

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 441, 486 and 498

[CMS–3064–F]

RIN: 0938–AK81

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

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

ACTION: Final rule.

SUMMARY: This rule finalizes the February 4, 2005 proposed rule entitled “Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs).” It establishes new conditions for coverage for organ procurement organizations (OPOs) that include multiple new outcome and process performance measures based on organ donor potential and other related factors in each service area of qualified OPOs. Our goal is to improve OPO performance and increase organ donation. In addition, this final rule re-certifies these 58 OPOs from August 1, 2006 through July 31, 2010 and provides an opportunity for them to sign agreements with the Secretary that will begin on August 1, 2006 and end on January 31, 2011. New agreements are needed so that the Medicare and Medicaid Programs can continue to pay them for their organ procurement activities after July 31, 2006.

DATES: *Effective Dates:* These regulations are effective July 31, 2006.

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I. Background

A. Organ Procurement Organizations and Their Importance

OPOs play a crucial role in ensuring that an immensely valuable, but scarce resource—transplantable human organs—becomes available to seriously ill patients who are on a waiting list for an organ transplant.

OPOs are responsible for identifying potential organ donors and for obtaining as many organs as possible from those donors. They are also responsible for ensuring that the organs they obtain are properly preserved and quickly delivered to a suitable recipient

awaiting transplantation. Therefore, OPO performance is a critical element of the organ transplantation system in the United States. An OPO that is efficient in procuring organs and delivering them to recipients will save more lives than an ineffective OPO.

The nation’s 58 OPOs are responsible for all organ recovery from deceased donors in the United States; without OPOs, organs from deceased donors will not be recovered. Without recovery of organs from deceased donors, only organs from living donors will be recovered and transplanted, and many patients waiting for organs will die.

B. 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 period, “Emergency Re-certification for Coverage for Organ Procurement Organizations (OPOs),” that re-certified all 59 (now 58) OPOs until December 31, 2005 and extended their agreements with us until July 31, 2006. (December 28, 2001, 66 FR 67109)

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 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. Moreover, section 1871 of the Act gives the Secretary broad authority to establish regulations that are necessary to carry out the administration of the Medicare program.

C. HHS Initiatives Related to OPOs’ Services

As discussed in the preamble of the February 4, 2005 proposed rule (70 FR 6086), in April 2003, the Secretary of the Department of Health and Human Services (HHS) initiated the Organ Donation Breakthrough Collaborative (the Collaborative). HHS’s Health Resources and Services Administration (HRSA) was charged with overseeing the Collaborative because HRSA’s Division of Transplantation administers the Federal contracts for the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) and has considerable experience and expertise in organ donation and transplantation. According to the Collaborative’s Web site, “The purpose of the Collaborative is to generate significant, measurable organ donation by helping the national community of organ procurement organizations and hospitals to identify, learn, adapt, replicate, and celebrate “breakthrough” practices associated with higher donation rates. Furthermore, it is designed to enhance the understanding of existing knowledge as well as contribute vital information about increasing organ donation rates.” (<http://organdonation.igsolutions.com/>).

Although the Collaborative has not yet met all of its goals, organ donation has increased significantly since the Collaborative began in April 2003. After years of single-digit annual improvements, organ donation increased by nearly 11 percent from 2003 to 2004.

All 58 OPOs are now participating in the Collaborative to varying degrees. Based upon the percentage of potential donors that become actual donors (that is, the donation rate), every OPO improved its performance after joining the Collaborative.

We believe that OPOs will sustain the gains they have made to improve their performance due to a variety of factors. We have four Regional OPO Coordinators, who work directly with

the OPOs to increase organ donation rates by assisting them in developing and implementing quality improvement programs. In addition, they also make periodic quality visits to identify areas in which an OPO needs to improve. Our Regional OPO Coordinators collaborate with HRSA, the OPOs, and the hospitals to ensure the continuous implementation of best practices identified through the Collaborative. However, it is important to note that the Collaborative is a voluntary initiative and, as such, has no enforcement mechanism.

D. Requirements for OPOs

To be an OPO, an entity must meet the applicable requirements of the Public Health Service Act (42 U.S.C. 273(b)(1)). Among other requirements, the OPO must be certified or re-certified by the Secretary. To receive payment from the Medicare and Medicaid programs for organ procurement costs, the entity must have an agreement with the Secretary. In addition, under section 1138 of the Social Security Act, an OPO must meet performance standards prescribed and designated by the Secretary. CMS is delegated the responsibility to designate each OPO for a specific geographic service area.

We re-certified the 58 OPOs through December 31, 2005 and designated each OPO for a specific geographic service area. Each OPO has an agreement with the Secretary that is valid through July 31, 2006. New agreements must be executed to extend the government's ability to make payment beyond July 31, 2006 and keep the nation's organ donation system in operation. In this final rule, we re-certify all 58 OPOs from August 1, 2006 through July 31, 2010 and re-designate them for the same geographic service areas. We will seek to enter into a new agreement with each OPO by July 31, 2006. These agreements will expire on January 31, 2011. Should an OPO not agree to sign the agreement, we would open the OPO's service area for competition from other OPOs using the procedures established in § 486.316 of this final rule.

II. Summary of the Proposed Provisions and Response to Comments on the February 4, 2005 Proposed Rule

In this final rule, we re-certify the 58 currently certified OPOs from August 1, 2006 through July 31, 2010. Each OPO will retain its currently designated service area. Since the OPOs' current agreements with the Secretary expire July 31, 2006, prior to that date, we will request each OPO to sign a new agreement with an ending date of January 31, 2011.

The February 4, 2005 proposed rule set forth new conditions for coverage for OPOs, including multiple new outcome and process performance measures based on organ donor potential and other related factors in each service area of qualified OPOs. We proposed new standards with the goal of improving OPO performance and increasing organ donation. We published the proposed rule with a 60-day public comment period ending on April 5, 2005. However, because individuals and organizations requested additional time for analysis of our proposals, we extended the comment period for an additional 60 days to June 6, 2005. We received 129 timely comments on the proposed rule. Interested parties that commented included: National organizations that represent OPOs, transplant surgeons and physicians, and organ procurement and transplant coordinators; state hospital associations and health departments; OPOs; tissue banks; medical examiners and coroners; large donor and transplant hospitals; Federally contracted organizations that oversee the nation's organ donation and transplantation systems; researchers; members of the public; and others. Below we provide a brief summary of each proposed provision, a summary of the public comments we received, and our responses to the comments.

Donation After Cardiac Death

We did not include any requirements for donation after cardiac death in our proposed rule. However, commenters expressed concern that the proposed rule did not address donation after cardiac death, pointing out that recovering organs from DCDs has increased in recent years and that recovering organs from DCDs will help address the shortage of organs for transplantation.

We agree that we should not ignore a practice that is becoming increasingly common across the United States and that has the potential to increase the supply of transplantable organs significantly. While commenters did not recommend specific requirements that we should consider including in the final rule, we believe donation after cardiac death is best addressed in three separate sections: § 486.322, Relationships with hospitals, critical access hospitals, and tissue banks; § 486.328, Administration and governing body; and § 486.344, Evaluation and management of potential donors and organ replacement and recovery. First, at § 486.322, we require that an OPO's agreement with its hospital must describe the responsibilities of both the OPO and the

hospital or critical access hospital in regard to donation after cardiac death, if the OPO has a protocol for donation after cardiac death. Second, at § 486.328, we require that an OPO's policies must state whether the OPO recovers organs from donors after cardiac death. Finally, at § 486.344, we require any OPO that recovers organs from donors after cardiac death to have a protocol that establishes the following: (1) Criteria for evaluating patients for donation after cardiac death; (2) withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support; (3) the use of medications and interventions not related to withdrawal of support; (4) the involvement of family members prior to organ recovery; and (5) criteria for declaration of death and the time period that must elapse prior to organ recovery. We have finalized these requirements to facilitate our oversight of donation after cardiac death, not specifically to encourage OPOs to recover organs from cardiac dead donors. In addition, we are requiring an OPO to address recovery and placement of organs from cardiac dead donors in the protocols it establishes in collaboration with the transplant hospitals in its service area. We expect OPOs to establish clear, effective protocols that address the unique nature of donation after cardiac death, include appropriate safeguards to protect the rights of the potential donor and the family of the potential donor, and are based on current technologies and practices in the field. We must emphasize that these requirements do not mean that an OPO must recover organs from donors after cardiac death. We understand that donation after cardiac death is an evolving practice and is not yet accepted in every area of the country. Some donor hospitals are reluctant to permit donation after cardiac death in their facilities and some transplant surgeons are unwilling to transplant organs from such donors into their patients. Thus, some OPOs are hesitant to advocate donation after cardiac death in their service areas.

Basis and Scope (Proposed § 486.301)

In the February 4, 2005 proposed rule, our proposed basis and scope was unchanged from the current regulations, except for adding a reference to section 1102 of the Social Security Act and adding the term, "non-renewal" to (b)(3) to clarify that the scope included the non-renewal of the agreements OPOs' have with the Secretary.

We received no comments on this section of the proposed regulation. However, upon review, we determined

that § 486.301(b)(4) needed to be revised. The existing section includes a performance data cycle from January 1, 2002 through December 31, 2005. However, this time period has expired, and this final regulation will be in effect for future re-certification cycles. We have revised § 486.301(b)(4) to clarify that the scope of the subpart sets forth "The requirements for an OPO to be re-certified." Further, we have added a reference to section 1871 of the Social Security Act, which is listed as one of the authorities for part 486.

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 proposed several amendments and additions to the existing definitions in part 486. For a detailed discussion of our proposed definitions, see the February 4, 2005 proposed rule. (70 FR 6089–6090)

Definitions Adopted as Proposed

We are finalizing the following terms and their definitions as proposed: "adverse event," "death record review," "designation," "donor," "donor document," "entire metropolitan statistical area," "open area," "organ," and "organ procurement organization." Further discussion of the definition of "adverse event" can be found in this preamble under "Quality Assessment and Performance Improvement (QAPI) (Proposed § 486.348)."

Summary of Changes to Definitions Based on Public Comments

We have provided the following summary of changes to our proposed definitions in response to public comments:

- We revised the proposed definition of "certification" with minor clarifying changes that are discussed in this preamble under "Certification (proposed § 486.303)."
- We revised the proposed definition of "de-certification" by removing language related to specific conditions, measures, and requirements and revising it so that it is consistent with the definition of "certification."
- We have amended the proposed definition of "designated requestor" by adding language to state that the terms a "designated requestor" and "effective requestor" are interchangeable. These terms are discussed more completely in the comments and responses in this section.
- We have revised the term "service area" to "donation service area (DSA)," so that our terminology is consistent with the terminology generally used and

accepted in the OPO and transplant communities. We have adopted the definition as proposed.

- We have revised the proposed definition for "re-certification cycle" to mean the 4-year cycle during which an OPO is certified, because the OPO re-certification cycle is not based on the calendar year in this final rule.
 - We are adding the following definitions to this final rule: "donor after cardiac death (DCD)," "eligible death," "eligible donor," "expected donation rate," "observed donation rate," and "standard criteria donor (SCD)." These terms were not proposed in our February 4, 2005 rule. Because we will be using data from the OPTN and the SRTR in assessing whether OPOs have satisfied these outcome measures, we are adopting the definitions currently used by the OPTN and SRTR in their statistical evaluation of OPO performance. Adopting these definitions should ensure their consistent interpretation and application and promote the uniform and consistent reporting of data to the OPTN. These definitions are integral to understanding the new outcome measures in this final rule. A discussion of the outcome measures, along with the public comments and our responses can be found in this preamble under "Section 486.318 Outcome Measures."
- We have added the term "donor after cardiac death (DCD)," which means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death also may be termed a non heartbeating or asystolic donor.

The OPO Certification Act requires the Secretary to base both outcome measures and process performance measures on "organ donor potential" in each OPO service area. (See 42 U.S.C. 273.) We have added the term "eligible death," to replace the proposed terms "organ donor potential" and "potential donor denominator." Commenters urged us to standardize the use of these terms to conform them to the terms used by the OPTN and the SRTR. Therefore, we are adopting the term "eligible death." Although it is recognized that this definition does not include all potential donors, for reporting purposes for outcome measures performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local

acceptance criteria or transplant center practice, who exhibits none of the following:

Active Infections (Specific Diagnoses)

Bacterial

Tuberculosis.
Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.

Viral

HIV infection by serologic or molecular detection.
Rabies.
Reactive Hepatitis B Surface Antigen.
Retroviral infections including HTLV I/II.
Viral Encephalitis or Meningitis.
Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia.
Acute Epstein Barr Virus (mononucleosis).
West Nile Virus infection.
Severe acute respiratory syndrome (SARS).

Fungal

Active infection with *Cryptococcus*, *Aspergillus*, *Histoplasma*, *Coccidioides*.
Active candidemia or invasive yeast infection.

Parasites

Active infection with *Trypanosoma cruzi* (Chagas'), *Leishmania*, *Strongyloides*, or *Malaria* (*Plasmodium* sp.).

Prion

Creutzfeldt-Jacob Disease.

General [Exclusions to the Definition of Eligible]

Aplastic Anemia.
Agranulocytosis.
Extreme Immaturity (<500 grams or gestational age of <32 weeks).
Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease.
Previous malignant neoplasms with current evident metastatic disease.
A history of melanoma.
Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma.
Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation.
Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis.
We have added the term "eligible donor," which means any donor that

meets the eligible death criteria. The number of eligible donors is the numerator for the donation rate outcome performance measure.

We have added the term “expected donation rate,” which the OPTN defines as the rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, CMS Case Mix Index, total bed size, number of ICU beds, primary service, presence of a neurosurgery unit, and hospital control/ownership, with an additional adjustment made for the expected notification rate. This definition corresponds to the SRTRs’ definition of “expected donation rate (hospital characteristics, notification rate).” We have added the term “observed donation rate,” which is the number of donors meeting the eligibility criteria per 100 deaths. The SRTR uses the expected donation rate and the observed donation rate to calculate the SRTR-based donation rate, which is one of the three outcome measures in this final rule.

We have added the term, “standard criteria donor (SCD),” which means a donor who meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor. Note that we are not including a definition of “expanded criteria donor” in this final rule because it is likely that the OPTN and SRTR will change the criteria for expanded criteria donor in response to changes in transplant technology.

We proposed that CMS can terminate an OPO in cases of “urgent need” and we have finalized this proposal at § 486.312(b). In response to comments, we have added a definition for “urgent need.” Urgent need occurs when an OPO’s noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual organ donor or an organ recipient. Discussion of the definition can be found in this preamble under “De-Certification (proposed § 486.312).”

Following is a summary of the public comments we received on our proposed definitions, along with our responses to the comments.

Comment: Several commenters noted that the term “designated requestor” is no longer used in the organ donation community. Commenters said that under the Collaborative, OPOs and hospitals refer to the person who fulfills the “designated requestor” role as an “effective requestor,” and they urged us

to adopt this term in the final OPO regulation. Some commenters said that hospitals are concerned that they may be cited by surveyors if their records show an “effective requestor” was involved in the consent process rather than a “designated requestor.”

Response: Under the Collaborative, an “effective requestor” is an individual who has demonstrated effectiveness and expertise in requesting donation from families of potential donors. The individual may be an OPO employee or hospital employee or another individual and may have received formal classroom training in requesting organs or less formal education and guidance from OPO staff. The person who will be the most effective requestor varies, depending upon the family and the specific donation situation. We will continue to use the term “designated requestor” because the hospital condition of participation (CoP) for organ, tissue, and eye procurement at § 482.45 includes the term “designated requestor.” However, we have revised the definition in § 486.302 to clarify that we regard the terms “designated requestor” and “effective requestor” to be interchangeable.

Comment: Many commenters said that there should be both a standardized definition of “organ donor potential” (termed “eligible deaths” by the OPTN and SRTR) as well as consistent and uniform application of that definition throughout the OPO community. As some commenters pointed out, we proposed using outcome measures data submitted to the OPTN for re-certifying OPOs. However, the proposed definition for

“organ donor potential” in the February 4, 2005 rule was not consistent with OPTN’s definition of “eligible deaths” or “eligible donors.” A national organization stated that different definitions, may “cause confusion in the field and lead to mistakes and inaccuracies.” However, the national organization submitted a recommended definition of “organ donor potential” that is different both from our proposed definition, as well as from the OPTN’s definition of “eligible death.”

Response: We agree that for the data to be accurate and consistently reported, the terms and definitions should be standardized to the greatest extent possible. Based on the public comments that emphasized the importance of uniform and consistent reporting of organ donor potential to the OPTN, we are adopting the OPTN term “eligible deaths” and its definition, instead of the proposed term “organ donor potential” and its proposed definition. We believe that other provisions in this final rule,

specifically, the requirements for death record reviews and reporting data, also will promote the consistent interpretation and application of “eligible deaths.”

Comment: Most comments we received on the definitions concerned the definition of “organ donor potential.” Most of these comments were favorable, with many commenters saying that they were pleased with the shift away from “donors per million population” to our emphasis on “organ donor potential.” Some indicated that the proposed definition is a far superior method of defining “donor potential” than the previous “donors per million population.”

Response: We appreciate the support expressed by commenters for basing OPO outcome measures on the organ donor potential in an OPO’s service area, rather than continuing to use a population-based approach, and we agree that it will be a more accurate measure of the donor potential in a DSA. As stated previously, we are using the term “eligible deaths” instead of “organ donor potential” because it is consistent with the OPTN and SRTR definition.

Comment: Two commenters were supportive of the exclusion of donors after cardiac death (DCDs) from the definition of “organ donor potential.” One commenter said that “DCD organs are still experimental” and that there needs to be “more scientific facts and long-term follow-up before we can honestly assure our patients that utilization of these kidneys is in their best interest long-term.” Another commenter noted that DCDs only represented 5 percent of the organs recovered in 2004. The commenter also noted that the recovery and transplantation of organs from DCD organs is not a common practice throughout the United States. The commenter said it would be premature to include DCDs in the standardized definition of “organ donor potential.” However, one commenter encouraged us to include DCDs in the potential donor pool.

Response: Although the number of DCD organs recovered and transplanted has increased significantly in recent years, we acknowledge that the procurement and transplantation of DCD organs is not a common practice throughout the United States and that some surgeons have concerns about using these organs. The OPTN’s current definition of “eligible deaths” does not include DCDs, and we are using the OPTN definition in this final rule. DCDs will be discussed further in this preamble under “Donor Evaluation and

Management and Organ Placement and Recovery (proposed § 486.344)."

Comment: One OPO was concerned about our including specific exclusionary criteria in the definition of "organ donor potential." That commenter noted that changes to the definition "would require a change through regulatory process." This commenter suggested we refer to the United Network for Organ Sharing's (UNOS) definition and "designate their guidelines as the clinical indications for OPOs to follow." (Note that UNOS is the Federal contractor that currently administers the OPTN.)

Response: To be enforced by CMS, rules and requirements of the OPTN (that is OPTN policies and bylaws, which include definitions of terminology used by the OPTN and its members) must be approved formally by the Secretary by being published in the **Federal Register** with an opportunity for the public to comment. However, no policy or bylaw of the OPTN has been approved by the Secretary in this manner. In most instances, we must include the specific language of the OPTN policy or bylaw in order to make it a requirement.

We acknowledge that because we are including some of the definitions used by the OPTN and SRTR, we may need to make changes to our definitions through future rulemaking if the OPTN and SRTR change their definitions. We will be monitoring these changes as they occur and will undertake further rulemaking if necessary.

Comment: Two commenters noted that the "organ donor potential" guidelines offered in the February 4, 2005 proposed rule would not cover all of the potential donor situations. One commenter suggested that there be some type of forum in which questionable cases could be presented and "an opinion rendered" as to whether or not it is a reportable "eligible death."

Response: We agree that the definition of "eligible death" may not cover all potential donor situations. We will work with HRSA to determine whether a procedure can be established to assist OPOs that are unsure whether a particular potential donor situation should be characterized as an "eligible death."

Comment: Two commenters recommended that we modify the definition of "donor" to include pancreata procured for islet cell transplantation or research pursuant to the requirements of the Pancreatic Islet Cell Transplantation Act of 2004 (Pub. L. 108-362).

Response: The Pancreatic Islet Cell Transplantation Act of 2004 states that

"* * * [p]ancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or re-certification." We have chosen not to modify the definition of "donor" in § 486.302 because there is nothing in the definition that precludes us from counting pancreata used for islet cell treatment for re-certification of OPOs. However, we are making other changes to the certification process to comply with this statute. We will count pancreata recovered for use in islet cell transplantation and research in the organs transplanted per donor and organs used for research per donor yield measure in this final rule. Outcome measures for pancreata used for islet cell transplantation and research are discussed in more detail in this preamble in the "Outcome Measures section (proposed § 486.318)."

Requirements for Certification (Proposed § 486.303)

In § 486.303, we proposed requirements that an OPO must meet to be certified. We proposed that an OPO must: Have received a grant under 42 U.S.C. 273(a); be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986; 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; have an agreement with the Secretary to be reimbursed under title XVIII for the procurement of kidneys; have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005; have procedures to obtain payment for non-renal organs provided to transplant centers; 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; and, meet or have met the conditions for coverage, including the outcome measures and the process performance measures.

We received few comments that specifically related to these proposed provisions. However, we requirements in § 486.303 as a result of revisions we made to the designation requirements in § 486.304 and to the de-certification requirements in § 486.312, based on comments on the proposed de-certification process. A detailed discussion of the changes to our proposed de-certification requirements are discussed in the preamble section that addresses § 486.312.

Comment: Commenters stated that the proposed requirement that an OPO must "have a grant under 42 U.S.C. 273(a)" as a requirement for certification is inaccurate and conflicts with the preamble language (page 6086, column 3, paragraph 3), 42 U.S.C. 1320B-8(b)(1)(A), and proposed § 486.303(a). They said that section 1320B-8(b)(1)(A) of the statute clearly provides that an OPO is qualified if it has received a grant or is otherwise certified by the Secretary. Commenters stated that the preamble correctly reflects the statutory requirement, but the proposed requirement does not. Commenters further stated that the proposed requirement at § 486.303(a) seems to make it a mandatory requirement instead of an alternative requirement.

Response: We agree with the commenters that 42 U.S.C. 1320B-8(b)(1)(A) includes an alternative requirement. Therefore, we are revising § 486.303(a) to state that in order to be certified as a qualified OPO, an OPO must have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO.

Requirements for Designation (Proposed § 486.304)

The existing regulations include requirements for designation of OPOs in two separate sections: § 486.304 and § 486.306. We have revised § 486.304 by moving some requirements to other sections of the rule. For a list of the organizational changes, see our crosswalk in section III—"Provisions of the final rule." For a detailed discussion of our proposed provisions for § 486.304, see the February 4, 2005 proposed rule (70 FR 6131.)

Only one comment was received on our proposed provisions in § 486.304. However, we received many comments containing major concerns about the de-certification requirements in § 486.312. The revisions that we made to § 486.312 based on the comments resulted in changes to § 486.304. (See the comments and responses in this preamble under "De-Certification (proposed § 486.312)" for a discussion of these changes.) Following is a summary of the comment on proposed § 486.304 and our response.

Comment: One commenter stated that to compete for an open area, OPOs should be required to meet all five, instead of only four of the outcome measures. The commenter stated that such a requirement would be helpful in addressing the concern that these outcome measures would create an incentive for OPOs to procure as many

organs as possible, including organs from extended criteria donors (ECDs) and donation after cardiac death (DCD) donors, regardless of whether they can be transplanted, and without considering graft and recipient outcomes.

Response: In this final rule, requirements for choosing an OPO when a donation service area is open have been moved to § 486.316 and revised in the context of the re-certification and competition processes in this final rule. In response to comments, we are changing the outcome measures significantly, as well as the standards for an OPO to compete for an open area. To be re-certified, an OPO is required to meet all three of the outcome measures in this final rule. A complete discussion of these competition standards can be found in “Re-Certification and Competition Processes (proposed § 486.316)” in this preamble.

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

We proposed several changes to the requirements in this section. We proposed that OPOs would no longer be required to provide population data to us since population would no longer be used as a basis for OPO certification. Although, we proposed retaining the requirement that an OPO must procure organs from an average of at least 24 donors per calendar year, we proposed changing 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. We proposed no longer permitting exceptions to the 24-donor per year rule.

Additionally, we proposed removing obsolete service area size standards for periods during 1996 and before. Finally, we proposed increasing the designation period from 2 years to 4 years to conform the designation period to the re-certification cycle.

Following is a summary of the comments we received and our response.

Comment: Some commenters recommended that CMS continue to allow an exception to the 24-donor requirement for Hawaii. One commenter pointed out that Hawaii is an island State that has only one hospital that performs transplants (kidney, liver, pancreas, and heart). In addition, the commenter stated that the next closest transplant center is 2000 miles away on

the mainland. Furthermore, there are few transplant surgeons in Hawaii and only one each for heart, liver, and pancreas. The commenter noted that if these surgeons are out of State, certain organs are not recovered because they cannot be transplanted.

Response: After reviewing the comments on this proposed provision, we considered retaining the 24-donor rule with an exception for an OPO whose service area includes Hawaii and does not include any part of the continental United States. However, OPOs on average now recover 130 donors per year. We believe it is unlikely that any OPO other than Hawaii would have difficulty surpassing the 24-donor threshold. Further, because of the unique challenges presented by recovering and placing organs so far from the mainland, we believe we would be likely to grant an exception to Hawaii if it failed to achieve the 24-donor threshold. Therefore, we have concluded that the 24-donor rule is no longer useful or necessary as a measure of the “sufficient size” of an OPO service area. We have revised this final rule accordingly by removing the 24-donor-per-year requirement.

Comment: One commenter stated that OPOs should be designated in a manner that optimizes organ recovery and allocation. The commenter pointed out that service areas have developed over the years in a manner that may not yield the best results and urged CMS to develop a long-term vision for a logical and productive way to divide the country among OPOs, using either a statewide system or a system reflecting optimal allocation units, based on research. The commenter predicted that such systems would make comparisons between OPOs more meaningful and urged CMS to use the final rule (CMS-3064-F) to move toward that goal.

Response: We appreciate the comment; however, we are unaware of any definitive research that would guide us in re-drawing the boundaries of the present OPOs in a manner that is both consistent with the statute and more likely to yield better results. Furthermore, based on our experience, we believe any attempt to implement a system that would require us to remove territory from one OPO’s service area to give it to another OPO would result in confusion that could negatively impact organ donation.

We received no comments on our other proposals under this section. We proposed removing the language from the existing regulations 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 proposed removing references related to designation of requirements for entities or organizations that are not currently OPOs. No commenters opposed this change, and we have adopted it as proposed.

We proposed a number of other relatively minor changes to the existing § 486.307. We proposed removing obsolete service area size standards for periods during 1996 and before. We proposed changing the current requirement that OPOs must submit information about acute care hospitals in their service areas that have an operating room and the equipment and personnel to retrieve organs, to a requirement that OPOs submit information about hospitals that have both a ventilator and an operating room (because in proposed § 486.320, we proposed requiring OPOs to have agreements with 95 percent of such hospitals). Finally, we proposed increasing the designation period from 2 years to 4 years to conform the designation period to the re-certification cycle. Because we received no public comments on these changes, we are adopting them as proposed.

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

We proposed no substantive changes to the current § 486.316, “Designation of one OPO for each service area,” with the exception of replacing the “tie-breaker” criteria used to designate an OPO when two or more OPOs apply for the same area. We did, however, propose re-locating these criteria to § 486.316 (“Re-certification and Competition Processes”). In addition, § 486.308(b) through § 486.308(f) has been re-designated as § 486.308(c) through § 486.308(g) and § 486.308(b) has been added. Newly added paragraph (b) was relocated from § 486.304(c) as part of our reorganization and clarification in this final rule of the sections that address certification and designation.

We received public comments about the process for a hospital to seek a waiver to work with an alternate OPO, even though we did not propose changing these regulations. Under section 1138(a)(2)(A) of the Social Security Act and the OPO regulations at 42 CFR 486.316(e) through (g), 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 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.

In making a determination on a request, CMS may consider: (1) Cost effectiveness; (2) improvements in quality; (3) changes in a hospital's designated OPO due to changes in the metropolitan statistical area designations, if applicable; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

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.

Comment: A few commenters recommended that we clarify "appropriate purposes" for waivers to avoid attempts at "cherry picking" or at influencing organ allocation patterns without considering patient access to organs. The commenters' recommended criteria would require a hospital to have certain organ donation policies and procedures in place before being eligible to apply for a waiver and would require CMS to take factors into consideration that are not included in the statute or in current regulations. One commenter said that there should be a presumption against creation of new waivers. The commenter recommended that the burden of proof for a hospital to show that it should receive a waiver to work with a different OPO should be high, and a waiver should be granted only if CMS finds a "material deficiency." Another commenter said that the waiver program should emphasize improved outcomes.

Commenters recommended that to seek a waiver to work with an alternate OPO, a hospital should be required to: (1) Have written policies and procedures to address its organ procurement responsibilities; (2) document that the hospital's governing body has approved the hospital's organ procurement policies; (3) integrate the organ, tissue, and eye donation program into the hospital's quality assessment and performance improvement (QAPI) program; and (4) have policies to ensure that potential donors are identified and declared deceased within an acceptable time frame by an appropriate practitioner.

Commenters also recommended that we incorporate a variety of additional considerations in our review process to determine whether to grant a waiver, such as the outcome of the most recent Joint Commission on Accreditation of Healthcare Organization's (JCAHO) review of the hospital's accreditation status and whether the hospital has policies and procedures in place so that any failure to identify a potential organ donor and/or refer such a potential donor to the OPO in a timely fashion would be investigated and reviewed by the hospital in a manner similar to that for other major adverse healthcare events.

