or arrangement, to screen hospital referral calls for organ donor potential and evaluate potential donors for medical suitability for organ donation in a timely manner. This means that once an OPO receives timely notification from a hospital about a patient who appears likely to be medically suitable for organ donation, the OPO must perform an assessment of the patient's medical suitability for organ donation early enough in the donation process so that there is sufficient time to discuss donation with the family of the potential donor, implement management protocols for the potential donor, place the organs for transplantation, and arrange for recovery and transportation of the organs while they are still viable.

In addition, we propose requiring an OPO to have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of donors, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development. We are not proposing specific staffing levels because we believe each OPO must determine the amount of staff it needs to ensure that families of potential donors are treated with sensitivity and respect and that the maximum number of viable organs are procured and provided to hospitals for transplantation.

However, we can provide guidance to OPOs so that they can determine if the number of staff they have would be "sufficient" under the proposed regulation. The determination is based primarily on outcomes, not just the ultimate outcome—procuring a healthy organ for transplantation—but the intermediate steps that lead to the procurement (such as assessing the potential donor and obtaining consent), as well as those critical activities that support and surround the actual donation process (such as hospital development and death record reviews).

An OPO should analyze the flow of the donation process in each of its hospitals, and determine whether the flow is impeded at any point by a lack of staff. Does the OPO have enough staff available at all times to: Assess potential donors promptly; spend as much time as necessary with the family to answer questions and provide support and counseling; manage the potential donor optimally; maximize the number of organs placed for transplantation; and recover (or arrange for the recovery of) organs as quickly as possible?

An OPO should scrutinize its QAPI program and determine whether additional staff would enable the OPO to broaden the scope of its QAPI program and lead to improved performance. Does the OPO have sufficient staff to monitor and evaluate all donation services; recommend steps to improve performance; track performance over time; and perform death record reviews at Medicare and Medicaid hospitals that have a level I or level II trauma center or 150 or more beds (with the exception of psychiatric and rehabilitation hospitals)?

An OPO also should look closely at hospital development staffing because effective hospital development creates a culture that supports and promotes donation. Does the OPO have sufficient staff to make its presence felt in hospitals (particularly those hospitals with high donation potential) by: Developing a relationship with emergency department and intensive care unit staff; providing ongoing education for hospital staff; meeting with hospital leaders and key physicians to gain their support for organ donation; providing donation data and encouraging hospitals to use the data in quality improvement activities?

As stated earlier, we do not propose to establish specific staffing levels because OPOs must have the flexibility to determine their own staffing needs. However, OPOs rightfully will be concerned about how such an imprecise requirement would be enforced. Certainly we understand that for reasons

beyond their control, OPOs (like all other businesses) sometimes will not have enough staff. We would not cite an OPO for having insufficient staff if the insufficiency is temporary or occasional or if the OPO clearly is doing its best to keep staffing at an optimal level. The requirement is intended to give surveyors the option of citing an OPO when there is a pattern of chronic understaffing in critical areas, and the OPO has not taken the appropriate steps to improve the situation (for example, if the board of directors consistently has refused to approve funds for additional staff needed to improve the OPO's performance).

The OPTN/UNOS Council for Organ Availability Requestor Project studied organ donation requestors who have the greatest success in getting families to consent to organ donation. Results of the study suggest that the experience of procurement coordinators is positively associated with increased consent rates; the average "expert requestor" has 4 years of experience. The LifeGift report notes that adequate staffing results in a staff that is not "spread too thin." The report also notes that adequate staffing allows, when appropriate, assigning two coordinators to one donor case, which may improve organ yield by allowing one coordinator to focus on donor management while another focuses on organ placement. We believe that adequate staffing by OPOs avoids staff burn out and frequent turnover of organ procurement coordinators, which is a significant problem for many OPOs.

A recent study published in the *Journal of the American Medical Association* on factors that influence family consent noted, "Our data strongly indicated that involvement of the family with a professional from the OPO is critical. The time spent with the OPO coordinator was a strong factor associated with the decision to donate." (Siminoff, L, Gordon, N, Hewlett, J, Arnold, R. *Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation*. *Journal of the American Medical Association*. 2001; 286:71-77.) It is clear that adequate staffing can ensure that procurement coordinators have ample time to spend with donor families. (Note that in citing this study, we are not suggesting that hospital designated requestors should not be involved in the donation process. Studies show that involvement of hospital staff with the OPO in requesting consent leads to the highest consent rates.)

Finally, we propose requiring an OPO to provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement,

to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation. This proposal is based on our OPO Coordinators' knowledge of situations in which organs were not recovered from medically suitable potential because local surgeons or other recovery personnel were not available. Some OPOs prevent these situations by hiring their own recovery personnel. For example, one of the high-performing OPOs studied in the Organ Donation Breakthrough Collaborative, Donor Alliance, has circumvented this problem by hiring "organ recovery specialists" with extensive training and experience in organ recovery.

The current OPO regulations have no requirements for an OPO's management of its human resources. We believe that prudent management of human resources, including provision of sufficient education, training, supervision and evaluation, is a fundamental necessity if OPOs are to have expert, highly qualified staff who can maximize organ donation. Ongoing staff training is a necessity at all OPOs in order to maintain staff skill sets and keep up with rapid advances in procurement and transplantation. However, we have found that a few OPOs do not provide these services for their staffs, which leads to confusion about roles and responsibilities, sub-optimal staff functioning, and resultant poor OPO performance. Conversely, our OPO Coordinators have noted lower staff turnover among OPOs that provide education and training and clearly define their staffs' roles and responsibilities.

Therefore, we propose requiring OPOs to provide their staffs with the education, training, and supervision necessary to furnish required services. Training must include, but is not limited to, performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. In addition, OPOs must evaluate the performance of their staff and provide training, as needed, to improve individual and overall staff performance and effectiveness. For example, staff who make donation requests can be evaluated by their consent rates; staff who clinically manage donors can be evaluated by how many organs are recovered and transplanted from donors and whether immediate organ function occurs in the recipient; and hospital development staff can be evaluated by the percentage of cases in which timely donation notifications are made and how often donation requests are conducted collaboratively between OPO and hospital. An OPO can utilize this

information to inform the development of training, tailor their training to the needs of their staffs, and identify individual staff who require additional training.

We believe in-depth training for procurement coordinators is particularly critical because procurement coordinators serve on the OPO front lines. They provide counseling to grieving families, explain donation options, make the request for donation, oversee recovery of organs, and package organs for transport to transplant hospitals. One of a procurement coordinator's most critical functions is management of potential donors to maintain the viability of their organs, which is a highly complex and demanding task. Nevertheless, some procurement coordinators have told us their OPOs do not provide sufficient training and supervision for new procurement coordinators, even though inexperienced coordinators run the risk of making errors that can lead to denial of consent or the loss of a donor.

Therefore, in an effort to decrease errors and provide support to the inexperienced coordinator, we are requesting comments on the advisability of including a requirement in the final rule for supervision of an inexperienced procurement coordinator by an experienced procurement coordinator, director of procurement, medical director, or other experienced individual during the consent process and during management of all donor cases. In addition, we are requesting comments on whether experience should be defined by length of service or number of donation cases, what experience thresholds would be appropriate, and how long an inexperienced procurement coordinator would need supervision.

We acknowledge that it can be difficult for OPOs to hire and retain staff with the necessary qualifications, experience, and dedication to fill critical staff positions, particularly procurement coordinator positions, and to provide their staffs with education and training. Many OPOs find high staff turnover to be a significant barrier to increasing organ donation in their service areas. Nevertheless, many OPOs are able to recruit and retain qualified staff by providing training, opportunities for growth, and a supportive atmosphere that encourages independence and innovation. It is clear that the six OPOs whose practices were studied as part of HRSA's Breakthrough Collaborative would all agree that professional, committed, and experienced staff have formed the basis for their success. One of the OPOs, New

England Organ Bank, emphasizes that its devoted staff and low staff turnover are contributing factors to its high performance.

The Collaborative's Best Practices Final Report identified five strategies OPOs can use to recruit and retain skilled and motivated staff.

The first strategy is to use various practices to identify and recruit staff. For example, according to the study report, LifeLink of Florida uses an extensive "reality" interview process in which candidates meet with staff and participate in actual organ referral and donation events. This process enables LifeLink to hire staff who are "aggressive, collaborative, assertive, and able to work under stressful conditions."

The second strategy is to offer adequate orientation and training. One of the six high-performing OPOs, New England Organ Bank, puts newly-hired staff through a formal training program "tailored to their specialized function."

The third strategy is to create a culture of collaboration and autonomy. Every high-performing OPO studied pointed to strong collaborative relationships as a factor that contributes to their success. These OPOs have forged successful relationships both within their own staffs and with outside organizations and other parties in the donation process, such as tissue banks, hospital administrators, physicians, and nurses.

Perhaps the best example of collaboration is the in-house coordinator (IHC) program developed by LifeGift Organ Donation Center in Houston, which places two full-time nurses in all Level I trauma centers. According to the study, the OPO staff are "fully integrated into hospital operations," which promotes "strong, transparent hospital partnerships."

The fourth strategy discussed in the study is to offer flexible work environments and other benefits. At Mid-America Transplant Services in St. Louis, OPO staff are given specialized roles in the donation process based on their professional experience. Staff have the flexibility to work from home and are given financial incentives when they meet performance targets.

The fifth strategy noted in the study is to provide opportunities for professional growth and development. The Report's authors provide many examples of the opportunities that the high-performing OPOs provide to their staffs. For example, since most "family support coordinators" at Donor alliance have non-clinical backgrounds, the OPO provides extensive training in the medical suitability of organ donors. In

another example, Mid-America's two operating rooms are used to give their clinical staff an opportunity to learn new skills and develop professionally.

We urge all OPOs to read the report of the Collaborative, titled, "The Organ Donation Breakthrough Collaborative: Best Practices Final Report," which is available on the Department's Web site at <http://www.organdonor.gov>.

Voluntary OPTN bylaws call for OPOs to have a medical director who is a licensed physician and is responsible for the medical and clinical activities of the OPO. Although current regulations do not require OPOs to have a medical director, most OPOs employ a medical director as part of their management staff and recognize the value and expertise this position brings to their OPO programs. Our OPO Coordinators have found that most high-performing OPOs have active, involved medical directors. Therefore, we propose requiring an OPO to have a medical director who would be responsible for implementation of protocols for donor evaluation and management and organ placement and recovery.

The medical director would be responsible for oversight of the clinical management of donation cases, including providing assistance in the medical management of a donor case when the surgeon on call is unavailable. We would expect that in meeting these requirements, OPOs would have medical directors who oversee clinical donation processes, facilitate best practices, and provide guidance for OPO staff, both clinical and non-clinical, about all clinical donation issues.

We believe the human resources requirements we propose would ensure efficient and effective operation of OPOs, which is in the best interests of the organ donation and transplantation system. In addition, the requirements would further the efficient administration of the Medicare program. As we stated earlier, section 1102 of the Act grants the Secretary the authority to establish requirements necessary for the efficient administration of the Medicare program.

Condition: Reporting of Data (Proposed § 486.328)

[If you choose to comment on this section, please include the caption "Reporting Data" at the beginning of your comments.]

The current regulations (§ 486.310) require an OPO to submit data to us annually showing the number of donors, the number of kidneys and extra-renal organs procured, and the number of kidneys and extra-renal organs transplanted so that we can determine

whether the OPO has met the performance requirements. We propose broadening this requirement to require OPOs to provide individually-identifiable, hospital-specific organ donation and transplantation data to the OPTN and the Scientific Registry of Transplant Recipients (SRTR), as directed by the Secretary. (Note that at present the SRTR does not collect data; its current mandate is to analyze data collected by the OPTN.) We also propose requiring OPOs to provide hospital-specific organ donation data to transplant hospitals, annually. Finally, we propose requiring OPOs to report individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Department, as requested by the Secretary.

Data could include, but would not be limited to, (1) The number of hospital deaths; (2) results of death record reviews; (3) number and timeliness of referral calls from hospitals; (4) potential donor denominator (as defined in § 486.302); (5) data related to non-recovery of organs, (6) data about consents for donation; (7) number of donors; (8) number of organs recovered (by type of organ); and (9) number of organs transplanted (by type of organ).

We would note that OPOs are specifically exempted from regulatory requirements for the privacy of individually identifiable health care information under the Health Insurance Portability and Accountability Act. Regulations at 45 CFR 164.512(h) state, "A covered entity may use or disclose protected health care information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye, or tissue donation and transplantation."

Our reasons for proposing this requirement are three-fold. First, it would bring data reporting requirements for OPOs into agreement with those for transplant hospitals. Hospital regulations at 42 CFR 482.45(b)(3) require transplant hospitals to provide organ-transplant-related data as requested by the OPTN, the SRTR, and the OPOs. Transplant hospitals must also provide those data directly to the Department when requested by the Secretary. Ensuring a flow of data between transplant hospitals and OPOs promotes collaboration and can enable transplant hospitals to improve their programs. For example, a transplant hospital can use data from OPOs in its QAPI program, such as data that allow it to compare its transplantation rates

with those of other transplant hospitals in the OPO's service area or data showing how many times and for what reasons the hospital's own transplant programs have turned down organ offers from the OPO.

Second, CMS Regional Office OPO Coordinators need data from OPOs to target areas for improvement both in OPOs and hospitals, and third, the OIG has recommended CMS use hospital-specific data provided by OPOs to monitor the impact of the hospital CoP and improve hospital compliance with the CoP. In short, we believe these data reporting requirements for OPOs are necessary for the efficient administration of the Medicare program and can be required based on the Secretary's authority under section 1102 of the Act.

We would note that most OPO data needed by us or other agencies within the Department can be obtained from the OPTN or the SRTR. In fact 42 CFR 121.11(b)(2) requires OPOs and transplant hospitals to submit information about transplant candidates, transplant recipients, organ donors, transplant program costs and performance, and "other information that the Secretary deems appropriate." We would not request data from OPOs if the data were readily available from other sources. We are including this provision only to give us and other entities the flexibility to request data from OPOs if data cannot be obtained expeditiously from other sources. The Secretary would use such data and other information for monitoring of hospital compliance with the CoP, monitoring of OPO compliance with the process performance measures and other requirements, and assisting OPOs with their QAPI programs.

We propose including language that defines how OPOs should report data for donors and organs procured and transplanted to ensure that all OPOs are following the same reporting protocol. A uniform process would ensure accurate reporting and will enable us to make a true comparison of the OPOs' performance. We propose including reporting protocols for the following: "kidneys procured," "kidneys transplanted," "extra-renal organs procured," and "extra-renal organs transplanted." For example, under "kidneys procured," en bloc kidneys are counted as two kidneys procured. Under "extra-renal organs procured," a heart and two lungs recovered from one donor would count as three organs procured.

In August 2000, the Office of the Inspector General (OIG) for the Department of Health and Human

Services released a report on the CoP titled, "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule." The OIG found that OPOs and hospitals had not yet taken full advantage of the CoP. The OIG noted, "Maximizing organ donation requires coordination and collaboration between hospitals and OPOs. The donation rule, however, is contained in the Medicare conditions of participation for hospitals. While it provides OPOs with significant leverage that they can use to work with hospitals on donation, the rule places the obligation for compliance solely on hospitals; it sets no requirements for OPOs. Effective implementation of the donation rule requires accountability on behalf of both OPOs and hospitals."

The OIG recommended that to increase OPO accountability, we require OPOs to provide hospital-specific data on referrals and organ recovery. The OIG stated that obtaining data from OPOs would be the most effective and efficient way to monitor the CoP and assess hospital compliance because OPOs already collect the necessary data and have them readily available. The report states, "We believe that OPOs could reasonably, inexpensively, and easily provide current data on a quarterly basis."

We agree with the OIG's conclusions. Although all OPOs collect hospital-specific data on referrals and organs recovered, current regulations do not require OPOs to share these data with us, and OPOs have been reluctant to share data with us voluntarily lest they affect their collegial relationships with their hospitals. Therefore, we must rely on surveys performed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and State survey agencies to monitor hospital compliance. However, JCAHO surveys usually are performed only once every 3 years and State Medicare surveys are performed even less frequently. Moreover, requirements for organ, tissue, and eye procurement are only a small part of hospital accreditation and certification surveys, and surveying for those requirements may have a lower priority than surveying for requirements affecting direct patient care. In fact, the OIG noted that some hospitals reported to them that surveyors asked only to see their policies and procedures for organ donation and did not probe further to determine whether the hospital was complying with all requirements in the regulation.

Based on the OIG's recommendations, HRSA, CMS, and the Association for Organ Procurement Organizations

(AOPO) determined what data should be reported to the OPTN (and, in turn, reported by the OPTN to HRSA and CMS). As stated earlier in this preamble, in September 2001, OPOs began reporting the following hospital-specific data electronically to the OPTN: (1) The number of referral calls received from hospitals; (2) the number of potential donors; and (3) the number of consents to donation. The OPTN calls for OPOs to report the number of donors and the number of organs recovered at each hospital. In the future, as data needs are identified (for example, the number of deaths in each hospital), the OPTN may begin collecting additional data. We can obtain data from the OPTN through HRSA at any time. OPOs currently report data to the OPTN within 30 days of the end of the month in which a death occurs, and we propose requiring that OPOs continue to report their data within this time frame. However, if an OPO determined through death record reviews or by other means that the data it reported to the OPTN was incorrect, we would require the OPO to report the corrected data to the OPTN within 30 days of the end of the month in which the error was identified.