Response: The waiver request process is open and transparent. By statute, we publish all pertinent information in a **Federal Register** Notice, giving the OPOs involved in the request and the public an opportunity to comment. Generally, we approve the request if the hospital requesting the waiver can demonstrate that the waiver is expected to increase organ donation and that 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.

Some of the commenters' recommendations for factors we should consider when making a decision on a waiver request currently are requirements hospitals must meet to participate in Medicare. Thus, adding these requirements to the waiver process would be duplicative. Other recommendations made by the commenters currently are not requirements hospitals must meet to participate in Medicare. We do not believe it would be fair to expect a hospital to meet requirements that fall outside the Medicare hospital conditions of participation in order to receive a waiver to work with an alternate OPO.

While we appreciate the comments, the commenters' recommendations would slow the waiver process and make it more difficult for hospitals to obtain a waiver. We believe making these changes in the process could harm organ donation by forcing a hospital to continue to participate in a difficult and unproductive relationship with an OPO and would weaken an incentive OPOs now have to provide superior services to the hospitals in their service areas. We are not adopting any of the suggested changes, which would appear to add additional burdens on hospitals and seem to be intended to discourage a hospital from exercising the rights that

the Congress provided in section 1138 of the Social Security Act.

Re-Certification From August 1, 2006 Through July 31, 2010 (§ 486.309)

We included language in our February 4, 2005 proposed rule for a time period that has now expired. Under this final rule, the first re-certification cycle for the 58 OPOs is August 1, 2006 through July 31, 2010. We are revising the language in § 486.309 accordingly.

Comment: Many commenters stated that they understood that the proposed outcome measures would not be applied retrospectively for the period of time from January 1, 2002 to December 31, 2005. Many other commenters wrote to us urging that the proposed performance measures not be applied retrospectively, and they urged us to establish a transition period before implementing any performance measures that would be contained in a final rule. Prior to publication of the February 4, 2005 proposed rule, many individual OPOs and their national association contacted us to express their concerns about the impending expiration of their certifications and to urge us to take action to ensure that OPOs would continue to be certified so there would be no disruption in service. A commenter noted, "The timing of these proposed regulations (given the passage of the legislation in 2000) creates the need for an interim course of action." Another commenter stated, "we are now in the 41st month of a 48 month review process."

Response: We agree with these commenters that the proposed performance measures should not be applied to evaluate an OPO's performance for the period of January 1, 2002 to December 31, 2005. As discussed earlier in this preamble, after careful deliberation concerning how to re-certify the existing 58 OPOs for the next re-certification cycle, we have decided that the most prudent course of action is to re-certify all existing OPOs from August 1, 2006 through July 31, 2010 and offer to extend their agreements with the Secretary through January 31, 2011, so that OPOs can maintain their present organ procurement functions. Therefore, we have revised § 486.309 accordingly.

Changes in Ownership or Service Area (Proposed § 486.310)

In § 486.310, we proposed that a designated OPO considering a change in ownership or in its service area must notify CMS before putting it into effect. In addition, we proposed that 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. The proposed provisions in this section were based on existing regulations.

We received only a few comments on this section, which are summarized below.

Comment: One commenter said that control, not ownership, is relevant to nonprofit corporations. The commenter recommended that we add the word "control" and a definition to paragraph (a).

Response: We appreciate the commenter's recommendation. Since all OPOs must be non-profit, we have added the word "control" to § 486.310(a) to clarify that this section applies to changes in the control over an OPO, as well as changes in ownership or in an OPO's service area. The term "control" is defined in § 413.17(b)(3), and we have added a cross reference in the regulations text for this final rule.

Comment: A commenter noted that this section does not contain a time frame within which we must make our decision to approve a change of ownership. The commenter suggested that we should require the OPO to provide 15 or 30 days notice of the impending change to us and that we should make our determination within 30 days of receipt of the information we request. The commenter said that this time frame would eliminate the uncertainty of a possible CMS challenge under paragraph (b) and would not hold up the consummation of a change of ownership or control transaction.

Response: We appreciate the comment. We will make a decision as soon as practical after receiving all the information we request from the OPO. However, every case is different, and it is not possible for us to specify a time frame within which we are able to make a decision.

Comment: A commenter stated that the information that we require under paragraph § 486.310(a)(2) should be only that information which is required for designation.

Response: The circumstances surrounding each change of ownership or merger are different, which may create the need for additional information. Thus, we have retained the language in (a)(2), which specifies that we may require "other written documentation CMS determines to be necessary for designation."

De-Certification (Proposed § 486.312)

We proposed de-certification requirements based on voluntary or involuntary termination of an agreement or non-renewal of an agreement. For a

detailed discussion of our proposed provisions, see the February 4, 2005 proposed rule (70 FR 6086).

We did not receive any comments on our proposed requirements for § 486.312(a) De-certification due to voluntary termination of agreement. Therefore, we made only a few minor conforming changes in the final rule.

In contrast, commenters expressed concerns regarding the two proposed involuntary de-certification process provisions at § 486.312(b), De-certification due to involuntary termination of agreement (that is, during the term of the agreement), and at § 486.312(c), Non-renewal of agreement (that is, at the end of the term of the agreement). Therefore, we have made revisions to § 486.312(b) and (c). We did not receive comments regarding § 486.312(e) Public notice. Therefore, we made only one minor clarifying edit in that subsection of the final rule.

Comment: Commenters stated that the statute requires that re-certification (and by inference de-certification) decisions be based on multiple outcome and process performance measures. Commenters stated that based on the proposed involuntary de-certification processes, an OPO could be de-certified based on non-compliance with a single certification requirement or, if it complies with all of the certification requirements, a single designation requirement. Commenters expressed concerns that the proposed § 486.312(b), De-certification during the term of the agreement, and § 486.312(c), De-certification due to non-renewal of agreement, permit de-certification based upon considerations not authorized by the OPO Certification Act.

Response: We disagree with the commenter's premise. The OPO Certification Act requires the Secretary to establish "multiple outcome measures as part of the certification process," and we are doing so. However, the Organ Procurement Organization Act did not define the terms "certification," "re-certification," or "de-certification." Moreover, the Congress did not suggest that an OPO could not be de-certified if the OPO violated other regulatory conditions of coverage, such as failure to ensure that donors are tested for human immunodeficiency viral markers. Nothing in the legislative history suggests that the Congress intended to continue to pay an OPO that violated such a condition for coverage. Rather, the legislative history suggests that the Congress was concerned with end-of-cycle de-certifications caused by an OPO's failure to meet the performance standards established at § 486.310, and

that were expressly authorized under section 1138(b)(1)(C) of the Social Security Act.

The congressional findings indicated a concern that the certification process had "created a level of uncertainty" that was interfering with the OPOs' effectiveness in raising the level of organ donation. We have addressed those concerns in this final rule by establishing, among other things: (1) A re-certification process that relies on outcome and process performance measures based on empirical evidence of organ donor potential in an OPO's service area, (2) multiple outcome measures, (3) rules that clearly delineate the steps in the appeals process for de-certifications, and (4) rules that delay the competition phase until the administrative appeals process has been completed. Therefore, this final rule is fully consistent with the statutory requirements.

Comment: Commenters expressed concern that the proposed de-certification requirements at § 486.312(b) and § 486.312(c) are inconsistent with the proposed definition of "de-certification;" and with the certification requirements. In addition, commenters expressed concern about inconsistency with the substantive grounds for de-certification proposed at § 486.312(b), as well as the fact that CMS provided no explanation for this disparity. Commenters stated that the grounds for de-certification should be consistent, or the administrative record should indicate the legal and policy reasons as to why they differ. Commenters stated that this provision permits non-renewal of an agreement based on only one criterion, that is, failure to meet the outcome measures. Commenters stated that a de-certification is a terminal action that we should make only after review of all relevant criteria, not simply based on simple arithmetic outcome measures that automatically trigger a de-certification decision.

Commenters recommended that § 486.312(b) should be changed to read as follows: "Decertification due to involuntary termination of agreement. The Secretary may terminate an agreement with an OPO if CMS finds that the OPO no longer meets the requirements for certification in § 486.318. CMS may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will decertify the OPO as of the effective date of the involuntary termination." Commenters recommended that § 486.312(c) be deleted.

Response: We agree with some but not all of the commenters' suggestions. As mentioned earlier, we have redefined "de-certification" and the requirements for certification in § 486.303. We also agree that OPOs can be de-certified during the 4-year re-certification cycle for many reasons, including situations where there is an urgent need. However, we do not agree that it is necessary or prudent to combine sections (b) and (c), as one commenter suggested, because the effective dates of a de-certification are not necessarily identical. We are making changes to the final rule to clarify that de-certification due to involuntary termination of an agreement occurs "during the term of the agreement." We have streamlined and clarified the provision by deleting the language that refers to termination if 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, SVIII, or XIX of the Act." In its place, we have inserted language that refers to termination if the OPO no longer meets the requirements for "certification at § 486.303." We have also made minor edits to the title. We have revised § 486.312(b) as follows:

Involuntary termination of agreement. During the term of the agreement, CMS may terminate an agreement with an OPO if the OPO no longer meets the requirements for certification at § 486.303. 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.

We have not deleted proposed § 486.312(c) as commenters suggested. We do not agree with the commenters that by de-certifying an OPO that fails to meet the outcome measures, we would be basing the OPO's de-certification solely on a single arithmetic computation. At the end of the re-certification cycle, we will determine each OPO's performance on the multiple outcome measures that we believe reflect the entire spectrum of an OPO's performance. Moreover, we expect every OPO to evaluate and improve its practices throughout the re-certification cycle to ensure that by the end of the cycle, it meets all of the measures. If it has not, we believe it is appropriate to de-certify the OPO. Holding all OPOs accountable for meeting all three outcome measures will provide a strong incentive for OPOs to excel. We believe this incentive will

increase organ donation in the United States.

Further, we expect OPOs to be in compliance with all the process performance measures and other regulatory conditions at all times. We will survey each OPO at some point during the re-certification to evaluate its compliance with the process performance measures and, if the OPO is out of compliance, to give the OPO an opportunity to come back into compliance through a plan of correction. Therefore, by the end of the re-certification cycle, all OPOs must be in compliance with the process performance measures and other regulatory conditions. If an OPO is not in compliance with the process performance measures and the other requirements at § 486.303 at the end of the re-certification cycle, we may De-certify the OPO at that time. Therefore, we have added language to clarify that non-renewal of an OPO's agreement is based on failure to meet the outcome measures or failure to comply with the other requirements for certification.

For the purpose of clarification, we have removed our proposed language in § 486.312(c), "or if the OPO's designation status has been terminated" because we streamlined the requirement by including most of the proposed requirements for designation in § 486.303. Based on public comments, we have revised § 486.312(c) in the final rule as follows:

"Non-renewal of agreement. CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the outcome measures at § 486.318, based on findings from the most recent re-certification cycle, or any of the other requirements for certification at § 486.303. CMS will de-certify the OPO as of the ending date of the agreement."

Comment: One commenter stated that the phrase "urgent need" in § 486.312(b) needs a more detailed definition. The commenter said that the proposal identifies only the discovery of "unsound medical practices," but there is no sense of the severity of the unsound medical practices. The commenter recommended that the definition of "urgent need" should include an "imminent and incurable threat to public safety, to donors, or a material failure of governance, management, or recovery practices and procedures which imminently threaten public safety and which cannot be or which are not likely to be cured by or with the cooperation of the OPO."

Response: We agree that the phrase "urgent need" requires a more detailed definition. To help us address this issue, we looked to the definition of

"immediate jeopardy" contained in the requirements for provider agreements and supplier approval at § 489.3, which states, "For the purposes of this part— Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." We modified this definition for OPOs and added the definition of "urgent need" at § 486.302 as follows, sbull 111:"Urgent need occurs when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual organ donor or organ recipient." For example, we would consider an OPO's failure to ensure that appropriate donor screening and testing are completed to be a situation of "urgent need."

Comment: One commenter stated that in the proposed § 486.312(d), if the 90-day notice is to be given for de-certification at a time other than at the end of a de-certification cycle, there are no standards set forth to justify why that notification should occur at a time other than at the end of a cycle. The commenter stated that if it were an emergent situation, the other provisions of the proposed section for a termination with no less than 3-days notice would apply. The commenter further stated that the regulations should clarify why a notice of de-certification will be given at a time other than the end of the certification cycle and explain how the giving of notice before the end of the cycle may impact an OPO's right of appeal. Finally, the commenter recommended that the regulation require that any notice of de-certification contain an explanation of the grounds for such de-certification.

Response: We agree with the commenters that additional information should be added to the final rule. Under the final rule at § 486.312(b) we may de-certify an OPO based on termination of the agreement during the term of the agreement for failure to meet the requirements for certification at § 486.303. For example, if an OPO is substantially out of compliance with one or more process performance measures and fails to submit or implement an acceptable plan of correction, we would terminate the OPO's agreement and de-certify the OPO. We may de-certify an OPO at the end of the 4-year agreement based on non-renewal of the agreement for failure to meet the outcome measures at § 486.318 or the other requirements for certification at § 486.303. Except in cases of urgent need, CMS is required to

give written notice of de-certification to an OPO at least 90 days before the effective date. In cases, of urgent need, CMS gives written notice of de-certification at least 3 calendar days before the effective date of the de-certification. This written notice will include all the reasons for de-certification. (See § 486.314(a).)

In summary, our intent is not to de-certify OPOs unnecessarily but to ensure that OPOs maximize the recovery of viable organs for transplantation and provide high quality care to families of potential donors, and provide efficient, effective services to transplant hospitals. However, if an OPO does not comply with the regulations, it will face enforcement actions during the agreement cycle, as well as at the end of the cycle. Revisions have been made in response to public comments that affect multiple requirements at § 486.302, Definitions; § 486.303, Requirements for certification; § 486.304, Requirements for designation; and § 486.312, De-certification. These revisions in the final rule clarify and streamline the regulations and comprehensively address commenters' concerns regarding internal inconsistency of the regulations.

Appeals (Proposed § 486.314)

To address the congressional mandate for an appeals process for OPOs to appeal a de-certification on substantive and procedural grounds, we proposed to streamline the appeals process so that an OPO facing de-certification could appeal and receive a decision on its appeal before we opened its service area for competition from other OPOs. Specifically, we proposed to delay competition until an administrative appeal was completed; expedite appeals by using a CMS hearing officer; and, at our discretion, extend the appellant OPO's agreement for 60 days to complete the appeals and competition processes and, if necessary, select a new OPO to take over the appellant OPO's service area.

In the final rule, we expand the circumstances under which an OPO can appeal a de-certification due to involuntary termination or non-renewal of its agreement with us, and the process will enable OPOs to appeal on both substantive and procedural grounds. We establish an appeals process that includes procedures for OPOs to request reconsideration and to request a hearing. To avoid undue procedural delays, the final rule also establishes certain specific time frames for both the appellant OPO, the reconsideration official, and the CMS

hearing officer. Further, in response to public comments, we have expanded the proposed appeals process to grant OPOs certain additional appeal rights.

We received many comments on the appeals process; no comments were positive. Many commenters said that they prefer the part 498 process, which sets forth procedures for providers and suppliers to appeal decisions that affect participation in the Medicare program. Some commenters argued that the Secretary is required to provide the part 498 process to OPOs.

However, the same commenters indicated that if we did not reinstate the part 498 process for OPO appeals, they would be satisfied with a specific alternative process utilizing a CMS hearing officer to hear appeals. The commenters described the process, which would include some part 498 procedures, such as the right to a reconsideration. Commenters said that regardless of what appeals process is included in the final rule, they want more detail about how the process will work. We have added such detail throughout our responses to the comments. Following is a summary of the public comments we received, along with our responses.

Comments on the Part 498 Process

Comment: Commenters said that the Secretary has consistently provided OPOs with the appeal rights outlined in 42 CFR part 498. They said that even before the OPO Certification Act, the statutory and regulatory language demonstrates that for purposes of appeals, OPOs were entitled to the same or an equivalent process to that of ESRD facilities (which were entitled to appeal under part 498). Commenters suggested that the Secretary's inclusion of OPOs in the part 498 hearing procedures was based on statutory obligations and was not discretionary. Commenters said that CMS must provide either the part 498 hearing or a process that is equivalent to the part 498 process. They stated that the OPO Certification Act underscored this obligation by including new language specifically addressing the appeal rights of OPOs and requiring the right to appeal on "substantive and procedural grounds." Commenters also noted that the proposed appeals process is inconsistent with the intent of the Congress, which, in enacting the OPO Certification Act, clearly relied on the Secretary's prior designation of OPOs as suppliers entitled to a part 498 hearing.

Response: We disagree that the Secretary's inclusion of OPOs in the part 498 hearings process was required under the statute. Section 1866(h) of the Social Security Act provides for a

hearing and for judicial review of the hearing only for providers; it is silent regarding appeal rights for suppliers and practitioners. See 42 CFR 498.1(g) (2004).

Further, the OPO Certification Act did not mandate that OPO appeals be heard by an administrative law judge or expressly require the use of the part 498 process. The statute mandated only that an OPO must be able to appeal on substantive and procedural grounds. Thus, under this final rule, a CMS hearing officer will hear OPO appeals. We have based the appeals process in this final rule on the appeals processes we use for appeals of contract terminations under the Medicare Advantage Program and for Medicaid State Plan Amendment hearings. The appeals process in this final rule is consistent with the requirements of the OPO Certification Act.

Comment: Commenters said that eliminating part 498 is inconsistent with the MMA, which requires "suppliers" to be afforded a hearing identical or comparable to what the Secretary provides under part 498. Section 901 of the MMA defines a "supplier" as "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 subchapter." Commenters said that in the preamble to the proposed rule, we concluded that the definition does not include OPOs, even though CMS has regarded OPOs as suppliers for the past 17 years.

Commenters said that the MMA definition is an "expansive" definition, meant to capture as many types of entities or persons as possible and that the definition basically provides that anyone or any entity that provides services pursuant to or under the Medicare program and that is paid under the program is a supplier (as long as it is not a provider). Commenters stated that they do not believe there is any statutory support to demonstrate that the Congress meant for an OPO to have fewer or different rights than it gives to other types of suppliers.

Commenters said that they do not think the Congress would support CMS's narrow interpretation of the term "supplier," since it granted OPOs an express right to appeal de-certifications on procedural and substantive grounds in the OPO Certification Act. They pointed out that at least three Civil Remedies Division cases specifically recognized the supplier status of OPOs, and two district court decisions did not set aside that status. They stated that the Congress clearly was aware of the

Secretary's conclusion that OPOs were suppliers and clearly relied on that designation when it enacted the 2000 amendments and that there is no evidence that the Congress, in passing the MMA, meant to undo the administrative hearing rights when it enacted the 2000 amendments.

Response: As commenters noted, we proposed removing OPOs from the definition of "suppliers" under the part 498 appeals process. In the preamble to the proposed rule, we said that the unique nature of OPOs and their special role in the Medicare program distinguishes them from other suppliers. (70 FR 6093) We noted that suppliers typically furnish medical items and services directly to Medicare beneficiaries and receive a direct payment for those services. We observed that many, if not most, organ donors are not Medicare beneficiaries, and many organs recovered by OPOs are not transplanted into Medicare beneficiaries. The services an OPO furnishes to obtain organs are not designed to diagnose or treat an illness or injury for the patient from whom the organs are recovered. Instead, the services are designed to benefit the recipient of the organs. We also said that OPOs have payment rules and methodologies that differ from the payment rules and methodologies used for other suppliers. The legal relationship between an OPO and the Medicare program is different from that of other suppliers and reflects important statutory differences. Within this specific context, we do not believe section 901 requires OPOs to be considered suppliers. This is particularly the case because the Congress enacted a specific statutory provision governing OPO appeal rights in 2000, before enacting the general provision relating to the definition of "suppliers" or gave other suppliers additional appeal rights.

We believe that an alternative appeals process will help to eliminate the uncertainty that the Congress found when it enacted the OPO Certification Act in 2000. In the Congressional findings accompanying the 2000 legislation, the Congress expressly found that the existing recertification process "created a level of uncertainty" that was interfering with OPOs ability to raise the level of organ donation. At least part of the uncertainty was due to the simultaneous administrative appeals process and the competition process that existed under the earlier regulations. Under the old process, CMS published a notice in local newspapers to solicit a new OPO to fill the incumbent's service area before the

appeals process was completed. In the 2000 recertification cycle, three of the OPOs that were slated for decertification immediately sought and were granted temporary restraining orders by Federal district courts to bar CMS from completing the competition process before the appeals process was completed. *Arkansas Regional Organ Procurement Agency, Inc. v. Shalala*, 104 F. Supp. 2d 1084 (E. D. Ark. 2000); *Nater-Lebron v. Shalala*, 120 F. Supp. 2d 175 (D. P.R. 2000) (rejecting challenge). While the enactment of the 2000 legislation ended those controversies, the Congressional findings suggest that a more streamlined, sequential process would help to reduce the uncertainty in the recertification process.

In the proposed rule, CMS explained that it was acting to reduce the level of uncertainty by allowing the OPO to appeal and receive a decision on the appeal before its service area would be opened for competition. (70 FR 6087). We will continue this approach in this final rule. Because of the time constraints between the end of the certification period and the beginning of the next contract cycle, we will use a hearing officer to ensure that a decertified OPO will receive a fair administrative process, and yet one that can be completed before the competition for a successor OPO (if needed) begins. The Supreme Court has previously recognized that the use of unbiased hearing officer can be used in an administrative process in a manner that is consistent with due process. *Schweiker v. McClure*, 456 U.S. 188 (1982).

Comment: Commenters said that there is no basis in the record for a conclusion that the current process is problematic. They noted that the preamble to the proposed rule explains that the part 498 process has proven inadequate because the appeals could not be completed before the OPO contract terminated, thus creating a situation in which competition by other OPOs would begin before the final decision on decertification is complete. Commenters also stated that the preamble to the proposed rule indicated that the 2-year re-certification cycle was a factor that complicated the part 498 appeals process. They said that it would be incorrect, therefore, to conclude that the delays in the appeals process are attributable solely, or even in major part, to part 498.

Response: We disagree with the commenter who suggested that the change from a 2-year agreement cycle to a 4-year cycle will automatically ensure that the appeals process is resolved in

a timely manner. The Congress has specified that multiple outcome measures must be used in the re-certification process. The data to support the outcome measures must be collected and analyzed before OPOs can be given a notice of de-certification that begins an appeals process. The limited time period between the end of the certification period and the beginning of the next agreement cycle exists whether the re-certification cycle is 2 years or 4 years.

Our experience demonstrates that appeals under the part 498 process take more than 7 months to resolve. For example, we notified an OPO located in Los Angeles, California, on July 23, 1998 that it would not be re-designated for its service area. On August 7, 1998, the OPO requested reconsideration and a hearing before an administrative law judge (ALJ). Upon reconsideration, we reaffirmed our decision. The OPO appealed to an ALJ, and we requested that the hearing be expedited, but the hearing was held on October 6 and 7, 1998. The ALJ's decision to uphold the de-certification was issued more than 7 months later on May 12, 1999. Thus, even with the expedited time frame for the hearing, more than 9 months elapsed between the OPO's request for reconsideration and a hearing and the final decision.

The Congress enacted legislation in 2000, in the aftermath of the OPO certification cycle that ended on December 31, 1999. At this time, numerous administrative and judicial proceedings were initiated or in process as a result of the application of the previous OPO performance measures. Early in 2000, CMS found that several OPOs had not satisfied the previous OPO performance measures and were more than 25 percent below the mean in comparison to other OPOs. After the notice of the administrative appeal rights were given to each OPO, CMS immediately initiated the actions required by the regulations then in effect to compete the OPO's service area and to choose a successor. Several of the OPOs initiated lawsuits at that time to challenge the basis of the performance standards and to stop CMS from choosing a successor while the administrative appeal process was still pending. There were several injunctions issued. Ultimately, one district court found that the performance standards were not valid and the government appealed this decision to the United States Court of Appeals for the Eighth Circuit. *Arkansas Regional Organ Procurement Agency, Inc. v. Shalala*, 104 F. Supp. 2d 1084 (E. D. Ark. 2000). On the other hand, a second district

court rejected a challenge that asserted that the performance regulations were arbitrary and capricious. *Nater-Lebron v. Shalala*, 120 F. Supp. 2d 175 (D.P.R. 2000). The enactment of the 2000 legislation ended those controversies.

It is within this setting that the Congress found that the process for the certification and re-certification of OPOs conducted by the Department in 2000 created a level of uncertainty that interferes with the effectiveness of organ procurement organizations in raising the level of organ donation. We proposed numerous changes to reduce the level of uncertainty by streamlining the process and altering the timing of the appeals process to facilitate appeals on substantive and procedural grounds. One of those changes, designed to expedite the resolution of any administrative appeals in a full, fair, and timely manner was to move the appeals process from part 498 and assign these cases to a CMS hearing officer for resolution before we initiate any competition for an open area.

We are gaining an additional 6 months for the appeals and competition processes under this final rule by beginning the process earlier, allowing a total of 13 months from 7 months prior to the end of the re-certification cycle until the expiration of agreements between CMS and the OPOs 6 months later. However, even this more generous time frame would not be sufficient for analysis of data on the front end, a 9-month appeal process, a competition process, and transition of an OPO's service area to another OPO.

Opposition to the Proposed Appeals Process

Comment: Commenters said that the proposed appeals process is constitutionally defective. They said that the proposed appeals process raises two constitutional concerns both grounded in the due process protections of the Fifth Amendment to the United States Constitution. The first is a concern over whether the proposed process is constitutionally adequate. Commenters stated that prior decisions indicate that due process generally requires consideration of three distinct factors: the private interest that will be affected by the official action; the risk of an erroneous deprivation of such interest through the procedures used; and the government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail. Commenters noted that a de-certified OPO must go out of business, and they pointed out that few property interests under any

HHS-administered programs reach this level of significance and those that do, have part 498 protections.

Response: We believe that the commenter has an inflated view of the private interests at issue when a party has signed a time-limited agreement to perform services on the government's behalf. These interests clearly do not rise to the same level as the welfare recipient presented to the Supreme Court in *Goldberg v. Kelly*, 397 U.S. 254 (1969). ("For qualified recipients, welfare provides the means to obtain essential food, clothing, housing, and medical care.") These regulations are fully consistent with the statute and with any due process rights that an OPO has with respect to its time-limited agreement with CMS.

Comment: Commenters also said that the proposed process is likely to cause an unconstitutional commingling of prosecutorial and adjudication functions. They noted that under proposed § 486.312(c), CMS may issue a notice based solely on failure to meet the outcome measures set forth in proposed § 486.318. However, the preamble to the proposed regulations states that the CMS hearing officer would consider additional evidence not considered by the primary CMS decision maker, including substantive and procedural evidence. Commenters stated that the CMS hearing officer would be considering this information on behalf of the agency for the first time. Therefore, the CMS hearing officer would not be reviewing the agency's initial determination; he/she would be making it.

Response: At the conclusion of the re-certification cycle, we will evaluate an OPO's performance based on its performance on the outcome and process performance measures and other regulatory requirements. If we make a decision to de-certify the OPO, the hearing officer will hear arguments on both substantive and procedural grounds under the OPO Certification Act legislation. The hearing officer is an impartial adjudicator, who will assess the reasonableness of the OPO's argument and make a decision based on the evidence in the record. In our view, this process is fully consistent with due process, and there is no commingling of a prosecutorial function.

Recommendations for Revising Proposed Appeals Process

Comment: Many commenters said that they do not oppose modifications to the part 498 process as long as: (1) The replacement process provides the same caliber of hearing process and the same protections as part 498, and (2) permits

sufficient time for a complete and meaningful hearing. However, commenters said that the proposed process would not meet these criteria.

Commenters said that the proposed rule would eliminate rights that OPOs now have under part 498, such as the right to reconsideration before pursuing a formal appeal. Commenters also criticized the proposed process because the burden of meeting the shortened time frame would fall entirely on the OPOs. That is, they noted that while we would require OPOs to meet specific time frames, the appeals process would not include a time frame for the hearing officer to render a decision on the appeal.

Commenters further criticized the proposed process because it does not define the hearing officer's powers. For example, commenters said that an ALJ has the power to compel discovery of documents and individuals but there are no written legally enforceable mechanisms available to the hearing officer.

Commenters also said that we provided insufficient detail for them to understand how the proposed appeals process would work.

These commenters recommended that we use a CMS hearing officer and retain the procedures used under part 498 with some modifications to expedite appeals. They said that their proposal would satisfy the twin objectives of avoiding an unnecessarily prolonged administrative process but preserving the important protections in existing part 498. The commenters provided specific regulatory text language for our consideration.

Response: After carefully considering the comments, we have made changes to the proposed appeals process to address some of the commenters' concerns. While we do not believe it would be appropriate to retain the part 498 process because of the potential for undue delay in resolving OPO appeals, we are finalizing an appeals process that incorporates many recommendations made by commenters. We have based the appeals process in this final rule on appeals procedures we use in other settings, including appeals by managed care organizations of contract terminations under the Medicare Advantage Program. These appeals procedures have expedited time frames because of the limited time before competition begins and new agreements must be signed. We have included additional rights and procedures that provide an opportunity for an OPO to obtain a fair and expeditious hearing and a decision on its appeal before the competition process begins. Although

we did not incorporate every procedure from part 498 or every recommendation suggested by the commenters for the appeals process, the new process will ensure that OPOs will have the opportunity to have their appeals heard in a timely and meaningful manner. An OPO will be able to appeal a de-certification on substantive and procedural grounds as the statute requires.

The appeals process in this final rule at § 486.314(g) contains specific rights for both an OPO appealing a de-certification and CMS.