The OIG report recommended that we require OPOs to make hospital-specific donation performance data publicly available in order to recognize hospitals that do a good job. They pointed out that one OPO in the nation already publishes organ donation data for every hospital in its service area. We agree that the efforts of hospitals that collaborate with their OPOs and support organ donation should be recognized. Publication of those data has the dual effect of recognizing the efforts of good-performing hospitals, while holding hospitals more accountable for organ donation. In addition, as we note elsewhere in this preamble, if OPOs report the same hospital-specific data publicly that they report to the OPTN, the published data would provide an additional opportunity to verify the completeness and accuracy of the OPTN data. Furthermore, publication of hospital-specific organ donation data would be an effective way to promote the exchange of information among OPOs, hospitals, and the public.

Therefore, we propose requiring OPOs to report hospital-specific organ donation data, including organ donor potential and the number of actual organ donors, at least annually to the public. We would suggest that OPOs include these data in their newsletters and their annual reports.

We are interested in other avenues to hold hospitals more accountable for organ donation and for implementing

the CoP. In fact, the AOPO has requested that we ask for public comment regarding specific actions we might consider to address problems some OPOs have encountered in regard to their hospitals. For example, OPOs have complained to us that hospitals sometimes refer a brain dead patient only after the patient has been removed from the ventilator (rendering the patient medically unsuitable for organ donation) and that hospital staff physicians sometimes are reluctant to declare brain death, provide assistance in evaluating potential donors, or provide services for intraoperative donor management.

We believe it is important to point out, however, that in these specific situations (and many others), there is regulatory relief available to OPOs under the hospital and critical access hospital CoPs, which requires hospitals to refer patients whose death is imminent and to cooperate with their OPOs in maintaining potential donors while necessary testing and placement of organs takes place. This means that a hospital could be in violation of the CoP if it did not refer a brain dead patient before removing the patient from the ventilator or if the hospital did not provide the support services necessary to maintain a potential donor.

We are aware that OPOs are reluctant to provide details about violations of the hospital CoP to us because they fear disturbing their relationships with hospitals. One OPO has stated, "it's not our intention to find fault with anybody. This is a relationship business." However, the CoP for organ, tissue, and eye procurement has been in effect since August 1998. We would suggest that if an OPO has not been able to urge a hospital into compliance with the CoP by now, it needs our assistance. We cannot aid hospitals and OPOs in improving their relationships and assure that all hospitals are complying with the CoP unless OPOs are willing to bring problems to our attention. Nevertheless, we are interested in receiving comments regarding other actions we might take to improve hospital compliance with the CoP and hold hospitals more accountable for organ donation.

[If you choose to comment on this issue, please include the caption "Hospital Accountability" at the beginning of your comments.]

Condition: Information Management
(Proposed § 486.330)

[If you choose to comment on this section, please include the caption "Information management" at the beginning of your comments.]

This section incorporates the data maintenance and record keeping requirements now found at § 486.304(c)(8). We believe these requirements should be retained to ensure that a smooth transition of records would occur if an OPO's service area were taken over by another OPO and so that OPOs maintain adequate information about each donor. We propose that, as in current regulations, an OPO would be required to establish and use an information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

OPOs have asked for guidance regarding how long records should be kept. We propose requiring OPOs to maintain donor and transplant recipient records for 7 years because the regulations that govern the OPTN at § 121.11(a)(2)(i) require OPOs to retain records for 7 years. We also propose requiring certain additional data that OPOs would be required to keep in their donor records.

Currently, OPOs are required to include the following in their donor records: information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, and all test results. We propose requiring the following additional data elements: donor management data, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information. We currently require OPOs to keep identifying information for each transplant recipient. We propose requiring OPOs to include a record of the disposition of organs recovered for transplantation.

In proposing these new data elements, we are expanding upon the data elements required for donor records under existing regulations at § 486.304(c)(8). There are three reasons why we propose requiring these additional data elements. First, such data is critically necessary to the investigation of the transmission of infectious disease from organ donors. Recently, CMS and the Centers for Disease Control and Prevention (CDC) needed donor records (including donor management data, hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information) to

investigate two separate cases of Hepatitis C transmission from organ donors and to determine whether the donors had been tested, why they had not tested positive for Hepatitis C, and whether the donors had exhibited signs of Hepatitis C that should have been apparent before donation taking place. In addition, CMS and the CDC needed to quickly establish the disposition of all organs recovered from the infected donors to establish whether other organ recipients were infected. Although some of the data we propose requiring would be available from the hospital where a donor died, some would be available from the OPTN, and some would be available from the OPO, it is important for all data to be available in one location to provide speedy access in cases of disease transmission.

In addition, CMS needs access to several of these additional data elements to determine whether an OPO has complied with the process performance measures. Donor management, hospital history, and past medical and social history would be used to assess compliance with § 486.344(a) and (b). Consent and next-of-kin information would be used to assess compliance with § 486.342.

Finally, we believe the additional data elements we propose for donor records would provide an invaluable source of information for OPOs to use in their QAPI programs. For example, an OPO may want to review donors' medical and social histories to assess and improve its protocol for obtaining medical and social histories from potential donor families.

Condition: Requesting Consent
(Proposed § 486.342)

[If you choose to comment on this section, please include the caption "Requesting consent" at the beginning of your comments.]

In addition to requesting consent for organ donation from families of potential donors, OPOs often request consent for tissue donation on behalf of their hospitals' designated tissue banks. In April 2000, the "Orange County (CA) Register" (*Register*) published a five-part series of articles based on its investigation of the tissue banking industry. One of the allegations made by the *Register* was that tissue donor families were not being fully informed before making the decision to donate. The *Register* articles noted that families of potential donors often are not informed about how donated tissues may be used (for example, skin may be used for cosmetic surgery, as well as grafts for burn patients) or that some

tissue banks make profits from donated tissues.

In January 2001, the OIG published a report entitled, "Informed Consent in Tissue Donation." The OIG noted that in recent years, tissue banking and processing practices have gradually diverged from tissue donor families' expectations. The expansion of the tissue banking industry, new technology, large profits, and tissue marketing practices have raised questions about the non-profit basis of tissue banking. Therefore, the OIG suggested that certain steps should be taken in regard to tissue donation to ensure that families and other decision-makers are fully informed before making a decision. One of the OIG's recommendations was that we add a provision to the OPO conditions for coverage to hold OPOs accountable for obtaining informed consent from tissue donor families when OPOs request consent on behalf of tissue banks. The OIG also recommended that we require OPOs to include tissue banks when developing and conducting training for hospital designated requestors for tissue.

We agree with the OIG's recommendations. Providing informed consent is an integral part of encouraging discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families, which is required for hospitals and critical access hospitals under section 1138(a)(1)(A)(ii) of the Social Security Act, in hospital regulations at § 482.45(a)(4), and in critical access hospital regulations at § 485.643, and which we propose as a requirement for OPOs in this proposed rule. Ensuring that all donor families and other individuals responsible for making donation decisions are fully informed before making a decision guards against negative publicity that may result if a donor family does not receive informed consent. As noted earlier in this preamble, negative perceptions of or publicity about tissue donation can affect the public's attitude about organ donation and individuals' willingness to donate. Therefore, we propose requiring that all requests made by OPOs for tissues, as well as organs, include a properly executed informed consent process.

An OPO would be required to have a written protocol to ensure that, in the absence of a donor document, the individual or individuals with responsibility to make the donation decision are informed of their option to donate organs or tissues or to decline to donate. We note that with respect to informed consent, a potential donor

may have executed a consent or indicated in an advance directive or power of attorney the individual who will make a decision about organ donation on his or her behalf. The OIG appended to its report a list of model elements of informed consent for organ and tissue donation developed by the American Association of Tissue Banks, AOPO, and the Eye Bank Association of America, as well as an informed consent policy for tissue donation developed by the National Donor Family Council. We have incorporated many of the recommendations made by these organizations into our proposal.

For example, the OIG noted that although tissue donor families assume the tissue they agree to donate will be used to meet important medical needs, tissue is sometimes processed into products used for elective cosmetic procedures. Tissues may also be used for research or education rather than transplantation. To address this issue, the National Donor Family Council recommends that tissue donor families be told they may restrict or limit use of the tissue they donate. We agree with this recommendation and propose requiring that individuals responsible for making the donation decision be informed that they may limit or restrict the use of donated organs or tissues.

In addition, we propose requiring OPOs to provide to the individual(s) responsible for making the donation decision, at a minimum, a list of the organs or tissues that may be recovered; a description of all possible uses for the donated organs or tissues; information (such as non-profit or for-profit status) about organizations that will recover, process, and distribute the tissues; a description of the screening and recovery processes; information regarding access to and release of the donor's medical records; an explanation of the impact the donation process may have on burial arrangements and the appearance of the donor's body; information about the procedure for filing a complaint; contact information in case the individual(s) making the decision have questions; and a copy of the signed consent form.

When developing protocols for informed consent for tissue donation, OPOs may wish to review the informed consent policies appended to the OIG report. The National Donor Family Council represents approximately 8,000 donor families, and the American Association of Tissue Banks accredits 58 tissue banks in the U.S. Their policies include specific descriptions of elements that address full disclosure for consent for tissue donation.

We would note that a recent survey of tissue donor families conducted by the National Donor Family Council and Case Western Reserve University found that a large majority of families said they would have preferred receiving more, rather than less, information to aid them in their decision making. For example, 79 percent of families surveyed said they would have wanted to know that some tissue banks are for-profit entities. To guarantee that all donor families and other individuals responsible for making donation decisions have the information they need to make an informed decision, as well as to avoid a negative impact on organ and tissue donation, we believe information should be provided about all facets of the donation process before a donation decision is made.

Finally, the family of the donor is likely to have many questions about the donation process, even if the OPO does not request consent. Thus, although we do not propose requiring an OPO to seek informed consent if the potential donor consented to donation before his or her death in a manner that satisfied the governing State law requirements, we propose requiring the OPO to provide information about the donation if it is requested by the donor's family.

Condition: Donor Evaluation and Management and Organ Placement and Recovery (Proposed § 486.344)

[If you choose to comment on this section, please include the caption "Donor evaluation and management, organ placement and recovery" at the beginning of your comments.]

The current OPO regulations have minimal requirements for donor evaluation and management and organ placement and recovery. They require OPOs only to: (1) Have a system to allocate donated organs equitably among transplant patients consistent with specific CDC guidelines for preventing the transmission of HIV and with the rules of the OPTN; and (2) ensure that appropriate donor screening and infection tests consistent with CDC and OPTN guidelines are performed by a laboratory certified in the appropriate specialty or subspecialty in accordance with CLIA requirements. There are no provisions in our regulations addressing donor management or organ recovery.

We propose requiring every OPO to have written protocols for donor evaluation and management and organ placement and recovery. The OPO would be required to ensure that protocols meet current standards of practice and that established practices and criteria are designed to optimize the number of donors and the number of

organs recovered and transplanted per donor.

As stated earlier, our OPO Coordinators have observed that the most successful OPOs have active, involved medical directors. Therefore, we are proposing requirements to ensure both that every OPO has a medical director and that medical directors are involved in the day-to-day oversight of clinical staff and the staff's evaluation and management of potential donors. We propose that an OPO's medical director would be responsible for ensuring that protocols for evaluation and management of donors are implemented correctly and appropriately to ensure every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

Managing a brain dead potential donor so that organs remain transplantable is very difficult. In fact, experienced OPO procurement coordinators agree that it can be more difficult to manage a brain dead potential donor successfully than to manage a living, critically ill patient. Sometimes donors are lost at this point in the donation process because cardiac arrest occurs before organs can be recovered. Therefore, we propose that OPOs be required to implement a system that ensures the medical director or other qualified physician is available to assist in the medical management of a donor when the surgeon on call is unavailable. We believe these proposals would ensure that once consent is obtained, every medically suitable potential donor will go to surgery and every transplantable organ will be recovered.

We believe detailed protocols whose implementation is well coordinated between the OPO medical director and procurement coordinators would work to safeguard against outcomes that hinder the goal of optimizing recovery of transplantable organs. The complex clinical interventions required for each stage of the donor evaluation and management and organ recovery processes contain numerous variables that would benefit from increased surveillance and accountability.

An excellent example of the importance of following a protocol for donor management can be found in a recent OPTN/UNOS study of the UNOS "Critical Pathway for the Organ Donor" protocol for donor management. The study found that when the critical pathway protocol was used, outcomes improved significantly. The number of organs recovered per donor increased by 10.3 percent, and the number of organs

transplanted per donor increased by 11.3 percent. (Chabalewski, F., Rosendale, J., Edwards, C.: *The Effect of a Critical Care Pathway on Donor Management Time and Cost—A Pilot Study*. Presented at the American Association of Critical Care Nurses, May 1, 2000.) The Secretary's Advisory Committee on Transplantation (ACOT) recently recommended that OPOs be encouraged to develop, evaluate, and support the implementation of improved management protocols for potential donors. The ACOT noted that the UNOS "Critical Pathway" is a "novel and improved" standard of care for heart and lung donors, and the Committee called for development of improved management standards for recovery of other types of organs.

Currently, the CDC's "Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs" are appended to our OPO regulations, but we are not proposing to include them in our new regulations. Once guidelines are appended to Federal regulations, agencies can incorporate new guidelines only through the rulemaking process.

Therefore, we propose removing the CDC guidelines from the OPO regulations and requiring, instead, that OPOs arrange for donor screening and testing for infectious disease following current standards of practice. This requirement would give OPOs the flexibility to follow the most up-to-date guidelines for preventing transmission of infectious disease. We would expect OPOs to change their testing practices quickly if the organ donation and transplantation community agrees that a change is indicated.

For example, in 2001 three transplant recipients were infected with the parasite that causes Chagas disease after receiving organs from a donor from Central America. One of the recipients later died from the disease. Chagas disease is endemic in Latin America but had not previously been reported in the United States. Although at present there is no test available in the United States to screen donors or organs for the presence of Chagas disease, if a test becomes available and the OPTN and CDC recommend that OPOs use the test to screen potential donors, we would regard that testing as being part of current standards of practice for donor testing.

We propose requiring that all testing of potential donors (including point-of-care testing and blood typing) be conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance

with part 493 (that is, the CLIA regulations). Thus, an OPO using its own mobile unit to perform point-of-care testing for management of donors before organ recovery would be required to have the appropriate CLIA certification. The OPO would be required to ensure that the donor's blood is typed using two separate blood samples. Furthermore, we would require OPOs to document donor records with all test results, including blood type, before organ recovery.

To provide opportunity for improvements in partnerships between OPOs and the transplant hospitals in their service areas, we would require OPOs to establish protocols collaboratively with transplant hospitals that clearly define the roles and responsibilities of the OPO and the transplant hospital for all activities associated with donor evaluation, donor management, and organ recovery.

In February 2003, a medical error occurred at a large university hospital that made headlines across the country. Surgeons at the hospital transplanted a heart and lungs from a type A donor into a type O recipient. The recipient immediately began to reject the mismatched organs, and a second transplant several days later from a donor of the correct blood type failed to save her life. Although a number of errors and mistaken assumptions on the part of the hospital and both OPOs involved in the procurement of the organs led to the mismatched transplant, it could have been prevented by better communication between the hospital and the OPOs involved in procuring and placing the organ.

Therefore, we propose requiring OPOs to include in the protocol the procedures to be used to ensure that the blood type of the donor is compared with the blood type of the intended recipient by two OPO staff members before organ recovery takes place and that documentation of the donor's blood type accompanies the organ to the transplant hospital.

OPOs would be required to review the protocols periodically with their transplant hospitals to incorporate best practices and maximize placement of transplantable organs. We believe that implementation of current, comprehensive protocols would improve donor evaluation, management and organ recovery and contribute to the maximum number of organs per donor recovered and transplanted.

In our investigation of the mismatched transplant, we found that the OPOs involved did not obtain documentation of the recipient's blood type or position on the waiting list from

the OPTN. Therefore, we propose requiring that before recovery of an organ for transplantation, an OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's OPTN identification number and blood type, as well as the recipient's position on the waiting list in relation to other suitable candidates. We have included additional safeguards in this proposed rule (see § 486.346) to prevent mismatched transplants.

Section 371(b)(3)(E) of the PHS Act requires OPOs to "have a system to allocate donated organs among transplant patients according to established medical criteria." The OPTN develops the medical criteria upon which allocation policies are based with the input of the organ donation and transplantation community. Therefore, we propose retaining the requirement in the current regulations that OPOs have a system to equitably allocate donated organs among transplant patients consistent with the rules of the OPTN. However, we propose adding language to clarify that the "rules" of the OPTN are those that have been approved as enforceable by the Secretary.

We are proposing a requirement that OPOs develop and implement a protocol that maximizes placement of transplantable organs. This means that OPOs should be aware of organ acceptance criteria for centers outside their service areas and make every possible effort to place healthy organs. We would encourage OPOs to include organ placement in their QAPI programs and explore innovative ideas for maximizing both organ recovery and transplantation.

According to the Collaborative's report, LifeLink of Florida evaluates every brain death on-site at the hospital, regardless of the patient's age, medical history, or social history, and makes every effort to find potential recipients for marginal or "extended criteria" organs. LifeGift's philosophy includes "turning potential donors previously considered unsuitable into actual donors."

Many OPOs have developed innovative methods for maximizing the number of organs they place and recover. For example, the Hawaii OPO has partnered with a California transplant hospital to arrange for hearts donated in Hawaii to be transplanted in California, even though the transport time to California is at the upper limits of the acceptable cold ischemic time for a heart. At the July 2002 meeting of the North American Transplant Coordinators Organization in Washington, DC, OPOs presented case

studies and abstracts describing their successes in recovering organs from marginal donors. Gift of Life OPO in Philadelphia presented an abstract documenting its success in implementing a comprehensive initiative for recovering organs from pediatric donors after cardiac death (that is, non-heartbeating donors). From 1995 through 2001, 55 organs recovered by the OPO from pediatric donors after cardiac death were successfully transplanted. Gift of Life also presented an abstract demonstrating the number of viable organs they recovered from donors over the age of 60 and a case study describing how optimal donor management, biopsy, and perfusion enabled them to recover viable kidneys from a donor with initially poor kidney function.

Condition: Organ Preparation and Transport (Proposed § 486.346)

[If you choose to comment on this section, please include the caption "Organ preparation and transport" at the beginning of your comments.]

Our current regulations have minimal requirements for OPOs for organ preparation and transport. OPOs are required only to arrange for appropriate tissue typing of organs and to provide or arrange for transportation of organs to transplant hospitals. There are no requirements for organ packaging in the current regulations.

We propose requiring OPOs to arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO would be required to ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

We propose requiring OPOs to develop and follow a protocol for packaging, labeling, handling and transporting organs in a manner that ensures their arrival without compromise to the quality of the organ or the health of the recipient. OPOs would be required to include procedures to check the accuracy and integrity of labels, packaging, and contents before transport, including two separate verifications of the data on the labels and in the documentation that accompanies an organ to a transplant center.

The impetus for this proposal came from an incident that occurred in Illinois in 2000. In packaging organs for shipment, an OPO mixed up the label identifying a kidney intended for transplantation with the label for a heart

intended for research. It was only after the intended kidney recipient had been anesthetized and surgery had begun that hospital staff discovered the OPO had sent a heart instead of a kidney.

In investigating the incident, we discovered that while organ mix-ups are rare, they are not unheard of, and no one in the OPO community seemed surprised that it had happened. In fact, the OPTN/UNOS OPO Committee recently documented 15 instances of organ packaging errors that occurred over a period of only 6 months. These errors included three organs shipped without sufficient ice, a right kidney shipped instead of the left kidney expected by the transplant hospital, a vessel container leaking (thus compromising the sterile integrity of segments of the donor's aorta and inferior vena cava intended for use in the transplant procedure), as well as other errors that may have resulted in organ wastage. Although the OPTN has packaging requirements for OPOs, clearly, the requirements have not been sufficient to prevent errors that waste organs and endanger recipients. In light of the critical nature of the organ shortage, such errors are unacceptable.

Finally, an OPO would be required to mark all packaging in which organs are transported with the identification number, specific contents, and donor's blood type. This requirement is one of our proposals to guard against transplantation of organs mismatched by blood type or delivery of the wrong organ to a transplant center.

Condition: Quality Assessment and Performance Improvement (QAPI) § 486.348

[If you choose to comment on this section, please include the caption "Quality Assessment and Performance Improvement" at the beginning of your comments.]

There is no requirement in current regulations that OPOs have a QAPI program. Although our regulations for most Medicare providers and suppliers require, at the least, a quality assurance program (the "find a problem, fix it" approach), there is no corresponding requirement in the OPO regulations.

QAPI is the process of using objective data to study and continually make improvements to all aspects of an organization's operations and services. QAPI rests on the assumption that an organization's own quality management system is the key to improved performance. It seeks to increase the amount and quality of information on which to base decisions and improve quality. QAPI programs allow health care entities to assess their functioning

continuously and make changes to improve their quality and efficiency.

QAPI is regarded by the health care community as the most efficient and effective method for improving the quality and performance of health care providers. QAPI has become so pervasive that in a recent publication of the Institute of Medicine (IOM) of the National Academy of Sciences, "Crossing the Quality Chasm: A New Health System for the 21st Century," the IOM recommended that the Department itself should monitor and track quality improvements in six key areas including safety, effectiveness, responsiveness to patients, timeliness, efficiency, and equity.

However, as the focus on improving outcomes in health care shifted from quality assurance to QAPI, OPOs seemed to be left behind, perhaps because they do not provide hands-on health care to patients. Nevertheless, an OPO's success in recovering healthy organs impacts patients who need transplants due to end-stage organ failure just as surely as if the OPO were providing direct care to those patients.

Although some OPOs have strong QAPI programs and use them to effect change both within their own organizations and within their hospitals, some OPOs' QAPI programs are inadequate to drive badly needed systemic changes. Some OPOs admit that, as a group, they tend to be reactive rather than proactive, fixing individual problems instead of systems.

Nonetheless, it appears that OPOs are catching up with the rest of the health care community. We know that most OPOs have a quality improvement program. Some programs are comprehensive, highly structured, and completely integrated into the day-to-day operations of the OPO. OPOs with these programs utilize them for data-based decision making and strategic planning. Other OPOs are still developing and formalizing their QAPI programs.

In November 2001, AOPO conducted a survey to assess quality improvement programs among OPOs. Of the 35 OPOs that responded to the survey, approximately 40 percent had been developing a quality program for 2 years or less, and only 43 percent had designated an individual whose primary responsibility was coordinating and monitoring a quality improvement program. However, approximately 67 percent had made quality improvement part of their strategic plans and had developed appropriate measures or indicators of work system effectiveness for most major activities.

However, AOPO notes that due to several factors, there has been significant growth in quality improvement among OPOs since the November 2001 survey. These factors include: (1) The Department's Breakthrough Collaborative, which utilizes QAPI-type strategies to improve donation rates; (2) the Department's initiative to provide comparative data from the SRTR to all OPOs and the public; (3) new perspectives on quality improvement gleaned from individuals hired by OPOs from outside the OPO community; (4) sharing of quality improvement plans among OPOs; and (5) the growth and activism of AOPO's Quality Council. These factors have provided all OPOs with opportunities to expand and improve their quality improvement programs.

All six high-performing OPOs studied during the Organ Donation Breakthrough Collaborative have a process (such as death record reviews) for collecting hospital-specific data and using the data both in their hospital development programs and to effect change within their own organizations. New England Organ Bank collects and monitors hospital-specific data on requests, consents, organs recovered, and organs transplants and reviews the data with hospital leadership every month. Included in their QAPI program are "formalized feedback mechanisms," such as weekly meetings with OPO staff, monthly meetings with hospital staff, post-donation briefings with all involved OPO and hospital staff, along with two data reporting mechanisms (quantitative and qualitative reports).

We believe it is critical for every OPO to have such a comprehensive QAPI program (that is, a program that addresses all aspects of an OPO's functioning and the functioning of its hospitals in the organ donation process). As a recent article describing characteristics of successful OPOs pointed out, "OPOs no longer have the luxury of using trial and error in determining which programs will increase organ donation, which factors are key for success." (Shafer, T., Kappel, D., Heinrichs, D., Strategies for success among OPOs: a study of three organ procurement organizations. *Journal of Transplant Coordination*. V.7, No.1: 22-31.)

Therefore, we are proposing a requirement for every OPO to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate all donation services, including services provided under contract or arrangement. The OPO's QAPI program must include the use of objective

measures to evaluate and demonstrate improved performance with regard to OPO activities.

These requirements are based on our commitment to encouraging continuous quality improvement for all Medicare providers and suppliers. As we develop new regulations, we are shifting our focus from targeting the substandard practices of a small number of poor performers to emphasizing the responsibility of all Medicare providers and suppliers for continuous quality improvement in their own organizations. QAPI is a regulatory requirement for hospitals, Medicare + Choice providers, and providers in the Program for All-Inclusive Care for the Elderly (PACE). QAPI has been proposed as a requirement for home health agencies and rural health clinics. We believe a requirement for OPOs to have a QAPI program will encourage continuous quality improvement, as well as the use of best practices, as determined by the individual OPO and the OPO community.

We do not intend to stipulate specific activities an OPO must include in its QAPI program. However, we suggest that all OPOs track and take actions to improve their consent rates. Although knowledge is the foundation for performance improvement, some OPOs do not know their consent rates, either for their service area as a whole or for individual hospitals. Nationwide, the consent rate to organ donation hovers around 50 percent, and it is generally agreed that families' failure to consent to donation is the single most important roadblock to increasing donation.

Although there is some evidence that public education efforts targeted toward increasing the public's awareness of and support for organ donation may result in an increase in consent rates, the single greatest opportunity for increasing consent rates lies within the interaction among OPO staffs, hospital staffs, and potential donor families.

We propose requiring an OPO's QAPI program to include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of response to hospital referrals, consent practices, organ recovery, and organ packaging and transport. The OPO would be required to take actions that result in performance improvements and track performance to ensure that improvements are sustained.

There are many resources available to OPOs to develop and improve QAPI within their organizations. The AOPO Quality Council is available to assist all

AOPO members interested in QAPI. The Council has a quality improvement list serve and a chat room used for mentoring and for scheduled discussions of quality improvement topics. The Council holds meetings for all interested OPOs three times per year, with training in basic and intermediate level QAPI, basic quality assurance statistics and data analysis, implementation of quality plans, flow charting, root cause analysis, and preparation for audits and surveys.

In addition, the resources of both CMS (through the OPO Coordinators) and HRSA's Division of Transplantation (DOT) are available to OPOs to assist them in implementing QAPI. CMS OPO Coordinators are always available to assist OPOs with their QAPI programs. Once a final rule is published, the CMS OPO Coordinators will provide guidance to OPOs so that they thoroughly understand how to implement the QAPI requirements in the regulation.

When OPOs are surveyed to see if they meet the requirements for QAPI, surveyors initially would focus on whether an OPO has or is developing a QAPI program. If a QAPI program were still in the development phase, surveyors would determine what remains to be accomplished, what steps the OPO needed to take to have a comprehensive, fully integrated program, and what resources it would need to reach that goal. When an OPO is surveyed for the QAPI requirement for the first time under the final OPO rule, the OPO would not be cited for being out of compliance, as long as it had a QAPI program in some stage of development and was working to expand and improve the program with the goal being a comprehensive, data-driven program to monitor and evaluate all donation services.

The hospital CoP at § 482.45(a)(5) and critical access hospital CoP at § 485.643 require hospitals to cooperate with OPOs in reviewing death records to improve identification of potential donors. We included this requirement in the hospital and critical access hospital CoPs because missed opportunities for donation are not uncommon, and review of hospitals' death records is essential for both OPOs and the hospitals they serve to determine where and how systems need to be changed to ensure future potential donors are identified.

We propose requiring hospital death record reviews as a component of every OPO's QAPI program. OPOs would be expected to use data from their death record reviews as the basis for their quality improvement efforts. We believe

that to have sufficient data on which to base changes in their organizations, OPOs must perform death record reviews on an ongoing basis. Death record reviews provide information about nearly the entire range of an OPO's critical operations, as well as the performance of the OPO's hospitals in the donation process. Death record reviews provide information about the timeliness of hospital referrals of potential donors, the timeliness of the OPO's response, OPO or hospital staffs' interactions with family members, management of potential donors, and other matters that affect quality. The information OPOs gain from periodic death record reviews can be used to identify and correct systemic problems that interfere with organ donation.

In a 1997 article, "Medical Record Review as a Measure of the Effectiveness of Organ Procurement Practices in the Hospital," [*The Joint Commission Journal on Quality Improvement*, Vol. 23, No. 6, June 1997] The Partnership for Organ Donation concluded that death record reviews provide a solid foundation for identifying gaps in organ procurement performance, implementing and tracking the success of [quality improvement] initiatives, and monitoring ongoing performance. The researchers recommended that OPOs conduct death record reviews annually at large hospitals where medically suitable donor candidates are concentrated and provide feedback from the death record reviews to key hospital staff concerning practice improvements that could be adopted. The researchers suggested annual death record reviews at hospitals with 150 or more beds or with trauma centers.

As stated earlier, the organ donation community recognizes that death record reviews are the "gold standard" for assessing donor potential and improving organ donation rates. In fact, in discussions with directors of OPOs that perform death record reviews, we were told that OPOs that do not perform them are "missing the boat" because they have no way of knowing their true donor potential and no way of identifying and addressing problems. Although death record reviews are labor intensive, they are well worth the effort expended.

The Michigan OPO, Gift of Life, recently demonstrated what can be accomplished by using death record reviews as the basis for improving organ donation rates. The OPO used data from death record reviews performed monthly in Michigan's leading organ donation hospital to determine that organ donors could be increased in key

critical care units in the hospital. The OPO partnered with the hospital to increase organ donation rates. The OPO made a commitment to (1) Respond on site to every referral; (2) provide monthly in-service education to resident physicians in the key units; and (3) follow up on all cases within 96 hours of every referral to obtain information for improving systems for donation. The result—from 2000 to 2001, the hospital's organ donation rate increased by 48 percent to 40 donors and the rate of organs recovered increased by 43 percent to 143 organs.

At the Joint American Transplant Meeting, "Transplantation 2001" conference held from May 11–16 2001 in Chicago, a group of researchers, including the researchers from the AOPO death record review study, presented results from a study that used death record reviews to understand opportunities for increasing organ donation within an OPO service area. The researchers concluded that: (1) Increasing organ donation can be achieved by focusing on hospitals with 150 or more beds known to have organ donor potential by death record review; (2) death record reviews offer an objective way to prioritize hospitals by potential and to tailor interventions within each hospital to address specific obstacles to donation; and (3) by focusing on hospitals with 150 or more beds, OPOs can reach more than 90 percent of their target market.

Therefore, we propose that an OPO be required to conduct death record reviews in every Medicare or Medicaid participating hospital with which it has an agreement if the hospital has 150 or more beds or if it has a level I or level II trauma center, with the exception of psychiatric or rehabilitation hospitals. (We propose excluding psychiatric and rehabilitation hospitals because of their limited organ donation potential.) When missed opportunities for donation are identified, the OPO would be required to implement actions to improve performance.

As part of the QAPI process, an OPO would be required to investigate adverse events and complete a thorough analysis. An adverse event for an OPO could be caused by mismanagement of a donor, failure to test organs for infectious disease, failure to compare the blood type of the donor with the blood type of the intended recipient, or mixing up the labels on packaged organs. Examples of situations involving direct patient outcomes that might qualify as adverse events include but are not limited to: (1) Avoidable loss of a medically suitable potential donor for whom consent for donation has been

obtained; (2) avoidable loss of a viable organ; (3) transmission of infectious disease to a recipient, and delivery to a transplant center of the wrong organ (for example, a left kidney instead of a right kidney or a kidney instead of pancreas) or an organ whose blood type does not match the blood type of the intended recipient.

In addition, we are proposing that an OPO be required to report an adverse event to us within 10 business days of becoming aware of the event and provide written documentation of the investigation and analysis of the adverse event to us within 15 days of becoming aware of the event. The OPO would be required to implement changes and safeguards to decrease the probability of the adverse event recurring. We believe that this formal analysis is essential to examining an OPO's existing policies and practices, improving the organ donation process, and improving outcomes. We believe the proposed time frames for reporting and providing written documentation would be sufficient and would ensure prompt attention by the OPO to adverse events.

We believe the requirements we propose for OPOs to develop and implement QAPI programs, perform death record reviews, report and analyze adverse events, and operate under a CAP, as needed, would provide concrete steps OPOs can use to improve their operations and increase organ donation. We also believe these proposed requirements are the single most important provision in this proposed rule to fulfill the congressional mandate for process performance measures based on empirical evidence of organ donor potential and other related factors in OPO service areas.

Additional Conforming Changes
(§ 413.200, § 413.202, § 441.13, and § 498.2)

In addition to the changes discussed above, we are also proposing a number of conforming and correcting amendments.

As discussed previously, we propose making changes to § 498.1 to remove OPOs from the definition of "supplier" under part 498. Since we propose a process for OPOs to appeal a de-certification on substantive and procedural grounds, OPOs would not need the part 498 appeals process.

We also propose to correct a number of cross-references related to the certification of OPOs. In § 441.13(c), and in § 498.2, we propose to change references to "part 485, subpart D" to read, "part 486, subpart G". On September 29, 1995 (60 FR 50447), the

conditions for coverage for OPOs was re-designated from part 485, subpart D to part 486, subpart G. When this re-designation occurred, these two references were not amended to reflect the change.

In addition, § 413.202 refers to OPOs "as defined in § 435.302 or this chapter". This is an error. We propose correcting this reference to read "as defined in § 486.302 of this chapter".

Request for Comments on Related Issues Living Donation

[If you choose to comment on this section, please include the caption "OPO role in living donation" at the beginning of your comments.]

In 2001, living donors outnumbered deceased donors for the first time, with 6,445 living donors and only 6,077 deceased donors. However, with the exception of two pilot programs in which OPOs assist transplant hospitals by arranging for medical and psychological evaluations of voluntary living kidney donors, the 59 OPOs do not play a role in living donation; their mission is to increase the number of deceased donors. Given the demonstrated risks to donors (primarily living liver donors), we believe that living donation should remain a medical decision between individuals interested in donating and their physicians. However, in view of the increasing importance of living donation, we are specifically requesting public comments on what role, if any, OPOs should play in living donation.