The parties may: (1) Appear by counsel or other authorized representative in all hearing proceedings; (2) participate in any pre-hearing conference held by the hearing officer; (3) agree to stipulations as to facts which will be made a part of the record; (4) make opening statements at the hearing; (5) present relevant evidence on the issues at the hearing; (6) present witnesses who then must be available for cross-examination; and (7) present oral arguments at the hearing. Additionally, CMS or its representative and the OPO or its representative may cross-examine the witnesses.

In addition, the final rule specifies that the notice of de-certification must contain the reasons for the de-certification. If a request for reconsideration is made, we will provide the administrative record that includes the evidence used in making the de-certification decision. The administrative record, may include, for example. The record does not include material that is privileged. While several commenters have requested that the final rule include provisions related to discovery, we have determined that discovery is inappropriate in this context. Instead, we will produce the administrative record on which we based our de-certification decision.

The hearing officer's authority in conducting the hearing is specified in this final rule. The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material; provides the parties with an opportunity to enter any objection to the inclusion of any document, considers the objection and rules on the document's admissibility; decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing; rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures; rules on motions and

other procedural items; regulates the course of the hearing and conduct of counsel; examines witnesses; receives, rules on, or excludes or admits evidence; sets the time for filing motions, petitions, briefs, or other items; and takes any action authorized by the rules in this subpart. Additionally, the final rule specifies that the hearing officer must render a decision on the notice of decertification within 10 business days of the hearing.

At the commenters' request, we have included an opportunity for an OPO to request a reconsideration as a mandatory step in the appeals process before the OPO may seek a hearing before the hearing officer. Under this final rule, an OPO has 15 business days from the date it receives the notice of de-certification to file a request for reconsideration. The notice of de-certification will contain instructions on how to file the request for reconsideration, including where to send the request. If an OPO does not request reconsideration or its request is not received timely, the OPO has no further administrative review rights. We agree with commenters who said that reconsideration can benefit both CMS and the appellant OPO. Under the reconsideration process established under this final rule, an OPO may submit additional information and arguments as to why it should not be de-certified.

The CMS Regional Administrator in the Region in which the OPO's main office is located will make the reconsideration decision. Regional Offices are knowledgeable about the OPOs in their regions, as well as the conditions and factors in a particular service area. The reconsideration process will allow the Regional Administrator to consider any procedural or substantive arguments that the OPO would like to raise to demonstrate that it should not have been de-certified. If the Regional Administrator determines that the OPO should not be de-certified, the OPO will be re-certified. If the Regional Administrator determines that the OPO should be de-certified, he or she will update the administrative record (which contains a copy of the de-certification notice, any documents concerning the OPO's performance during the relevant re-certification cycle, all documents submitted by both sides to the Regional Administrator during the reconsideration process, and the Regional Administrator's reconsidered decision) and forward the record to the CMS hearing officer.

The OPO may file a request for a hearing. The OPO has 40 business days

to file its request. If the OPO does not file a request for a hearing or its request is not received timely, the OPO has no further administrative review rights.

We believe the appeals process in this final rule will protect a de-certified OPO's rights, provide it with sufficient time to pursue its appeal, and ensure that it receives a fair hearing. Our responses to the following comments provide additional details about the appeals process in this final rule.

Details of the Appeals Process

Comment: Some commenters suggested that CMS should start the de-certification analysis prior to the ending date of the re-certification cycle. They said that CMS could base the certification data on 48 months of data, but the first 6 months of data could be derived from the prior re-certification cycle. Commenters pointed out that their recommended time frames would provide an additional 6 months to complete the process, which they said would be preferable to a truncated appeals process.

Response: We agree with the commenters that beginning our analysis of OPO performance sooner makes sense in view of the time needed for the appeals and competition processes. Providing additional time for these processes also helps to avoid the uncertainty identified by the Congress in 2000. However, we disagree that we should accomplish this by using data from a prior re-certification cycle. Using 6 months of data from a prior re-certification cycle would create a comparison problem when we evaluate the performance of an OPO that takes over another OPO's service area at the beginning of a re-certification cycle because we could not use the de-certified OPO's data from the previous re-certification cycle to evaluate the incoming OPO. Because the outcome measures evaluate OPOs in comparison to one another, we believe it is better to use the same amount of data from the same time period for evaluation of all OPOs. Thus, we will not use data from the previous re-certification cycle to re-certify OPOs. Instead, we will use a lesser amount (36 months) of data so that we will ensure that there is enough time to complete the appeals and certification processes. Further discussion of the time frames for the data and the outcome measures is found in this preamble in "Section 486.318, Outcome Measures."

The first re-certification cycle under this final rule will be August 1, 2006 through July 31, 2010. Thus, we will request data from the beginning of the 6th month of the re-certification cycle,

January 1, 2007 through the end of the 41st month, December 31, 2009. We expect that it will take about 2 months (until February 28, 2010) for OPOs and transplant hospitals to update their data and for the SRTR to compile the data to provide an OPO-to-OPO comparison. We expect to receive the data from the SRTR in early March and notify OPOs by March 15 if an OPO will be de-certified. We have retained a 6-month lag between the end of the re-certification cycle and the end of the agreement between OPOs, which means we will have a total of 13 months from the beginning of the process until agreements between CMS and the OPOs expire. Note that under this final rule, agreements will expire on January 31, 2011.

OPOs that have met all 3 outcome measures will be notified about their re-certification on a flow basis after they have been shown by survey to be in compliance with all other conditions for coverage. At this time, we will also notify OPOs that did not meet the outcome measures or other requirements that the OPO will be de-certified. Once we notify OPOs of their status, we will have more than 10 months (until agreements expire on January 31, 2011) for the appeals and competition processes. This will provide 5 to 6 months for the appeals process, about 2 months for the competition process, and the remaining months for transition of service areas to new OPOs, if necessary.

Comment: Commenters suggested that CMS provide some type of pre-termination notice and suggested that the need for an appeal might be avoided if CMS provided some type of preliminary or provisional notice of an imminent or likely non-renewal and permitted the OPO the opportunity to provide additional, responsive material prior to a de-certification notice.

Response: As stated earlier in this preamble under "De-Certification (proposed § 486.312)," an OPO will be provided with a 90-day notice prior to termination, except in cases of urgent need. When a termination notice is given during the re-certification cycle because the OPO is substantially out of compliance with a process performance measure, the OPO is given an opportunity to come back into compliance prior to termination.

If an OPO has not met all 3 of the outcome measures at the end of the re-certification cycle, the OPO will receive a de-certification notice that includes the reasons for the de-certification. A reconsideration process is included within the appeals process we are finalizing, which will give an OPO that

receives a de-certification notice the opportunity to provide additional material for consideration.

Comment: Commenters recommended that one outcome of the appeals process should be re-certification subject to successfully achieving a corrective action plan or restoration of status subject to successfully achieving a corrective action plan.

Response: In general, we do not agree that re-certifying an OPO based on its achievement of a corrective action plan or restoring its status based on its achievement of a corrective action plan is an appropriate outcome of the appeals process. If the OPO has been de-certified based on non-compliance with the requirements for certification at § 486.303 but that decision is reversed on reconsideration or on appeal, the OPO is able to continue to perform under the terms of the agreement without a corrective action plan. If the OPO has been de-certified based on failure to meet the outcome measures or requirements for certification at § 486.303 at the end of the re-certification cycle, but that decision is reversed on reconsideration or on appeal, the OPO will be re-certified without a corrective action plan.

If we find during the term of the re-certification cycle that an OPO is substantially out of compliance with one or more of the process performance requirements, we will not necessarily immediately take steps to de-certify the OPO. Instead, we may exercise our enforcement discretion to provide the OPO with the opportunity to develop and implement a plan of correction to come back into compliance. If the OPO does not come back into compliance, we will issue a notice of de-certification to the OPO.

We are not willing to exercise our enforcement discretion at the end of a 4-year cycle. If an OPO has not been able to improve its performance over the course of the 4-year re-certification cycle, we believe it is unlikely that an additional attempt at improvement through a corrective action plan would prove successful. The 4-year re-certification cycle provides OPOs with more than enough opportunity to improve their performance on the outcome measures prior to the end of the re-certification cycle. OPOs should use data derived from their QAPI programs to monitor and improve their performance continuously. OPOs can track their performance in comparison to other OPOs by accessing data on the SRTR Web site at <http://www.ustransplant.org>.

Comment: Commenters said that according to the preamble of the

proposed rule, the timing of de-certification is an issue only if de-certification occurs at the end of the term of the OPO's agreement with CMS. Therefore, commenters said that a de-certification proceeding that began during the term of the agreement with the intention of making the de-certification effective prior to the end of the term, would not have the same timing issues. Commenters concluded that there would not be any reason for eliminating the part 498 process for involuntary de-certifications taking place during the term of the agreement.

Response: We do not agree that OPOs should use the part 498 process to appeal a de-certification that takes place during the re-certification cycle. We believe it would be more efficient if both types of OPO appeals used the same administrative appeals process. If an OPO is not performing well, a decision on the OPO's de-certification should be made expeditiously so that, if necessary, we can replace the OPO with an OPO that will increase organ donation in the service area.

Comment: Commenters said they were pleased that CMS recognized both the need to preserve an OPO's business by delaying the competition process until after a final de-certification decision is made by a CMS hearing officer, as well as the need to ensure that the area served is not left without an OPO, so that organ donation and transplantation continues without interruption. However, commenters suggested that there are other means to address these concerns and yet provide a fair appeals process for OPOs that is consistent with the statute.

Response: We agree with the commenters that CMS must ensure that an OPO facing de-certification is given adequate appeal rights to resolve disputes and that those appeals will permit challenges based on substantive and procedural grounds. Nevertheless, the public has an interest in increasing organ donation, and the appeals and competition processes are designed to replace an OPO that is not performing well with an OPO that is likely to produce better results. If an OPO is de-certified, the appeals process in this final rule protects the OPO's rights under the statute and ensures that it does not face competition from a potential successor until after the administrative appeal has concluded. We believe that the process established in this final rule is fair and consistent with the statute and the public's interest.

Comment: Commenters said that the final rule should explicitly provide that the CMS agreement and payment for

services will continue during an appeal of a termination or non-renewal. They said that under the proposed regulations, the possibility exists that an OPO may not be paid while an appeal is pending because there are no time limits provided for the length of time that a CMS hearing officer may take to decide an appeal and because the entire notification process might “slip” or run behind schedule. Commenters also said that by terminating the agreement on July 31, and allowing only a discretionary extension, the proposal fails to protect an OPO’s constitutionally protected property interest adequately.

Response: Using 36 months of data will start the process sooner. Thus, we believe it is unlikely that we will need to extend the agreements. With respect to an OPO that was de-certified for failure to meet the outcome measures and where the de-certification was upheld in the appeals process, the OPO can be paid until the end of the agreement with CMS. The appeals process we are establishing under this final rule places no time limitation on the extension of the agreement between CMS and the appellant OPO if needed in some cases to complete the appeals and competition processes. If the OPO appeals and loses the appeal, we would pay the OPO during and after the competition process until a successor OPO has taken over the service area to ensure that there is no disruption in organ procurement activities.

Comment: Commenters questioned proposed § 486.314(b) which states that if the OPO wins on appeal, CMS will not de-certify the OPO “at that time.” Commenters asked whether “at that time” means the time the hearing officer’s decision is announced or whether it is retroactive to the date CMS imposed the involuntary termination.

Response: The language in question, “CMS will not terminate the OPO’s agreement and will not de-certify the OPO at that time” meant that by not de-certifying the OPO following its successful appeal, CMS was not waiving the right to de-certify the OPO at some time in the future if it were found to be out of compliance with one or more of the outcome and process performance measures. If the reconsideration official or hearing officer overturns the OPO’s de-certification, CMS will re-certify the OPO.

Re-Certification and Competition Processes (Proposed § 486.316)

In our February 4, 2005 proposed rule, we proposed opening every OPO’s service area for competition at the end of every re-certification cycle, as in the

existing regulations. However, we proposed certain limitations that we said would address the uncertainty in the re-certification process that the Congress noted. We said that the proposed 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.

We proposed that once we determined that an OPO met the outcome measures at proposed § 486.318 for the previous re-certification cycle and was found to be in compliance with the process performance measures at §§ 486.320 through 486.348, we would open the OPO’s service area for competition from other OPOs. Under the proposed rule, 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. OPOs would be required to compete for an entire service area. The incumbent OPO would be permitted to compete for its own service area.

We proposed that 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 proposed 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.

We received more comments on our proposed requirements for the re-certification and competition processes than on any other section in the proposed rule. All comments on the proposal were negative, and all

commenters who expressed a preference for one of the alternatives we described in the preamble to the proposed rule chose the highly restricted competition process in which only service areas of de-certified OPOs would be opened for competition. In this final rule, we are making changes to the competition process consistent with the public comments, which we discuss in detail below.

Comment: Commenters, including state hospital associations and many large hospitals that have participated in the Department’s Organ Donation Breakthrough Collaborative, strongly objected to our proposed competition process, stating that it would have a negative affect on the Collaborative. Commenters noted that the foundation for the success of the Collaborative—cooperation, collaboration, and the sharing of best practices and change strategies—would be threatened by the proposed competition process.

Many commenters said that the nearly 11 percent increase in organ donation from 2003 to 2004 can be directly attributed to the Collaborative. Numerous commenters, including hospitals that participated in the Collaborative, said that the Collaborative has had a significant impact on their own donation rates. A 600-bed hospital said that its donation rate increased from 47 percent prior to the Collaborative to 75 percent. A transplant hospital said that it was able to start a liver transplant program because the number of livers recovered locally increased so much under the Collaborative.

Commenters voiced concern that open competition would promote a return to proprietary information and limited data transfers between OPOs rather than advancing the sharing of “best practices” and change strategies. All who commented on our competition proposal said the competition process we proposed would seriously undermine the prospects for sustaining the recent outcomes attributable to the Collaborative.

Response: We acknowledge that the Collaborative has been, and continues to be, an extraordinary success, and we are pleased that OPOs and hospitals continue to participate. Clearly, much of the Collaborative’s success has resulted from the willingness of OPOs to share data and information on what works best to increase organ donation. We understand the commenters’ concern regarding the potential impact of competition on the collaboration and partnerships that are the hallmark of the Collaborative, and we do not wish to finalize a competition process that will

unnecessarily interfere with the free flow of data and other information among OPOs.

We have reassessed our proposed competition model in view of the comments, and we agree that open competition has the potential to threaten the widespread collaboration and sharing of best practices that has led to such large gains in organ donation and transplantation. We have concluded that it would be inadvisable to finalize a process that opens every OPO's service area to competition at the end of every re-certification cycle. Therefore, we are finalizing this rule with a competition process that applies only to the service areas of OPOs that have been de-certified. Thus, most OPOs, as they monitor their performance throughout the re-certification cycle, can be confident that we will not open their service areas for competition from other OPOs.

Instead of all OPO service areas being opened for competition at the end of every re-certification cycle, an OPO that meets the following criteria at § 486.316(a) will be re-certified for an additional 4 years, and its service area will not be opened for competition: (1) Meets all 3 of the outcome measure requirements at 486.318; and (2) has been shown by survey to be in compliance with the requirements for certification at § 486.303. We have revised § 486.316 accordingly.

Comment: Some commenters referred to the congressional findings associated with the OPO Certification Act, stating that the 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. These commenters said that the proposed competitive framework is antithetical to the findings of the Congress that the prior process was disruptive and that the Secretary needed to undertake regulatory reform.

Response: We believe that replacing the open competition model in the existing regulations with a competition process that applies only to the service areas of de-certified OPOs, as well as permitting OPOs to compete only for entire service areas, will reduce or eliminate any uncertainty associated with the re-certification of OPOs.

Comment: Many commenters noted that under the proposed framework, an OPO would risk losing its service area, regardless of its success in meeting the outcome and process performance measures. Commenters said that the proposed process would degrade the point of having performance measures.

Response: We agree with the commenters that an OPO's relative success in meeting the outcome and process performance measures should be the deciding factor when we open an OPO's service area to competition. As stated in our previous responses, under this final rule we will open only the service areas of de-certified OPOs to competition.

Comment: Commenters agreed with us that the criteria OPOs must meet to compete for an open area should recognize higher performance. One commenter provided recommendations for defining a high performing OPO, specifying that the competing OPO should be required to have an adjusted 4-year conversion rate of 110 percent of the mean or an SRTR-based donation rate (hospital characteristics, notification rate) statistically higher than expected for 3 of the 4 years of the performance cycle.

Response: We appreciate the commenter's specific recommendations. We agree that we must ensure that an OPO permitted to compete for another OPO's service area both performs well in its own service area and demonstrates a performance that is significantly better than the performance of the de-certified OPO. To compete for an open service area, an OPO's performance on the donation rate outcome measure and yield outcome measure must be at or above 100 percent of the mean national rate averaged over the 3 years during the re-certification cycle. In addition, the OPO's donation rate must be at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area. The criteria we have included in this final rule fulfill both of those objectives, and we do not believe it is necessary to add complexity to the process by including another criterion.

Comment: Commenters said they agreed that when an OPO is de-certified, we should not permit the OPO to compete for its own service area. Commenters also endorsed our proposal to permit OPOs to compete for entire service areas.

Response: We appreciate the commenters' support. We believe one of the most important changes we are making to improve the current competition process is to preclude OPOs from competing for partial service areas. As we stated in the proposed rule, we found that permitting competition for partial service areas provided an incentive for OPOs to attempt to take over portions of neighboring service areas for purely business reasons, with no regard to whether they could increase organ donation in those areas.

We believe that limiting OPOs to competition for whole service areas will cause them to think carefully about the advantages and disadvantages of operating throughout the service area and will discourage OPOs from competing merely to gain access to a portion of the area that has a high donor potential.

Comment: Several commenters said that we should not implement an OPO competition decision until the competing OPO(s) are able to verify independently the outcome measures on which the competition is based. This analytic audit should include, but not be limited to, empirically obtained information, such as, death record reviews and analysis of data associated with hospital donor potential in each service area. Commenters added that an independent entity should conduct an onsite audit.

Response: We understand the concern that prompted these comments. OPOs want to be certain that the data used as the basis for competition decisions (as well as re-certification and de-certification decisions) are completely accurate. We share the commenters' desire for accuracy, and we believe the checks and balances used throughout the performance cycle to verify the OPO's self-reported data will guarantee to the extent possible, the accuracy of the data. For example, as discussed in this preamble under "486.318, Outcome Measures," the SRTR-based donation rate, because it is based on data from the National Center for Health Statistics, will act as an independent validation of the OPO self-reported donation rate data. If the SRTR-based donation rate data cast doubt on the accuracy of an OPO's self-reported data at any point during the re-certification cycle, CMS may conduct a complaint investigation to determine whether the OPO is out of compliance with the requirements at § 486.328.

Additionally, we expect that OPOs will monitor their data reporting throughout the performance cycle to confirm that they are reporting data accurately to the OPTN and the SRTR and that the data published by the OPTN and the SRTR are accurate. The average OPO recovers about 120 donors per year; it should not be difficult or burdensome for each OPO to verify independently whether its data are reflected accurately on the OPTN and SRTR Web sites.

We believe that efforts by CMS and the OPOs to validate the accuracy of data throughout the re-certification cycle, along with the ongoing data monitoring of the OPTN and SRTR, will ensure that the data used for the

competition process are as accurate as possible, without the need for audits that must be conducted after the close of the re-certification cycle, delaying decision making and adding to the uncertainty of the process. Once we choose an OPO for a donation service area, the OPO must be able to move into the area quickly, so that disruption of organ donation is minimized.

Comment: Commenters said that the proposed regulations do not provide for an appeal by any of the unsuccessful prospective bidders for the open service area, whereas the existing regulations permit an unsuccessful bidder to appeal using the procedures set forth in part 498. Commenters suggested that we should finalize regulations that permit part 498 appeals between or among potential bidders for an open area.

Commenters further said that the proposed rule did not include an opportunity for an OPO to inspect or challenge the assertions made by a competing OPO in its application (for example, through some type of review and rebuttal procedure). They said that this shortcoming removes an important safeguard and requires CMS to make decisions based merely on the assertions of an applicant.

Response: We do not agree that OPOs competing for an open service area should have the right to appeal if they are unsuccessful competitors. The statute requires only that we provide the opportunity to appeal a de-certification. An appeals process following competition would be both expensive and unwieldy. We believe it would increase uncertainty for the OPO that prevailed in the competition and that this may disrupt the new OPO's ability to increase organ donation in the service area.

An OPO that seeks to compete for an additional service area does not have an intrinsic right to be awarded the service area. The competition process is designed to enable CMS to choose the OPO that is most likely to increase organ donation in the service area and thereby serve the best interests of organ donation, potential organ donors and recipients in the service area, and the organ donation and transplantation system in the United States. Thus, if we make a decision that an open service area will be taken over by one of a number of OPOs bidding for the open area, our competition decision is final. We are rejecting the public comments suggesting that we provide an additional appeal following competition.

Comment: Many OPOs that commented recommended that when a service area is open because CMS de-certified the OPO, and no OPO applies

for the entire area, CMS should not force another OPO to take over the service area but should first permit OPOs to apply for portions of the open area. Some commenters suggested that if some areas were still open after allowing competition for partial areas, CMS should use the opportunity to permit the introduction of entirely new organizations to qualify as OPOs.

Response: We do not agree with the commenters. If an OPO is de-certified and the CMS hearing officer upholds the appeal, the best interests of organ donation in the open area dictate that we should replace the de-certified OPO as quickly as possible. If no OPO applies for the open area, there would not be time to sort out the competing interests of OPOs that seek to take over only a small portion of the service area. Therefore, we have finalized this provision of the proposed rule as it was proposed. If no OPO applies to compete for a de-certified OPO's open area, we 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.

Note that we currently do not have the authority to permit new entities to take over part or all of an OPO's service area, as one commenter suggested. This would be possible only if the Congress enacts legislation to change the requirement in the PHS Act because currently to be re-certified, an OPO must have been certified as of January 1, 2000. (See 42 U.S.C. 273(b)(1)(D).)

Comment: One commenter suggested that we should permit only OPOs with contiguous service areas to participate in the competition in order to reduce inefficiencies created by operating multiple service areas. The commenter also noted that permitting only OPOs with contiguous service areas to compete would also increase the chance that competing OPOs would have a greater knowledge of the service area, thus supporting smoother transitions and a greater likelihood of increasing the donation rate.

Response: We believe the commenter may have a valid point. An OPO that is contiguous to an open service area may have more knowledge than a non-contiguous OPO of the operations of the incumbent OPO, as well as knowledge of factors in the service area that work both for and against organ donation. Nevertheless, we would not want to eliminate the possibility of a non-contiguous OPO that has performed very well on the outcome measures taking over an open service area. Therefore, rather than prohibiting competition by non-contiguous OPOs,

we will take an OPO's contiguity to an open area into consideration when selecting an OPO for the open area. We have added language to the regulatory text at § 486.316(d) to include contiguity of a competing OPO's service area to that of the open area as one of the factors we will consider in selecting the OPO that will be designated for the open area.

Comment: Commenters said that the proposed regulations do not set forth quantitative criteria for CMS's selection of one OPO over another. Commenters said that the proposed rule essentially would eliminate any tangible criteria to compare competing OPOs and grant CMS officials unlimited discretion to apply the three very vague and minimal standards. Commenters recommended that CMS insert objective outcome criteria in place of the less quantifiable performance criteria when comparing OPO applicants, and they recommended that CMS indicate in advance the degree of weight that it intends to place on each decision factor that it uses.

Some commenters suggested that we reinstate the "tie-breaker" decision criteria in the existing regulations so that there are more concrete means to measure the success of the bidding OPOs.

Response: We agree with the commenters' recommendations for more objective measures, and we have made changes in the selection criteria based on their comments. However, we do not agree that we should reinstate the tie-breaker criteria in the existing regulations because some of the tie-breaker criteria are subjective. For example, one of the six criteria is an OPO's "willingness and ability" to place organs within the service area.

Therefore, under this final rule, we will base our selection of an OPO for an open donation service area on the following criteria: (1) Performance on the outcome measures; (2) relative success in meeting the process performance measures; (3) success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area; and (4) contiguity to the open donation service area. While these criteria are more objective than those we proposed, we will have the flexibility to exercise reasonable judgment in choosing between competing OPOs.

When comparing competing OPOs, we will first consider each OPO's performance on the outcome measures and the degree to which the top-performing OPO's performance on the outcome measures exceeds the performance of other competitors. We

may judge small variations in performance among competitors to be relatively unimportant. However, if one OPO performed significantly better than its competitors on all three outcome measures, we will rank the OPO very highly.

We will also take into account each competitor's relative success in meeting the process performance measures. By "relative success," we mean that we will judge whether the OPO simply satisfied the requirements necessary to meet the process performance measures or whether the OPO exceeded the requirements. For example, we will consider whether an OPO used the data from its QAPI program to track a few functions, such as requesting consent, and instituted minor adjustments to its operations or whether the OPO tracked every aspect of its functioning and, where necessary, made systemic changes throughout the organization to effect improvement.

Further, we will carefully assess each OPO's experience and success in identifying and surmounting barriers to organ donation in its own donation service area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome the barriers (such as hospital development, training, or public education), and the results.

In addition, we will take into account whether a competitor's experience is relevant to the specific barriers in the open service area. Although all OPOs may face obstacles to organ donation in their donation service areas, the nature of the barriers and the degree to which they interfere with organ donation vary widely throughout the country. Thus, for example, an OPO's experience in overcoming geographic barriers to organ donation in remote areas of the southwestern United States is not a guarantee that the OPO can successfully overcome other types of barriers, such as demographic barriers, that may exist in a large urban area.

Finally, we will take into consideration a competitor's contiguity to the open area. When we select among competing OPOs, we will weigh each of the first three criteria equally. We will use contiguity to the open area as a deciding factor if we determine that two competing OPOs are equally competent to take over an open area. However, if no OPO applies for an open service area, and we must select one or more OPOs to take over a service area, contiguity to the open area will be a significant consideration.

Comment: We received a comment from a large university hospital criticizing our proposed competition model because it is "based on a premise that does not consider regional variation in donation service area cultures." The hospital said that because an OPO performs well in its own service area and better than an OPO serving in a different service area, it does not necessarily follow that the more successful OPO will be able to improve donation rates in a new service area with a different culture. The hospital stated, "* * * there is a risk in allowing OPOs to assume new service areas under this assumption because we have learned in the collaborative that relationships with donor hospitals are key to the successful functioning of OPOs. If an OPO assumes a new DSA, begins new relationships with every donor hospital, and is implementing new ways of approaching organ donation, given the amount of change and lack of established relationships, it is more likely donation rates could decrease rather than increase."

Response: We agree with the comments. As stated in our previous response, we have made changes to the proposed criteria for selecting an OPO to take over an open area. One of the criteria is the degree of an OPO's success in identifying and overcoming donation in its own service area, as well as whether the competitor's experience is relevant to the barriers that are specific to the open area. We will encourage competing OPOs to submit information and data to us that demonstrate their own experience in conquering barriers to organ donation, as well as a description of the strategies they would use to overcome barriers in the open area. We will carefully consider the extent to which an OPO's familiarity with obstacles to organ donation and its experience in overcoming them would transfer successfully to the open service area.

Condition: Outcome Measures
(§ 486.318).

The February 4, 2005 proposed rule set forth five outcome measures for OPOs not operating exclusively in non-contiguous U.S. States, territories, possessions, or commonwealths. We proposed that an OPO would be required to achieve at least 75 percent of the national mean for 4 of the 5 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. We proposed that an OPO operating exclusively in non-contiguous U.S. 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. We have made changes to this proposed section, which we discuss in detail below.

Comment: Many commenters said that because the five proposed outcome measures are highly correlated, the proposed outcome measures do not satisfy the mandate of the Organ Procurement Organization Certification Act (section 701 of Pub. L. 106-505) (OPO Certification Act) to "establish multiple outcome measures." A national association that represents all OPOs stated that its analysis indicates that if an OPO does not meet the threshold for the overall conversion rate (that is, the number of organ donors as a percentage of potential donors, the first of the five measures in the proposed rule), it is highly unlikely that the OPO will be able to meet the threshold for the four remaining measures. The association said that "the correlation between kidneys recovered per eligible death, kidneys transplanted per eligible death, extra-renal organs recovered per eligible death, and extra-renal organs transplanted per eligible death with organ donors per eligible death is very high and ranges from .81 to .97." According to the association, "Given the high inter-correlation between the five proposed conversion ratios, little additional information regarding performance is provided by the inclusion of the proposed four organ-related conversion ratios." Many commenters, including individual OPOs, specifically endorsed the association's comments.

Response: We agree with the commenters' suggestions that the proposed outcome measures were highly correlated. The OPO Certification Act required that the Secretary establish regulations to require, among other things, the use of "multiple outcome measures as part of the certification process." Because the proposed

measures were highly correlated, we agree with the commenters that a broader set of measures would better satisfy the statutory requirement for multiple outcome measures. Thus, we are not adopting the proposed outcome measures contained in § 486.318(a). Instead, in this final rule, we establish 3 outcome measures for OPOs: (1) Donation rate; (2) observed donation rate compared to the expected donation rate, as calculated by the SRTR; and (3) a yield measure for both organs transplanted per donor and organs used for research per donor.