Public Education

[If you choose to comment on this section, please include the caption "Public Education" at the beginning of your comments.]

The current regulations at § 486.306(p) require that OPOs conduct and participate in professional education concerning organ procurement, but they do not contain a requirement for public education. However, most OPOs are aware of the importance of the role public education plays in reaching ethnic populations, dispelling myths about organ donation, and addressing other issues that create barriers for consent to donation. Many in the OPO community believe that targeted public education about organ donation plays a key role in overcoming these barriers. Some researchers however, believe that available funding should go to basic research, professional education, and hospital development rather than public education.

While we believe that systematic efforts by OPOs to identify specific

barriers to donation, along with public education programs designed to address those barriers, may result in increased rates of consent to donation among targeted populations, the OPO community appears to lack consensus about this issue. Therefore, we have not included requirements for public education in this proposed rule. However, we are specifically requesting comments on the advisability of requiring OPOs to conduct public education based on systematic evaluation of specific barriers to donation within their individual service areas.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

General Requirements (§ 486.304)

For designation purposes, an organization would have to meet specified requirements, including:

It would have to have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for organs provided to transplant centers.

It would have to submit to CMS a written application for designation, using the application form prescribed by CMS.

It would have to document that it has a defined service area that meets the requirements of § 486.306.

An OPO would have to enter into an agreement with CMS. In the agreement,

the OPO would have to agree to do comply with the following ICRs:

(1) Maintain compliance with cited laws, regulations and rules of the OPTN, as defined by § 486.20, and to report promptly to the Secretary any failure to do so.

(2) File a cost report in accordance with § 413.24(f) of this chapter within 5 months after the end of each fiscal year.

(3) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

The ICRs in this section are those that would require an OPO to have accounting and other fiscal procedures; to submit a written application for designation, using a form prescribed by CMS; to enter into an agreement with CMS; and to document that it has a defined service area that meets specified requirements.

These ICRs are currently approved under OMB approval #0938–0512.

OPO Service Area Size Designation and Documentation Requirements (§ 486.306)

Under this section, an OPO would have to make available to CMS documentation verifying that the OPO meets the requirements of paragraph (b) and (c) of this section at the time of application and throughout the period of its designation.

Under paragraph (c), Service area location and characteristics, an OPO would have to precisely define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area for which U.S. population statistics are available.

(3) Total population in service area.

(4) The number of and the names of hospitals in the service area with an operating room and the equipment and personnel to retrieve organs.

The ICR in this section would be that requiring making documentation available. We believe that it would take a typical OPO an average of 1 hour to make the information available. There are 59 OPOs that would have to comply with this requirement; therefore, there would be a total of 59 hours needed to comply annually.

Designation of One OPO for Each Service Area (§ 486.308)

If CMS changes the OPO designated for an area, hospitals located in that area would have to enter into agreements

with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

A hospital would be able to request and CMS might grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital would have to submit data to CMS establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

The burden associated with this section is the time it would take a hospital to request a waiver and to create an agreement with an OPO. We estimate that there will be 6 hospitals that would request a waiver and that all of these would need to enter into an agreement with the designated OPO.

Under 5 CFR 1320.3(c), a "collection of information" does not include requirements imposed on fewer than ten entities. Therefore, the ICRs of this section are not subject to the PRA.

Changes in Ownership or Service Area (§ 486.310)

Under this section, a designated OPO considering a change in ownership or in its service area would have to notify CMS before putting it into effect and would have to obtain prior CMS approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the entities would have to submit anew the information required in an application for designation. The OPO would have to provide information specific to the board structure of the new organization, as well as operating budgets, financial information, or other written documentation CMS determines to be necessary for designation.

The burden associated with this section is the time it takes to gather and submit the information CMS needs. We estimate that two OPOs would be affected annually and that it will be the same amount of time it would take a potential OPO requesting designation and is covered under OMB approval #0938–0512.

De-Certification (§ 486.312)

Under this section, if an OPO wishes to terminate its agreement, it would

have to send written notice of its intention with the proposed effective date to CMS. In the case of voluntary termination, the OPO would have to give prompt public notice of the date of termination, and such information regarding the effect of that termination as CMS may require, through publication in local newspapers in the service area. In the case of involuntary termination, CMS gives notice of the date of termination.

The burden associated with these requirements is the time it would take to send written notice to CMS and to publish pertinent information in the local newspapers. We estimate that one OPO would be affected by these requirements per year.

Under 5 CFR 1320.3(c), a "collection of information" does not include requirements imposed on fewer than ten entities. Therefore, the ICRs of this section are not subject to the PRA.

Appeals (§ 486.314)

Under this section, if an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive or procedural grounds. The OPO must file its appeal within 30 calendar days of the date of the notice of de-certification. In its appeal, the OPO may submit evidence to demonstrate why it should not be de-certified.

The burden associated with this provision is the time it will take an OPO to file an appeal. We do not expect to de-certify more than three OPOs in a given year.

Under 5 CFR 1320.3(c), a "collection of information" does not include requirements imposed on fewer than ten entities. Therefore, the ICRs of this section are not subject to the PRA.

Re-Certification and Competition Processes (§ 486.316)

Under this section, OPOs competing for the open service area must submit an acceptable plan to increase organ donation in the open service area. An acceptable plan to increase organ donation would, at a minimum:

(1) Be based on the competing OPO's experience and success in its own service area;

(2) Include an analysis of existing barriers, both internal and external, to increasing organ donation in the open area; and

(3) Provide a detailed description of specific activities and interventions for increasing organ donation in the open area.

The burden associated with this requirement is the time it would take to create the plan and to submit it. We expect that it would take approximately 16 hours to develop an acceptable plan to increase organ donation. In each of the 1996, 1998, and 2000 re-certification cycles, approximately two to three OPOs failed the performance standards. Therefore, we do not anticipate terminating more than three OPOs in any four-year period. In previous re-certification cycles no more than two OPOs have competed for an open service area. Therefore, we do not believe that more than two OPOs would compete for an open area. Therefore, we expect that no more than 6 OPOs would compete for service areas of OPOs being de-certified by CMS.

We propose limiting competition for the service areas of OPOs that have met the conditions of coverage to OPOs that have met 4 out of 5 outcome measures at 100 percent of the mean and whose conversion rate of potential donors to actual donors is at least 15 percentage points higher than the incumbent's conversion rate. It is likely that no more than 15 OPOs (those in the upper quartile) would fall into this category.

Therefore, we expect that no more than 21 OPOs would want to develop an acceptable plan to increase organ donation as part of a bid to expand into a new service area. Assuming that it would take 16 hours to develop such a plan, the burden would be 336 hours.

Condition: Relationships With Hospitals, Tissue Banks, and Eye Banks (§ 486.322)

Under this section, an OPO would have to have a written agreement with 95% of the Medicare and Medicaid hospitals in its service area that have both a ventilator and an operating room, that describes the responsibilities of both the OPO and hospital in regard to the requirements for hospitals in § 482.45. The agreement would have to address the requirement in § 486.326 that the OPO would have to maintain credentialing records for physicians who routinely recover organs in hospitals under contract or arrangement with the OPO and would have to assure that physicians and other practitioners who recover organs in hospitals are qualified and trained.

The burden associated with these ICRs would be the time it will take an OPO to enter into an agreement with a hospital. Currently, OPOs are likely to have agreements with all hospitals in their service areas because the hospital CoP for organ, tissue, and eye procurement, which was effective August 21, 1998 (see section 482.45)

requires all hospitals to have agreements with their OPO. We believe that it would take an average of two hours to draft an agreement with a hospital.

Condition: Administration and Governing Body (§ 486.324)

Under this section, the OPO would have to have bylaws for its board(s) that address conflicts of interest, length of terms, and criteria for selecting and removing members.

A governing body or individual would have to have full legal authority and responsibility for the management and provision of all OPO services and would have to develop and implement policies and procedures necessary for the effective administration of the OPO, including services furnished under contract or arrangement, fiscal operations, and continuous quality assessment and performance improvement.

The OPO would have to have a procedure to address conflicts of interest for the governing body or individual described above.

The burden associated with the above requirements is the time it would take an OPO to create bylaws and to develop policies and procedures necessary for the effective administration of the OPO. It is usual and customary business practice to have such bylaws, policies, and procedures; therefore, there would be no additional burden.

Condition: Human Resources (§ 486.326)

The first ICR in this section is that we would require the OPO to have a written policy that addresses conflicts of interest for the OPO's director, medical director, and senior management, and procurement coordinators.

Another ICR would be that the OPO must maintain credentialing records for physicians who routinely recover organs in hospitals with which the OPO has an agreement.

The third ICR is that the OPO would have to reevaluate staff competency at least yearly and provide individual job descriptions and performance expectations to staff.

The burden associated with this section is the time it would take an OPO to document policy, maintain records and to provide job descriptions and expectations. These requirements reflect usual and customary business practices and thus do not create any additional burden.

Condition: Reporting of Data (§ 486.328)

Under this section, the OPO would have to provide individually identifiable, hospital-specific organ

donation and transplantation data to the OPTN and the SRTR, as directed by the Secretary. The OPO would have to provide hospital-specific data directly to transplant hospitals, annually. In addition, the OPO would be required to provide individually identifiable, hospital-specific organ donation and transplantation and other information to the Secretary, as requested. Such data may include, but are not limited to—

- (1) Number of hospital deaths;
- (2) Results of death record reviews;
- (3) Number and timeliness of referral calls from hospitals;
- (4) Potential donor denominator (as defined in 486.302);
- (5) Data related to non-recovery of organs,
- (6) Data about consents for donation;
- (7) Number of donors;
- (8) Number of organs recovered (by type of organ); and
- (9) Number of organs transplanted (by type of organ).

This section would also require that potential donor data reported to the OPTN to be used for OPO re-certification would have to include data for all deaths that occurred in hospitals in the OPO's service area, unless a hospital has a waiver to work with a different OPO. If an OPO determines through death record review or other means that the potential donor denominator data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN.

The OPO would have to report hospital-specific organ donation data to the public at least annually.

The burden associated with these requirements is the time it would take the OPOs to report certain information. We believe that this would take no more than 4 hours per OPO per year, or a national total of 236 hours. In addition, although it appears this requirement has the potential to add a significant new reporting burden, OPOs are required as a condition of their membership in the OPTN to report a large amount of data to the OPTN (which, in turn, provides the data to the SRTR for analysis). For example, the cadaver donor registration form (OMB approval #0915-0157) OPOs are required to complete for each donor contains more than 300 data elements. In addition, 42 CFR 121.11(b)(2) requires OPOs and transplant hospitals to submit information about transplant candidates, transplant recipients, organ donors, transplant program costs and performance, and "other information that the Secretary deems appropriate." Thus, most information needed by the OPTN, the SRTR or the Department is already being reported by OPOs.

We cannot quantify the number of hours it would take to comply with the data reporting requirement, as data would be requested on an as-needed basis. We believe that almost any OPO data needed by CMS or other agencies within the Department could be obtained from the OPTN or the SRTR. We are including this provision only to give CMS and other agencies the flexibility to request data from OPOs in the event that needed data cannot be obtained expeditiously from the OPTN or the SRTR. We would not request data from OPOs if the data were readily available from other sources.

Concerning the requirement that OPOs give data to the public, almost all OPOs publish newsletters to inform the public of their activities, and, most likely, OPOs would report the hospital data in their newsletters at very little additional cost. For those OPOs that do not publish newsletters, we estimate that it would take 4 hours to create a document suitable for publication yearly. We estimate that three OPOs do not have newsletters, for an annual burden of 12 hours.

Condition: Information Management (§ 486.330)

The ICRs under this section would require the OPO to maintain a record for every donor. The record would have to include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number), organs and (when applicable) tissues and eyes recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, pronouncement of death, consent and next-of-kin information. Donor records would have to be maintained in a human readable and reproducible format for 5 years.

The OPO would have to maintain data in a format that can readily be continued by a successor OPO and would have to provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement would include records of individual donors, records on transplant candidates (including identifying data and data on immune system and other medical indications) and procedural manuals and other materials used in conducting OPO operations.

Although these ICRs would be subject to the PRA, we believe that all of them reflect usual and customary business practice and therefore have no added burden.

Condition: Informed Consent (§ 486.342)

The ICRs of this section would require that an OPO have a written protocol to ensure that the individual(s) making the donation decision for each potential organ donor is informed of their options to donate organs and tissues or eyes (when the OPO is making a request for tissues or eyes) or to decline to donate and are given sufficient time to consider their decisions and sufficient information on which to base fully informed decisions. The OPO would have to provide to the individual(s) making the donation decision, at a minimum, the following:

- (1) A list of the organs, tissues, or eyes to be recovered,
- (2) All possible uses for the donated organs and/or tissues,
- (3) The information that the individual(s) have the right to limit or restrict use of the organs or tissues,
- (4) A description of the screening and recovery processes,
- (5) Information (such as profit or non-profit status) about organizations that will recover, process, and distribute tissue,
- (6) Information regarding access to and release of the donor's medical records,
- (7) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body,
- (8) Information about the procedure for filing a complaint,
- (9) Contact information in case the individual(s) have questions, and
- (10) A copy of the signed consent form.

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

We believe that all OPOs currently have policies regarding informed consent, so there would basically be no additional burden to them as the policies are usual and customary business practice. (Some OPOs might have to add some information, which could minimally increase the time it takes to inform the individual(s) making the donation decision.)

Condition: Donor Evaluation and Maintenance and Organ Placement and Recovery (§ 486.344)

Under this section, the OPO must have an effective written protocol for donor evaluation and management and organ placement and recovery.

The OPO must document the donor's record with all test results, including blood type, prior to organ recovery.

Prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's position on the waiting list in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

The burden associated with this requirement is the time it would take to create the protocols. We believe that good business practices would dictate that an OPO have written protocols that meet the requirements of this section. Therefore, there would be no additional burden.

Condition: Organ Preparation and Transport (§ 486.346)

The ICR in this section requires that the OPO develop and follow a written protocol for packaging, labeling, handling and shipping of organs in a manner that ensures their arrival without compromise to the quality of the organ or health of the recipient. The protocol would have to include procedures to check the accuracy and integrity of labels prior to transport.

The burden associated with this requirement is the time it would take to create the protocols. We believe that good business practices would dictate that an OPO have written protocols that meet the requirements of this section. Therefore, there would be no additional burden.

Section 486.348 Condition: Quality Assessment and Performance Improvement (QAPI)

The ICRs under this section would require the OPO to develop, implement, and maintain a comprehensive, data-driven quality assessment and performance improvement (QAPI) program designed to monitor and evaluate ongoing and overall performance of all donation services, including services provided under contract or arrangement

An OPO would have to establish in writing a policy to address adverse events that occur during any phase of an organ donation case. The policy would have to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events.

The OPO would have to report an adverse event to CMS and would have to provide to CMS written documentation of the investigation and analysis of the adverse event within 15 days of reporting the adverse event.

The burden associated with these requirements would be the time required to develop a QAPI and policy regarding adverse events. It is also the time it would take to report the adverse events to CMS.

We believe that, as part of its usual and customary business, a typical OPO would already have a QAPI and a policy regarding reviewing adverse events.

While we believe that each of the 58 OPOs already has a QAPI program in place, the burden of reporting adverse events is subject to the PRA. We estimate that on average, CMS would receive 30 adverse event reports annually. We have assumed that each report would require 30 minutes to prepare, yielding a total annual burden of 15 hours.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn.: Dawn Willingham, CMS-3064-P, Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer.

Comments submitted to OMB may also be e-mailed to the following address: e-mail: CMartin@omb.eop.gov; or faxed to OMB at (202) 395-6974.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA)(September 19, 1980 Pub. L. 96-354). Section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). This proposed rule is an economically significant rulemaking under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of \$6 million to \$29 million in any one year. For purposes of the RFA, all OPOs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For the purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose substantial direct requirement costs on State or local governments and does not preempt State law or have other Federalism implications.

Section 701 of Pub. L. 106-505, which was passed by Congress in 2000, requires us to promulgate regulations with new OPO outcome measures and to certify OPOs under those new measures by January 1, 2002. The new

outcome and process performance measures must rely on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each OPO's service area. The regulations must include multiple outcome measures.

All 59 OPOs would be affected by the requirements in this proposed rule to a greater or lesser degree. Many—probably the majority—of OPOs have already put into practice many of the requirements we propose. However, OPO practices vary widely. Some requirements would impact many OPOs but have relatively little economic impact; others would have a larger economic impact but would impact very few OPOs. Thus, while we do not believe the requirements in this proposed rule would have a substantial economic impact on a significant number of OPOs, we believe it is desirable to inform the public of our projections of the likely effects of the final rule on OPOs. It is important to note that since OPOs are paid by the Medicare program on a cost basis, any additional costs that exceed an OPO's annual revenues would be fully reimbursed by the Medicare program.

Our projections are based largely on data and information provided by the CMS OPO Coordinators. Each Coordinator is responsible for the OPOs located in one of the four CMS Consortia areas (Midwest, West, South, and Northeast). In some cases, no data were available for one or more of the Consortia. However, OPO practices typically vary by size and affiliation (hospital-based or independent), rather than by geographic location. Since all types of OPOs are represented within each Consortium, we feel confident that the practices and experiences of the OPOs within two or three of the Consortia are representative of all OPOs. Therefore, where data were not available for all four Consortia, we based our projections on data from fewer than four.

The provisions of this proposed rule would have a very limited economic impact on hospitals. It is expected that improved OPO performance would result from the rule and would increase organ donation and, therefore, the number of organs available for transplantation. However, transplant hospitals are reimbursed for their costs related to performing transplants, and donor hospitals are reimbursed by OPOs for the cost of maintaining potential donors. Therefore, there are no negative economic impacts on hospitals that would result from the rule.

Reason for This Regulation

Approximately 70 people receive an organ transplant every day. However, another 16 die due to the lack of transplantable organs (<http://organdonor.org>). OPOs play a critical role in securing transplantable human organs for seriously ill patients suffering from end-stage organ failure. In fact, OPO performance is one of the most critical elements in the nation's organ transplantation system. An OPO that is effective in procuring organs and delivering them safely to transplant centers clearly will save more lives than an ineffective one.

In passing the Organ Procurement Organization Certification Act of 2000, Pub. L. 106–505, Section 701, Congress made certain findings related to OPOs and the current re-certification process for OPOs. These findings included:

- a. Organ Procurement Organizations play an important role in increasing organ donation.
- b. The uncertainty that resulted from the Department of Health and Human Services' current certification and recertification process was actually interfering with the OPOs' effectiveness in increasing the level of organ donation.
- c. The limitations noted in the DHHS' recertification process included:
 - i. Sole reliance on population-based measures of performance that do not take into consideration a particular population's organ donation potential.
 - ii. No allowance for other outcome and process standards that may more precisely reflect each OPO's performance and potential.
 - iii. Lack of a process to appeal for recertification on either procedural or substantive grounds to the Secretary of DHHS.

The Organ Procurement Organization Certification Act required that the Secretary of DHHS promulgate regulations that incorporate certain key requirements. Those requirements have been incorporated into this proposed rule.

Congress clearly wanted the Secretary to establish a certification process that would decrease the uncertainty inherent in the current CMS certification process and improve OPO performance. The goal was to increase organ donation and the number of transplantable organs available for persons experiencing organ failure. We believe that this proposed rule establishes certification and competition processes that will meet those goals.

1. Feasible Alternatives for Competition Among OPOs for Service Areas

Under this proposed rule, OPOs may compete for an OPO's service if the OPO has been de-certified by CMS. OPOs may also compete for other OPOs' service areas at the end of each 4-year re-certification cycle. OMB Circular A–4 recommends that agencies explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. CMS believes that an important policy decision in this rulemaking is the level of competition that would be allowed between the OPOs.

Three levels of competition were considered. We have defined these alternatives, some of which are also discussed in the preamble, as:

- a. Full Competition. Every OPO that has met the re-certification criteria would be eligible to compete for another OPO's service area.
- b. Limited Competition. Only those OPOs that meet specific criteria would be allowed to compete for another OPO's service area.
- c. Restricted Competition. The only competition allowed between OPOs would be for the service area of an OPO that had been de-certified by CMS.

In this proposed rule, CMS has attempted to strike a balance between the costs of competition in terms of resource use and disruption of normal business operations and the benefits of competition, namely the ability of competition to improve performance and inspire innovative activity.

Under this proposed rule, we would select an OPO to replace an incumbent OPO if, in our assessment, the OPO could significantly increase organ donation within that service area. This assessment would be based on the past performance of the competing OPOs and our assessment of the plans to increase organ donation submitted by each competing OPO. These plans would, at a minimum:

- a. Be based on the competing OPO's experience in its own service area;
- b. Include an analysis of existing barriers to increasing organ donation in the open service area, both internal and external; and
- c. Contain a detailed description of specific activities and interventions for increasing organ donation in the open service area.

Many factors can affect organ donation rates. For example, a service area might have a large elderly population, a low motor vehicle accident rate, or a high incidence of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome

(HIV/AIDS). It is possible that cultural, ethnic, or racial factors may affect organ donation rates. For example, if there is a large immigrant population in a service area, there might be significant cultural and language barriers to donation. Therefore, an OPO that decided to compete for an open service area might need to perform significant research and data analysis to determine the barriers to increased organ donation in a particular service area. Once this analysis was completed, the OPO's staff would have to develop a detailed description of specific activities and interventions for increasing organ donation in the open service area. Therefore, the development of an acceptable bid would require the diversion of staff resources from the OPO's normal operations.

Full Competition Under Existing Regulations

Under the current Conditions for Coverage for OPOs, there was full competition for each service area at the end of each re-certification cycle (42 CFR 486.316). OPOs that did not meet the performance standards were de-certified and were not able to compete. Therefore, only OPOs that met the performance standards were permitted to compete for service areas.

Benefits of this approach: All other things being equal, greater competition between OPOs should improve performance. If an OPO knows that it is in danger of losing its service area during the recertification process, it should have an incentive to perform well. This incentive would likely cause some OPOs to develop new, innovative practices.

Costs of this approach: As explained above, the process of competing for a service area involves the expenditure of resources. However, there would be little additional effort or resource expenditure for an incumbent OPO to compete for its own area. In addition, full competition is an adversarial process. This may adversely affect the current collaborative atmosphere that exists between the OPOs.

Finally, full competition provides an opportunity for a minimally effective OPO to take over a failing OPO. Depending upon which OPOs competed for a particular service area, however, there is no guarantee that a winning OPO would have more than the minimum requirements to be re-certified, and thus the winning OPO may be unable to improve donation in the service area. Therefore, we are not proposing that OPO service areas be opened to competition from all OPOs. We have not yet quantitatively analyzed

the costs and benefits from this full competition approach, but we will do so for the final rule. However, we are requesting comment on this and other approaches that allow for more intense competition than our preferred option.

Limited Competition

Under this option, all OPO service areas would be open to competition as under the full competition option; however, only those OPOs that met specific criteria would be allowed to compete for another OPO's service area.

The specific criteria used to designate which OPOs would be eligible to compete for another OPO's service area would ensure that the competition was limited to OPOs that had demonstrated above average performance and that OPOs permitted to compete for open service areas would be measurably superior to the incumbent OPOs.

Benefits of this approach: The intent of establishing competition between the OPOs is to improve the overall performance of OPOs by allowing above average OPOs to take over the service areas of poorly or marginally performing OPOs, and to allow OPOs to bid for areas in which they have the potential to significantly outperform the incumbent OPO. The intent is not to have OPOs competing against one another when there are only marginal differences between the OPOs. Therefore, we believe the specific criteria would have to establish a measurable differential. We have not yet quantitatively analyzed the costs and benefits from this limited competition approach, but we will do so for the final rule. However, we are requesting comments on this and other approaches that allow for more intense competition than our preferred option.

Costs of this approach: Although limited competition would require fewer resources from OPOs, the competitive activities would require resources from OPOs that decide to compete for an open service area, especially a large amount of staff time. For OPOs competing for another OPO's service area, these resources would be in addition to those used to improve an OPO's performance in its existing service area.

Although fewer OPOs would be involved with limited competition, it would still be an adversarial process. We anticipate that most OPOs would soon realize who their potential competitors were and this could adversely affect the current collaborative atmosphere that exists between many of the OPOs. Although this effect would be to a much lesser extent than with full competition, the

collaborative atmosphere between some OPOs may be adversely affected by limited competition.

Thus, limited competition offers the advantage of having a better performing OPO take over the service area of an incumbent OPO that is not performing as well. It also offers the advantage of setting specific criteria to ensure that the better performing OPO has the expertise to increase organ donation in another service area. This should result in increased organ donation in the competed service area. Further, while limited competition has disadvantages, those disadvantages can be minimized.

Restricted Competition

Under this option, the only competition allowed between OPOs would be for the service areas of OPOs that had been de-certified by CMS. However, the competition would still be limited to OPOs that met specific criteria. The specific criteria would need to ensure that the competing OPOs were more than minimally performing OPOs. The intent would be to have an OPO that is performing measurably better than the de-certified OPO take over the service area.

Benefits of this approach: Limiting competition in this way would restrict competition to areas in which the expectation of significant improvement in service could be met. In addition, fewer resources would be diverted from organ procurement itself to the competitive process.

Costs of this approach: Clearly, restricted competition would severely limit the competition between OPOs. Only service areas of de-certified OPOs would be opened for competition. The service areas of minimally performing OPOs (that is, OPOs whose performance was only slightly above the performance of failing OPOs) would not be opened for competition from OPOs that had performed measurably better. Therefore, restricted competition could not improve organ donation in service areas of minimally performing OPOs.

2. Competition for De-Certified OPO's Service Area

Our preferred option for competing service areas of de-certified OPOs is limited competition, as we feel this option best balances the benefits and costs of the competitive process. However, we are soliciting comments on this conclusion. We propose that a de-certified OPO would not be allowed to compete. The competition would be limited to OPOs that met 4 out of 5 of the outcome performance measures at or above the mean in the preceding re-certification cycle. We would select an

OPO for the service area based on its success in meeting the process performance standards, as well as submission of an acceptable plan to increase organ donation in the service.

By requiring an OPO to have attained the mean or greater in 4 out of 5 outcome performance measures in the preceding re-certification cycle, we would limit competition to OPOs that had performed measurably better than the de-certified OPO. We believe such OPOs would have the expertise to take over a poorly performing OPO's service area and improve organ donation. Also, our preferred competition process would require fewer resources from the OPOs than full competition, ensure timely completion of the competitive process, and minimize disruption to operations in service areas.

3. Quadrennial Certification Competition

For the quadrennial certification competition, our preferred option is also limited competition with the following characteristics. We propose that for an OPO to compete for an incumbent OPO's service area, the competing OPO must have achieved at least 100 percent of the mean in 4 out of 5 outcome performance measures in the preceding re-certification cycle. In addition, the competing OPO's conversion rate of potential donors to actual donors must be at least 15 percentage points above the incumbent OPO's conversion rate for the preceding re-certification cycle.

This option offers two clear advantages. First, the competition is limited to at least average performing OPOs because of the requirement that an OPO must have achieved at least 100 percent of the mean in 4 out of 5 outcome performance measures for the preceding re-certification cycle. Second, OPOs permitted to compete for open service areas would be measurably superior to the incumbent OPOs due to the requirement for an OPO to have a conversion rate at least 15 percentage points greater than the conversion rate of the incumbent. These advantages provide us with the assurance that a competing OPO would have the expertise needed to increase organ donation in an incumbent OPO's service area.

This option would restrict the number of OPOs that would be eligible to compete for another OPO's service area. However, we anticipate that there would be a substantial number of OPOs that would qualify to compete.

Under this option, it is possible that a superior performing OPO could compete for the service area of an above average performing OPO. For example,

an OPO that achieved 120 percent of the mean in 4 out of 5 outcome performance measures could compete for the service area of an OPO that achieved 105 percent of the mean in 4 out of 5 outcome performance measures. However, as long as the better-performing OPO could significantly increase organ donation in the open area, we believe it would be worthwhile for the competition to take place.

In determining the necessary differential that would be required to allow competition we had two goals. The first was that we wanted the differential to be large enough to assure us that the competing OPO had the expertise to take over another service area and increase organ donation; in other words, we wanted the differential to reflect significant differences in performance. The second was that we wanted to minimize the disturbance to routine OPO operations that is inherent in the competition process.

We believe that our proposed 15 percentage point differential strikes the balance needed to achieve both of these goals. It is large enough to demonstrate that the competing OPO is performing measurably better than the incumbent OPO. It will also limit the competition to OPOs that we can reasonably expect will be able to take over another service territory and increase organ donation.

Congress clearly intended that a competitive process would reduce uncertainty and result in improved performance by OPOs. We believe that such a competition would result in an increase in organ donation and the number of transplantable organs available for patients on the waiting list. We are specifically soliciting comment, however, on modifications within our chosen limited competition framework. These options are discussed below.

Option 1

Under this option, an OPO competing for an open service area must have achieved at least 120 percent of the mean in 4 out of 5 outcome performance measures for the preceding re-certification cycle. In addition, the competing OPO must have at least a 15 percentage point conversion rate advantage over the incumbent OPO. That is, the competing OPO's conversion rate of potential donors to actual donors (the first of the five performance measures) must be 15 percentage points higher than the incumbent OPO's conversion rate.

This option would ensure that the competing OPO had above average performance and that its performance was measurably superior to the performance of the incumbent OPO. It

also would provide us with the assurance that the competing OPO had the expertise to increase organ donation in the incumbent OPO's service area.

We are, however, concerned that this option would severely restrict competition among OPOs because we anticipate that few OPOs would meet 120 percent of the mean for 4 out of 5 performance measures. In addition, since most OPOs would probably be interested only in competing for service areas in their own geographical areas, this could result in virtually no competition in certain areas of the country.

Option 2

As in the first option, option 2 would require that to compete for an incumbent OPO's service area, the competing OPO must have at least a 15 percentage point conversion rate advantage over the incumbent OPO for the preceding re-certification cycle. The advantage of this option is that the competing OPO would be required to demonstrate that it had performed measurably better than the incumbent OPO. While a variation of a few points would not be a reliable indicator of an OPO's superior quality, we believe a 15 percentage point advantage in conversion rate is a large enough difference to assure us that the competing OPO's performance is actually superior to the incumbent OPO's performance.

However, this option would not require an OPO to have achieved a certain level of performance in the outcome performance measures during the prior re-certification cycle. Thus, we are concerned that a 15 percentage point advantage is an insufficient criterion to determine whether or not a competing OPO has the expertise to perform measurably better in the incumbent OPO's service area because, under this option, an OPO that is a below average performer could compete for the service area of a poorly performing OPO. For example, an OPO that achieved 90 percent of the mean in 4 out of 5 outcome performance measures would be permitted to compete for a service area in which the incumbent OPO achieved 75 percent of the mean in 4 out of 5 outcome performance measures. While the 15 percentage point difference indicates that the competing OPO is measurably superior to the incumbent OPO, it does not require that the OPO is at a minimum an average performer.

We are concerned about an OPO with below average performance competing for the service area of another OPO because we do not believe that a OPO

that is performing below average in its own service area would have the expertise needed to increase organ donation in another OPO's service area, especially when the incumbent is performing poorly.

In addition, the competitive process itself causes disturbance in the operations of both the competing and incumbent OPOs. Each must develop an acceptable plan for the competition. This requires resources from both OPOs that may have to be diverted from their routine operations, as well as from their efforts to increase organ donation in their service areas. In order to justify the disruption to OPO operations, there should be some assurance that the competing OPO would be able to increase organ donation in the incumbent OPO's service area. With only a 15 percentage point difference and no requirement that the competing OPO be a good performer, we would not feel confident that the competing OPO would have the expertise needed to increase organ donation in the incumbent OPO's service area. Therefore, we believe that if the competing OPO is not at least an average performer, the potential for a slight improvement in the service area would not justify this disruption to the service area.

We also are requesting comments on the option of restricted competition. Under this option, the only competition allowed between OPOs would be for the service areas of OPOs that had been de-certified by CMS. The competition would be limited to OPOs that met 4 out of 5 performance measures at 100 percent of the mean or greater. These specific criteria would ensure that the competing OPOs were more than minimally-performing OPOs and that they were performing measurably better than the de-certified OPO.

Under this option, fewer resources would be diverted from organ procurement itself to the competitive process, and collaboration among OPOs would not be disturbed. However, this option would not allow for competition for the service areas of OPOs that only barely met the qualifications for re-certification.

Cost-Effectiveness and Cost-Benefit Analysis of Preferred Option

Our proposed criteria for selecting a competing OPO are success in meeting the process performance measures during the prior re-certification cycle and an acceptable plan to increase organ donation in the open service area. The minimum requirements for an acceptable plan would be:

- Demonstrate the competing OPO's experience in its own service area;
- Include an analysis of existing barriers to increasing organ donation in the open service area, both internal and external; and
- Provide a detailed description of specific activities and interventions for increasing organ donation in the open service area.

We feel that it would take a competing OPO approximately 16 hours to develop an acceptable plan. A competing OPO would need to assess the incumbent OPO's service area, determine the reasons for or the factors that affected the incumbent's performance, develop an analysis of the existing internal and external barriers to increasing organ donation in the service area, determine the specific activities and interventions the competing OPO can perform to increase organ donation, and finally, prepare and submit the plan.

CMS has not yet fully analyzed the costs and benefits of the alternatives presented above. We expect that the costs per bid assumed in this analysis will be roughly linear as the number of bids increases or decreases based on the allowed level of competition; however, the costs of preparing a bid may depend on local variation in labor rates. We expect that the benefits of competition are not linear; under limited competition, CMS would limit bids only to those situations where we expect that competition will be especially successful in improving performance. We expect that the marginal returns to competition are greater for the more restrictive limited competition options, and that the marginal returns to competition diminish as the options become more permissive. CMS plans to fully analyze the costs and the benefits of the competitive process in the final rule.

Under the statute and current OPO regulations, OPOs must be members of and abide by the rules of the OPTN (as defined in § 486.320); therefore, there is no additional burden associated with this condition.