The first outcome measure will allow us to assess an OPO's conversion rate of potential donors to actual donors so that we can determine how an OPO has performed in regard to the donor potential (that is, the number of eligible deaths) in its own DSA, as well as how it has performed when compared to other OPOs. This outcome measure—the donation rate—is nearly identical to the first of our proposed outcome measures. Our proposed measure assessed the number of actual donors as a percentage of organ donor potential. DCDs were counted in the numerator but not the denominator of this proposed measure. However, commenters believed that including DCDs only in the numerator of the donation rate outcome measure weighted DCDs too heavily; therefore, in the donation rate outcome measure in this final rule, we will account for DCDs and donors over the age of 70 by adding a 1 to both the numerator and the denominator for each DCD and each donor over the age of 70. We agree with the commenters that this methodology weights these donors appropriately in the donation rate ratio.

The second outcome measure uses the statistical methodology developed by the SRTR for determining an expected donation rate for each OPO, which will allow us to assess with a reliable degree of accuracy how an OPO has performed in view of its expected performance. In the proposed rule we said that the existing methodologies for estimating donor potential, which are based on regression analysis, were unreliable and could not be used for OPO certification. However, the SRTR statistical methodology for determining an OPO's expected donation rate is more reliable and more precise than these earlier methodologies. This second outcome measure, which assesses an OPO's observed donation rate as a percentage of its expected donation rate, that is, the Standardized Ratio, is an integral piece of our three-part OPO outcome measures framework. The Standardized Ratio is calculated as the ratio of the observed donation rate to the expected

donation rate where 1.0 is equal to the reference. A ratio above 1.0 indicates that the observed donation rate for an OPO is greater than the expected, while ratios below 1.0 indicate that the observed donation rate is less than what would be expected given the national experience.

The third outcome measure is comprised of three individual measures for organs transplanted per donor and organs used for research per donor. This third measure allows us to assess how well an OPO fulfills its ultimate mission—recovering viable organs and placing them with transplant centers for transplantation, as well as its commitment to placing organs for research.

The OPTN, SRTR, HRSA, and the CMS OPO Coordinators use these outcome measures in the Collaborative and their other quality improvement projects with OPOs. We have found that the three measures, when used together, form a better picture of overall OPO performance than any of the other measures available today or anticipated in the near future.

We also believe that the new measures satisfy the OPO Certification Act's requirement that we use multiple outcome measures as part of the certification process, and that the outcome measures are based on empirical evidence, that has been obtained through reasonable efforts of organ donor potential and other related factors in each OPO's service area. Each measure is empirical, that is, based upon observation or statistically derived from data. Most of the data are already self-reported to the OPTN, so they are obtained through reasonable efforts. In addition, all three measures are based on organ donor potential or other related factors in each DSA. These individual outcome measures will be discussed in detail in our responses to the public comments recommending the measures.

Comment: We received comments on proposed § 486.314, Appeals Process, that relate to the time period we proposed using to calculate the outcome measures. That is, we proposed using 4 years of data from the most recent 4-year re-certification cycle. However, many commenters suggested that to extend the time period available for the appeals and competition processes, we should consider using fewer months of data from what would be the most current re-certification cycle, along with 6 months of data from the previous re-certification cycle.

Response: We agree with the commenters that it would be sensible to extend the amount of time available for

the appeals and competition processes by beginning the appeals process prior to the end of the re-certification cycle, and we have incorporated their recommendation into this final rule. However, we disagree that it is necessary to utilize data from a previous re-certification cycle. We believe that using data from a previous re-certification cycle would be problematic when we compare the performance of an OPO that takes over another OPO's service area at the beginning of a re-certification cycle to the performance of all other OPOs, because data from the previous re-certification cycle would reflect the performance of the de-certified OPO, not the incoming OPO. We believe that to be fair, we should use the same amount of data from the same period of time for evaluation of OPOs. Therefore, although we will begin the appeals process sooner, we will not include data from a past re-certification cycle when applying the outcome measures to evaluate OPO performance.

In addition, we will not use data from the first 5 months of a re-certification cycle to re-certify OPOs, which means that we will base the outcome measures on only 36 months of data. For example, when re-certifying OPOs in 2010, we will use data from January 1, 2007 through December 31, 2009. This will ensure that all OPOs are evaluated using the same amount of data from the same period of time. We made this decision for three reasons. First, in the future, if we use data from the very beginning of the re-certification cycle and an incoming OPO is unable to take over its new service area at the beginning of the re-certification cycle (because the appeals or competition processes take longer than expected), we would not have the same amount of data for the incoming OPO that we have for other OPOs. Second, in most cases, this method of handling data will provide an OPO that takes over a service area with some time to orient new staff and develop relationships with the hospitals in its new service area before we evaluate its performance. Finally, since the SRTR already compares OPOs based on data from each discrete calendar year, re-certifying OPOs based on 3 calendar years of data is the most efficient method for re-certification.

In the rare instance that an OPO takes over another OPO's service area during the term of the re-certification cycle (on a date later than January 1 of the first full year of the re-certification cycle), so that we do not have 36 months of data available to evaluate the OPO's performance in its new service area, we will not include the OPO's performance on the outcome measures in the new

service area until the end of the following re-certification cycle when a full 36 months of data are available.

Comment: Many commenters said they were pleased that the proposed outcome measures were based on organ donor potential rather than population.

Response: We agree that “organ donor potential” (termed “eligible deaths” in this final rule) is a more precise measure than population for evaluating an OPO’s performance within its DSA. (See discussion of § 486.302, Definitions, in this preamble.) In 2001, the OPTN began collecting and the SRTR began analyzing “eligible death” data from each OPO.

Comment: One commenter said that whereas organ donor potential is a far better denominator than population, there are still significant differences among populations in different areas of the country. The commenter stated, as an example, that certain minority groups have lower rates of consent to organ donation. The commenter recommended that we develop an “expected consent rate” that takes into consideration the percentage of minorities, new immigrants, and undocumented immigrants in each OPO’s service area and measure the OPO’s consent rate against its expected consent rate.

Response: We are not aware of any currently available measure for “expected consent rate.” Therefore, we are not including an expected consent rate outcome performance measure in this final rule. Although an OPO cannot change the number of potential organ donors in its DSA, there are many steps, such as public education and using “like” requestors (that is, designated requestors with backgrounds similar to those of potential donor families) that an OPO can take to raise its conversion rate.

Comment: A commenter who supports the use of organ donation potential in the CMS outcome measures said that population demographics should be considered along with potential. For example, the commenter pointed out that in some areas, donors are older and that even “standard criteria” donors may be sicker than in other parts of the country.

Response: HRSA has advised us that the OPTN and SRTR are considering whether certain conditions and circumstances that may affect the health of standard criteria donors (SCDs) should be factored into the measures used to evaluate OPO performance. If the OPTN and SRTR make this change, we will consider whether we should incorporate it into our outcome measures through future rulemaking.

Nevertheless, we believe the outcome measures in this final rule are sufficiently comprehensive in their evaluation of OPO performance to ensure their validity, regardless of whether changes are made in the future to the definition of “standard criteria donor.”

Comment: Commenters said that differentiating kidneys from extra-renal organs in the outcome measures is irrelevant and that we should include kidneys and extra-renal organs as one measure.

Response: We agree with the commenters that we should no longer differentiate between kidneys and extra-renal organs under most circumstances. As discussed below, under the outcome measures adopted in this final rule, there will no longer be a distinction between kidneys and extra-renal organs, except for OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions. (See § 486.318(b).)

First Outcome Measure: Donation Rate

Comment: Instead of the five proposed conversion ratios, the national association that represents the OPOs, as well as many other commenters, recommended that one single conversion or donation rate—the number of actual donors as a percentage of the potential donor pool—be utilized, along with other outcome measures.

Response: We have accepted the commenter’s recommendations. The first of the three outcome measures in this final rule is a donation rate, that is, the number of eligible donors (actual donors who met the eligibility criteria) as a percentage of the number of eligible deaths. “Eligible deaths” constitute the pool of potential donors who meet the criteria for medical suitability for donation. (See § 486.302 for the specific criteria for an “eligible death.”)

Comment: Some commenters drew attention to the fact that a donation rate outcome measure would be based on self-reported hospital referral data. (In both the proposed rule and in this final rule, the first outcome measure is a donation rate, that is, the number of actual organ donors (“eligible donors” in this final rule) as a percentage of the number of potential organ donors (“eligible deaths” in this final rule). The number of eligible deaths is a subset of the deaths that hospitals report to their designated OPOs. Hospitals are required to report all deaths and imminent deaths to OPOs under § 486.345.) Commenters said that if an OPO does not develop good working relationships with its hospitals, the hospitals likely will not refer all deaths or imminent

deaths to the OPO or they will not refer them in a timely fashion. Commenters said that basing an outcome measure on hospital referrals lets the OPO that has not worked at developing its relationships with hospitals “off the hook.” That is, the number of eligible deaths would be under reported by the hospital to the OPO and thus by the OPO to the OPTN, resulting in a “false high” donation rate. Commenters pointed out that the proposed rule did not include a provision for independent verification of the self-reported data.

Response: We will monitor OPOs closely to ensure that they develop their relationships with hospitals appropriately, particularly those hospitals with a large number of potential donors, to ensure that the OPO receives hospital referrals timely. Further, although the donation rate outcome measure in this final rule is based on self-reported data, the SRTR statistical methodology is not. (See § 486.318(a)(2).) While the number of “eligible deaths” is reported by OPOs to the OPTN, the number of “notifiable deaths” (the subset of all in-hospital deaths age 0–70 with no exclusionary medical diagnoses for possible donation) is calculated by the SRTR based on data from the Office of Analysis and Epidemiology, National Center for Health Statistics, Centers for Disease Control and Prevention. By assessing an OPO’s reported number of eligible deaths in view of its notifiable deaths, the SRTR can ascertain whether the data reported by an OPO are likely to be correct. If the data indicate that an OPO may not be reporting the number of eligible deaths in its service area correctly, we will treat this information as a complaint and will conduct a complaint investigation of the OPO. Ultimately, it is each OPO’s responsibility to ensure that the data they submit to the OPTN are valid.

Comment: Commenters also said that the outcome measures for kidneys and extra-renal organs procured are subject to manipulation by OPOs that recover organs that can not be transplanted, simply to increase their procurement rate.

Response: We consider a “donor” to be a deceased individual from whom at least one vascularized organ is removed for the purpose of transplantation. Thus, data on the number of donors, as well as the number of organs recovered, are subject to manipulation by an OPO that recovers an organ that is not suitable for transplantation, solely for the purpose of increasing its performance numbers. However, this final rule includes a measure that can not be manipulated—organs transplanted per donor. (See

§ 486.318(a)(3).) This outcome measure will provide a true picture of an OPO's performance in regards to the number of viable organs it recovers.

Comment: Many commenters recommended that any donation rate outcome measure should include incentives for maximizing the number of donors, including DCDs (donors after cardiac death) and ECDs (expanded criteria donors). Commenters criticized our proposal for including such donors in the numerator of the donation rate ratio without including them in the denominator. They said that incorporating DCDs and ECDs in the numerator alone: (1) Places a disproportionate weight on these donors; (2) raises the national conversion rate to the detriment of OPOs that do not recover many DCDs and ECDs (perhaps because they have fewer potential DCDs and ECDs); and (3) may inadvertently mask opportunities for improvement in recovery of standard criteria donors. Therefore, commenters recommended that we exclude these donors from the national rate but include them in the numerator and denominator of each individual OPO's donation rate ratio as adjustments to individual OPO conversion rates.

Response: We agree with the commenters' recommendation, and we are adopting this change in this final rule. Absent this change, OPOs that have a low number of potential DCDs and ECDs could be disadvantaged, even de-certified, if the SRTR were to include these donors in the numerator of the donation rate ratio when computing the national donation rate. Therefore, under this final rule, when an OPO recovers an "additional donor," that is, a deceased donor over the age of 70 or a DCD, a "1" will be added to both the numerator and the denominator of the OPO's donation rate ratio. The SRTR includes data on additional donors in its organ donation tables at <http://www.ustransplant.org>. We believe this method of quantifying additional donors will provide an appropriate incentive for OPOs to recover donors that do not fall under the current definition of "eligible death," while ensuring that OPOs with a low number of potential additional donors are not disadvantaged.

Comment: A national association representing transplant physicians and surgeons commented that requiring OPOs to add DCDs and ECDs to the numerator but not the denominator of the conversion ratio would provide an incentive for OPOs to recover DCD and ECD organs preferentially, resulting in fewer extra-renal organs available for transplantation. (The association pointed out that the number of organs

transplanted per donor for DCDs is 2.04 compared to 3.62 for non-DCDs, which suggests that kidneys are often the only organs transplanted from DCDs.) Additionally, the association stated that because kidneys from DCDs are more likely than kidneys from other donors to have delayed graft function, and livers from DCDs have a lower graft survival rate, transplant recipients' health would be affected. The association also contended in its comments that the goal of increasing the supply of organs from DCDs and ECDs is not consistent with the goal of the CMS proposed conditions of participation for transplant centers (published February 4, 2005, 70 FR 6140), which seek to optimize transplant center patient and graft survival. The association suggested that we require OPOs to meet all five (instead of only four) proposed outcome measures to ensure that an OPO would be required to meet the measure for extra-renal organs transplanted. The association stated that DCDs and donors over the age of 70 should not be added to either the numerator or the denominator of the conversion rate ratio. However, the association qualified this statement by adding that if DCDs and ECDs are not excluded from the ratio, they should be added to both the numerator and denominator of the donation rate ratio.

Response: We understand the commenter's concerns and agree that the goals of the OPO and transplant center rules should be closely aligned. Although we want to provide an incentive for OPOs to recover organs from ECDs and DCDs, we certainly do not want such an incentive to lead to fewer extra-renal organs available for transplantation or to poorer outcomes for transplant recipients. As stated in our previous response, under this proposed rule, when an OPO recovers an "additional donor," that is a deceased donor over age 70 or a DCD donor, a "1" will be added to both the numerator and the denominator of the donation rate ratio. We believe weighting the data in this manner creates an appropriate incentive for OPOs to recover organs from additional donors, which will make more kidneys and extra-renal organs available for transplantation and create more options for transplant recipients who might otherwise not receive an organ.

Second Outcome Measure: Observed/Expected Donation Rate

Comment: Many commenters praised the innovative analytic work conducted by the SRTR to improve donation rate measurement, including the SRTR's efforts to identify "eligible deaths" and

expected donation rates for each OPO's DSA. Commenters voiced strong support for adopting the SRTR's statistical methodology for evaluating OPO performance for re-certification purposes. Commenters said that using the SRTR measure would provide an independent statistical assessment of how OPOs perform relative to their own service area capabilities, such as the presence or absence of large hospitals and trauma centers. Commenters also pointed out that including the SRTR methodology would provide an approach grounded in science similar to our proposed use of the SRTR statistical methodology for transplant centers, which we proposed using for approval and re-approval of OPOs. Commenters said that using the SRTR methodology in conjunction with a national conversion rate would mean that OPOs would be evaluated both in comparison to other OPOs, as well as in comparison to each OPO's statistically expected performance.

Response: The SRTR methodology can be used to determine the expected organ donation rate in a DSA based on the following hospital characteristics: Level I or Level II trauma center, metropolitan statistical area size, CMS case mix index, total bed size, number of ICU beds, primary service, presence of a neurosurgery unit, and hospital control/ownership. An adjustment is made for the expected notification rate. (A Ojo, R Wolfe, A Leichtman, *et al*; *A Practical Approach to Evaluate the Potential Donor Pool and Trends in Cadaveric Kidney Donation*, Transplantation, Vol. 67, No. 4, February 27, 1999 and A Ojo, R Pietroski, K O'Connor, *et al*; *Quantifying Organ Donation Rates by Donation Service Area*, American Journal of Transplantation 2005; 5 (Part 2).) Several commenters pointed out that OPOs and hospitals now use the SRTR statistical methodology in evaluating their own performance and that the SRTR methodology is used in the Collaborative.

We agree with the commenters that the SRTR statistical methodology for evaluating OPO performance should be used by CMS for re-certification of OPOs. In fact, since the SRTR methodology incorporates specific characteristics of the hospitals in an OPO's service area, utilizing the SRTR methodology will satisfy the requirement in the OPO Certification Act for considering "other related factors in each service area" in OPO re-certification. Therefore, under this final rule, one of the three outcome measures for OPOs is as follows: the observed donation rate is not significantly lower

than the expected donation rate (hospital characteristics, notification rate) for 18 months or more of the 36 months of data included from the re-certification cycle, as calculated by the SRTR.

Comment: Commenters who recommended that CMS use the SRTR methodology also suggested that refinements should be made to the methodology and the donation (conversion) rate measures before the methodology is used for re-certification of OPOs. Commenters said that the SRTR should: (1) Review patient-specific data for refining the methodology, (2) incorporate DCDs and ECDs into its methodology; (3) review the statistical analysis for an entire 4-year period (since the data collection did not begin until September of 2001); (4) address the effect of statistical bias created by the use of dated International Classification of Disease codes on the organ-specific donation rates first published by the SRTR in January 2005; and (5) independently validate inter-OPO reporting of data and the impact of an outcomes approach heavily reliant on referral data.

Response: The SRTR methodology is defined and will not change. The data to which the models are applied will be updated to the relevant time period, and the weighting (coefficients) of the parameters (variables) in the model will be adjusted to best fit the data. Each OPO will be adjusted in the same way so that all OPOs are adjusted to national data.

Comment: Some commenters recommended that when we determine an OPO's performance, we also determine whether the OPO's outcomes are statistically significant at $p < .01$. That is, to determine inadequate performance, an OPO's outcome must fall below the threshold and be statistically significantly lower than the performance of other OPOs.

Response: The SRTR publishes data on its Web site showing the observed and the expected donation rate for each OPO, including a standardized ratio; p-value; whether the observed donation rate is statistically lower, higher or not significantly different; and the lower and upper confidence intervals. A ratio above 1.0 indicates that the observed measure for an OPO is greater than what would be expected based on the national experience, while a ratio below 1.0 indicates that the observed measure for an OPO is less than what would be expected. The 95 percent confidence intervals of the ratios, which are published on the SRTR's Web site, describe the uncertainty of the estimated expected measures and vary

by DSA, depending on the amount of data and the variability within the data. The p-value is a test for statistical significance between the observed and expected measures. The p-value is an indication of whether a given result represents a genuine difference or if it could be due to random chance. A p-value of less than or equal to 0.05 indicates that the difference between the observed and expected is probably a genuine difference and is not due to random chance, and a p-value greater than 0.05 indicates that the difference could be due to random chance. A p-value of 0.05 is utilized in the same manner in the SRTR's statistical methodology for evaluating transplant center performance.

Third Outcome Measure: Organs Transplanted Per Donor

Comment: Many commenters said that the adoption of a "yield" measure (organs transplanted per donor) more fully meets the legislative expectation of multiple measures; is consistent with the recently launched HHS Organ Transplantation Initiative; provides incentives for greater recovery and transplantation of extra-renal as well as renal organs; and allows for incorporation of legislative expectations regarding pancreas recovery for islet cell transplantation and research. Further, commenters pointed out that unlike the four proposed organ-related conversion rates, the unit of analysis is the donor rather than a self-reported eligible donor population.

Response: We agree that a "yield" measure should be added to our outcome measures for evaluation and re-certification of OPOs in the future. The number of organs transplanted per donor is an invaluable measure of OPO performance that has been used successfully by the Collaborative. The measure goes beyond simply quantifying the number of donors or the number of organs recovered from donors, by assessing donor quality based on the number of organs that can be used for transplantation. Clearly, transplantation of viable organs is the ultimate goal of organ procurement, and we believe that OPOs should be able to demonstrate that they have performed well in this regard. Therefore, we have included in this final rule an outcome performance measure for the number of organs transplanted per donor. We have revised proposed § 486.318 accordingly. In this final rule at 486.318(a)(3) we require that at least 2 out of the 3 following measures are no more than 1 standard deviation below the national mean, averaged over 3 years during the re-certification cycle: (1) Number of

organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation; (2) Number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and (3) Number of organs used for research per donor, including pancreata used for islet cell research. The first two measures are calculated by dividing the number of organs transplanted by the number of donors (either SCDs or ECDs). The third measure is calculated by dividing the number of organs used for research by the total number of donors (all donor types). Although we are establishing the thresholds for the outcome measures as we described earlier in this preamble, we will reconsider the appropriateness and the validity of the thresholds every 4 years when we review and analyze data from the previous re-certification cycle. If overall OPO performance improves and the mean increases, as we expect, we may find that OPOs that do a good job are falling below a threshold established by this final rule. If so, we will consider whether the threshold should be lowered. Conversely, if we find that a threshold established by this final rule is so low that it provides no incentive for OPOs to excel, we will consider whether to raise the threshold.

We will continue to monitor the OPOs performance under the third outcome measure. In the future (after the first agreement cycle), we may seek to make the standard more stringent if that appears warranted. We would only make this change after obtaining public comment through a separate rulemaking.

Comment: Some commenters suggested that each recovered pancreas used for islet cell transplantation or research should be added to the numerator and denominator of the organs transplanted per donor rate ratio for each individual OPO. One commenter pointed out that the pancreas adjustment would provide appropriate incentives for OPOs to recover pancreata for islet cell transplantation or research and would be consistent with the Pancreatic Islet Cell Act of 2004, which requires CMS to count pancreata used for islet cell transplantation and research towards an individual OPO's performance for re-certification purposes.

Response: We agree with the commenters' suggestion to include pancreata used for islet cell transplantation in the organs transplanted per donor outcome measure. In view of the variability in recovery of pancreata across the nation, adjusting an individual OPO's organs transplanted per donor rate for

pancreata recovered for islet cell transplantation, rather than adding these pancreata to the national mean, weights these data appropriately. Thus, in this final rule, we specify that for the organs transplanted per donor outcome measure, "organs" include pancreata used for islet cell transplantation. However, we do not agree that it is appropriate to include pancreata used for islet cell research in the organs transplanted per donor measure. We believe the measure should reflect only organs that were used for transplantation.

In this final rule, we are adding an additional yield measure for organs used for research, which is discussed below. By including pancreata that are used for islet cell research in this measure, the pancreata will be counted for re-certification purposes, pursuant to the Pancreata Islet Cell Transplantation Act, and it will also provide an incentive to OPOs to procure pancreata for islet cell research. We believe that this is the most appropriate measure we can use to account for pancreata used in islet cell research.

Comment: Many commenters recommended that a case-mix expected rate be incorporated into the outcome performance measure for organs transplanted per donor. One commenter stated that case-mix adjusting would account for important variations reflecting types of donors, as well as the age and race of donors, and would allow for appropriate incentives to OPOs to recover organs from all donors without worrying about the negative impact on their performance. A commenter stated that the use of such an approach for outcome performance purposes would provide a sounder analytic basis than using unadjusted measures to make inter-OPO assessments. The commenter pointed out that under the Collaborative, HHS has identified individual, organs-transplanted-per-donor goals for the three different types of donors: donors after cardiac deaths (DCDs), expanded criteria donors (ECDs), and standard criteria donors (SCDs).

Response: We agree that there are variations in the number of organs transplanted per donor, depending upon the donor type, that is, DCD, ECD, or SCD. Since currently there is no methodology for case-mix adjusting the number of organs transplanted per donor, in this final rule, we have included within the outcome measure for organs transplanted per donor two subgroups of donors: the number of organs transplanted per ECD and the number of organs transplanted per SCD. We have not included the number of

organs transplanted per DCD because we do not want to disadvantage OPOs that do not recover organs from such donors. The current definition for an "expanded criteria donor" or "ECD" used by the OPTN is a donor who is over 60 years of age, or who is between 50 and 59 years of age and meets two of the following three conditions: died of a stroke, had a history of hypertension, or had a serum creatinine of greater than 1.5. Note that we are not finalizing a definition for ECD in this final rule because we believe the definition for ECD will change over time in response to changes in transplant technology.

It is important to note that OPOs will be required to meet only 2 out of the 3 yield measures at the 1 standard deviation below the mean threshold for each subgroup.

Third Outcome Measure: Organs Used for Research Per Donor

Comment: Some commenters urged CMS to count all organs recovered for research in the outcome measures for OPOs. One commenter noted that organs that are not suitable for transplantation may aid researchers in developing experimental techniques that could assist in reducing the transplant waiting list. A researcher wrote to say that his research on a cellular-based treatment for liver disease is nearing the clinical trial phase but that a limiting factor for the speed of entry into human clinical trials is access to tissue from organs. The researcher commented that tissue from organs for research would not be limited if every OPO made the same effort as the highest performing OPOs to recover organs for research. He pointed out that in 2003, there were 6455 deceased donors and 5348 liver transplants. Of the 1107 livers that were not transplanted, only 168 were sent for research. The researcher also said that OPOs have told him that there is no incentive for OPOs to recover and place organs for research because their standard acquisition charge is reduced by the amount the OPO receives for the organ. This commenter suggested that we establish within the outcome measures, a measure for consent rate for organs recovered for research.

Response: We agree overall with the commenters' recommendations. Like organs for transplantation, organs for research are a precious national resource. We believe OPOs should recover organs for research whenever possible to aid researchers looking for new therapies for debilitating and fatal diseases, many of them the same diseases that cause end-stage organ

failure in patients waiting for transplants. Although recovering organs for research is not an OPO's primary mission, the organs it places with researchers may help lead to treatments or cures that will reduce the transplant waiting list as surely as organs that are used for transplantation.

We believe that providing an incentive for OPOs to recover organs for research will increase the number of organs available to researchers throughout the country. However, we believe measuring how many organs an OPO actually places for research is a more useful measure than the rate of consent to donating organs for research. Thus, the third OPO outcome performance measure (the "yield" measure) for OPOs that do not operate exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions will include a measure of the number of organs used for research (including organs used for islet cell research) per deceased organ donor. The policy is consistent with the Pancreatic Islet Cell Transplantation Act, which requires that pancreata used for islet cell research be counted for OPO certification. When determining the number of organs "used" for research, we will consider any organ that an OPO sends to an individual or organization for research purposes as having been used for research. Nevertheless, while recovering organs for research is vitally important, we do not want OPOs to recover organs for research at the expense of organs for transplantation. An OPO's primary mission is to maximize the number of viable organs it recovers and places for the purpose of transplantation. To ensure that OPOs focus on this mission, we have weighted the overall yield measure toward recovering organs for transplantation. That is, there are two sub-measures for organs for transplantation (number of organs transplanted per SCDs, ECDs) and only one sub-measure for research organs (number of organs recovered for research per deceased donor).

OPOs That Serve Non-Contiguous Areas

Comment: Some commenters recommended different performance standards for Puerto Rico and Hawaii. A national association that represents all of the OPOs suggested the following outcome measures for Puerto Rico and Hawaii: (1) Thresholds of 50 percent of the national mean, instead of 75 percent, for both conversion rate and organs transplanted per donor; (2) an organs transplanted per donor measure based only on kidneys recovered per donor; and (3) that a national mean be calculated for kidneys recovered per

donor solely for the purpose of determining if Puerto Rico and Hawaii exceed 50 percent of the national mean. That association also suggested that these be the only outcome measures for Puerto Rico and Hawaii.

Response: We have historically used different performance standards for OPOs that operate exclusively in non-contiguous States, territories, and commonwealths. The performance standards in the existing regulations require such OPOs to meet only two performance standards (kidneys recovered and kidneys transplanted) and to meet them at only 50 percent of the national mean. These differences recognized that OPOs operating exclusively in non-contiguous locales have fewer options for placing organs because they have fewer transplant centers (particularly extra-renal transplant centers) and may be located too far from the continental United States for the viability of extra-renal organs (including pancreata used for islet cell transplantation or research) to be maintained until transplantation can take place.

Therefore, under this final rule, we set forth the following outcome measures for OPOs operating exclusively in non-contiguous U.S. States, commonwealths, territories, or possessions: (1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over 3 years during the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70; (2) the observed donation rate is not significantly lower than the expected donation rate for 2 or more years of the 4 year re-certification cycle, as calculated by the SRTR; and (3) at least 2 out of the 3 following measures are no more than 1 standard deviation below the national mean, averaged over the 3 years during the re-certification cycle:

- The number of kidneys transplanted per standard criteria donor;
- The number of kidneys transplanted per expanded criteria donor; and
- The number of organs used for research per donor, including pancreata used for islet cell research.

Performance Thresholds

Comment: Many commenters recommended the following specific thresholds for inadequate performance

by an OPO that does not serve only non-contiguous areas:

- Not achieving 75 percent of the mean overall donation rate, and
- Having a SRTR-based donation rate for at least 3 years of the 4-year cycle statistically lower than expected, and
- Not achieving 75 percent of a case-mix expected organs per donors transplanted measure.

Response: We agree in theory with the commenters' recommendation for the second measure (a ratio of the observed donation rate/expected donation rate that is not significantly lower than expected for at least 2 years out of the 4-year re-certification cycle) is reasonable. (We have finalized this as a ratio of the observed donation rate/expected donation rate that is not significantly lower than expected for at least 18 months out of 36 months, because we are using a lesser amount of data.) However, we disagree with the commenters that an OPO's performance is not adequate if it has not achieved 75 percent of the mean national donation rate and 75 percent of the organs transplanted per donor measure.

Historically, we have used a threshold of 75 percent of the national mean for the OPO performance standards. (See 42 CFR 486.310(b).) However, we believe that using standard deviations provides more statistical validity and ensures that OPOs screened out for de-certification are outliers. We believe this threshold screens out OPOs that are not effective yet takes into consideration the likelihood that the national mean will continue to rise, as well as the fact that each OPO's performance on the outcome measures is based on a relatively small number of donors and organs. Therefore, rather than using a percentage threshold, we are adopting a statistically-based threshold. In this final rule, to meet the donation rate outcome measure and the "yield" measure of organs transplanted per donor/organs used for research per donor, an OPO's performance must be at or above 1.5 standard deviations below the mean national rate for the 3 years during the re-certification cycle for the donation rate measure and at or above 1 standard deviation below the mean national rate for the 3 years during the re-certification cycle for the yield measure.