Current OPO regulations require OPOs to have a board of directors or an advisory board with a specific membership composition. The condition for administration and governing body in this proposed rule might require an OPO to add one additional member to its board. If the tissue banks in the OPO's service area currently are represented on the board by the OPO's own tissue bank, the OPO would be required to add a member from a tissue bank that is not affiliated with the OPO. This condition would

also require OPOs to have bylaws to address potential conflicts of interest, length of terms, and criteria for selection and removal of board members. It requires an individual or a governing body to have full legal authority and responsibility for management and provision of all OPO services, including development and implementation of policies and procedures for administration of the OPO.

The economic impact to add a tissue bank member to an OPO board would be negligible because OPOs generally do not pay board members for their services. The economic impact on OPOs that do not have bylaws for their boards addressing conflicts of interest, length of terms, and criteria for selection and removal of board members would be the cost of developing such bylaws. The extent of the impact would depend on the process used to develop the bylaws. For example, at some OPOs, it is likely an executive committee of the board would develop bylaws for approval by the entire board. This process would result in little or no cost to the OPO because the bylaws would be developed by unpaid board members. However, other OPOs might include the OPO director in the development of the bylaws. In this case, there would be a cost to the OPO, based on the number of hours needed to develop the bylaws and the director's salary. We do not expect that development of bylaws would take more than a few hours, since information and advice regarding development of bylaws would be available from OPOs that already have bylaws in place for their boards.

It appears that about 70 percent of OPOs do not have bylaws for their boards addressing conflicts of interest, and approximately 22 percent do not have bylaws addressing length of terms and criteria for selection and removal of board members. This would mean that approximately 18 OPOs would need to develop bylaws addressing conflicts of interest, and approximately 46 would need to develop bylaws addressing length of terms and criteria for selection and removal of board members. Thus, under this proposed rule, OPOs would need to write 64 sets of bylaws for their boards of directors.

In one CMS Consortium, OPO Directors' salaries range from approximately \$80,000 to more than \$130,000. To estimate the economic impact, we assumed that all OPOs would choose to have their directors participate in developing bylaws for their boards, and that the development of each set of bylaws would take 8 hours of an OPO director's time. If every director made \$105,000 per year

(approximately \$50 per hour), it would cost an OPO \$400 to develop a set of bylaws, for a total of \$25,600 to develop 64 sets of bylaws. We expect that most, if not all, OPOs currently have an individual or governing body legally responsible for management and provision of OPO services. Therefore, we do not expect that there would be a cost to OPOs to implement this provision of the regulation.

It is extremely difficult to quantify the costs for OPOs of meeting the requirements for human resources. The human resources condition would require every OPO to have a medical director, although it would not specify that the medical director must be full time. We believe all OPOs have medical directors, because the OPTN states that OPOs must have medical directors who are licensed physicians and who are responsible for medical and clinical activities of the OPO. However, our proposal would require the medical director to be involved in the day-to-day operations of the OPO because he or she would be responsible for implementation of protocols for donor evaluation and management and organ placement and recovery, as well as assisting in management of donor cases if the surgeon on call were unavailable.

We believe that nearly all OPOs have a full-time medical director or one or more part-time directors whose responsibilities include implementation of protocols for donor evaluation and management and organ placement and recovery and who assist in the management of donor cases if the surgeon on call is unavailable. These OPOs would already meet the requirements of the proposed rule. In fact, we believe that every OPO in two of the CMS Consortia already fully meet this proposed requirement. However, in a very small number of OPOs, medical directors are not actively engaged in OPO operations; their participation may be limited to consulting and attending board meetings.

It is difficult to quantify the cost to these few OPOs of meeting the proposed requirement because the cost to an individual OPO would be dependent on whether the OPO needed to hire a full-time medical director, hire one or more additional part-time medical directors, or increase the hours of an existing medical director, and to what extent. Furthermore, salaries of medical directors vary widely. Some local transplant surgeons who serve as part-time OPO medical directors do not accept a salary for the services they provide to the OPO; other part-time medical directors are paid up to \$100,000 per year. A full-time medical

director may be paid less than \$100,000 or as much as \$250,000 annually.

To estimate the economic impact of the medical director requirement, we assumed that 10 percent of OPOs (6 OPOs) would need to hire a part-time or full-time medical director or increase the hours of an existing director and that, on average, each of these OPOs would need a medical director for an additional 20 hours per week. If the OPOs reimbursed the medical directors based on a rate of \$125,000 annually, it would cost each OPO \$62,500, and the total economic impact would be \$375,000.

We are also proposing to require an OPO to maintain sufficient staff to carry on essential OPO activities, such as answering hospital referral calls in a timely manner and providing information and support to potential donor families. Most OPOs have sufficient staffing to carry on essential activities; to the extent that they do not, this rule would require them to hire additional staff. However, the impact on individual OPOs would vary, depending upon their situations. For example, all OPOs in one CMS Consortium appear to have sufficient staff to carry on essential activities. In another Consortium, all but two OPOs have sufficient staff. These two OPOs are adding staff based on comparative data from successful OPOs and from the AOPO Annual Report and expect to be staffed fully by mid-2004. However, in a third Consortium, slightly more than half of the OPOs most likely would need one or two procurement coordinators or other professionals in order to have sufficient staff.

Most staff carrying on what would be considered "essential" activities (for example, procurement, hospital development, and screening of referral calls) have a medical background. Procurement coordinators are usually registered nurses (RNs), but sometimes they are social workers. In 2000, the median annual income of an RN was \$44,840, and the median annual income of medical and public health social workers was \$40,020. We have observed that procurement coordinators generally earn about \$40,000 to \$45,000 to start. Hospital development staff are sometimes RNs and sometimes individuals with public relations backgrounds. In 2000, public relations managers had a median annual income of \$54,540. Sometimes OPOs' hospital development and procurement staffs screen referral calls; however, OPOs may hire other individuals to screen calls, such as medical and nursing students or emergency medical technicians. In 2000, emergency

medical technicians had a median annual income of \$24,460.

We estimate that 10 percent of OPOs (6 OPOs) would need to add one additional professional staff person and 5 percent (3 OPOs) would need to hire 2 additional staff, for a total 12 additional staff. (This estimate includes additional staff needed to meet all proposed requirements except the QAPI requirements, which are discussed later in this preamble.) If each staff person was paid \$45,000, the total economic impact would be \$540,000.

The human resources condition also would require OPOs to provide the education, training, and supervision to their staffs necessary to furnish required services. We have found that OPOs generally offer three types of staff education and training, depending upon the size and resources of the OPO: (1) On-the-job-training; (2) in-depth training provided within the OPO, sometimes using a modular training structure; and/or (3) classroom training that, in some cases, leads to certification in procurement and transplantation.

Costs for training vary widely; however, we have found that good staff training need not be expensive. OPOs provide no-cost training to each other, in the form of on-site training sessions in hospital development, as well as opportunities for staff details and "shadowing" of staff at high-performing OPOs. UNOS Regional Forums, which are held once or twice per year in the 11 UNOS Regions, provide opportunities for staff training at a low cost (for example, \$75 per day). Since the training is held within the UNOS Region, travel costs are kept to a minimum. Two OPOs in one of the CMS Regional Consortia have elected to use modular training with demonstration and examination required to move to the next level. Training will be provided to all new and existing OPO professional staff; the cost is estimated at \$5000 per OPO. Some OPOs send their procurement coordinators for training provided by the North American Transplant Coordinators Organization, which costs approximately \$1000 to \$1500 per coordinator.

If we estimate that 25 percent of OPOs (approximately 15 OPOs) would need to provide additional education and training to their professional staff in order to meet the requirements of the proposed rule, and all 15 chose to use in-depth modular training within the OPO, the cost to each OPO would be approximately \$5,000, and the total cost for all 15 OPOs would be \$75,000.

The human resources condition would require an OPO to have a written

policy to address potential conflicts of interest for its director, medical director, senior management, and procurement coordinators. Although we expect that most OPOs have written policies in place, we know that some OPOs do not. If an OPO had to develop such a policy, it is likely it would be developed by the OPO director and would take approximately 8 hours. If the director is paid \$105,000 annually (approximately \$50 per hour), the cost to the OPO would be approximately \$400. If 25 percent of OPOs (approximately 15 OPOs) needed to develop such bylaws, the total economic impact would be \$6000.

The human resources condition also would require OPOs to maintain credentialing records for physicians and other practitioners who routinely recover organs in donor hospitals with which the OPO has agreements and ensure that all physicians and other practitioners who recover organs in hospitals are qualified and trained. We have been told by OPOs that most, if not all, OPOs have some type of process to ensure that physicians and other practitioners who recover organs are qualified.

In most cases, organs are recovered by transplant surgeons from the hospital that will perform the transplant or by physicians or technicians employed by or under contract with OPOs. OPOs that do not have a process to ensure that physicians and other practitioners are qualified and trained would incur some costs to put a process into place. An OPO would incur a cost for the staff time needed to request and review credentialing records for transplant surgeons and to request and review documentation of the qualifications of other recovery personnel.

We estimate that requesting and reviewing a record would take no more than 15 minutes. There are approximately 270 hospitals in the United States with transplant programs. Thus, each of the 59 OPOs has, on average, about five transplant hospitals in its service area. If each hospital has 20 surgeons who recover organs, an OPO would have to request and review approximately 100 records. Presuming this activity was performed by an OPO medical director making \$125,000 per year (\$60 per hour), the cost to the OPO for the medical director to spend 25 hours reviewing 100 records would be \$1500. If we estimate that 10 percent of OPOs (approximately 6 OPOs) will need to perform this activity, the total cost would be \$9000.

We have not assigned a cost for an OPO to request and review records for physicians or other recovery personnel

who work for or are under contract to the OPO because we assume the OPO would perform those activities in the normal course of business. Likewise, we have not assigned a cost for activities associated with ensuring the qualifications and training of physicians and other recovery personnel from outside an OPO's service area. The time needed to verify qualifications and training of these recovery personnel, who only occasionally recover organs in an OPO's service area, would be minimal and could be accomplished by contacting a transplant hospital to confirm that a surgeon who will recover an organ at one of the OPO's hospitals is credentialed and has privileges at the transplant hospital.

The current OPO regulations require OPOs to maintain donor records with specific data elements, although there is no requirement for how long the records must be kept. The proposed information management condition would require OPOs to include specific data elements in their records and maintain their records for 7 years. We do not anticipate a significant burden associated with this requirement because, the final rule governing the operation of the OPTN state that OPOs must maintain donor records for 7 years; thus, we expect OPOs already meet the proposed requirement.

The condition for reporting of data specifies that an OPO must provide organ donation and transplantation data as requested by the OPTN, the SRTR, and transplant hospitals. Additionally, the OPO would be required to provide data and other information directly to the Department as requested by the Secretary. The current regulations require only that OPOs report five performance data elements to us annually and "maintain and make available to CMS, the Comptroller General, or their designees data that show the number of organs procured and transplanted."

Although it appears this requirement has the potential to add a significant new reporting burden, OPOs already report a large amount of data to the OPTN (which, in turn, provides the data to the SRTR for analysis). For example, the cadaver donor registration form that OPOs are required to complete for each donor contains more than 300 data elements. Further, regulations governing the operation of the OPTN at 42 CFR 121.11(b)(2) require OPOs, as specified by the Secretary, to submit data to the OPTN. Thus, most information needed by the OPTN, the SRTR or the Secretary would already be reported by OPOs.

Although it is impossible to quantify the impact of the data reporting

requirement, as data would be requested on an as-needed basis, we believe that almost any OPO data needed by us or other agencies within the Department could be obtained from the OPTN or the SRTR. We are including this provision only to give us and other agencies the flexibility to request data from OPOs in the event that needed data cannot be obtained expeditiously from the OPTN or the SRTR. We would not request data from OPOs if the data were readily available from other sources.

However, we can quantify the impact on OPOs of reporting the four hospital-specific data elements they currently report voluntarily to the OPTN (that is, referrals, medically suitable potential donors, consents, and donors). All 59 OPOs have the capability of reporting data to the OPTN electronically. HRSA estimates that reporting the four data elements takes OPOs about 1 hour per month. If the data are entered by a data coordinator earning \$40,000 per year (approximately \$19.25 per hour), the cost to the OPO would be approximately \$231 annually, for a total cost for all 59 OPOs of approximately \$13,629.

At the recommendation of the OIG, we are including a requirement for OPOs to report hospital-specific donation data to the public. More than 90 percent of OPOs publish newsletters and annual reports to inform the public of their activities, and, most likely, OPOs will report the hospital data in their newsletters and annual reports at very little additional cost. Since all 59 OPOs maintain Internet sites, they could include the hospital data on their sites at a negligible cost.

There are provisions in the proposed condition for OPOs' relationships with hospitals that do not appear in our current regulations for OPOs. First, the condition would require an OPO to have written agreements with 95 percent of the hospitals and critical access hospitals in the OPO's service area (unless a hospital has a waiver to work with another OPO) that have both a ventilator and an operating room. We expect that OPOs already have agreements with all Medicare and Medicaid hospitals in their service areas (unless a hospital in the service area has a waiver to work with another OPO) because the hospital and critical access hospital CoPs for organ, tissue, and eye procurement (see 42 CFR 482.45 and 485.643), require Medicare and Medicaid participating hospitals and critical access hospitals to have an agreement with an OPO. We have found that most agreements between OPOs and hospitals are "generic" in nature and do not specify the OPO and hospital roles in the donation process. However,

we propose requiring OPOs to address the responsibilities of both the OPO and the hospital in implementing § 482.45 and § 485.643 and include definitions for the terms "imminent death" and "timely referral."

Many OPOs would be required to rewrite their agreements; however, we expect OPOs would develop a standard agreement that addresses OPO and hospital responsibilities and defines "imminent death" and "timely death" and would ask each of their hospitals to sign the standard agreement. We estimate that it would take an attorney 8 hours to draft a new standard agreement that the OPO could present to each hospital. The average hourly wage for an attorney is \$40; therefore, the cost to the OPO would be \$320. The total cost for all 59 OPOs to have a new standard agreement drafted would be \$18,880.

The average OPO has approximately 100 hospitals in its service area. Based on past experience, we expect that between 50 percent and 67 percent of the hospitals in an OPO's service area would sign the standard agreement with no changes. With few exceptions, the remainder of the hospitals would sign the agreements after a minimal amount of negotiation. If 50 hospitals (50 percent of the 100 hospitals in an OPO's service area) requested changes in the agreement before signing, and it took the OPO's attorney 2 hours per agreement to make the changes, it would cost the average OPO \$4000. The total cost for all OPOs to make changes in their agreements with hospitals would be \$236,000.

The condition also would require OPOs to offer annual designated requestor training to hospital and critical access hospital staffs. Although the hospital and critical access hospital CoPs give OPOs the responsibility for offering or approving designated requestor training for hospitals, very few OPOs have actually provided a significant amount of training to their hospitals. In fact, an August 2000 OIG report (Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule) criticized OPOs for not providing more designated requestor training.

Therefore, complying with this proposed requirement may add some costs for an OPO that has provided little or no designated requestor training if hospitals and critical access hospitals in its service area respond positively to the OPO's offer to provide training. However, we do not anticipate a significant economic impact because most hospitals cannot spare staff to attend training in the entire consent

process and prefer to have their OPO handle most of the consent process. Additionally, although many hospital staff act as designated requestors in a supportive or collaborative role, we expect training for the supportive or collaborative role to be significantly less extensive (and therefore less costly) than training hospital staff for a requestor role. For example, complete designated requestor training might last for 4 to 8 hours, whereas, supporter or collaborator training might last for 2 hours or less. Designated requestor training also may be provided through the use of a videotape. At least one OPO provides designated requestor training over the Internet.

Generally OPO hospital development staff (who are likely to earn about \$45,000 per year) provide designated requestor training in hospitals. If the average training session lasts 4 hours and is given at a hospital located 20 miles from the OPO, the total cost of a training session (including salaries for two trainers for preparation, travel, and training time; mileage; and preparing and printing training packets) would be approximately \$300. Based on our experience, we expect that nationwide, approximately 75 hospitals might request designated requestor training. Thus, the total economic impact would be approximately \$22,500, with an average of less than \$400 per OPO.

An OPO would be required to have arrangements to cooperate with tissue banks that have agreements with hospitals with which the OPO has agreements. OPOs would be required to cooperate in screening and referring potential tissue donors, obtaining informed consent on behalf of tissue banks, and in the retrieval, processing, preservation, storage, and distribution of tissues. Most OPOs already have arrangements with the tissue banks in their service areas that address such issues as screening and referral of tissue donors. We are proposing this requirement to address situations in which an OPO has refused to have an arrangement with the tissue bank selected by the hospital.

There are approximately 300 tissue banks in the United States (166 conventional tissue banks and 134 eye banks) or approximately 5 tissue banks per OPO service. In many service areas, the OPO owns or is affiliated with one of the tissue banks. In nearly all service areas, OPOs have arrangements with all tissue banks that have agreements with the hospitals in the service area. Based on our experience, we would expect that fewer than 5 percent of tissue banks (15 tissue banks) that do not have

arrangements with an OPO would request an arrangement.

If an OPO and tissue bank elected to have a written agreement, we would expect that the cost to the OPO of preparing the written agreement and making any changes negotiated with the tissue bank would be similar to the costs of preparing and making changes to a written agreement between an OPO and a hospital (that is, a one-time cost to the OPO of \$320 for preparing an agreement, and an additional cost of \$80 to make changes). However, unlike hospital agreements which could be standardized, we would assume that OPO/tissue bank agreements would be individualized, since it is unlikely that more than one tissue bank in an OPO's service area would request an arrangement. Therefore, the total cost of preparing each agreement and making changes would be \$400, and the cost of preparing agreements with 15 tissue banks would be \$6000.

For several reasons, we do not believe the proposed requirement to have a QAPI program will have a significant impact on a large number of OPOs. First, as stated earlier in this preamble, most OPOs have a QAPI-type program (although not all programs are sufficiently comprehensive to meet the requirements of the proposed regulation). Second, AOPO is actively encouraging all OPOs to expand and improve their programs; in fact, AOPO recently added the development of a quality improvement program to their requirements for AOPO accreditation, although the new requirements will be phased in over 3 years. Third, in November 2001, AOPO surveyed OPOs to assess its programs and found that 43 percent of the 35 OPOs that responded had designated a staff person whose primary job responsibility was coordinating and monitoring quality improvement. We have reason to believe this percentage would be much higher if the survey were performed today. Since AOPO conducted their survey, the majority of the OPO community has embraced continuous quality improvement and taken steps to integrate quality improvement into their core business structure.

Additionally, there are numerous low-cost or no-cost resources available to OPOs to develop QAPI programs, including the Breakthrough Collaborative, assistance from CMS OPO Coordinators, and the AOPO Quality Council. While we know that some OPOs will be impacted by the proposed QAPI requirement, we do not expect the impact to be significant because, at this time, all OPOs appear to be working

toward developing a comprehensive QAPI program.

We believe it is likely that approximately 20 percent of the 59 OPOs (12 OPOs) would need 1/2 of a full-time equivalent (FTE) position to bring their QAPI programs into compliance with the requirement, and 15 percent (9 OPOs) would need 1 FTE. An OPO would be likely to use an experienced individual from its hospital development or procurement staff, and we estimate that the individual would be paid approximately \$50,000 annually. Thus, the cost to each of the 12 OPOs that would need to add 1/2 of an FTE would be approximately \$25,000 per year, and the cost to each of the 9 OPOs that would need to add a full FTE would be \$50,000 per year, for a total cost of \$750,000.

In addition, the proposed requirement for QAPI would require an OPO to perform death record reviews in every Medicare and Medicaid hospital in its service area that has 150 or more beds or a level I or level II trauma center, with the exception of rehabilitation or psychiatric hospitals. Based on our experience, all OPOs routinely perform death record reviews in hospitals they consider to have significant donor potential, but an OPO's definition of "significant donor potential" may not encompass as many hospitals as the requirement in the proposed rule. To the extent that it does not, the OPO might need to increase staff hours to perform the additional death record reviews. We estimate that approximately 20 percent of OPOs (12 OPOs) may need to add 1/2 of an FTE in order to expand the number of hospitals in which it performs death record reviews. It is likely the death record reviews would be performed by RNs earning approximately \$45,000 per year, thus the cost to an OPO of adding 1/2 of an FTE to perform death record reviews would be approximately \$22,500. The total economic impact for all 12 OPOs would be \$270,000.

The proposed rule requires that an OPO's QAPI program include a written policy to address adverse events. We estimate that about 90 percent of OPOs (53 OPOs) would need to develop a written adverse event policy and that development of the policy would require 40 staff hours. We expect that the policy would be developed by professional staff, including procurement coordinators, medical directors, and OPO directors. We estimated an annual salary of \$45,000 (approximately \$22 per hour) for a procurement coordinator, \$125,000 (approximately \$60 per hour) for a medical director, and \$105,000

(approximately \$50 per hour) for an OPO director, and we averaged the three hourly rates to arrive at a cost of \$44 per staff hour to develop an adverse event policy. Therefore, the cost to one OPO of developing an adverse event policy would be \$1760 for 40 hours of work. The total cost to all 53 OPOs that would need to develop such policies would be \$93,280.

The condition for requesting consent will have little impact on OPOs. We believe all OPOs have policies for obtaining informed consent and provide training to their staffs in the informed consent process. Under the proposed conditions, some OPOs may have to broaden their informed consent policies, but there will be little resultant economic impact.

The proposed rule would require OPOs to have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor. Based on our experience, all OPOs have written protocols for donor evaluation and management and organ placement and recovery. The OPTN also has model protocols OPOs can follow for evaluation and management of potential donors. Some OPOs might need to update or change their protocols somewhat to meet the proposed requirements, but we believe the cost to individual OPOs would be negligible.

The condition for donor evaluation and management and organ placement and recovery requires the medical director from the OPO to be responsible for ensuring that the OPO has written protocols for donor evaluation and management and for ensuring the implementation of the protocols for each donor. Costs related to hiring or increasing the hours of a medical director are discussed as part of the human resources condition.

This condition also requires OPOs to establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and the transplant program. It appears that all OPOs have some type of agreement or arrangement with the transplant centers in their service areas, but often these agreements or arrangements are informal in nature. Based on our experience, we expect that developing a protocol with a transplant center as required under the proposed rule would take approximately 10 hours. There are approximately 824 transplant programs in the U.S.; therefore, each of the 59 OPOs has approximately 14 transplant

programs in its service area. If it took an OPO medical director 10 hours to develop a protocol with a transplant center and the medical director earned a salary of \$125,000 annually (approximately \$60 per hour), it would cost an OPO \$600 for development of a single protocol and a total of \$8400 to develop 14 protocols. (We assume that each protocol would be individualized.) If we assume that 70 percent of the 59 OPOs (41 OPOs) needed to develop protocols, the total economic impact would be \$344,400.

We foresee little economic impact from the proposed requirements in the condition for organ preparation and transport. We believe nearly all OPOs follow appropriate standards of practice for testing and tissue typing of organs. Developing and following a protocol for packaging, labeling, handling and shipping of organs can be done at very little added cost. For example, the cost of additional supplies for labeling inner and outer packaging of organs with the donor blood type would be negligible.

Our estimates of the economic impact on OPOs to meet the requirements in this proposed rule are as follows.

- \$25,600 to develop bylaws for OPO boards
- \$375,000 annually for medical director salaries
- \$540,000 annually for additional staff to meet human resources requirements
- \$75,000 initial cost for staff training
- \$6,000 to develop bylaws for OPO directors and other management staff
- \$9,000 to develop credentialing records for recovery staff
- \$13,629 annually to report data
- \$18,880 to develop hospital agreements
- \$22,500 for designated requestor training
- \$6,000 to develop arrangements with tissue banks
- \$750,000 annually for QAPI staff
- \$270,000 to perform death record reviews
- \$93,280 to develop an adverse event policy
- \$344,400 to develop protocols with transplant centers.

Summary of Direct Cost

Therefore, the first-year economic impact would be \$2,549,289, and the average first-year cost to each of the 59 OPOs would be \$43,208.

Benefits

The primary economic impact of this proposed rule would lie with its potential to increase organ donation. However, it is nearly impossible to predict what that impact will be.

Although many in the donation organ community believe that little can be done to increase the number of deceased donors, we would note that in 1998, the year in which the hospital CoP (see § 482.45) went into effect, organ donation increased by nearly 6 percent. Therefore, we estimate that by increasing OPOs' efficiency and adherence to continuous quality improvement measures, the provisions of this proposed rule could increase the number of organ donors by as much as 3 percent per year, resulting in an additional 180 donors in the regulation's first year. Based on 2000 data for the number of organs transplanted per donor (2.87), a 3 percent increase would result in approximately 517 additional transplants in the first year after implementation of the regulation.

Transplants are performed both to save lives and to improve the quality of recipients' lives. For end-stage renal disease patients, dialysis is an alternative to transplantation for extended periods of time. Nevertheless, physical health while on dialysis is significantly impaired, and dialysis imposes major stresses and substantial inconveniences in carrying out normal activities. Therefore, while for most patients, kidney transplantation is not necessary for survival, it significantly improves the quality of the transplant recipient's life. For all other organs, a transplant is, in most cases, necessary for survival.

Of the 17,219 transplants from deceased donors performed in 2000, slightly less than half (46.7 percent), or 8,040, were kidney transplants. Thus, we estimate that in the first year, this regulation could result in approximately 241 (46.7 percent of 517 transplants) lives vastly improved by kidney transplants and 276 (53.3 percent of 517) lives both vastly improved and prolonged by transplantation of other major organs.

The following reasoning was used to construct an estimate of the benefits of this proposed rule. It is common, in cost benefit analysis, to use a concept termed "value of a statistical life" (VSL) to estimate in monetary terms the benefits from lives saved. Estimates of this value can be derived from information on the preferences of individuals for reduction in the risk of death, and their willingness to pay for those reductions. For purposes of our cost benefit analysis, we have used a VSL of \$5,000,000. Applying this VSL, the social benefit from 276 non-renal transplants would be \$1,380,000,000.

Kidney transplantation costs are offset by reductions in other medical costs

over time, primarily dialysis costs. Since private payers generally base their payments on Medicare payment rates, we used data on Medicare payments to estimate the total cost to the economy of the additional non-renal transplants that would be performed. Below, based on 2000 payment data, are 1-year estimated costs to the Medicare program resulting from a 3 percent increase in non-renal organ transplants. Costs for intestinal transplants were not available as

Medicare did not begin paying for intestinal transplants until April 2001. However, the number was small—only 36 intestine transplants were performed in the United States in 1999. In addition, the chart does not include heart-lung, kidney-pancreas, and other multi-organ transplants, since complete data are not available for these transplants. In 1999, there were 48 heart-lung, 928 kidney-pancreas, and 120 other multi-organ transplants in the

United States, for a total, with intestinal transplants, of 1,132 transplants. Therefore, the figures below underestimate the economic impact of a 3 percent increase in the number of transplants by approximately 14 percent (1,132 is approximately 14 percent of the 15,670 heart, liver, lung, pancreas, and kidney transplants performed in 1999).

ESTIMATED ONE-YEAR COSTS OF NON-RENAL TRANSPLANTS

Organ type	3 percent increase	Cost (inpatient hospital & physician)
Heart	66	\$9,277,620
Liver	137	11,227,835
Lung	28	2,012,976
Pancreas	13	357,565
Total	244	22,875,996

In order to estimate the costs of providing post-transplant care, we turned to the Milliman and Robertson 5-year cost estimates that were used by us in the regulation for Medicare and Medicaid hospitals, Identification of Potential Organ, Tissue, and Eye Donors. They are as follows: heart, \$317,000; liver, \$394,000; lung, \$312,000; and pancreas, \$149,000. However, note that in recent years, inpatient hospital stays for heart transplant patients have increased considerably (with a resultant rise in costs), whereas inpatient stays for liver transplant patients have decreased considerably. Nevertheless, as Milliman and Robertson estimates are the only transplant data available on post-transplant costs, we used their estimates.

Based on their estimates, the 5-year costs would be as shown on the following chart.

Organ type	5-year cost
Heart	\$20,922,000
Liver	53,978,000
Lung	8,736,000
Pancreas	1,937,000
Total	85,573,000

Formal Uncertainty Analysis

As discussed elsewhere in this preamble, our best estimate of the impact of this proposed rule is a benefit of more than \$1 billion each year, based on the number of lives we expect would be saved by an increase in organ donation and transplantation due to increased OPO performance. We have

not prepared a formal uncertainty analysis for this proposed rule; however, we will prepare a formal uncertainty analysis for the final rule. Possible sources of uncertainty are the actual percentage improvement in organ donation expected by this rule and alternatives; the number of expected total donations, which varies somewhat year to year; the cost of competitive bids; the expected number of OPOs de-certified, and the number of OPOs eligible to compete based on their performance measures. We request comments on other potential sources of uncertainty.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 441

Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 486

Health professionals, Medicare, Organ procurement, X-rays.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1138(b), 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, 1395ww, and 1395(x)(v)).

§ 413.200 [Amended]

2. Section 413.200(f) is amended by removing the phrase “part 485, subpart D” and by adding “part 486, subpart D” in its place.

§ 413.202 [Amended]

3. Section 413.202 is amended by removing the phrase “as defined in § 435.302 of this chapter” and by adding “as defined in § 486.302 of this chapter” in its place.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

1. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 441.13 [Amended]

2. Section 441.13(c) is amended by removing the reference “part 485, subpart D” and adding “part 486 subpart G” in its place.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

1. The authority citation for part 486 is revised to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–g, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

2. Section 486.1 is amended by revising paragraph (a) to read as follows:

§ 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1102 and 1138(b)—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

* * * * *

3. Part 486 is further amended by revising subpart G to read as follows:

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

Sec.

486.301 Basis and scope.

486.302 Definitions.

Requirements for Certification and Designation

486.303 Requirements for certification.

486.304 Requirements for designation.

486.306 OPO service area size designation and documentation requirements.

486.308 Designation of one OPO for each service area.

486.310 Changes in ownership or service area.

Re-Certification and De-Certification

486.312 De-certification.

486.314 Appeals.

486.316 Re-certification and competition processes.

Organ Procurement Organization Outcome Requirements

486.318 Condition: Outcome measures.

Organ Procurement Organization Process Performance Measures

486.320 Condition: Participation in Organ Procurement and Transplantation Network.

486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

486.324 Condition: Administration and governing body.

486.326 Condition: Human resources.

486.328 Condition: Reporting of data.

486.330 Condition: Information management.

486.342 Condition: Requesting consent.

486.344 Condition: Donor evaluation and management, and organ placement and recovery.

486.346 Condition: Organ preparation and transport.

486.348 Condition: Quality assessment and performance improvement (QAPI).

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations**§ 486.301 Basis and scope.**

(a) *Statutory basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization (OPO) must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a “qualified” OPO and designation as the OPO for a particular service area.

(2) Section 371(b) of the Public Health Service Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(3) Section 1102 of the Act authorizes the Secretary of Health and Human Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with CMS and the basis for and the effect of termination or non-renewal of the agreement.

(4) The requirements for an OPO to be re-certified for the performance data cycle from January 1, 2002 through December 31, 2005.

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ

whose blood type does not match the blood type of the intended recipient.

Agreement cycle refers to the 4-year time period of the agreement between CMS and an OPO. To provide sufficient time for CMS to analyze outcome performance data and assign OPO service areas, the OPO agreement cycle generally begins on August 1 of the year following the end of the re-certification cycle and lasts for 4 years.

Certification means a determination by the Secretary that an OPO meets the requirements at § 486.303 and is eligible for designation if it meets the additional requirements for designation.

Death record review is an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

De-certification means a CMS determination that an OPO no longer meets one or more conditions for coverage, including the outcome measures, the process performance measures and other requirements, or no longer meets the requirements for certification or designation. In addition, if an OPO’s agreement with CMS is terminated or is not renewed, the OPO is de-certified.

Designated requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor document means any documented indication of an individual’s choice in regard to donation that meets the requirements of the governing state law.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan

Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

Organ donor potential means the number of patients whose age is 70 or less meeting death by neurological criteria, based on generally accepted practice parameters for determining brain death, who do not have any of the following clinical indications:

- (1) Tuberculosis.
- (2) Creutzfeldt-Jacob Disease or any other prion-induced disease.
- (3) Viral septicemia.
- (4) Rabies.
- (5) Reactive hepatitis B surface antigen.
- (6) Any retro virus infection.
- (7) Active malignant neoplasms, except primary central nervous system tumors and basal and squamous cell carcinomas.
- (8) Aplastic anemia.
- (9) Agranulocytosis.
- (10) Active viral and systemic fungal infections.
- (11) Gangrene of bowel.
- (12) Extreme prematurity.
- (13) Positive serological or viral culture findings for HIV.
- (14) Chagas disease.

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs.

Potential donor denominator is the basis for the OPO outcome measures. The potential donor denominator indicates the number of individuals in an OPO's service area who meet the criteria for organ donor potential.

Re-certification cycle means the 4-calendar-year cycle of outcome measure data on which an OPO's re-certification is based. The re-certification cycle begins on January 1 and ends (4 years later) on December 31.

Service area means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or more types of organ transplant centers operating within the same transplant hospital.

Requirements for Certification and Designation

§ 486.303 Requirements for certification.

In order to be certified, an organ procurement organization must:

- (a) Have received a grant under 42 U.S.C. 273(a).
- (b) Be a non-profit entity that is exempt from Federal income taxation under § 501 of the Internal Revenue Code of 1986.
- (c) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals.
- (d) Have an agreement with the Secretary to be reimbursed under title XVIII for the procurement of kidneys.
- (e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.
- (f) Have procedures to obtain payment for non-renal organs provided to transplant centers.
- (g) Agree to enter into an agreement with any hospital or critical access hospital in the OPO's service area, including a transplant hospital, that requests an agreement.
- (h) Meet or have met the conditions for coverage, including the outcome measures and the process performance measures and other requirements.

§ 486.304 Requirements for designation.

(a) *Designation is a condition for payment.* Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by the Secretary as an OPO.

(b) *Requirements for designation.* An OPO must do the following:

- (1) Be certified as a qualified OPO by the Secretary under 42 U.S.C. 273(b) and § 486.303.
- (2) Enter into an agreement with CMS that meets the requirements set forth in paragraph (c) of this section.
- (3) Document that it has a defined service area that meets the requirements of § 486.306.