Under this final rule, an OPO's donation rate of eligible donors as a percentage of eligible deaths must be no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 3 years during the re-certification cycle. Both the numerator and denominator of

an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70. (See § 486.318(a)(1).)

As discussed above, we are not adopting a case-mix-expected organs per donor transplanted measure because the SRTR currently does not case mix adjust this measure. However, we are adopting separate organs transplanted per donor measures for SCDs and ECDs, as well as a measure for the number of organs used for research per donor. OPOs will be required to meet 2 out of 3 of these measures at no less than 1 standard deviation below the mean national rate for the following: organs transplanted per donor for SCDs, organs transplanted per donor for ECDs, and organs used for research per donor. (See § 486.318(a)(3).) Therefore, we have established a threshold of 1.5 standard deviations below the national mean for the donation rate outcome measure and 1 standard deviation below the national mean for the yield measure.

General

Comment: Some commenters said that OPOs should suffer no reimbursement consequences if they procure organs that are not accepted for transplantation. Since an OPO's costs for procuring these organs are added to its overall standard acquisition charge for organs, its costs are passed through to transplant hospitals and the Medicare program.

Response: Medicare payment policy and OPO standard acquisition charges are beyond the scope of this regulation. We are not making changes to the final rule based on this comment.

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

The February 4, 2005 proposed rule included language to clarify that an OPO becomes a member of the OPTN only after becoming designated by CMS. We proposed requiring that 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 approved by the Secretary.) We are adopting this section with one change, which is discussed below.

Comment: A few commenters pointed out that the Public Health Service Act requires OPOs to "participate in the OPTN" (42 U.S.C 273(b)(3)(H)). They suggested including this phrase in the requirements for OPTN membership.

Response: We agree with the commenter. Therefore, we have revised § 486.320 to require OPOs to participate in the OPTN.

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

We proposed three standards for this condition of participation. For the standards regarding hospital agreements, we proposed that 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. With regard to training, we proposed that the OPO must offer designated requestor training on at least an annual basis for hospital and critical access hospital staff. Finally, we proposed a standard regarding cooperation with tissue banks that specified the OPO must have arrangements to cooperate with tissue banks that have arrangements with hospitals and critical access hospitals with which the OPO has agreements. We are implementing this section with some changes, which are discussed in detail below.

We received many comments on this proposed condition of participation, particularly on the subsection requiring cooperative arrangements with tissue banks. Overall, commenters approved of our proposal to require agreements with 95 percent of hospitals with a ventilator and an operating room. We received only a few comments on our proposal to require OPOs to offer designated requestor training annually, and commenters strongly disagreed with our proposal to require OPOs to have cooperative agreements with tissue banks.

Comment: One commenter said that we should require OPOs to have agreements with 100 percent (not just 95 percent) of the hospitals in their service areas with a ventilator and an operating room.

Response: We believe that it would be optimal for OPOs to have agreements with 100 percent of the hospitals in their service area that have a ventilator and an operating room. However, as we stated in the preamble to the proposed rule, the PHS Act requires only that an OPO have agreements with a “substantial majority” of the hospitals in its service area that have facilities for organ donation. Therefore, we proposed 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.) We reasoned that because 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. For these reasons, we are adopting the requirement that OPOs have agreements with 95 percent of the qualifying hospitals in their service area, as proposed.

Comment: One commenter pointed out that currently OPOs are required to have agreements with only 75 percent of the Medicare and Medicaid hospitals in their service areas. The commenter said that there is no reason to make a change. Another commenter suggested that OPOs should be required to have agreements only with hospitals that have 150 or more acute care beds with an intensive care unit and a ventilator or with a Level I or Level II trauma center.

Response: We disagree that OPOs should be required to have agreements with only 75 percent of the Medicare and Medicaid hospitals in their service areas that have an operating room and the equipment and staff to maintain a potential organ donor, as required under the current regulations. We also disagree that OPOs should be required to have agreements only with hospitals that have 150 or more acute care beds with an intensive care unit and a ventilator or with a Level I or Level II trauma center.

We acknowledge that many hospitals in an OPO’s service area do not have a high potential for organ donation. Nevertheless, it is important for OPOs to work with these hospitals to develop appropriate agreements to define terms, ensure that all deaths and imminent deaths are referred to the OPO, and address how the organ donation process will occur, so that when hospitals have potential donors, the organ donation process proceeds smoothly and organ donation is maximized. The success of the Collaborative has proven that organ donation will increase in hospitals where hospital leaders and OPOs have worked together to develop comprehensive, functional agreements that spell out the roles and

responsibilities of all parties in the donation process.

Comment: A commenter voiced support for including a requirement that OPOs’ agreements with hospitals define both “imminent death” and “timely referral.” Another commenter said that we should change the term “imminent death” to “clinical triggers,” because many OPOs and hospitals across the country are using the term “clinical triggers” to define the point in time when a hospital should contact the OPO about a patient whose death may be imminent.

Response: We have no objection to OPOs using the term “clinical triggers” in their agreements with hospitals. The term has been widely used among OPOs and hospitals participating in the Collaborative as a substitute for the term “imminent death.” However, the regulatory text of this final rule includes the term “imminent death” because it is the term used in § 482.45, Hospital Condition of Participation for Organ, Tissue, and Eye Procurement, which requires hospitals to report all deaths and imminent deaths to an OPO. Therefore, we would advise OPOs when using the term “clinical triggers” in their agreements to include the term “imminent death” as well, so that a surveyor reviewing an agreement between an OPO and a hospital can determine that the OPO has met the requirement to include the definition of “imminent death.”

Comment: A commenter asked for clarification regarding the information an OPO will need to have on hand to show a surveyor that it tried but failed to sign an agreement with a hospital in its service area.

Response: Following publication of this final rule, CMS will develop Interpretive Guidelines for OPO surveyors that will include such specific details. However, we would expect an OPO to be able to show due diligence in attempting to meet this requirement, such as copies of written requests for meetings with hospital leadership, letters to the hospital administration, or documentation of telephone calls and other contacts with hospital decision makers.

Comment: One commenter stated that our proposal to require OPOs to offer designated requestor training on at least an annual basis conflicts with § 482.45, which states that designated requestor training should be provided if it is requested by the hospital.

Response: We did not propose requiring OPOs to provide designated requestor training annually for their hospitals. However, because the commenter misunderstood the proposed

language, we have clarified that the OPO is required only to *offer to provide* designated requestor training annually. If a hospital does not want designated requestor training for its staff, the OPO is not required to provide it. We have revised § 486.322(b) accordingly.

Comment: A commenter said that requiring designated requestor training conflicts with demonstrated best practices (such as the best practices of the Collaborative), which emphasize the importance of a partnership between the OPO representative and hospital staff.

Response: Effective requestors also receive training from OPOs, although the training may take place in real time and not in a classroom setting. Therefore, if an OPO partners with hospital staff and, as a team, the OPO and hospital staff discuss and determine the most appropriate way to approach a potential organ donor family to request consent, the hospital staff are considered trained designated requestors for the purposes of this regulation. We have added language to the proposed definition of “designated requestor” to clarify that the terms “designated requestor” and “effective requestor” are interchangeable.

Comment: One commenter said that we should require OPOs to include tissue and eye agency staff when designated requestor training is provided to a hospital.

Response: The hospital CoP for organ, tissue, and eye procurement at § 482.45 requires hospitals to assure that designated requestor training is “designed in conjunction with the tissue and eye bank community.” This final rule requires OPOs to cooperate with tissue banks in providing designated requestor training. This means that if an OPO provides designated requestor training to a hospital, and the hospital or a tissue bank with which the hospital has an agreement asks the OPO to include the tissue bank in the training, the OPO must provide an opportunity for the tissue bank to participate in the training. We have added language to § 486.322(c) that requires OPOs to cooperate with tissue banks in offering designated requestor training.

Comment: Many commenters said that we should not require an OPO to have an arrangement with a tissue bank if the OPO does not agree with the tissue bank’s practices. Some OPOs commented that they do not want to be associated with such tissue banks for a variety of reasons, including the possibility of legal liability. Many of the OPOs that commented expressed a willingness to act as a gatekeeper for hospital referrals and pass those

referrals to the hospital’s tissue bank(s). However, commenters said they should not be required to cooperate with such a tissue bank in obtaining consent from families (in the absence of a donor document) or in the retrieval, processing, preservation, storage, or distribution of tissues.

Response: In developing this subsection for the final rule, we took into consideration three factors: (1) An OPO’s role as the agency that receives most referrals of deaths and imminent deaths from the hospitals in its service area (unless referrals are screened by a third-party designated by the OPO); (2) the need to show sensitivity toward the circumstances of potential organ and tissue donor families (such as, ensuring that potential donor families are not approached by more than one agency unnecessarily); and (3) the statutory requirement that an OPO have arrangements to cooperate with tissue banks to assure that all useable tissues are obtained.

The hospital CoP for organ, tissue, and eye procurement at § 482.45, which went into effect in August 1998, requires hospitals to refer all deaths and imminent deaths (rather than just potential organ donors) to an OPO or a third party designated by the OPO. Critical access hospitals also have a CoP for organ, tissue, and eye procurement. (See § 485.643.) 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. It has been our experience that very few hospitals have been willing to have alternative arrangements that would require them to make two phone calls: one to the OPO to report a death or imminent death and one to the tissue bank to report a potential tissue donor. Thus, in most areas of the country, OPOs became the de facto gatekeepers for information about potential tissue donors even though our regulations permit alternative arrangements.

The PHS Act, as well as the existing regulations for OPOs at § 486.308(i), require OPOs to have “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.” Cooperation between OPOs and tissue banks often results 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. Further, as we stated in the

preamble to the proposed rule, collaboration and cooperation between donation organizations promote a positive public opinion about donation.

Recent years have seen significant growth in the number of OPOs that have their own tissue banks or that have agreements with a specific tissue bank to provide various services, such as obtaining consent on behalf of the tissue bank or recovering tissue. In some cases, this flexibility has worked well, but in other areas, the increased involvement of OPOs in tissue banking has created tension between certain OPOs and the tissue banks in their service areas. It is clear that because of an OPO’s role in regard to hospital referrals, we must ensure that the OPO cooperates in the screening and referral of potential tissue donors. Thus, as we proposed at 486.322(c), when an OPO receives a referral of a death or an imminent death from the hospital with which it has an agreement, the OPO must cooperate with the tissue bank with which the hospital has an agreement to ensure that the referral is screened for tissue donation potential and, as appropriate, referred to the tissue bank.

Additionally, as proposed at 486.322(c)(ii), an OPO must cooperate with tissue banks with which a hospital has an agreement in obtaining informed consent for tissue donation. Note that the OPO is *not* required to request tissue donation on behalf of a tissue bank that does not have an agreement with the hospital.

Under the PHS Act at section 371(b)(3)(I), an OPO is required to have arrangements to cooperate with tissue banks in the “retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors.” The proposed rule has a similar requirement at proposed § 486.322(c)(iii). Although we are finalizing our requirement as proposed, we are clarifying that this requirement does not obligate an OPO to have arrangements with the tissue bank with which the hospital has an agreement (or with any other tissue bank) to collaborate or cooperate with the tissue bank *routinely* in the “retrieval, processing, preservation, storage, and distribution of tissues.” An OPO’s mission is recovering and distributing organs, not recovering, processing, preserving, storing, or distributing tissues. We do not believe it would be appropriate to require an OPO to engage in these activities on a regular basis. Therefore, a tissue bank should make its own arrangements for these activities, without relying on the OPO.

Comment: One commenter said that CMS should request information directly from tissue banks about OPOs, for example, by sending an annual questionnaire to the tissue banks and eye banks working in conjunction with the OPO. The commenter said that as the Federally mandated OPO, an OPO has a responsibility to provide services to all their customers in the community, including tissue banks and eye banks.

Response: OPOs are responsible for cooperating with the tissue banks and eye banks with which the hospitals in its service area have agreements. Such a tissue bank (or eye bank) that believes an OPO is not cooperating, as required by the OPO regulations, should contact us, and we will assess the situation to see if the OPO has violated a regulatory requirement. However, we are not requiring OPOs to provide services to all the tissue banks and eye banks in their service areas or sending an annual questionnaire to each tissue bank.

Comment: One commenter said that when determining whether an OPO is creating a spirit of cooperation and collaboration, we should look at the issue of referral fees and timely access to data. The commenter described a situation in which an OPO that uses a third party to answer referral calls from hospitals has refused to provide timely access for tissue banks and eye banks to referral calls and other information. Thus, the tissue banks and eye banks were forced to contract with an alternate third party to gain access to needed information. The commenter said that as a result, the tissue banks and eye banks are forced to pay a referral fee both to the OPO and to the alternate third party.

Response: As we stated in our previous response, if we receive a complaint from a tissue bank about an OPO that involves hospital referrals and/or the OPO's gatekeeper function, we assess the situation to see if a regulatory requirement has been violated. We have made no change in the regulations text in response to this comment.

Comment: A commenter suggested that CMS should hold OPOs accountable for obtaining consents on behalf of tissue banks by tracking their consent rates for tissues and making this information public. The commenter said that some OPO procurement coordinators choose not to ask families to donate tissue because they believe such a request may cause a family to say no to organ donation.

Response: An OPO's primary mission is organ donation; therefore, we have no plans to track OPOs' tissue consent rates. As stated earlier, this final rule requires OPOs to cooperate with tissue

banks that have agreements with the hospitals with which the OPO has agreements to obtain informed consent from families of potential tissue donors. Further, this final rule at § 486.42(a) requires OPOs 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 * * *."

Comment: A commenter requested clarification of proposed § 486.322(c)(2), "An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO." The commenter said that regulations must be established that would verify that unreasonable obstacles were not created by the OPO to create an unwillingness to have an arrangement in an effort to keep certain tissue banks out of the hospital. The commenter suggested that we should strengthen the proposed language to say that an OPO "must make every reasonable effort to have an arrangement with *all* tissue banks that serve their hospitals."

Response: We are not parties to the agreement, and our regulations do not specify the precise terms of any agreement between an OPO and a tissue bank. The parties to the agreement are in the best position to develop the exact language of the agreement. Our regulations give the parties the flexibility to establish appropriate procedures without the government attempting to impose a one-size-fits-all solution. We included the proposed language to which the commenter refers only to ensure that OPOs would not be penalized if a tissue bank were unwilling to have an arrangement with the OPO. We do not agree with the commenter that we should require OPOs to have a cooperative arrangement with "all tissue banks that serve their hospitals." The suggested language is ambiguous and could be understood to obligate an OPO to have an agreement with a tissue bank that does not have an agreement with a hospital with which the OPO has an agreement. For example, if a tissue bank has an agreement with a medical examiner or coroner for recovery of tissue from potential tissue donors who fall under medical examiner or coroner jurisdiction but does not have an agreement with the hospital, this final rule does not require the OPO to have a cooperative arrangement with the tissue bank.

Comment: A commenter said that it would be helpful if CMS could provide guidance in regard to medical/examiner coroner cases. The commenter stated that in many instances, a medical

examiner or coroner may have an affiliation with a tissue bank and may refuse to honor a hospital's agreement with a different tissue bank (or with the OPO) for tissue donation, choosing, rather to "assert jurisdiction" over the body and pass the referral to its affiliated tissue bank, one not chosen by the hospital to serve its patients and families.

Response: As stated in our previous response, we do not require an OPO to have a cooperative arrangement with a tissue bank whose agreement is not with the hospital but with a medical examiner or coroner. Moreover, we do not regulate medical examiners or coroners and, thus, we cannot intervene if a medical examiner or coroner refuses to honor an agreement that the hospital has with a tissue bank.

Condition: Administration and Governing Body (§ 486.324)

We proposed creating a separate condition for coverage for administration and governing body with a number of new requirements for membership composition of and bylaws for 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.

We proposed that an OPO may have more than one board, and we set forth specific requirements regarding the membership composition of the board. We proposed making certain changes to the structure and composition of OPO boards, including prohibiting cross membership between OPO boards. Other proposals were intended to strengthen requirements for OPO governance to ensure OPOs have policies and procedures to address possible conflicts of interest.

We proposed 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 that would be limited to recommending policies for the OPO. We proposed that an OPO must 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. We proposed that the board would serve only in an advisory capacity and could not also serve as the OPO's board of directors or any other OPO board. We also proposed a requirement for 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.

We proposed a requirement for OPOs to 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. 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 also proposed a requirement for an OPO to have a procedure to address potential conflicts of interest for the governing body. Finally, we asked the public to comment on 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 are finalizing the proposed provisions with changes, which are discussed in detail below.

We received numerous comments about our proposals to prohibit cross membership between governing and advisory boards, to require OPOs to have a separate advisory board, and to require OPOs to have conflict of interest policies for their boards and governing bodies. Most commenters were firmly in support of the spirit of these proposals—ensuring that all OPOs are administered and governed in a manner that makes the recovery of viable organs for transplantation the OPOs' first priority. However, many OPO commenters pointed out that some of our proposals, such as prohibiting cross representation between boards and requiring OPOs to have separate advisory boards, would force them to abandon administration and governance frameworks that they believe work very well.

Most commenters were in strong agreement with the need for strict conflict of interest policies. OPO commenters said that by enforcing their conflict of interest policies zealously, they have managed to avoid problems with over representation by transplant centers. However, nearly all commenters disagreed with our proposal to require OPOs to include as a board member, a representative from a tissue bank not affiliated with the OPO.

Transplant Center Representation

Comment: Many commenters said they are concerned about the influence of transplant surgeons and transplant centers on fiduciary matters. One

commenter noted that transplant centers and transplant surgeons are overwhelmingly concerned with the volume of organs and the cost of organs to the centers. The commenter said that this understandable concern makes it difficult for transplant centers and surgeons who serve on OPO boards to maintain a proper fiduciary responsibility as OPO board members. The commenter stated, "They are often unable to focus on the long term needs and investment requirements of the OPO and lack the motivation and incentive to increase costs to their own organizations for the long term well being of the OPO. Some transplant programs are in arrears on organ acquisition fees or are willing to tolerate dangerously low financial reserves for the OPO * * *."

The commenter suggested that the transplant community should be permitted to serve on an OPO's advisory board to coordinate clinical and operational needs and protocols, as well as placement of organs, but should not be permitted to serve on an OPO's board of directors. The commenter urged CMS to close the "huge loopholes" in the regulations for OPO boards and predicted that if loopholes are not closed, there will be national scandals and high profile investigations.

Another commenter agreed that transplant surgeons and their representatives and related parties should be restricted from any involvement in the business affairs of an OPO. Other commenters said that they welcome the involvement of transplant surgeons and other transplant center representatives on their boards, including their boards of directors and other governing bodies.

Response: We do not believe it would be acceptable or in the best interests of all OPOs to prohibit transplant surgeons from serving on an OPO's board of directors or an advisory board. Note that in the proposed rule, we explained that we were proposing to change the PHS Act term "transplant center" to "transplant hospital" to clarify that we do not expect an OPO to have a transplant surgeon from each individual organ transplant program within a transplant hospital. We said that 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 result in OPO boards with an overwhelming number of members. We have finalized this clarification. Therefore, an OPO needs to have a transplant surgeon from each transplant hospital but not from each transplant program within the

transplant hospital. This rule is consistent with 42 U.S.C. 274b(d)(1), which defines the term "transplant center" to mean "a health care facility in which transplants of organs are performed."

Comment: One commenter suggested that the CMS regulations for OPOs should specifically prohibit a board structure that could result in violations of laws (such as the Stark Amendments) and other regulations that prohibit fraud and abuse. The commenter added that the "transplant-dominated groups can easily create excess benefit transactions and invite intermediate sanctions" in violation of the Internal Revenue Service (IRS) rules for non-profit organizations. The commenter stated, "The grip of control on the business affairs, charge structure, financial objectives, professional fees to [transplant surgeons] and their friends is extremely tight and there are often threats and intimidation and harassment used against those who want reform. The high level board committees * * * are often overwhelmingly controlled by transplant surgeons or their proxies." The commenter also charged that the individuals and organizations "are already planning to circumvent the intent of the proposed OPO governance regulations by simply maintaining control of their executive and finance committees and have their business associates or other colleagues appointed to the boards * * *."

Response: Possible violations of law or regulations by OPO board members should be reported to the appropriate authority, such as the IRS, the Department's Office of Inspector General, or CMS. If we receive a complaint that OPO board members are attempting to circumvent the requirements for administration and governing body in this final rule, we will conduct a complaint investigation. A violation of a regulatory condition for coverage may lead to de-certification.

Comment: Some commenters recommended that we limit the percentage of governing board members representing transplant hospitals. One commenter stated that the composition of the OPO's governing body should provide a balance between lay people and community representatives on the one hand and transplant professionals on the other. The commenter recommended that at least 50 percent of the members of the governing body should *not* be connected with transplant hospitals that receive organs from the OPO. Other commenters said that transplant physicians and surgeons should comprise less than 50 percent of the membership of the governing board.

One commenter predicted that such a limitation on transplant center representation, in conjunction with enhanced conflict of interest provisions, would allow for adequate protection from conflicts and simultaneously maintain the necessary consultation and input from the members represented on the advisory board.

Response: By statute, the board of directors or an advisory board is composed of a variety of parties with particular perspectives on organ procurement. A transplant surgeon for each transplant hospital (termed "transplant center" in the statute) in the service area is a statutory requirement. Some of the requested changes would require additional legislation and are beyond the scope of this regulation. Further, we believe that generally an OPO should have the flexibility to decide the composition of its boards and governing body based on its particular needs, as long as the OPO complies with statutory and regulatory requirements.

Comment: One commenter addressed our proposal to clarify that the OPO's advisory board should have a transplant surgeon from each transplant hospital and said that instead the requirement should be that there must be a transplant surgeon from each "unique UNOS transplant center" because a single center may contain a number of hospitals.

Response: We proposed changing 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 in keeping with our definition of "transplant hospital" in § 486.302. We said in the preamble to the proposed rule that 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. While the PHS Act specifies that an OPO must have a transplant surgeon from each transplant center on its board, we said that we did not consider a "transplant center" to be a program for transplantation of a single organ type but a hospital that performs transplants. Thus, we proposed a change in language to clarify that even if a hospital has multiple transplant programs, the OPO need have only one transplant surgeon per transplant hospital. We have included this language in the final rule.

Cross Representation and Separate Advisory Boards

Comment: Many commenters disagreed with our proposal to require OPOs to have more than one board and to prohibit individuals from serving on more than one board, such as both the governing and advisory boards. These commenters said that our proposal would unnecessarily force it to revert to multiple boards. Some commenters said they would have difficulty recruiting an adequate number of qualified individuals with the required backgrounds and specialties to serve on two boards. Commenters said that cross membership provides an essential link between matters considered by both boards. An OPO said that prohibiting cross representation would inhibit communication and coordination between boards and would deny both groups access to appropriate qualified individuals to serve as members. One commenter said that preventing cross representation could delay decision making because of the difficulty of communicating between two bodies. Several commenters recommended that we allow OPOs that have more than one board the flexibility to decide whether to have cross representation among their boards.

Response: The PHS Act requires an OPO to have an advisory board whose members are limited to making recommendations on specific, delineated activities, and the statute specifically prohibits the board from having authority over other activities. (See U.S.C. 273(b)(1)(H).) This limitation was included to ensure that those making recommendations on the policy issues described in the statute would not also be in the position of making decisions on other issues, such as budgeting. Therefore, permitting advisory board members simply to be on both boards at the same time would subvert the intent of the statute. Thus, we are retaining the language from our proposed rule.

Comment: One commenter said that CMS should consider adding language to paragraph (b) that describes the expectation for and duties of advisory board members, such as the specific subject matters that may be addressed (but not the standards to be applied or how the governing board should evaluate their contributions). The commenter recommended that this paragraph should provide that individuals on the advisory board should use their expertise to assist the governing body with its duties and functions.

Response: This final rule includes the PHS Act language we proposed, which specifies the OPO activities that an OPO's advisory board is permitted to address. Under the Act, members of the advisory board have no authority over any other activity of the OPO.

Conflict of Interest

Comment: One commenter said that the proposed rule ignores already-existing State and Federal laws that address conflicts of interest, such as state corporate laws. The commenter said that state laws and common law have clear standards requiring board members to uphold their fiduciary responsibility to the organization they serve. The commenter pointed out that Federal law governing tax-exempt organizations also imposes standards and safeguards.

Response: We acknowledge that there are existing laws requiring board members to uphold their fiduciary responsibility to the organizations they serve. However, given the unique nature of an OPO's business, we believe that OPOs need specific bylaws and procedures to address potential conflicts of interest for OPO boards and governing bodies. We believe the most important decisions entrusted to the members who make decisions for the administration and governing of an OPO are those that directly affect the OPO's ability to maximize the recovery of viable organs for transplantation. Thus, we urge OPOs to adopt conflict of interest policies that are clear and unequivocal in addressing these matters.

Comment: An OPO commented that it supports the intent of the proposed rule to mitigate the influence of transplant centers on OPO operations. However, the OPO said that by adding community-based members who are not affiliated with the transplant centers and by enforcing a strong conflict of interest policy, it has developed a diverse and appropriately involved board of directors. Another OPO commented favorably on our proposal to address conflict of interest issues within OPO boards. The OPO said it enforces its conflict of interest policies to prevent members from asserting their own agendas in board votes.

Response: We agree that adding board members who are not affiliated with transplant centers helps to balance transplant center representation on an OPO's board, and implementing strong conflict of interest policies can prevent members from asserting their own agendas. Therefore, although we are making no changes to the regulations text, we suggest that OPOs consider

balancing transplant center representation on their boards by adding community-based members and developing and implementing strong conflict of interest policies.

Comment: A commenter said that OPOs' conflict of interest policies should require conflict of interest disclosure statements consistent with state corporation law and IRS requirements and practices.

Response: We expect that OPOs will follow all pertinent local, State, and Federal laws that govern conflict of interest, including the specifics of those laws in regard to conflicts of interest disclosure statements.

Comment: One commenter recommended that OPO surveyors review board minutes to ensure that OPOs are complying with the requirement to have conflict of interest policies.

Response: We will develop Interpretive Guidelines for surveyors following publication of this final rule. The Guidelines will provide specific information about how surveys will be conducted under the new regulations, including how surveyors will determine whether OPOs are in compliance with the requirement to have conflict of interest policies.

Representation on OPO Boards

Comment: In the preamble to the proposed rule, we asked the public to comment on whether OPOs should be required to have a certain board membership beyond that which is already required under the PHS Act, for example, we asked whether we should require OPOs to include members representing donor families, chaplains, and research institutions. One commenter said that OPOs should consider OPO board representation from other stakeholders, but the commenter did not agree that such representation should be required. The commenter stated that OPOs should have the discretion to add stakeholders to advisory boards consistent with the OPOs needs and priorities. The commenter acknowledged that constituents such as research facilities, donor family members, transplant recipients, coroners or medical examiners, social workers, and chaplains can all add valuable input for an OPO and bring considerable influence. Several OPOs said that they have added donor hospitals, non-transplant health professionals, donor family members, transplant recipients, clergy, minorities, and others to their board of directors. However, most commenters said that OPOs must have the flexibility to bring those resources to

bear as needed in each community. One commenter who said we should not require specific board representation pointed out that Medicare conditions of participation for hospitals do not have specific requirements for board membership. However, one commenter recommended that we require OPOs to include donor families on OPO boards.

Response: We agree with the commenters who stated that the addition of stakeholders and community representatives to OPO boards provides OPOs with valuable input and helps to balance the interests of the transplantation community. We would urge OPOs that do not have such wide representation to add additional members to their boards. For the most part, we agree that OPOs should have the flexibility to determine the knowledge, skills, and background they need for the members who will serve on their boards and their governing bodies (except, of course, for the membership required under the PHS Act). However, we agree with the commenter who recommended that donor family members be included on OPO boards. OPOs have many "customers," including transplant centers and tissue banks, but, arguably, the most important of an OPO's customers is the donor family. Every OPO needs the unique perspective that a donor family member brings to the table to address the many issues that relate to the interaction between donor families and the OPO. These issues range from consent rates to whether family members are permitted in the operating room prior to a donation after cardiac death. Therefore, in addition to those representatives required under the PHS Act, this final rule requires an OPO to have a representative from an organ donor family on one of its boards.

Comment: One commenter said that our proposal that only a transplant surgeon (not a transplant physician) can represent a transplant center on an OPO's board ignores the valuable input that a transplant physician can provide.

Response: We agree that a transplant physician is likely to be a useful and effective addition to an OPO board, and we would encourage all OPOs to consider adding a transplant physician. However, OPOs that have a large number of transplant hospitals in their service areas and, therefore, a large number of transplant surgeons on their boards may find that adding an additional transplant physician is too burdensome. Therefore, this final rule does not include a requirement for an OPO board to include a transplant physician.

Tissue Bank Representative

Comment: One commenter said that the PHS Act requirement to include a tissue bank representative is intended only to ensure that there is a board member with tissue banking experience. The commenter suggested that the tissue bank representative could be from a tissue bank outside the OPO's service area.

Response: We disagree with the commenter. Clearly, the intention of the PHS Act is that OPOs should include tissue banks from within their service areas. The Act requires, "members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO's service area * * *." Thus, we are not accepting the commenter's suggestion to change the final rule.

Comment: Several commenters said that if the OPO is offering competitive tissue recovery or banking services, it is inappropriate to put a competitor on its board. They said that if the OPO is not offering such services, then it is likely using a tissue bank or processor as a vendor and it would be just as inappropriate to place a major vendor on the board because the conflict would be too pervasive. Commenters also said that vendor relationships can change quickly, which could leave an ex-vendor on the board as a director. Several commenters objected to the proposed requirement because they said that tissue banks are OPOs' competitors. One commenter stated that the requirement appears to expand the statutory objective to a market objective of ensuring that the commercial issues of competitive or vendor tissue banks in the OPO's service area are addressed by the OPO. The commenter questioned whether CMS should be concerned about tissue banks since they are not regulated by CMS.

Other commenters suggested that a tissue bank representative would act as the representative of an outside entity rather than as a fiduciary of the OPO. Commenters said that an individual from a tissue bank, by the very nature of the appointment, would appear to have primary responsibilities back to the tissue bank. Commenters said that we should be concerned only about whether an OPO is making a good faith effort to cooperate with the tissue banks in its service area. Other commenters said that our proposal would create a conflict of interest situation by expecting one tissue bank representative to represent the best interests of all the competing tissue banks in the OPO's service area.

Response: We understand the commenters' concerns, and acknowledge that it may not be appropriate for a tissue bank to be privy to or have the right to vote on an OPO's fiduciary matters. Furthermore, since tissue banks are often in competition with one another, we agree with the commenter that it would be difficult for one tissue bank to represent the interests of every tissue bank in an OPO's service area.

Nevertheless, under this final rule, an OPO still is required to have tissue bank members on one of its boards, because it is required by the PHS Act. However, the tissue bank members may be from the OPO's tissue bank or any other tissue bank of the OPO's choice. It is not necessary that the tissue bank members represent all tissue banks in the service area. We have revised our proposed language accordingly. (See § 486.324(a)(1).)

Governing Body

Comment: Commenters noted that we asked for comments about whether "legal authority and responsibility for management and provision of all OPO services should lie with an individual rather than a governing body." The commenters said that this form of governance would be inconsistent with the requirements of state nonprofit corporation law and IRS rules for 501c(3) organizations. Commenters also said that giving a single individual all legal authority and responsibility for an OPO would have the effect of eviscerating the valuable "checks and balances" provided by a board of directors and that the OPO would be likely to lose its tax-exempt status. One commenter said that it would be inappropriate to charge an individual with all OPO functions without oversight. The commenter said that OPOs should have a chief executive officer who is charged with day-to-day operations but who remains subject to board oversight. One commenter stated that OPOs should be able to select the most efficient and effective form of government and management because it permits innovation.

Response: We agree with the commenters that OPOs should have flexibility to structure its business to the greatest extent possible, consistent with the restrictions in our statutes and regulations. Therefore, in this final rule, we have finalized our proposed language, which states that 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. (See § 486.24(e).)

Comment: One commenter questioned the existence of hospital-based OPOs and said that their elimination should be seriously considered. The commenter said that because hospitals are under such extreme financial pressure, hospital-based OPOs might not be given sufficient resources to maximize donation.

Response: We understand the commenter's concern that an OPO's mission to maximize organ donation may not be supported sufficiently by those who make financial decisions for the OPO. However, it is not within the purview of this regulation to eliminate hospital-based OPOs.

Condition: Human Resources (Proposed § 486.326)

In the February 4, 2005 proposed rule, we proposed that all OPOs have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators (OPCs), and hospital development staff, to ensure that they obtain all usable organs from potential donors. We proposed that the OPO must have sufficient staff to ensure that the families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research receive all of the services required by the proposed rule.

We proposed that OPOs ensure that all persons who provide services and/or supervise services are qualified to provide or supervise those services. This requirement would include services that were furnished both under contract or provided through another arrangement. We proposed that each OPO would be required to develop and implement a written policy to address conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.

We proposed requiring OPOs to have credentialing records for the physicians and other practitioners who routinely recover organs in hospitals that are under contract or have an arrangement with the OPO. We proposed that an OPO also would be required to ensure that all physicians and other practitioners who recover organs in

hospitals with which the OPO has agreements are qualified and trained.

We proposed staffing requirements, including sufficient coverage to assure that both referral calls from hospitals are screened for donor potential and potential donors are evaluated timely for medical suitability. We proposed requiring that OPOs have sufficient 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. We also proposed that OPOs must have sufficient recovery personnel to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation.

We proposed that OPOs must provide their staff with the education, training, and supervision necessary to furnish required services. At a minimum, that training was to include performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. We proposed that OPOs would be required to evaluate the performance of their staffs and provide training, as needed, to improve both individual and overall staff performance and effectiveness.

We proposed that all OPOs must have a medical director who would be responsible for implementing the OPO's protocol for donor evaluation and management and organ recovery and placement. We proposed that the medical director would be 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.

Below we have provided a summary of the public comments we received on our proposed provisions, along with our responses to the comments.

General Comments

Comment: Commenters expressed concern that the requirements in the human resources section at § 486.326 were too prescriptive, especially the staffing requirements. They stated that the requirements would not allow OPOs to decide upon the staffing arrangements that would best suit their needs. They were also concerned about the cost implications of these requirements.

Commenters recommended that instead of our proposed human resources requirements at § 486.326, we require OPOs merely to develop and implement a human resources plan and

policy. Each OPO's practices would be expected to conform to its own plan and policy. These commenters stated that an OPO's human resources plan and policy should include staff adequacy, education and training, supervision, and performance assessment. One commenter pointed out the Collaborative has already demonstrated that OPOs can be successful with a variety of staff configurations.

Response: Our intention is not to publish prescriptive staffing requirements for OPOs. In fact, we believe the staffing requirements in this final rule will give OPOs the flexibility to decide upon the staffing configurations that best suit their needs. We require only that each OPO have sufficient staffing for the activities that we require OPOs to perform or provide, but we do not require specific numbers or ratios of staff for these activities. Each OPO is free to decide how to staff their OPO to best provide the required activities and services. We believe the human resources requirements will result in consistency of outcomes among OPOs to ensure that all OPOs provide required services.

Comment: Some commenters stated that the accountability for an OPO's success or outcomes should be broader than the OPO itself. They wanted other entities, especially the donor hospitals and transplant centers, to share accountability for OPO's performance.

Response: Standards or requirements for donor hospitals and transplant centers are outside the scope of this regulation. We acknowledge that the actions of others, including donor hospitals and transplant centers, can affect an OPO's performance and/or outcomes. However, we must stress that OPOs are responsible for all requirements and outcomes in this final regulation. If OPOs encounter problems with other entities, they should first try to resolve the problem with that entity. If they cannot, they can seek assistance from the appropriate CMS Regional OPO Coordinator.

Section 486.326(a) Standard: Qualifications

Comment: Many commenters expressed concern over the requirement at 486.326(a)(3) that each OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals that have agreements with the OPO and that the OPO must ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has an agreement are qualified and trained. Some commenters stated that they agreed that OPOs should verify

physician and surgeon credentials, but asked for clarification on exactly what would be required.

Response: As we stated in the February 4, 2005 proposed rule, OPOs would be required "to have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO * * *." We are not requiring that OPOs actually conduct a credentialing process of their own. We expect OPOs to have records that clearly demonstrate that these practitioners are credentialed in their own medical or surgical facilities. An OPO could satisfy this requirement with a letter from the credentialing facility indicating that a practitioner is credentialed in their facility and any limitations or conditions that facility has placed upon the practitioner's practice. An OPO does not need to maintain the entire credentialing file. However, if the OPO does not have the entire file or a copy of it, the OPO should have an agreement with the appropriate facility for access to the entire record should the OPO have any questions or concerns about a practitioner's qualifications or training.

Comment: Some commenters supported verification of recovery personnel's credentials or qualifications and training but did not believe it should be the OPO's responsibility. Commenters stated that OPOs should be allowed to rely on a transplant hospital's extensive credentialing system to determine that recovery surgeons and other personnel are qualified. They stated that to require OPOs to maintain credentialing records was duplicative.

Other commenters suggested that we should require transplant centers to be responsible for verifying physicians' credentials prior to recovery. A commenter suggested that credentialing be a requirement in the Hospital Conditions of Participation, especially for recovering physicians and other practitioners utilized by the OPO on an infrequent basis and outside the designated service area. Commenters noted that since the transplant hospital sends the recovery team, the transplant hospital has both the leverage and the authority to require compliance with a credentialing process. Commenters said that we should require the transplant hospital that sends out the recovery team to provide the OPO with information about the recovery staff's qualifications in advance of any recovery and respond promptly to OPO requests for information.

Another commenter said there should be a national standard and suggested

that DHHS ask the OPTN to develop policies for recovery team qualifications that OPTN members would be required to follow as a condition of membership in the OPTN.

Response: We disagree with the commenters. We believe that an OPO should be responsible for ensuring that personnel who recover organs and tissues in hospitals with which the OPO has agreements are appropriately credentialed. As we pointed out in the preamble to the proposed rule, it is difficult, if not impossible, for a donor hospital to credential and grant privileges to recovery surgeons and other members of the recovery teams who are not members of the hospital's medical staff and who may recover organs in a particular donor hospital no more than once in a period of several years (70 FR 6105). The recovery personnel's work in the donor hospital is too limited to undergo effective review by the donor hospital for the granting of clinical privileges (70 FR 6105).

However, all hospitals, including transplant hospitals, are responsible for credentialing and granting privileges to medical staff. Section 482.22 of the Hospital Conditions of Participation requires that a hospital's medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body for appointments. Further, the medical staff bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

In this final rule at § 486.344(d), OPOs are required to collaborate with transplant programs to establish protocols that define the roles and responsibilities of the OPO and the transplant program for all activities associated with, among other activities, organ recovery. We expect that OPOs will use these collaborative agreements to spell out how they will obtain credentialing information on recovery personnel. We believe that OPOs should verify that recovery personnel are credentialed by a transplant hospital or that they are otherwise qualified and trained as part of the services they provide to donor hospitals. Therefore, we will finalize § 486.326(a)(3) as proposed.

The suggestion that the OPTN develop policies for recovery team qualifications is beyond the scope of this final regulation. However, this suggestion will be forwarded for consideration to the agency that oversees the contract for the OPTN, the

Health Resources and Services Administration (HRSA).

Comment: Commenters recommended that the Memorandum of Agreement or Understanding between a transplant hospital and the OPO should specify how the credentialing responsibility would be handled between the transplant hospital and OPO. Other commenters recommended that any surgical recovery team that is currently provided privileges by one OPO should receive reciprocity from other OPOs.

Response: As we stated in our previous response, § 486.344(d) requires OPOs to collaborate with transplant programs to establish protocols that define the roles and responsibilities of the OPO and the transplant program for all activities associated with organ recovery. Therefore, we agree with the commenters that the Memorandum of Agreement or Understanding may provide an opportunity to address how the credentialing responsibility will be handled. However, we believe that the OPO and the transplant hospital should have the flexibility to determine what works best for their situation.

Reciprocity is certainly one method that OPOs can use to ensure the credentialing and/or qualifications and training of the recovery personnel. However, we believe that OPOs need the flexibility to decide how to handle this responsibility.

Comment: Some commenters noted that OPOs should have a way to verify the credentials of recovery personnel 24 hours a day, especially for a "visiting team."

Response: We agree with the commenters. OPOs operate on a 24-hour-a-day, 7-day-a-week schedule, 365 days a year. OPOs should maintain documentation of credentialing and/or qualifications and training for recovery personnel who routinely recover organs for the OPO. Each OPO should have a method in place for quickly obtaining verification of the credentials and/or qualifications and training of recovery personnel who do not routinely recover organs for the OPO.

Section 486.326(b) Standard: Staffing

Comment: Many commenters agreed that sufficient staffing is an extremely important consideration for an OPO's successful performance and that each OPO needs the flexibility to determine what staffing levels should be. However, there were concerns that CMS was suggesting specific staffing levels. Commenters noted that CMS indicated in the February 4, 2005 proposed rule that " * * * we do not propose to establish specific staffing levels because OPOs must have the flexibility to

determine their own staffing levels." (70 FR 6106). Yet, commenters said that we provided "guidance to OPOs so that they can determine if the number of staff they have would be sufficient." (70 FR 6106). One commenter specifically noted one of the examples, that an "OPO should look closely at hospital development staffing because effective hospital development creates a culture that supports and promotes donation." (70 FR 6106). Commenters expressed concern that requests we made for comments on various "staff markers" and the guidance we provided would eventually lead to a requirement for actual numbers of staff. Commenters also noted that many successful OPOs have different staffing patterns.

Response: We agree with the commenters that there is no one staffing pattern that all OPOs should follow. As we stated in the February 4, 2005 proposed rule, we are not requiring specific staffing levels for OPOs because we believe that OPOs need the flexibility to establish those levels based upon their needs (70 FR 6106). The guidance provided in the proposed rule was intended only to provide some direction to OPOs in assessing what staffing levels their own OPO needs to provide the services and activities required by this regulation. We would note that we do not prescribe staffing levels for other Medicare providers or suppliers and have no intention of doing so for OPOs.

Comment: Commenters were concerned about how CMS was going to determine what was sufficient or adequate staffing. They were also concerned about how CMS was going to enforce this requirement.

Response: The determination of whether or not an OPO has adequate staffing is primarily based upon outcomes (70 FR 6106). We also noted that outcomes included 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)." (70 FR 6106). We would not expect to cite an OPO for having insufficient staff if the patient outcomes are good. The requirement is intended to give surveyors the option of citing an OPO when there is a pattern of consistent understaffing in critical areas, and the OPO has not taken the appropriate steps to improve the situation (for example, if the board of directors has refused to approve funds for additional staff needed to improve the OPO's performance).

Comment: Commenters expressed concern that the requirements for sufficient staffing could ultimately be inconsistent or out-of-date with the "best practices" being shared through HRSA's Collaborative. Commenters noted that the Collaborative has resulted in a rapid evaluation of staffing models and organizational change in OPOs. As staffing models are modified as a result of the Collaborative, the proposed requirements may be "out of synch" with what the OPOs are doing with staffing. One commenter suggested that adequacy of staffing levels should be an element in an OPO's human resources plan.

Response: As we stated in our previous response, we are not requiring any specific number of staff to achieve "sufficient" staffing levels. We are requiring only that OPOs determine how much staff they need to achieve the outcomes mandated under this final rule. This final rule requires OPOs to have sufficient staff to provide the activities and services required of all OPOs, but we believe the requirements are flexible enough to accommodate any changes in staffing models that may be developed in the future.

Comment: Commenters said that in § 486.326(b)(1), we proposed that OPOs "provide sufficient coverage * * * to assure * * * that potential donors are evaluated for medical suitability in a timely manner." This language concerned commenters who said that if OPO staff made a "suitability determination," it would interfere with the transplant surgeon's decision whether or not to transplant a particular organ into a particular patient.

Response: We do not intend to interfere with any transplant surgeon's decision whether to transplant a particular organ into a particular patient. However, OPOs are responsible for assessing potential organ donors to determine whether they meet the initial medical criteria for organ donation. The proposed language merely requires that OPOs have sufficient staff coverage to ensure that this assessment takes place in a timely manner. Therefore, we have revised the language in § 486.326(b) by adding "for organ and/or tissue donation" after "medical suitability" to clarify that this is for the initial determination of whether or not the potential donor meets the criteria for organ and/or tissue donation.

Comment: Commenters were also concerned that the "suitability" language in the proposed rule discussed above could result in increased liability for the OPOs. Commenters noted that OPOs have been dismissed from "bad organ" state malpractice cases because

the OPOs make no determination as to the suitability of organs. They felt that the language above could result in OPOs no longer having that defense.

Response: OPOs do not make any determination as to the suitability of a particular organ for a particular patient. That determination remains the exclusive prerogative of the transplant surgeon. As discussed in the previous comment and response, we have revised the language in § 486.326(b) to clarify that the “medical suitability” determination made by an OPO concerns only whether or not the potential donor meets the medical criteria for organ and/or tissue donation.

Comment: One commenter expressed particular concern with the working conditions of OPO procurement coordinators. The commenter pointed out that by not mandating a maximum number of working hours, procurement coordinators will continue to be worked to the “point of physical and emotional exhaustion and profound sleep deprivation.” The commenter noted that the Federal Government mandates working hours for several occupations, such as air traffic controllers and truck drivers and said that a procurement coordinator’s work is just as crucial as other occupations for which the Federal government mandates working hours. The commenter also wanted CMS to mandate maximum hours before a rest period and on-call hours for OPCs.

The commenter also said that some OPOs are not hiring a sufficient number of procurement coordinators, which results in many procurement coordinators suffering from sleep deprivation due to working very long hours. The commenter stated that even though some OPOs may claim they cannot afford to hire more staff, the situation results in increased turnover of procurement coordinators. As a result, the OPOs must pay higher wages, they have less cohesive work teams, and their relationships with their hospitals are impaired.

Response: We too are concerned that some OPOs do not have enough procurement coordinators to prevent staff burnout and high staff turnover, and we agree that OPO procurement coordinators and other staff must have adequate rest and reasonable working hours to perform their jobs properly. Also, we would expect that high staff turnover could impair working relationships among OPO staff and between OPO staff and hospitals. In the February 4, 2005 proposed rule, we provided guidance to “OPOs so they can determine if the number of staff they have would be “sufficient” (70 FR 6106). This guidance recommends

looking at the intermediate steps in the donation process, not just the ultimate outcome. We will not mandate working hours for OPO staff in this final rule, because we believe each OPO must have the flexibility to determine its own staffing protocols. However, we expect OPOs to take whatever steps are necessary to ameliorate their staffing problems, including the hiring of additional procurement coordinators. OPOs that do not address consistently inadequate staffing in critical areas are likely to find that their shortcomings are reflected in their performance on the outcome measures in this final rule.

Section 486.326(c) Standard: Education, Training, and Performance Evaluation

Comment: Some commenters urged CMS to require the certification of procurement coordinators through the American Board of Transplant Certification (ABTC). They pointed out that certification ensures that the evaluation of potential donors, medical management of donors, retrieval arrangements, and family consultation are performed with the highest standards accepted within the transplant community.

Response: There is no evidence available at this time that indicates that certification increases the quality of services provided. While it is likely that certification guarantees a certain level of competence, many OPOs have highly competent, successful procurement coordinators who are not certified. Therefore, we believe that to impose a certification requirement for procurement coordinators may be unduly burdensome. Furthermore, this final rule at § 486.326(c), requires OPOs to ensure that their staff get the necessary education and training to perform their required responsibilities. One way for an OPO to satisfy this requirement in regard to procurement coordinators would be to assist them in obtaining certification, but this final rule does not require procurement coordinators to be certified. Therefore, we have made no changes to our proposed language.

Comment: Commenters urged us to be less prescriptive in our human resources requirements, including the requirements for competency through industry training.

Response: We disagree that our requirements for education, training, and performance evaluation are too prescriptive. This standard requires an OPO to 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. We are not requiring OPOs to conduct the required training, education, or performance evaluation in any specific manner or use a particular method. We believe that these are reasonable requirements and that they provide the OPOs with sufficient flexibility to develop and implement training programs, policies, and procedures that will suit their particular needs.

Comment: One commenter expressed approval for the requirement for OPOs to conduct training. However, the commenter recommended that we establish a national standard for training. Conversely, one commenter said that while each staff member should have an appropriate orientation to his or her job, we should not mandate that staff handle a particular number of donation cases during an orientation or that an orientation should last for a specified amount of time. The commenter stated that such a requirement could result in OPOs providing only that amount of training without allowing for the individual staff member’s needs.

Response: We disagree with the commenter. We do not believe that we should either endorse or require a particular type or length of training for all OPOs beyond the minimum requirements established in this final rule at § 486.326(c). Each OPO should have the ability to develop training programs tailored to its own particular circumstances, policies, and activities.

Thus, the requirements in this final rule provide flexibility for OPOs to evaluate their staff and provide the training necessary to meet the needs of individual staff members.

Section 486.326(d) Standard: Medical Director

Comment: One commenter stated that the requirement for OPOs to have a medical director was overly prescriptive.

Response: We disagree. As we stated in the February 4, 2005 proposed rule, “Although current regulations do not require OPOs to have a medical director, most if not all OPOs employ a medical director as part of their management staff and recognize the value and expertise this position brings to their OPO programs.” (70 FR 6108). We also noted that “We believe that nearly all OPOs have a full-time or one or more

part-time directors * * *.” (70 FR 6124).

In addition, the OPTN’s bylaws for their members state that all OPOs must have a medical director. Under this final rule, we are requiring OPOs to be members of and participate in the OPTN. Thus, rather than being overly prescriptive, a requirement that OPOs have a medical director reflects the current practice in the industry.

Comment: In addition to requiring that OPOs have a medical director, some commenters wanted us to impose additional conditions on this position. One commenter wanted us to include a requirement for a medical director to be a “licensed physician” and to define “licensed physician” as a physician licensed in the United States to prevent physicians licensed outside the United States from becoming OPO medical directors.

Response: We agree with the commenter. In fact, § 1861(r)(1) of the Act defines “physician” for the Medicare program as “a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action * * *.” We expect each OPO to hire a medical director who is able to fulfill all the functions required under this final rule and under the laws of the State(s) or territory in which the OPO operates. Since the OPO medical director is responsible for overseeing the clinical management of potential donors and providing assistance in managing donor cases when the surgeon on call is unavailable, the OPO medical director should be a physician licensed in at least one of the States within the OPO’s service area or as required by state law. Thus, we are revising the first sentence in § 486.326(d) to read, “(d) Standard: Medical Director. The OPO’s medical director is a physician licensed in at least one of the States or territory within the OPO’s service area or as required by State or territory law.” The medical director is responsible for * * *.”

Comment: Some commenters stated that medical directors should be physicians with specific expertise or experience. Some commenters recommended that medical directors have experience in organ donor intensive care medical management or organ transplantation. Another commenter simply stated that the medical director should have the knowledge and experience to support the OPO.

Response: Once again, we believe that flexibility is the key. In this final rule, we have attempted to avoid overly prescriptive requirements that would

force OPOs to make changes in successful OPO staffing arrangements or OPO functioning. We believe that requiring an OPO to have a medical director is sufficient. Although we expect that most OPOs want and need medical directors who have relevant expertise and experience, we do not believe that we should establish minimum qualifications for a medical director, beyond requiring that the medical director be a physician licensed in at least one of the States within the OPO’s service area or as required by State or territory law.

Comment: Commenters expressed concern that having a medical director involved in donor evaluation could interfere with the transplant surgeon’s decision on whether to transplant a particular organ or tissue into a particular patient. Commenters stated that transplant surgeons or physicians should make the ultimate decision on transplantation. When these commenters were discussing the role of medical directors, they also added that the organ offers and placement by the OPO staff should be made in accordance with United Network for Organ Sharing (UNOS) allocation policies.

Response: As stated in our earlier response, the suitability determination made by OPO staff, including the medical director, concerns only a potential donor’s medical suitability for organ and/or tissue donation. OPOs are not required by this final rule to make any determination as to the suitability of a particular organ for a particular patient. That determination remains the exclusive prerogative of the transplant surgeon.

Comment: Commenters requested that the role of the medical director be clarified, especially regarding the expected level of medical oversight and involvement. Commenters stated that medical directors should provide medical consultation on specific cases when needed but should not be required to evaluate each case. Commenters were very concerned that requiring the medical director to be involved in day-to-day operations in the clinical management of donors would be very onerous and would vary greatly among the OPOs. Commenters said that the medical director’s role should be to guide the development of donor management policies.

Response: In § 486.344 of the February 4, 2005 proposed rule, we proposed requiring that the OPO medical director would be 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 and/or tissue donation and clinically managed to optimize organ viability and function. We also proposed that an 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.

The level of oversight provided by a medical director will vary from case to case. We are not requiring that the medical director either evaluate every potential donor or be involved in the management of every donor case. While the medical director is responsible for overall implementation of the protocols, we expect that in most cases, he or she will delegate the responsibility for direct implementation of the protocols to other staff. We agree with the commenters who said that medical directors should provide medical consultation on specific cases when needed but should not be required to evaluate each case. We also expect that a medical director will provide assistance in the clinical management of donation cases when needed.

Condition: Reporting of Data (Proposed § 486.328)

The February 4, 2005 proposed rule we stated that we would require OPOs to provide individually-identifiable, hospital-specific organ donation and transplantation data to the OPTN and the SRTR, as directed by the Secretary. In addition, we proposed requiring OPOs to provide hospital-specific organ donation data to transplant hospitals annually. We also proposed requiring OPOs to report individually-identifiable, hospital-specific organ donation and transplantation data and other information to us, as requested by the Secretary.

We proposed that the data would include, but not be limited to, number of hospital deaths; results of death record reviews; number and timeliness of referral calls from hospitals; potential donor denominator; data related to non-recovery of organs; data about consents for donation; number of donors; number of organs recovered (by type of organ); and number of organs transplanted (by type of organ). We also proposed that 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 was granted a waiver to work with a different OPO. We proposed requiring OPOs to report data to the OPTN within 30 days after

the end of the month in which a death occurred. We proposed that if an OPO determined through death record review or other means that the potential donor denominator data it reported to the OPTN was incorrect, it would be required to report the corrected data to the OPTN within 30 days of the end of the month in which the mistake was identified. We proposed specific definitions for determining the information to be collected, such as how a split liver would be counted. Finally, we proposed requiring an OPO to report organ donation data to hospitals annually.

Based on public comments, we are not finalizing our proposal to require OPOs to report hospital organ donation data to the public annually because those data are readily available on the SRTR Web site, <http://www.ustransplant.org>. We have made minor changes to our proposed data reporting requirements to incorporate the definitions of "eligible deaths" and "eligible donors."

We have provided a summary of the comments we received on our proposed section and our responses are discussed below:

Comment: A few commenters asked for clarification about which data would need to be "individually identifiable." One commenter stated that OPOs currently report individually-identifiable data on actual organ donors to the OPTN, but the data reported on eligible deaths is aggregated by hospital. Commenters pointed out that reporting individually-identifiable data on eligible deaths would add a significant reporting burden.

Response: Currently, OPOs report the data on eligible deaths to the OPTN as aggregated by hospitals. However, for all individuals who become organ donors for the purpose of transplantation or research, the OPOs do report individually-identifiable health information to the OPTN.

The type of data and how it is reported to the OPTN is governed by the OPTN. We are not asking for individually-identifiable health information to be reported directly to us.

Comment: One commenter took exception to the proposed requirement to report an error in data reporting "within 30 days of the end of the month in which the mistake is identified." The commenter said that because we proposed no required time frame for conducting death record reviews, it could be a year or more before a mistake was identified and reported.

Response: We agree that data reporting errors must be corrected

promptly because the data will be used for certification purposes in the future and both OPOs and hospitals need reliable eligible donor and eligible death data to inform their decision making and their quality improvement programs. We have decided to retain the language in proposed § 486.328(b) concerning an OPO reporting data and corrected data to the OPTN. In the final rule, this language has been moved to § 486.328(d). We are retaining this language due to a change we have made in the requirement for death record reviews. In § 486.348(b), we are now requiring OPOs to conduct death record reviews at least monthly in every Medicare and Medicaid participating hospital with a Level I or Level II trauma center or with 150 or more beds and a ventilator and an intensive care unit (ICU). The only exceptions are hospitals that have a waiver to work with another OPO and psychiatric and rehabilitation hospitals. This requirement will provide OPOs with timely data so that they can inform the OPTN of data reporting errors promptly.

Comment: Commenters protested our proposed requirement for OPOs to report hospital organ donation data to the public annually. They pointed out that the SRTR publishes on its website extensive hospital organ donation data, which is updated twice each year.

Response: We agree with the commenters. At the time we developed the OPO proposed rule, the SRTR did not publish hospital organ donation data. Now that it is readily available to the public, we see no need to burden OPOs with this requirement. However, we would urge OPOs to inform their hospitals where to access the data and to provide the data directly to hospitals that request it.

Comment: Many commenters voiced apprehension that data on organ donor potential would not be reported correctly. They said that the outcome measures would not be fair to all OPOs if some OPOs under reported their donor potential.

Response: Because organ donor potential (now termed "eligible deaths") forms the basis for one of the outcome measures in this final rule, accurate reporting of data is critically important. We would strongly emphasize that OPOs must adhere meticulously to the definition of "eligible deaths" when reporting data to the OPTN. Whereas we acknowledge there is some potential for inaccurate reporting, as we stated earlier in this preamble in our discussion of the outcome measures, the SRTR statistical methodology will act as a "check" on the eligible donor and eligible death data OPOs report to the OPTN. In

addition, CMS Regional OPO Coordinators will be working with the OPOs and are available to provide guidance to the OPOs. We will also work with HRSA to determine whether a procedure can be established to assist OPOs that have a questionable case.

Condition: Information Management (Proposed § 486.330)

In the February 4, 2005 proposed rule, we proposed that OPOs 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. We proposed specific information that must be maintained in the record for every donor. We proposed that an OPO must also maintain records showing the disposition of each organ that is recovered for the purpose of transplantation, including information identifying the transplant recipient. We proposed requiring OPOs to maintain donor and recipient records for 7 years in a format readable by humans and reproducible in a paper or electronic format. In addition, in the event that a successor OPO takes over an OPO's donation service area, we proposed that an OPO must maintain the data in a format that can be readily transferred to a successor OPO and must be able to provide copies to CMS of all records. We proposed that the records and data subject to this requirement would include donor and transplant recipient records and procedural manuals and other materials used in conducting OPO operations.

Comment: One commenter recommended that we insert "electronic" before "information management system" at the beginning of this provision. The commenter said that donor information needs to be maintained in an electronic format so that the data can be communicated to Federal agencies and contractors, as well as to ensure that the information can be transferred easily to a successor OPO. The commenter also noted that each OPO should specify in its agreements with hospitals the method of electronic access that will be used so that information can be communicated during the donation process to its own data systems, the OPTN, and any other organization to which the OPO grants access.