(c) *Agreement with CMS.* In order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid, an OPO must

enter into an agreement with CMS. The agreement is effective upon submission by the OPO and acceptance by CMS but may be canceled by either party. If an OPO is de-certified under § 486.312, payment for organ procurement services attributable to that OPO will not be made for services furnished on or after the effective date of the de-certification. In the agreement, the OPO must agree to do the following:

(1) Maintain compliance with the requirements of titles XVIII and XIX of the Act, section 1138 of the Act, section 371(b) of the Public Health Service Act, and applicable regulations, including the conditions set forth in this subpart and the rules and requirements of the OPTN, as defined by § 486.320, and to report promptly to the Secretary any failure to do so.

(2) Become a member of the OPTN.

(3) File a cost report in accordance with § 413.24(f) of this chapter within 5 months after the end of each fiscal year.

(4) Permit CMS to designate an intermediary to determine the interim payment rate payable to transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based on the cost report in the OPO files.

(5) Provide budget or cost projection information as may be required to establish an initial interim payment rate.

(6) Pay to CMS amounts that have been paid by CMS to transplant hospitals as Medicare payment for organ recovery fees that are determined to be in excess of the reasonable cost of the services provided by the OPO.

(7) Not charge an individual for items or services for which that individual is entitled to have payment made under the Medicare program.

(d) *Application for designation.* An OPO that has met 4 out of 5 outcome performance measures at or above the mean for the previous re-certification cycle may apply for designation for the service area of an OPO that did not meet the conditions for coverage for the previous re-certification cycle. An OPO that has met 4 out of 5 outcome performance measures at 100 percent of the mean may apply for designation whenever a service area becomes an open area if the OPO's conversion rate of potential donors to actual donors is at least 15 percentage points greater than the conversion rate of the OPO currently designated for the service area.

(e) *Designation periods—*

(1) *General.* An OPO is normally designated for 4 years. A designation period may be shorter, for example, an interim designation for the service area of an OPO that has terminated its

agreement with CMS. A designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.

(2) *Re-designation.* Re-certification and re-designation must occur not more frequently than every 4 years.

§ 486.306 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Service area designation.* The defined service area either includes an entire metropolitan statistical area or a New England county metropolitan statistical area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area.

(3) The number of and the names of all hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

(d) It must procure organs from an average of at least 24 donors per calendar year in the 4 years before the year of re-designation.

§ 486.308 Designation of one OPO for each service area.

(a) CMS designates only one OPO per service area. A service area is open for competition once the existing designation period has expired or when the existing designated status of the OPO for the service area has been terminated.

(b) Unless CMS has granted a hospital a waiver under paragraphs (d) through (f) of this section, the hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located.

(c) If CMS changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in

accordance with paragraph (d) of this section within 30 days of notice of the change in designation.

(d) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients listed for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(e) In making a determination on waiver requests, CMS considers—

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the definitions of metropolitan statistical areas, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(f) A hospital may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§ 486.310 Changes in ownership or service area.

(a) *OPO requirements.* (1) A designated OPO considering a change in ownership or in its service area must notify CMS before putting it into effect. This notification is required to ensure that the OPO, if changed, will continue to satisfy Medicare and Medicaid requirements. The merger of one OPO into another or the consolidation of one OPO with another is considered a change in ownership.

(2) A designated OPO considering a change in its service area must obtain prior CMS approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the OPOs must resubmit the information required in an application for designation. The OPO must provide information specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation CMS determines to be necessary for designation.

(b) *CMS requirements.* (1) If CMS finds that the OPO has changed to such

an extent that it no longer satisfies the requirements for OPO designation, CMS may de-certify the OPO and declare the OPO's service area to be an open area. An OPO may appeal such a de-certification as set forth in § 486.314. The OPO's service area is not opened for competition until the conclusion of the appeals process.

(2) If CMS finds that the changed OPO continues to satisfy the requirements for OPO designation, the period of designation of the changed OPO is the remaining portion of the 4 year term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is the longest of the remaining periods unless CMS determines that a shorter period is in the best interest of the Medicare and Medicaid programs. The changed OPO must continue to meet the process performance measures and other requirements at § 486.20 through § 486.48 throughout the remaining period and must meet the outcome measures at § 486.318 at the end of this remaining period.

Re-Certification and De-Certification

§ 486.312 De-certification.

(a) *De-certification due to voluntary termination of agreement.* If an OPO wishes to terminate its agreement, it must send written notice of its intention to terminate its agreement and the proposed effective date of the termination to CMS. CMS may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area or otherwise interfere with the effective and efficient administration of the Medicare and Medicaid programs. If CMS determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by CMS. CMS will de-certify the OPO as of the effective date of the voluntary termination.

(b) *De-certification due to involuntary termination of agreement.* CMS may terminate an agreement with an OPO if CMS finds that the OPO no longer meets the requirements for designation or certification or the conditions for coverage in this subpart or is not in substantial compliance with any other applicable Federal regulations or provisions of titles XI, XVIII, or XIX of the Act. CMS may also terminate an

agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will de-certify the OPO as of the effective date of the involuntary termination.

(c) *De-certification due to non-renewal of agreement.* CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the condition for coverage at § 486.318 based on data from the most recent re-certification cycle or if the OPO's designation has been terminated. CMS will de-certify the OPO as of the ending date of the agreement.

(d) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of de-certification to an OPO at least 90 days before the effective date of the de-certification. In cases of urgent need, CMS gives written notice of de-certification at least three calendar days prior to the effective date of the de-certification. The notice of de-certification states the reason for de-certification and the effective date.

(e) *Public notice.* Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice of the date of de-certification and such other information as CMS may require through publication in local newspapers in the service area. In the case of involuntary termination or non-renewal of an agreement, CMS provides public notice of the date of de-certification through publication in local newspapers in the service area. No payment under title XVIII or title XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the date the de-certification is effective.

§ 486.314 Appeals.

If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive or procedural grounds.

(a) *Appeal process.* The OPO must file its appeal within 30 calendar days of the date of the notice of de-certification. In its appeal, the OPO may submit evidence to demonstrate why it should not be de-certified. Within 2 weeks of receipt of the OPO's appeal, a CMS hearing officer will schedule a hearing. The hearing officer will issue notice of his or her decision to the OPO by certified mail within 2 weeks of the hearing.

(b) *Reversal of de-certification.* If the hearing officer reverses CMS' determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, CMS will not terminate the OPO's agreement and will not de-certify the OPO at that time.

(c) *De-certification is upheld.* If the de-certification determination is upheld by the hearing officer, Medicare and Medicaid payment may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. There are no further administrative appeal rights.

(d) *Effects of de-certification.* When an OPO agreement is terminated or is not renewed, CMS will accept applications from other OPOs to be designated for the open area as set forth in § 486.316(b). An OPO that is de-certified may not apply or be designated for an open area.

(e) *Extension of agreement.* If there is insufficient time prior to expiration of an agreement with CMS to allow for competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to extend the OPO's agreement with CMS for a period not to exceed an additional 60 days.

§ 486.316 Re-certification and competition processes.

CMS opens all OPO service areas for competition at the end of every re-certification cycle.

(a) *OPO meets conditions for coverage.* When an OPO meets the outcome measures in § 486.318 and has been found to be in compliance with the process performance measures and other requirements in §§ 486.320 through 486.348, CMS will open the OPO's service area for competition. An OPO may compete for the open area only if it met 4 out of 5 outcome measures at or above 100 percent of the mean for the preceding re-certification cycle and its conversion rate of potential donors to actual donors is at least 15 percentage points higher than the conversion rate of the OPO currently designated for the service area. The OPO must compete for the entire service area. The incumbent OPO may compete for its own service area.

(b) *OPO does not meet conditions for coverage.* If CMS notifies an OPO that it will be de-certified because its agreement will not be renewed or will be terminated by CMS, and the OPO does not appeal within the time frame specified in § 486.314(a) or the OPO's de-certification is upheld on appeal, CMS will open the OPO's service area for competition from other OPOs. An OPO may compete for the open service area only if it met 4 out of 5 outcome measures at or above the mean for the preceding re-certification cycle. The OPO must compete for the entire area.

(c) *Criteria for selection.* CMS will designate an OPO for an open service area based on the competing OPOs'

degree of success in meeting the process performance measures during the preceding re-certification cycle and the submission of an acceptable plan to increase organ donation in the open service area. An acceptable plan to increase organ donation, at a minimum—

(1) Is based on the competing OPO's experience and success in its own service area;

(2) Includes an analysis of existing barriers, both internal and external, to increasing organ donation in the open area; and

(3) Provides a detailed description of specific activities and interventions for increasing organ donation in the open service area.

(d) *No OPO applies.* If no OPO applies to compete for the open area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS will make its decision based on the OPOs' success in meeting the process performance measures during the preceding re-certification cycle.

Organ Procurement Organization Outcome Requirements

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. States, U.S. territories, U.S. possessions, or U.S. commonwealths, an OPO must achieve at least 75 percent of the national mean in 4 of the 5 following performance categories, averaged over the 4 calendar years before the year of re-certification:

(1) Donors, as a percentage of the potential donor denominator.

(2) Number of kidneys procured, as a percentage of the potential donor denominator.

(3) Number of kidneys transplanted, as a percentage of the potential donor denominator.

(4) Number of extra-renal organs procured, as a percentage of the potential donor denominator.

(5) Number of extra-renal organs transplanted, as a percentage of the potential donor denominator.

(b) An OPO operating exclusively in non-contiguous U.S. States, U.S. territories, U.S. possessions, or U.S. commonwealths must meet the following outcome measures at 50 percent or more of the national mean, averaged over the 4 calendar years before the year of re-certification:

(1) Number of kidneys procured, as a percentage of the potential donor denominator.

(2) Number of kidneys transplanted, as a percentage of the potential donor denominator.

Organ Procurement Organization Process Performance Measures

§ 486.320 Condition: Participation in Organ Procurement and Transplantation Network.

After being designated, an OPO must become a member of and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary. No OPO is considered out of compliance with section 1138(b)(1)(D) of the Act or this section until the Secretary approves the determination that the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such non-compliance has been determined in this manner.

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) *Standard: Hospital agreements.* An OPO must have a written agreement with 95 percent of the hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to the requirements for hospitals at § 482.45 or § 485.643 and specify the meaning of the terms "timely referral" and "imminent death."

(b) *Standard: Designated requestor training for hospital staff.* The OPO must offer designated requestor training on at least an annual basis for hospital and critical access hospital staff.

(c) *Standard: Cooperation with tissue banks.* (1) The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:

(i) Screening and referral of potential tissue donors.

(ii) Obtaining informed consent from families of potential tissue donors.

(iii) Retrieval, processing, preservation, storage, and distribution of tissues.

(2) An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

§ 486.324 Condition: Administration and governing body.

(a) While an OPO may have more than one board, the OPO must have an advisory board that has both the authority described in paragraph (b) of this section and the following membership:

(1) Members who represent hospital administrators, voluntary health associations in the OPO's service area, and either intensive care or emergency room personnel.

(2) An individual from a tissue bank who represents all tissue banks that have agreements with hospitals with which the OPO has agreements (if such an individual is available to serve on the board). The individual must be from a tissue bank not affiliated with the OPO, unless the only tissue bank in the service area is affiliated with the OPO.

(3) Individuals who represent the public residing in the OPO's service area.

(4) A physician with knowledge, experience, or skill in the field of human histocompatibility or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(5) A neurosurgeon or other physician with knowledge or skills in neurosciences.

(6) A transplant surgeon representing each transplant hospital in the service area with which the OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the transplant hospital represented.

(b) The advisory board described in paragraph (a) of this section has the authority to recommend policies for the following:

(1) Procurement of organs.

(2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.

(3) Systematic efforts, including professional education, to acquire all useable organs from potential donors.

(4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected

with the etiologic agent for acquired immune deficiency syndrome.

(5) Appropriate tissue typing of organs.

(6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(7) Transportation of organs to transplant hospitals.

(8) Coordination of activities with transplant hospitals in the OPO's service area.

(9) Participation in the OPTN.

(10) Arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors.

(11) Annual evaluation of the effectiveness of the OPO in acquiring organs.

(12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) The advisory board described in paragraph (a) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. Members of the advisory board described in paragraph (a) of this section are prohibited from serving on any other OPO board.

(d) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.

(e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(f) The OPO must have a procedure to address potential conflicts of interest for the governing body described in paragraph (e) of this section.

§ 486.326 Condition: Human resources.

All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital

development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

(a) *Standard: Qualifications.* (1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services.

(2) The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, and senior management, and procurement coordinators.

(3) The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.

(b) *Standard: Staffing.* (1) The OPO must provide sufficient coverage, either by its own staff or under contract or arrangement, to assure both that hospital referral calls are screened for donor potential and that potential donors are evaluated for medical suitability in a timely manner.

(2) The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development.

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

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

(d) *Standard: Medical director.* The OPO's medical director is responsible for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

§ 486.328 Condition: Reporting of data.

(a) The OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data to the OPTN and the Scientific Registry of Transplant Recipients (SRTR), as directed by the Secretary. The OPO must provide

hospital-specific organ donation data to transplant hospitals, annually. The OPO must report individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Department, as requested by the Secretary. The data may include, but are not limited to—

- (1) Number of hospital deaths;
- (2) Results of death record reviews;
- (3) Number and timeliness of referral calls from hospitals;
- (4) Potential donor denominator (as defined in § 486.302);
- (5) Data related to non-recovery of organs;
- (6) Data about consents for donation;
- (7) Number of donors;
- (8) Number of organs recovered (by type of organ); and
- (9) Number of organs transplanted (by type of organ).

(b) The potential donor denominator data reported to the OPTN to be used for OPO re-certification must include data for all deaths that occurred in hospitals and critical access hospitals in the OPO's service area, unless a hospital or critical access hospital has been granted a waiver under 486.308(d) to work with a different OPO. Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the potential donor denominator data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the mistake is identified.

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

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

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

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

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

(d) The OPO must report hospital-specific organ donation data, including organ donor potential and the number of donors, to the public at least annually.

§ 486.330 Condition: Information management.

An OPO must establish and use an information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

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

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

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

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

transplant recipient records and procedural manuals and other materials used in conducting OPO operations.

§ 486.342 Condition: Requesting consent.

An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.

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

- (1) A list of the organs or tissues that may be recovered.
- (2) All possible uses for the donated organs or tissues.
- (3) The information that the individual(s) have the right to limit or restrict use of the organs or tissues.
- (4) A description of the screening and recovery processes.
- (5) Information (such as for-profit or non-profit status) about organizations that will recover, process, and distribute the tissue.
- (6) Information regarding access to and release of the donor's medical records.
- (7) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.
- (8) Information about the procedure for filing a complaint.
- (9) Contact information in case the individual(s) making the donation decision have questions.
- (10) A copy of the signed consent form if a donation is made.

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

§ 486.344 Condition: Donor evaluation and management and organ placement and recovery.

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

(a) *Donor protocol management.* (1) The medical director is responsible for

ensuring that donor evaluation and management protocols are implemented correctly and appropriately to ensure that every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

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

(b) *Evaluation.* The OPO must do the following:

- (1) Verify that death has been pronounced according to applicable local, state, and federal laws pertaining to organ donation.
- (2) Determine whether there are conditions that may contraindicate donation.
- (3) If possible, obtain the potential donor's medical and social history.
- (4) Review the potential donor's medical chart and perform a physical examination of the donor.
- (5) Obtain the donor's vital signs and perform all pertinent tests.

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

- (1) Arrange for screening and testing of the donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus.
- (2) Ensure that screening and testing of the donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.
- (3) Ensure that the donor's blood is typed using two separate blood samples.
- (4) Document the donor's record with all test results, including blood type, before organ recovery.

(d) *Standard: Collaboration with transplant programs.* (1) The OPO must establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and the transplant program for all activities associated with donor evaluation, donor management, organ recovery, and organ placement. The protocol for organ placement must include procedures to ensure that the blood type of the donor is compared with the blood type of the intended recipient by two OPO staff members before organ recovery takes place and that documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.

(2) The established protocols must be reviewed periodically with the transplant programs to incorporate best

practices in the field and maximize organ donation.

(e) *Documentation of recipient information.* Prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's position on the waiting list in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

(f) *Organ allocation.* The OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(g) *Organ placement.* The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

§ 486.346 Condition: Organ preparation and transport.

(a) The OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO must ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(b) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. Two OPO staff members must verify that the documentation that accompanies an organ to a transplant center is correct.

(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ or health of the recipient. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two OPO staff members that information listed on the labels is correct.

(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.

§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all

donation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Death record reviews.* As part of its ongoing QAPI efforts, an OPO must conduct death record reviews in every Medicare and Medicaid participating hospital in its service area that has a level I or level II trauma center or 150 or more beds (unless the hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals. When missed opportunities for donation are identified, the OPO must implement actions to improve performance.

(c) *Standard: Adverse events.* (1) An OPO must establish a written policy to

address adverse events that occur during any phase of an organ donation case. The policy must address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events.

(2) The OPO must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO's policies and practices to prevent repeat incidents.

(3) The OPO must—

(i) Report an adverse event to CMS within 10 business days of becoming aware of the adverse event; and

(ii) Provide to CMS written documentation of the investigation and analysis of the adverse event within 15 business days of becoming aware of the event.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

1. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 498.2 [Amended]

2. In § 498.2, the definition of “Supplier” is amended by removing “organ procurement organization (OPO),”.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

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Tommy G. Thompson,

Secretary.

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