Response: We agree with the commenter that in today's health care environment, information management systems must be electronic. In fact, the Department released a health

information technology plan in 2004 that was ordered by President Bush and prepared by the National Coordinator for Health Information Technology, David J. Brailer, M.D. The 10-year plan would transform the delivery of health care by building a new health information infrastructure, including electronic health records and a new network to link health records nationwide. At the time, then Secretary Tommy Thompson said, "America needs to move much faster to adopt information technology in our health care system * * *. We can't wait any longer."

It is our understanding that all of the OPOs already have electronic information management systems to manage the immense amount of information they must maintain. Thus, we will add "electronic" before "information management system" to the § 486.330 introductory text.

We also agree that it would be a good business practice for an OPO to include information about electronic access in their agreements with hospitals, but we do not believe it is necessary to include such a requirement in this final rule. We believe OPOs should be free to work out the logistics of electronic access with their individual hospitals.

Comment: A commenter recommended that we add a new subsection to § 486.330 to address data confidentiality and security. The commenter said that the subsection should require OPOs to adhere to federally-published data confidentiality and security standards and follow security and confidentiality requirements established by the OPTN. The commenter added that in maintaining data within its physical control, the OPO should consider and include patient data confidentiality measures outlined by the National Institute of Standards and Technology and required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to protect the identities of potential donors, donors, donor next-of-kin, transplant candidates, and transplant recipients.

Response: We agree that OPOs must ensure the confidentiality and security of the information they acquire and maintain. However, § 486.330 already requires that OPOs "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." We believe that this language is sufficient and that the new section proposed by the commenter is

unnecessary. We expect OPOs to adhere to all applicable Federal, State, and local requirements to ensure the confidentiality and security of the information they maintain.

Comment: A commenter recommended that we insert a new subsection addressing technology standards. The commenter recommended that the subsection should require OPOs to maintain basic technology standards, as published by CMS and the OPTN, to provide for donation information access, communication, storage, redundancy, privacy and security.

Response: We appreciate the comment. However, we believe the proposed requirements, which we have finalized in this rule, are sufficient to ensure that OPOs maintain basic technology standards to provide for information access, communication, storage, redundancy, privacy and security.

Comment: One commenter objected to OPOs having to maintain donor records related to tissue and eye donation when the OPO is not a tissue or eye recovery agency.

Response: We proposed this requirement at the request of the Food and Drug Administration and the Centers for Disease Control and Prevention so that Federal and State authorities can access both organ and tissue donor information from one central point when they investigate any potential transmission of infectious disease from donated organs or tissues. The requirement does not apply to all recovered tissue. It applies only when tissue is recovered in addition to organs. Whether or not the OPO provides tissue and eye recovery services, the OPO is still in the best position to maintain these records. Thus, the section concerning data retention requirements will be finalized as proposed.

Comment: One commenter submitted a sample of a form developed to provide documentation of the donor and recipients data.

Response: We appreciate the commenter's submission of the proposed form. However, CMS is not the appropriate agency to review the submitted form. Therefore, we have forwarded the form to HRSA for the OPTN's review.

Comment: Commenters recommended that we request public comment regarding additional requirements for hospitals under the CMS conditions of participation for hospitals. Commenters recommended requirements for hospitals to: (1) Ensure that OPOs have access to key physicians and other health care professionals; (2) have

provisions for neurologists or other qualified medical professionals to adopt brain death declaration criteria consistent with state law; (3) notify OPOs prior to the withdrawal of life support to a patient; (4) if the hospital has more than 100 beds, identify an advocate for organ and tissue donation from within the hospital clinical staff; and (5) establish policies and procedures in conjunction with the OPO to manage and maximize organ retrieval from donors without a heartbeat. Commenters also said that if a patient is a potential donor, the OPO should reimburse the hospital for appropriate costs related to maintaining that patient as a potential donor.

Response: Although these recommendations for hospital conditions of participation are beyond the scope of this final regulation for OPOs, we will consider integrating them into a future regulation for the hospital conditions for participation.

Condition: Requesting Consent (Proposed § 486.342)

In the February 5, 2005 proposed rule, we proposed that OPOs must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families. We also proposed requiring that OPOs have a written protocol to ensure that the individual(s) responsible for making the donation decision are informed of their options to donate organs and tissues (when the OPO is also requesting consent for tissue donation) or to decline to donate. We proposed several items of information that OPOs would be required to provide in requesting consent. The specific items we proposed were: A list of the organs or tissues that may be recovered; all possible uses for the donated organs or tissues; information that the individual(s) have the right to limit or restrict use of the organs or tissues; a description of the screening and recovery processes; the information (such as for-profit or non-profit status) about the organizations that will recover, process, and distribute the tissue; information regarding access to and release of the donor's medical records; an explanation of the impact the donation process will 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 donation decision have questions; and a copy of the signed consent form, if the donation is made. In addition, we proposed that if the OPO does not request consent because the donor previously completed a donor document that satisfies applicable state

law, the OPO would be required to provide information to the donor's family upon their request.

Comment: Some commenters believed the provision was overly prescriptive and too detailed concerning the minimum amount and types of information that are required for informed consent. However, other commenters endorsed the principles expressed in the requesting consent requirements and said that the provision reflected current practices in the industry.

Response: In general, we disagree with the commenters who stated that the provision is overly prescriptive and too detailed concerning the amount and types of information that is required for informed consent. Donor families need a certain amount of information upon which to base their donation decision. We believe there must be a minimum standard to assure that when families provide consent, they are providing informed consent. However, after analyzing the comments we received on some specific proposed items of required information, we have changed or eliminated some of the requirements. These items are discussed below in the following comments and responses.

Comment: Some commenters stated that the requirements for requesting consent are unnecessary. They noted that each State's anatomical gift law has requirements for informed consent and that the applicable state law should determine the standard for each OPO.

Response: We disagree with the commenters. We are not aware of any State anatomical gift legislation that has detailed requirements for information that must be provided to potential donor families to ensure informed consent. We believe there must be a minimum standard that will apply to all of the OPOs and ensure that when an OPO requests consent, potential donor families receive the information they need to make an informed decision about donation.

Comment: One commenter provided the following alternative language for § 486.342(a): “* * *. The OPO must provide *adequate information* to the individual(s) responsible for making the donation, *which may include* the following if appropriate and *if sensitive to the individual(s) circumstances, views, and beliefs* * * *.”

Response: The commenter has provided very subjective language that does not appear to establish any minimum requirements. Section 486.342 in this final rule states, “An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of

potential donor families.” We believe that OPOs can tailor the informed consent requirement in this final rule, so that it can be conveyed in a sensitive and appropriate manner based upon the circumstances of each potential donor family's situation. Thus, we are not adopting the commenter's suggested language.

Comment: Some commenters noted that the language requiring “information about the procedure for filing a complaint” could be problematic. A commenter pointed out that to their knowledge “the doctrine of informed consent has never included a procedural component for filing a complaint.” The commenter noted that adding information about a complaint process could adversely affect an OPO's efforts to obtain consent for donation and said that “introducing an unnecessary element, particularly one that suggests subsequent failure, unhappiness, or change of mind, will likely undercut the consent success rate that OPOs are struggling so hard to improve.” The commenter said that their experience has shown that parties who are unhappy about something that occurred during the donation process have not had any difficulty with locating the OPO to discuss their concerns.

Response: We believe the commenters have a good point. OPOs approach potential donor families during an extremely sensitive time: the death or imminent death of a loved one. It is important that the decision maker(s) for organ and/or tissue donation receive all the information they need for informed consent; however, there is no reason to introduce unnecessary information that may adversely affect the donation decision. Therefore, we have removed the proposed 486.342(a)(8) and revised the proposed § 486.342(a)(9). Thus, in the final rule § 486.342(a)(7) reads, “Contact information for individuals with questions or concerns.”

Comment: Some commenters felt that the requirement for informed consent to include “All possible uses for the donated organs or tissues” was unreasonable and overly burdensome. One commenter questioned to what degree the OPO had to go to satisfy this requirement. The commenter asked the following questions:

- Does every research project have to be disclosed?
- Does every type of therapeutic surgical procedure for which donated gifts can be used have to be disclosed to the family?

One commenter noted that the typical standard under State law is whatever a “reasonable person” would want to know. Another commenter felt that

complying with this provision could result in the consent process being lengthy, time consuming, and too graphic to be appropriate considering the sensitive nature of the consent process and the need for compassion for the potential donor family. One commenter recommended that we simply remove the word “all” from (a)(2).

Response: We agree with the commenters that informing families of potential donors and other decision makers of all possible uses for the donated organs and tissues may be more information than they need or want to know. However, the decision makers should be informed in general terms of the “most likely” uses of the organs and/or tissues they are being asked to donate. We believe this can be done without going into the detail that the above questions posed by the commenter suggest. For example, we believe most families would be satisfied with knowing that the organs and/or tissue might be used for research without wanting to know the specific research projects or that tissue might be used for therapeutic surgeries without wanting to know the specific types of surgeries. However, if a family requests additional or more detailed information, we would expect the OPO to provide that information. We believe that OPOs need the flexibility to determine what is appropriate to disclose concerning the most likely uses of donated organs and tissue and that they can tailor this information so that it is presented in a sensitive and appropriate manner.

Thus, in § 486.342(a)(2) we are deleting the words “all possible” before “uses” and inserting the words “the most likely” before “uses.” The revised § 486.342(a)(2) reads as follows: “The most likely uses for the donated organs or tissues.”

Comment: One commenter stated that the requirement to describe the screening and recovery processes, as well as give information about all of the potential organizations that may be involved in the recovery, process, and distribution of tissues could generate a substantial amount of paperwork. And, rather than being helpful and informative, it could actually be more confusing and distracting to the potential donor family or perhaps too graphic.

Response: We disagree with the commenter that any of these requirements would generate a substantial amount of paperwork. Once an OPO has developed a standard consent form, the OPO's staff needs to explain only the applicable sections to the donor family during the consent

process. We believe OPOs can explain the screening and recovery process to potential donor families and decision makers in a manner that is not too graphic, confusing, or upsetting to the potential donor family.

Comment: A large number of commenters objected to the parenthetical language in § 486.342(a)(5), "Information (such as for-profit or non-profit status) about organizations that will recover, process, and distribute the tissue." While a few commenters felt that disclosing the profit status of tissue banks involved in the donation process conformed to the tissue banking industry's standards, others did not. Some commenters noted that informed consent guidelines developed by the Association of Organ Procurement Organizations, the American Association of Tissue Banks, and the Eye Bank Association of America, the Model Elements of Informed Consent for Organ and Tissue Donation (adopted November 30, 2000) (Model Elements of Informed Consent), indicate that disclosing whether businesses involved in the donation process are non-profit or for-profit should be viewed as an additional or supplemental element rather than included in minimum requirements for informed consent.

Some commenters felt that the requirement would be contrary to the statute, saying that the OPO Certification Act of 2000 mandates that process performance measures must be 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. These commenters stated that the proposed requirement had the potential to impede efforts to increase organ donation.

Although some commenters suggested specific language that could be used to inform families about the profit status of tissue banks, other commenters stated that disclosing profit status is not relevant or meaningful information for the donor family. Some commenters pointed out that the organizations involved in the tissue donation process (tissue banks) are inherently a mixture of both for-profit and non-profit entities. Further, commenters said that there is no realistic way to assure a potential donor family that a for-profit entity will not at some point be involved in handling the tissue they donate.

Most commenters' chief concern was that informing potential donor families that for-profit entities will be involved in the tissue donation process could result in fewer families consenting to tissue and even organ donation or to

decision makers restricting their donation to non-profit tissue banks. Commenters pointed out that many people have misconceptions about for-profit tissue banks. One commenter pointed out that technological advances in tissue donation generally are made by for-profit, not non-profit, tissue banks. Commenters also noted that there was a common misconception that non-profits are more altruistic and more deserving of the donation. However, other commenters stated that it was important to explain the differences between for-profit and non-profit tissue banks so that families can appreciate the important contributions of both.

Response: Based upon these comments, we believe that requiring OPOs to disclose that for-profit entities will be involved in recovering, processing, and distributing tissue is not necessary. Both for-profit and non-profit tissue banks contribute significantly to the tissue industry and to the benefits that patients receive from donated tissue. However, explaining the nuances of for-profit and non-profit tissue banking to the families of potential donors being asked to consent to organ and/or tissue donation simply is not feasible.

We believe the most appropriate course of action is to allow each OPO to determine independently what information it needs to disclose about the various organizations that will be involved in the donation process. Thus, we have not finalized a requirement for OPOs to disclose the profit status of tissue banks to families of potential donors and other decision makers.

In addition, in reviewing the Model Elements of Informed Consent, we noted that neither the basic elements nor the additional elements of informed consent contain any requirement to inform decision makers about the right to limit or restrict the use of organs and/or tissue. As noted above, we believe there should be a minimum standard for informed consent. However, there is no reason to introduce unnecessary information that may adversely affect the donation decision. The disclosure of the decision maker's right to limit or restrict the use of organs and/or tissue could result in unreasonable or unnecessary limitations on donated organs and tissue. Since this could have an adverse effect on organ and/or tissue donation and availability, this requirement has been removed from the final rule. We believe it should be up to each individual OPO if and how the right to limit or restrict the use of donated organs and/or tissue should be handled.

Evaluation and Management of Potential Donors and Organ Placement and Recovery (Proposed § 486.344)

We proposed that an 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.

We also proposed that an OPO's medical director must be 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. We proposed that an OPO must implement a system that ensures that 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 proposed that to evaluate a potential donor, an OPO must: Verify that death has been pronounced according to applicable local, State, and Federal laws pertaining to organ donation; determine whether there are conditions that may contraindicate donation; if possible, obtain the potential donor's medical and social history; review the potential donor's medical chart and perform a physical examination of the donor; and obtain the donor's vital signs and perform all pertinent tests.

We proposed that the OPO must: Arrange for screening and testing of the donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus (HIV); 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 the Clinical Laboratory Improvement Amendments (CLIA) regulations; ensure that the donor's blood is typed using two separate blood samples; and document the donor's record with all test results, including blood type, before organ recovery.

We also proposed requiring OPOs to collaborate with transplant programs by establishing protocols 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. We

proposed that 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 must accompany the organ to the hospital where the transplant will take place. Further, we proposed that the protocols must be reviewed periodically with the transplant programs to incorporate best practices in the field and maximize organ donation.

We proposed a requirement for OPOs for documentation of recipient information. We proposed that prior to recovery of an organ for transplantation, an 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.

We also proposed that an 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. Finally, we proposed that an OPO must develop and implement a protocol to maximize placement of organs for transplantation.

Comment: Some commenters objected to our proposal that the medical director would be 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. Commenters pointed out that some medical directors are transplant surgeons who may have expertise only in their own specialty. Commenters said that such medical directors might rule out a case before all options have been exhausted and that leaving the rule-in/out decision to one individual may do a disservice to the goal of maximizing organ utilization.

Response: We believe the commenters may have misunderstood our proposed language. We were not proposing to require that the OPO medical director be directly responsible for determining medical suitability for every potential organ donor. Rather we proposed (and are finalizing) language at § 486.344(a) to require the medical director to be responsible for ensuring that the OPO's protocols for evaluating and managing potential donors are implemented correctly.

To accomplish this, we expect that a medical director will: Fulfill his or her own responsibilities under the OPO's protocols for donor evaluation and management; review organ donation cases periodically or in real time to determine whether the OPO's protocols were followed correctly (both in regard to the evaluation of potential donors and the clinical management of potential donors to "optimize organ viability and function") and, as needed, work with the OPO procurement coordinators and other OPO staff to improve the protocols, as well as implementation of the protocols.

Comment: A few commenters viewed our proposal to make the OPO medical director responsible for implementation of protocols for donor evaluation and management as inappropriately interfering in the transplant surgeon's judgment and relationship with his or her patient. One commenter said that our requirement would interfere with the transplant surgeon's/physician's decision whether to accept a particular organ for transplant into a particular patient.

Response: Under our proposal, a protocol for donor evaluation would include only the evaluation activities necessary to determine whether a patient is medically suitable for organ donation, such as reading the patient's chart, examining the patient, and ordering or performing any necessary lab work or other testing. The protocol would not cover evaluation of an individual organ's suitability for transplantation into a specific patient, which is the purview of the individual patient's transplant surgeon. We have changed the title of § 486.344 and § 486.344(b) and other wording throughout the regulatory text to clarify that the required protocols are for evaluation and management of *potential* donors.

Comment: Commenters said that OPOs should be able to decide who should provide assistance in clinical management of donors. Several commenters said that the OPO medical director may not always be the best physician to assist with donor management challenges faced in the field. Commenters said that a hospital's critical care intensivist physicians may be in a better position to look objectively at the donor picture and provide management expertise. However, the commenter also stated that some OPOs have highly trained clinical experts who function in the role of donor management consultants on a case-by-case basis within their OPOs and these OPOs have very high organs-per-donor yields. The commenter said

that other OPOs may consult with the intensivist groups at individual hospitals on a case-by-case basis to receive input on management and that these OPOs also have high organs per donor yields.

Response: We agree with the commenters that the OPO medical director may not always be the best individual to consult on issues of donor management. We proposed that "an OPO must implement a system to ensure that 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." Our intention was simply to ensure that assistance in managing a potential donor would be available to the OPO's procurement coordinator if the surgeon on call was unavailable. However, OPOs clearly have the expertise to determine whether the medical director, a critical care intensivist physician, or another clinical expert is the best person to assist a procurement coordinator in medically managing a potential donor. Many OPOs with high organs-per-donor outcomes utilize the services of a non-physician clinical expert. Therefore, in § 486.344(a)(2) we are removing the word "physician" after the words "or other qualified" and inserting "individual. The language in this final rule provides OPOs with the flexibility to determine who will assist in medically managing potential donor cases. To provide OPOs with the highest degree of latitude possible, we will not define "clinical expert" or "other qualified individual." Instead, under this final rule we require an OPO, in their policies and procedures, to define who is considered a "qualified individual" based on current standards of practice and implement a system that ensures that a qualified physician or other qualified individual is available to assist in the medical management of a donor when the surgeon on call is unavailable.

Comment: One commenter suggested that the phrase in 486.344(b)(1), "pertaining to death and/or declaration of death," be substituted for "pertaining to organ donation."

Response: We do not believe it is necessary to revise the text as suggested by the commenter. Stating that when pronouncing death, an OPO must abide by "applicable" State, Federal, and local laws and, in addition, describing the laws as "pertaining to death/and/or declaration of death" is unnecessarily descriptive. In fact, after reviewing our proposed language in § 486.344(b)(1), we have concluded that the phrase "pertaining to organ donation" is not

necessary and could be confusing. Therefore, we have changed the language in 486.344(b)(1) to read simply, "Verify that death has been pronounced according to applicable local, State, and Federal laws."

Comment: One commenter said that the proposed requirement at 486.344(b)(2) for an OPO to "determine whether there are conditions that may contraindicate donation," is overly broad and too generally stated. The commenter stated that it is unclear whether the language refers to the overall quality of the donor or to organ-specific decisions.

Response: We are not adopting this comment. We do not believe the requirement is overly broad, as all donors must be evaluated by the OPO for clinical contraindications to donation. Further, we have changed the language to reflect the OPTN's requirement that potential donors be evaluated to determine whether there are conditions that influence donation. However, we have added the word "potential donor" to the title of paragraph § 486.344(b) to clarify that the evaluation pertains only to the donor, not to specific organs.

Comment: One commenter said that with respect to the requirement for OPOs to "obtain the donor's vital signs and perform all pertinent tests," CMS should require that the activities be performed according to current OPTN standards.

Response: As we have stated previously, the "rules and requirements of the OPTN" are those OPTN policies and bylaws that have been approved formally by the Secretary by being published in the **Federal Register** with an opportunity for the public to comment. Therefore, simply adding language to a regulation that states OPOs must adhere to OPTN standards is not sufficient. We must include the specific language of the OPTN standard as a rule in order to make the standard a requirement.

Comment: One commenter said that we should not use the term "waiting list" in the final rule because a "waiting list" is a pool of transplant candidates, whereas, in the OPO community, the term "match run" is commonly used to describe a list generated to rank and match potential transplant recipients with the donor's specific characteristics. The commenter suggested that we use the terms "match run" or "match program" instead of "waiting list."

Response: We agree with the commenter that the use of the term "waiting list" is misleading when used in this context. However, we will not use the term "match run" or the term

"match program" because of the possibility that the OPTN may change its terminology. Therefore, in this final rule, we have revised § 486.344(e) to require OPOs to have written documentation from the OPTN showing, at a minimum, the intended recipient's ranking in relation to other suitable candidates.

Comment: Some commenters disagreed with our proposal specifying that prior to recovery of an organ for transplant, the OPO must have documentation from the OPTN showing, at a minimum, the intended organ recipient's position on the waiting list in relation to other suitable candidates and the recipient's OPTN identification number and blood type. The commenters said that it would be impossible for OPOs to meet this requirement because the OPO may not know the identity of the recipient prior to organ recovery.

Response: Our proposal was intended only to require OPOs to obtain documentation of the recipient's information when the identity of the recipient is known prior to recovery of the organ. Clearly, if the recipient has not yet been identified, the OPO cannot obtain such documentation. We have clarified our language at § 486.344(e) to say, "If the intended recipient has been identified 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 ranking in relation to other suitable candidates and the recipient's OPTN identification number and blood type."

Comment: A commenter recommended that to align practices between OPO, OPTN, and transplant center policies for blood type verification, CMS should not include the following proposed sentence in the final rule: "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." The commenter recommended that instead, CMS should add the following sentences to the final rule, "The OPO shall have two separate determinations of the donor's ABO type prior to incision for ensuring the accuracy of the donor's ABO during the OPTN match run. Each OPO shall establish and implement a procedure for proving on-line verification by another OPO staff person other than the one initially entering the donor's ABO into the OPTN donor's registration. The protocol for organ placement must ensure that all donor versus transplant candidate blood

type verification will be completed through the OPTN match run."

Response: The language recommended by the commenter was taken from the OPTN policies for verification of donor blood type. While we believe it is advisable in many cases for us to align our requirements for OPOs with the policies of the OPTN and the policies and procedures of transplant centers, we believe the recommended language is too specific and too prescriptive. If the OPTN were to change these detailed policies, we could change our requirements, if necessary, only by initiating rulemaking. However, in this final rule, we have added additional detail to our proposed requirement that we believe will satisfy the intent of the commenter. Therefore, this final rule requires an OPO to have a protocol to ensure that: (1) The OPO is responsible for two separate determinations of the donor's blood type; (2) if the identity of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual; and (3) documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place. Note that in meeting the requirements of paragraph (2), the individual who verifies the donor's blood type does not have to be from the OPO because a second member of the OPO's staff may not be available for verification. Therefore, as an example, an individual on the staff of the donor hospital could verify the donor's blood type.

Comment: A commenter objected to our use of the term "best practices" in 486.344(d)(2). The commenter said that the use and interpretation of "best practices" in this context would be problematic, since there is no consensus on "best practices" for donor evaluation and management or organ placement and recovery. The commenter said that in using the term "best practices," CMS would be mandating "extremely unclear" standards subject to the interpretation that OPOs should be held to standards far in excess of "typical standards."

Response: We agree with the commenter that the use of the term "best practices" could be problematic. We will rephrase our proposed language to clarify our intention that in collaboration with their transplant centers, OPOs must regularly reassess their protocols for potential donor evaluation and management and organ

placement and recovery to incorporate practices that have been shown to maximize organ donation and transplantation. Therefore, we have removed the term “best practices” from the language and moved the language in the proposed § 486.344(d)(2) to § 486.344(d)(3) in the final rule. Thus, in § 486.344(d)(3), we require OPOs to review their established protocols regularly with their transplant programs “to incorporate practices that have been shown to maximize organ donation and transplantation.”

Section 486.346 Condition: Organ Preparation and Transport

We proposed that OPOs must arrange for organs to be tested for infectious diseases according to the current standards of practice by appropriately certified laboratories.

We also proposed that OPOs would be required to send complete documentation of donor information with the organ(s) to the transplant center and that the information must include donor evaluation, the complete record of the donor's management, as well as documentation of consent, pronouncement of death, and determination of organ quality. In addition, we proposed requiring that two OPO staff members must verify the accuracy of the information being sent with the organ(s).

We proposed that OPOs develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures that they arrive without compromising the quality of the organ or the health of the recipient. We proposed that this 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. We proposed that all of the packaging for the organ(s) must be marked with the identification number, specific contents, and donor's blood type.

We received several comments on this section. Commenters expressed a great deal of concern over how some of the language could affect the donation process, as well as the OPO's potential liability under state tort laws. We have summarized those comments below and explained the changes we have made to the regulation text.

Comment: One commenter questioned the need for this proposed section. The commenter noted that UNOS had determined “that the root cause of many of these errors involved the reuse of organ shipping boxes.” Commenters also noted that the OPTN/UNOS Board

of Directors had instituted policy changes that prohibit reuse of organ shipment boxes and implemented requirements that are the same as those proposed by CMS.

Response: Although the OPTN/UNOS Board of Directors have instituted policy changes similar or even identical to those in this provision, this section is needed to make them mandatory for the OPOs and to enable CMS to enforce these requirements. Thus, we will be finalizing this condition with only the three revisions discussed in the comments and responses below.

Comment: A commenter noted that the proposed rule would require two OPO staff members to verify that the labels, packaging, and contents are correct prior to transport. However, the commenter said that there may be only one OPO staff member present in the operating room when the organs are packaged. The commenter said that we should not require both individuals who check the labels, packaging, and contents to be OPO employees.

Response: We agree with the commenter. There may be times when two OPO staff members are not available to verify that organs are correctly packaged and labeled. Thus, we will revise the language in the proposed § 486.346(c) to read, “* * *”. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.”

Comment: A commenter expressed concern about “language suggesting that the OPO would be held responsible for ensuring that an organ would not compromise the health of a recipient.” The commenter stated that the transplant center decides whether to transplant a particular organ into a particular recipient. Thus, the transplant center's decision affects the recipient's health, not any decision or action by an OPO. The commenter pointed out that the OPO cannot always control what happens to the organ once it leaves the OPO for transport to the transplant hospitals.

Response: We understand the commenter's concern regarding the proposed language, “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.” [Emphasis added.] The OPO is responsible for ensuring that an organ(s) arrive at the transplant center “without compromise

to the quality of the organ,” because it is the OPO that labels, packages, handles, and ships the organ(s) to the transplant center. However, the transplant center, specifically the transplant surgeon, makes the decision to transplant a particular organ(s) into a particular patient and, thus, is responsible for the health of the recipient. Thus, we have revised § 486.346(c) by deleting the words “or health of the recipient.”

Comment: A commenter submitted a new form that he developed that would be sent to UNOS with the intent that copies would be kept with the UNOS donor documentation at the transplanting OPO.

Response: CMS is not the appropriate agency to review the submitted form. Therefore, we have forwarded the form to HRSA for review by the OPTN. This regulation does not require OPOs to use a specific form.

Comment: One commenter said that there should be an “enforceable consequence” for making errors in the packaging and transporting of organs. If the errors continued, the commenters indicated, “immediate decertification should be implemented even if the OPO is meeting the established criteria to maintain its certification.”

Response: We agree with the commenter that there must be an enforceable consequence for making errors in the packaging and transportation of organs. As discussed earlier in this preamble, OPOs are required to satisfy all requirements of the conditions for coverage in this final regulation. An OPO's failure to satisfy any of these requirements, including those in this condition, could result in action being taken by CMS. The severity of the action depends upon the severity of the deficiency. However, an immediate de-certification would be based on urgent need. (See discussion in this preamble of the definition of “urgent need” in “Definitions (proposed § 486.302)” and “De-Certification (proposed § 486.312).”

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

We proposed that OPOs must develop, implement, and maintain a comprehensive, data-driven QAPI program that is designed to monitor and evaluate performance of all donation services, including services provided under a contract or an agreement. We proposed that the QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities. We included examples of components that

should be included in a QAPI program: 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. (Hospital development refers to an OPO's activities related to developing good working relationships with the hospitals with which the OPO has an agreement.) We also proposed requiring OPOs to take actions that will result in performance improvements and to track performance to ensure that improvements are sustained.

We proposed that each OPO must conduct death record reviews as part of its QAPI program. We proposed requiring OPOs to 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. We proposed that when an OPO identifies missed opportunities for donation, it must implement actions to improve its performance.

We proposed defining an adverse event "as an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof." We indicated that for OPOs, adverse events would include, but were 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.

We proposed that an OPO be required to establish a written policy to address adverse events that occur during any phase of an organ donation case. We proposed that at a minimum, the policy must address a process for the identification, reporting, analysis, and prevention of adverse events. Under the proposed rule, an OPO would be required to conduct a thorough analysis of any adverse event they identify and use their analysis to change its policies and practices to prevent any reoccurrence of similar incidents. In addition, we proposed 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.

Comment: Many commenters wrote to us expressing their approval of the requirement to establish a QAPI program. Most who commented on the proposed QAPI requirement specifically endorsed the language in proposed § 486.348(a). One commenter suggested that an OPO QAPI program should include specific goals to enhance consent rates and the quality of donor management.

Response: We appreciate the overwhelming support expressed by commenters for a QAPI program requirement. We agree that increasing consent and the quality of donor management are worthy goals for OPO QAPI programs. In fact, the regulations text of the February 4, 2005 proposed rule lists examples of OPO activities for which OPOs can develop objective measures to evaluate and demonstrate improved performance and includes donor management and consent practices. However, in this final rule, we do not mandate that OPOs include any specific activities in their QAPI programs. OPO operations and function vary throughout the country, along with the demographics within each OPO's service area. We believe it is important to give an OPO sufficient flexibility to design its QAPI program in a manner that will raise its level of performance, given the OPO's specific weaknesses and strengths. Therefore, we are finalizing § 486.348(a) as proposed.

Comment: Most commenters supported our proposal to require an OPO to perform 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 a hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals. However, some commenters recommended that we change the language slightly so that the requirement would read, "150 or more acute care beds, a ventilator and an ICU * * *"

Response: We believe this change is reasonable in part, because a hospital without a ventilator would be unable to maintain a potential donor, and a hospital without an intensive care unit is unlikely to have 150 or more beds. However, we disagree that death record reviews should be limited to hospitals with 150 or more "acute care" beds. Medicare does not recognize the term "acute care bed" for certification purposes. For example, in recent years, many hospitals have been converting some hospital units to "sub-acute care units" or "a hospital within a hospital." Unless such a unit or "hospital"

becomes a separate provider and provider type (such as a skilled nursing facility), Medicare regards the beds in these units or "hospitals" as hospital beds. However, an OPO might argue that such beds are not "acute care" beds. We believe using this term would lead to confusion and could lead OPOs to overlook some hospitals with significant donor potential. Therefore, we have modified the requirement to say that an OPO is required to perform death record reviews in hospitals with 150 or more beds, a ventilator, and an intensive care unit.

Comment: Some commenters recommended that we establish requirements for the frequency of conducting death record reviews. One commenter stated that some OPOs do not perform death record reviews, even in their large hospitals and that other OPOs conduct death record reviews only annually. One commenter suggested that we should require OPOs to perform death record reviews monthly for hospitals with 200 or more beds that have an emergency department, an operating room, and an intensive care unit.

Response: As we stated in the preamble to our February 4, 2005 proposed rule, death record reviews are a critical component of any QAPI program. They form the foundation every OPO needs to assess its own performance and the performance of its hospitals so that missed opportunities for donation can be identified and changes made to address the problem. It is important for death record reviews to be performed frequently in large hospitals with the greatest donation potential. HRSA and the CMS OPO Coordinators report that many successful OPOs perform death record reviews weekly in their large hospitals. Some OPOs even perform death record reviews in "real time."

Therefore, we agree with the commenters who urged us to establish a time frame for death record reviews. However, we do not agree with the commenter who suggested 200 beds as the appropriate parameter. A recent study found that 19 percent of hospitals account for 80 percent of potential donors. Hospitals with 150 or more beds were more likely than smaller hospitals to have both potential donors and actual donors. (E Sheehy, S Conrad, L Brigham, et al, *Estimating the Number of Potential Organ Donors in the United States*; New England Journal of Medicine, Vol. 349: 667-674, August 14, 2003). We believe that performing death record reviews monthly in these large hospitals is both reasonable and absolutely necessary for an OPO to

determine where it needs to improve. Therefore, in this final rule, we require OPOs to perform death record reviews at least monthly 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, a ventilator, and an intensive care unit (unless a hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals.

Comment: Many commenters said that the performance of death record reviews should be standardized, so that death record review practices are uniform and the reviews are performed correctly. Some commenters suggested that HRSA should establish a technical assistance program to train OPOs; one commenter said that CMS should hire staff to review results of OPO medical record reviews.

Response: We disagree that the Federal Government should be responsible for teaching the OPOs how to conduct death record reviews.

Each OPO should put into place a system to make sure that staff who perform death record reviews are qualified and trained to perform the reviews correctly. Further, we would expect that as part of its QAPI program, every OPO would have a procedure to check the accuracy of the death record reviews after they are performed. Therefore, we are not adopting the commenters' suggestion.

Comment: A few commenters were concerned about using data obtained from death record reviews performed by OPOs. They said that the data, especially data concerning missed referrals, should not be used in the outcome measures until there is a uniform death record review procedure used by all OPOs. One commenter said there could be inter-OPO variations.

Response: Although there is some potential for intra-and/or inter-OPO variability in performing death record reviews, we would point out that any system for conducting death record reviews has some potential for variability. However, we believe that death record reviews will increase organ donation because these reviews will enable OPOs to identify any problems that result in missed opportunities for donation so that they can make changes to address those problems. In addition, since the information in the OPO's death record reviews will be included in the statistical measures for re-certification, it is in each OPO's best interest to develop procedures and processes to ensure that their death record reviews are accurate and valid.

Further, we are adopting the same definition of "eligible deaths" that the OPTN uses. This should promote consistency in the reporting of the data if the death record reviews are conducted by staff with the appropriate background and training. As we stated earlier in this preamble, the CMS Regional OPO Coordinators are available to work with the OPOs in implementing their QAPI programs, including the OPOs' performance of death record reviews. Also, we will work with HRSA to determine whether a procedure can be established to assist OPOs that are not sure whether a particular death was an eligible death.

Comment: A few commenters said that there should be some type of validation of the data from death record reviews. Two commenters noted that the current OPTN database requires additional validation. One commenter suggested that CMS surveyors compare death record review results with the SRTR's research on eligible deaths.

Response: We appreciate the recommendation that death record review results should be validated. However, we must point out that OPOs are responsible for ensuring that the data they submit to the OPTN are valid. As stated above, we expect that every OPO will have a procedure to check the accuracy of the death record reviews after they are performed.

Also, it is important to note that the donation rate outcome measures in this final rule are based on *both* self-reported data and the SRTR statistical methodology. Although the number of "eligible deaths" is reported by OPOs to the OPTN, the number of "notifiable deaths" (the subset of all in-hospital deaths age 0–70 with no exclusionary medical diagnoses for possible donation) is calculated by the SRTR based on data from the Office of Analysis and Epidemiology, National Center for Health Statistics, Centers for Disease Control and Prevention. By assessing an OPO's reported number of eligible deaths in view of its notifiable deaths, the SRTR can ascertain whether the data reported by an OPO are likely to be correct. If the data indicate that an OPO may not be reporting the number of eligible deaths in its donation service area correctly, CMS will regard this information as a complaint and will conduct a complaint investigation of the OPO.

Comment: One commenter suggested we add " * * * language to hold hospitals accountable to provide computerized mortality lists within 15 days of the last day of the month and work to provide for timely review of records to all donation agencies." This

same commenter also encouraged the " * * * hiring of CMS representatives to begin to review results of OPO medical record reviews and reports to hospitals and for CMS to set guidelines on how and when those fines would be established."

Response: We support hospitals providing timely information to the OPOs. However, this final rule is a regulation for OPOs; hospital performance is not within the purview of this regulation.

Adverse Event Definition

Comment: Some commenters requested that CMS clarify the definition of "adverse event." Commenters stated that the proposed definition was too broad or that it should be limited to situations where there was an immediate risk to the patient.

Response: We agree that the definition of "adverse event" is broad and could be subject to varying interpretations. We would expect that as part of an OPO's effort to develop, implement and maintain a comprehensive, data-driven QAPI program, the OPO would customize the definition of "adverse event" in their written policies to meet their own needs, as well as ensure compliance with the QAPI requirements. Therefore, we have finalized the definition as proposed.

Adverse Event Reporting

Comment: While most of the comments were supportive of adverse event identification and analysis, many of the commenters were concerned about the reporting requirement. Many commenters said that their major concerns were related to the mechanical issues of reporting. Their primary concern, however, was whether CMS would be able to keep the information confidential or whether we would be required to release it under the Freedom of Information Act (FOIA). Other commenters were concerned about their liability should the information become public. Some commenters were also concerned over how CMS would use the information; specifically, they wanted to know if CMS intended to use the information in future re-certification or designation decisions.

Other specific issues identified by commenters included the need to: Clarify what constitutes a "business day;" expand the 5-day timeframe between the initial report and the second report to give the OPO adequate time for a thorough analysis of the incident; and, clarify CMS's intention to publish or share this information (without identifying information) so that

other OPOs can avoid similar incidents. Commenters recommended that CMS address these specific issues before mandating a requirement of this nature. Commenters also expressed concern regarding the broad approach to addressing adverse events “that occur during any phase of an organ donation case” as part of an OPO’s QAPI program.

Commenters also noted the proposed rule for Transplant Centers, CMS–3835–P, that was published on February 4, 2005, has a requirement that transplant centers “establish and implement written policies to address adverse events that occur during any phase of the organ transplantation case.” (§ 482.96(b)). However, there is no reporting requirement for transplant hospitals that corresponds to the proposed reporting requirement for OPOs.

Response: Based on public comments, we have deleted the reporting requirement in this final rule. We have retained the requirement that OPOs establish and implement written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events. We agree that the phrase referring to adverse events “that occur during any phase of an organ donation case” needs to be clarified. We believe that an OPO should be responsible for the identification, reporting, analysis and prevention of any adverse events that occur during the organ donation process. We believe that this process begins when an OPO is notified by the hospital or critical access hospital of a death or imminent death and concludes when the organ(s) are delivered to a transplant center. It would also include any adverse events that were identified or occurred at a transplant center but the root cause of the adverse event appears to have occurred before the organ(s) arrived at the transplant center. * * * (should be say anything about organs for research-based on our definition of adverse event it appears it would have to be something that could affect a patient? Also, what about tissue?) Thus, § 486.348(c)(1) will be revised to read “An OPO must establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process.”

We have also retained the requirement that OPOs must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in OPO policies and practices to prevent repeat incidents. Although CMS will not receive written reports

from OPOs on identified adverse events, a description of the adverse event, the circumstances surrounding the incident, the OPO’s analysis and subsequent policy and practice changes must be available on-site at the OPO for the OPO coordinator’s and surveyor’s use in reviewing this information and monitoring the OPOs’ response to an adverse event.

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

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

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

We also proposed to correct a number of cross-references related to the certification of OPOs. In § 441.13(c), and in § 498.2, we proposed 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 proposed correcting this reference to read “as defined in § 486.302 of this chapter”.

We received no public comments on these conforming changes in the proposed provisions. Therefore, we are adopting the provisions as final without change.

Living Donation

In the February 4, 2005 proposed rule, we noted that living donation was becoming increasingly important. In 2001, for the first time, living donors outnumbered deceased donors, with 6,445 living donors and 6,077 deceased donors. In 2004, there were 7,150 living donors and 7,004 deceased donors. However, OPOs do not play a role in living donation, with the exception of two pilot programs in which OPOs assist transplant hospitals by arranging for medical and psychological evaluations of living kidney donors. We stated that the mission of the OPOs was to increase the number of deceased donors. However, in view of the increasing importance of living donation, we specifically requested

public comments on what, if any, role OPOs should play in living donation.

Comment: Commenters had very diverse views on what role, if any, an OPO should play in living donation. Many commenters recognized the importance of living donation but stated that the OPOs’ core or primary mission is increasing donation from deceased donors. Some commenters expressed concern that living donation could divert resources that should be directed to increasing deceased donation. Further, commenters did not want living donation to play any part in how we evaluate an OPO’s performance.

Some commenters were strongly opposed to OPOs having any role. One commenter noted that the OPOs do not have the skills or staffing to address living donors’ needs and that this could strain the OPO’s relationships with their hospitals. Some commenters felt that if the OPOs played any role, it should be a very limited one. Another commenter suggested that OPOs simply refer any inquiries to their transplant centers.

One commenter wanted to limit the OPOs that could be involved in living donation. That commenter noted that devoting resources to living donation would only divert the OPO’s resources from increasing deceased donation. Therefore, unless an OPO is in the top one-third of performing OPOs, an OPO should not be required to play any role in living donation. This commenter said that living donation should be arranged between the potential donors and the transplant center.

Conversely, one OPO indicated that some OPOs are recognized as the sources of information on both deceased and living donation and receive many questions from both individuals and volunteer groups concerning living donation. The commenter said that OPOs should play a coordination role, especially when it concerns unrelated living donors. One commenter suggested that OPOs could play a role by including information on living donation in their public education efforts. Other commenters simply said that OPOs should play a more active role in living donation.

Response: We agree that living donation should not play any role in the evaluation of an OPO’s performance. As many commenters stated, the OPOs’ core mission is increasing donation from deceased donors. Therefore, we will continue to evaluate OPOs only on their performance in regard to deceased donation.

Further, we share the concern some commenters expressed that an OPO’s involvement in living donation could result in the diversion of resources from

its core mission. As we stated in the proposed rule, given the demonstrated risks to living donors (primarily living liver donors), we believe that living donation should remain a medical decision between individuals interested in donating and their physicians. Thus, our expectation is that OPOs will have only limited involvement in living donation, and we will not be including any requirement concerning living donation in this final regulation.

Public Education

In the February 4, 2005 proposed rule, we noted that the current regulations contained a requirement for professional education but no requirement for public education. We also noted that most OPOs were aware of how important public education is in “reaching ethnic populations, dispelling myths about organ donation, and addressing other issues that create barriers to consent to donation.” However, we acknowledged that some researchers believe that available funding should go to basic research, professional education, and hospital development rather than public education. We said, “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.” Thus, we specifically requested comments on whether we should require OPOs to conduct public education based on systematic evaluation of specific barriers to donation within their individual service areas.

Comment: Many commenters stated that they were very supportive of OPOs conducting public education and believed that it was very important in increasing donation. Some commenters noted that they had already seen increases in individuals signed up for donor registries due to public education. Another commenter noted that it was important to conduct public education in addition to professional education. However, one commenter noted that it can be difficult to determine the effectiveness of public education and other commenters noted that public education is really a long-term process, and the positive effects may not be seen for months or years.

Many commenters were supportive of including a general requirement in this final regulation for OPOs to provide public education. Some commenters wanted the requirement to be more specific, such as assessing and targeting or focusing on specific needs in an

OPO’s donation service area. One commenter said that we should require OPOs to include their public education efforts in their QAPI programs. Another commenter expressed concern that the lack of a requirement for public education in CMS regulations may hinder or even discourage public education efforts by OPOs. Other commenters believed that even if we did not make this a requirement, we should encourage OPOs to conduct public education.

Response: Although we agree with the commenters who emphasized the importance of public education, we also agree with the commenter who said that it is difficult to determine the effectiveness of public education. Clearly, public education is important for increasing public awareness of the importance of donation, and it appears that most, if not all, OPOs conduct some public education efforts. However, we believe that OPOs need the flexibility to decide how they will use their educational resources. Many OPOs may need to devote resources to public education; however, other OPOs may have a greater need for professional education. Thus, although we certainly encourage OPOs to assess the needs for public education in their donation service areas and address them and appreciate the comments we received, we will not be incorporating a requirement for public education in this final regulation.

III. Provisions of the Final Rule

In this final rule we are adopting the provisions as set forth in the February 4, 2005 proposed rule with the following revisions:

Amend § 486.301, “Basis and scope” by revising paragraph (b)(4) to clarify that the scope of the subpart sets forth the requirements for an OPO to be re-certified.

Amend 486.302, “Definitions” by—

- Revising the definition of “certification” with minor clarifying changes that are discussed in this preamble under “Certification (proposed § 486.303).”

- Amending the definition of “de-certification” by removing language related to specific conditions, measures, and requirements and revising it so to be consistent with the definition of “certification.”

- Amending the definition of “designated requestor” by adding language to state that a “designated requestor” is also known as an “effective requestor.”

- Revising the term “service area” to read “donation service area (DSA)”, so that our terminology is consistent with

the terminology generally used and accepted in the OPO and transplant communities. We have adopted the definition as proposed.

- Revising the definition for “re-certification cycle.”

- Adding the following definitions to this final rule: “donor after cardiac death”, “eligible death”, “eligible donor”, “expected donation rate”, “observed donation rate,” and “standard criteria donor (SCD)” These terms were not proposed in our February 4, 2005 rule. Because we will be using data from the OPTN and the SRTR in assessing whether OPOs have satisfied these outcome measures, we are adopting the definitions currently used by the OPTN and SRTR in their statistical evaluation of OPO performance.

- Adding the term “urgent need”. This occurs when an OPO’s noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to an organ recipient.

Amend § 486.303, “Requirements for certification” by—

- Revising to make conforming changes we made to § 486.312 (De-certification).

- Revising paragraph (a) to state that in order to be certified as a qualified OPO, an OPO must have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO.

- Revising § 486.304 “Requirements for Designation” by moving some standards to other conditions of coverage or deleting them. We moved the requirements for designation at § 486.304(a) through (c)(1) and combined them with the requirements for certification at § 486.303. We deleted the requirements at § 486.304 (c)(2) through (c)(7) that specify elements of the agreement. The remaining elements of the agreement with CMS specified at § 486.304(c)(3) through (c)(7) are standard elements of provider/supplier agreements with CMS and will be addressed in manual instructions. The requirements at § 486.304(d) Application for designation has been moved to § 486.316 Re-certification and competition processes. Finally, the requirements at § 486.304(e) Designation periods have been moved to § 486.308. The changes are identified in the following crosswalk:

Proposed	Final
§ 486.304(a)–(c)(1)	Moved to § 486.303.
§ 486.304(c)(2)–(c)(7)	Deleted.

Proposed	Final
§ 486.304(d)	Moved to § 486.316.
§ 486.304(e)	Moved to § 486.308.

Amend § 486.306, "OPO service area size designation and documentation requirements" by revising paragraph (d)(2) to permit an exception for an OPO whose service area includes Hawaii and does not include any part of the continental United States.

Amend § 486.308, "Designation of one OPO for each service area" by—

- Redesignating § 486.308(b) through § 486.308(f) as § 486.308(c) through § 486.308(g) and adding § 486.308(b). Newly added paragraph (b) was relocated from § 486.304(c) as part of our reorganization and clarification in this final rule of the sections that address certification and designation.

Amend § 486.309, "Re-certification from August 1, 2006 through July 31, 2010" to specify that OPOs that were certified by CMS in the past and currently have agreements with the Secretary are re-certified August 1, 2006 through July 31, 2010 and the current agreements will be extended through January 31, 2011.

Amend § 486.310, Changes in control or ownership or service area by clarifying that this section applies to changes in the control over an OPO, as well as changes in ownership or in an OPO's service area.

Amend § 486.312, "De-certification" by—

- Clarifying in paragraph (b) that de-certification due to involuntary termination of an agreement occurs "during the term of the agreement."
- Clarifying paragraph (c) de-certification due to non-renewal of an agreement. We removed our proposed language "or if the OPO's designation status has been terminated" because we have streamlined the requirement by including requirements for designation status at § 486.303. We added language that requires the OPO to meet the requirements for certification at § 486.303. We made these revisions to clarify that CMS's decision not to renew an OPO's agreement is not based on a single requirement but rather is based on multiple outcome measures and other information collected over the course of the 4-year agreement, consistent with statutory requirements.

Amend § 486.314, "Appeals" by—

- Revising the appeals section to expand the circumstances under which an OPO can appeal a decertification due to involuntary termination or non-renewal of its agreement with us to include both substantive and procedural grounds. We also establish new

procedures for notice of an initial decertification determination, requirements for evidence and the OPO's right to reconsideration. To avoid undue procedural delays, the final rule also establishes a time-sensitive process by which an OPO can request reconsideration, other requirements for filing, and a hearing before a hearing officer. Further, to ensure that protections available in existing regulations were maintained, the appeals process was expanded to specify CMS requirements for reconsiderations, hearings, standards of evidence.

Amend § 486.316, "Re-certification and competition processes" by—

- Removing the proposed requirement that all OPO service areas are open for competition at the end of every recertification cycle. Under this final rule, an OPO that meets the following criteria will be re-certified for an additional 4 years and its service area will not be opened for competition if the OPO: (1) Meets all 3 of the outcome measure requirements in 486.318; (2) meets the requirements for certification at 486.303 and (3) has been shown by survey to be in compliance with the conditions for coverage at 486.320 through 486.348.

- Revising the section to establish that the contiguity of a competing OPO's service area to that of an open area is one of the factors that we will consider when selecting the OPO for designation of the open area.

Amend § 486.318, "Condition: Outcome measures" by—

- Establishing 3 revised outcome measures for OPOs that differ from what we proposed: (1) Donation rate; (we will account for DCDs and donors over the age of 70 by adding a 1 to both the numerator and the denominator); (2) observed donation rate compared to the expected donation rate, as calculated by the SRTR; and (3) a yield measure for both organs transplanted per donor (including pancreata used for islet cell transplantation) and organs used for research per donor. We are not adopting the proposed outcome measures.

- Removing, from the revised outcome measures, the distinction between kidneys and extra-renal organs, except for OPOs operating exclusively in non-contiguous U.S. States, commonwealths, territories, and possessions.

- Revising the outcome measure for OPOs operating exclusively in non-contiguous U.S. States, commonwealths, territories, or possessions.

Amend § 486.320, "Condition: Participation in organ procurement and transplantation network" by revising the

section to include language that requires OPOs to "participate" in the OPTN.

Amend § 486.322, "Condition:

Relationships with hospitals, critical access hospitals, and tissue banks" by—

- Revising to clarify that the OPO is required only to offer to provide designated requestor training annually. If a hospital does not want training, the OPO is not required to provide it.

- Revising to require OPOs to cooperate with tissue banks in offering designated requestor training.

Amend § 486.324, "Condition: Administration and governing body" by revising to clarify that tissue bank members may be from the OPO's tissue bank or any other tissue bank of the OPO's choice. It is not necessary that the tissue bank member represent all tissue banks in the service area.

Amend § 486.326, "Condition: Human resources," by revising paragraph (b)(1), by inserting the words "for organ and/or tissue donation" before "in a timely manner."

Amend § 486.328, "Condition: Reporting of data" by removing paragraph (d) that requires the OPO to report hospital-specific organ donation data, including organ donor potential and the number of donors, to the public at least annually, because that data is readily available on the SRTR website. We also revised § 486.328(a) to remove the term "potential donor denominator" and added the terms "eligible deaths" and "eligible donors". In addition, in § 486.328(b) we clarified that an OPO must provide hospital-specific organ donation data annually to the transplant hospital with which it has agreements.

Amend § 486.330, "Condition: Information management" by adding "electronic" before information management system in the introductory text.

Amend § 486.342 "Condition: Requesting consent" by revising paragraph (a)(8) to read, "Contact information for individuals with questions or concerns."

Amend § 486.344 "Condition: Donor evaluation and management and organ placement and recovery" by—

- Removing, the word "physician" in paragraph (a)(2) and replacing it with the word "individual" to provide OPO's with the flexibility to determine who will assist in medically managing potential donor cases.

- Adding the word "potential donor" to the heading of § 486.344(b) to clarify the evaluation pertains only to the donor, not the specific organs.

- Removing the phrase "pertaining to organ donation" in paragraph (b)(1) because it is not necessary and could be confusing. We have revised paragraph

(b)(1) to read simply, "Verify that death has been pronounced according to applicable local, state, and federal laws."

- Revising paragraph (e) to require OPOs to have written documentation from the OPTN showing at a minimum, the intended recipients ranking in relation to other suitable candidates.

Amend § 486.346, "Condition: Organ preparation and transport" by—

- Removing the words "OPO staff members" and inserting "individuals, one of whom must be an OPO employee," in paragraph (b)

- Removing the words, "or health of the recipient." after the words "quality of the organ" in paragraph (c) and removing the words, "OPO staff members" and inserting the words, "individuals, one of whom must be an OPO employee," in the last sentence.

Amend § 486.348 "Condition: Quality assessment and performance improvement (QAPI)" by—

- Adding a requirement for OPOs to develop, implement, and maintain a QAPI program that is designed to monitor and evaluate the performance of all donation services.

- Adding a requirement that the OPO's QAPI program include objective measures designed to evaluate and demonstrate improved performance with regard to OPO activities, including services provided under contract or arrangement.

- Adding a requirement that OPOs conduct death record reviews at least once a month 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, a ventilator, and an intensive care unit. There is an exception for any hospital that has been granted a waiver to work with another OPO and psychiatric and rehabilitation hospitals.

- Revising paragraph (c) to require that "[a]n OPO must establish written policies to address at a minimum, the process for identification, reporting, analysis, and prevention of adverse events."

- Removing paragraph (c)(3) which had required that OPOs report adverse events to CMS.

IV. Collection of Information Requirement

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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):

Section 486.306 OPO Service Area Size Designation and Documentation Requirements

Section 486.306(a) states that an OPO must make available to CMS documentation which verifies that it

meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

The burden associated with this requirement is the time and effort it would take for an OPO to provide such documentation to CMS. We estimate that it would take one OPO 30 minutes to gather the documentation necessary for such verification. In order to conduct business, an OPO would need to have all of this data readily available. The requirement for the retention of documentation of this type is usual and customary business practice. Therefore, we estimate the annual burden hours for this requirement to be 29 hours.

Section 486.306(c)(1) through (3) requires an OPO to define and document a proposed service area's location and characteristics 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 hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

The burden associated with this requirement is the time and effort necessary for an OPO to document such information. We estimated that it would take a typical OPO an average of 1 hour to document such information. There are 58 OPOs that would have to comply with this requirement; therefore, there would be a total of 58 hours needed to comply annually.

Hours/est. salary/# of OPOs	Annual burden hours	Annual cost estimate
1 organ procurement coordinator (RN or SW) @ \$26.87 hr. × ½ hr. annually per 58 OPOs × 58 OPOs	29.00	\$779.23
1 secretary @ \$16.11/hr. × ½ hr. annually per 58 OPOs	29.00	467.19
Totals	58.00	1,246.42

Section 486.308 Designation of One OPO for Each Service Area

Section 486.308(d) states that 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 (e) of this section within 30 days of notice of the change in designation.

Section 486.308 (e) states that a may 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 listed 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. Based upon historical data, we estimate that

about 2 hospitals would request a waiver annually 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 final regulations of this section are not subject to the PRA.

Section 486.310 Changes in Control or Ownership or Service Area

Sections 486.310(a)(1)&(2) requires 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 OPOs would have to resubmit 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. While this requirement is subject to the PRA, we believe it is exempt because there are less than 10 respondents.

Section 486.312 De-Certification

Sections 486.312(a) states that 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, Section 486.312(e) states that the OPO would have to give 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, Section 486.312(e) states that CMS would provide public notice of the date of de-certification.

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.

While this requirement is subject to the PRA, we believe it is exempt because there are less than 10 respondents.

Section 486.314 Appeals

Section 486.314 states that 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 and procedural grounds. In its appeal, the OPO may request a reconsideration before the Regional Administrator for the OPO's region. If the de-certification is upheld by the Regional Administrator, the OPO may request a hearing before a CMS Hearing Officer.

The burden associated with this provision is the time it will take an OPO to request a reconsideration, and if necessary, a hearing, as well as the time to prepare for both proceedings. However, we do not expect to de-certify more than nine OPOs in a given year. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 486.316 Re-Certification and Competition Processes

Section 486.316(a) requires OPOs to meet all 3 outcome measures requirements at § 486.318 and to be shown to be in substantial compliance with the requirements for certification at § 486.303, including the conditions for coverage at § 486.320 through § 486.348. If all of these requirements are not met, the OPO is de-certified. The de-certified OPO can appeal. If the de-certification is upheld, the de-certified OPO cannot compete for its service area. If the de-certification is overturned on appeal, the OPO is re-certified and its service area is not opened for competition.

Section 486.316(d) states that for an OPO to compete for an open service area, it must have meet the criteria for re-certification at § 486.316(a), donation rate and yield outcome measures at or above 100 percent of the mean national rate averaged over 4 years of the re-certification cycle, and its donation rate must be at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area. Section 486.316(e) states that CMS will determine which OPO to designate for an open service area based upon (1) performance on the outcome measures at § 486.318; (2) relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.348; (3) contiguity to the open service area; and (4) success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. The competing OPO must submit information and data that describe the

barriers in its own service area, how those barriers affected organ donation, what steps the OPO took to overcome them, and the results.

The burden associated with this requirement is the time it would take to create a document that contains the required information and data related to the OPO's success in identifying and addressing the barriers in its own service area and how they relate to the open service area. We will refer to this documentation as a plan.

In the February 4, 2005 proposed rule, we proposed that it would take approximately 16 hours to develop an acceptable plan to increase organ donation. We believe that the document or plan that OPOs would be required to prepare to compete under the final rule would require approximately the same amount of resources. However, we received public comments stating that 16 hours is underestimated. Thus, based on further analysis of the multitude of tasks involved in meeting this requirement, we are estimating it will take an average of 104 burden hours to develop the plan needed to meet this requirement to compete for an open service area.

In each of the 1996, 1998, and 2000 re-certification cycles, approximately two to three OPOs failed the performance standards. However, with the new outcome and process measures in this rule, we believe that as many as 9 OPOs may be de-certified. All de-certified OPOs will have the right to appeal their de-certifications. We believe that 3 OPOs will have their de-certifications reversed at some point during the appeal process. Therefore, 6 de-certifications will be upheld and 6 service areas will be open for competition.

Based on historical data and our previous experience with the OPOs, we would expect a total of 9 OPOs will want to compete for a new service area and 3 of those OPOs may want to compete for more than one service area. Thus, we believe there will be a total of 12 plans that will need to be developed for the competition process.

We believe that developing each plan will require the collective efforts of the QAPI director (Registered Nurse) (RN), organ procurement coordinator (RN or social worker (SW)), medical director, OPO director, and secretary would be expected in developing a plan.

Assuming that it would take these professionals 104 hours, instead of the proposed 16 hours, to develop such a plan, each competition would require 1,248 burden hours for all 9 OPOs to complete 12 plans and would cost all 9 OPOs \$50,022. For the annual burden,

each of these figures needs to be divided by 4, since competition for open service areas will typically occur every 4 years.

Thus, the annual burden hours for all 9 OPOs to prepare 12 plans would be 312 [1,248 divided by 4 = 312] and the

annual cost estimate would be \$12,505.50 [\$50,022 divided by 4 = \$12,505.50].

PER COMPETITION AND ANNUAL BURDEN HOURS AND COSTS ESTIMATES FOR 9 COMPETING OPOS PREPARING 12 PLANS

Hours/Est. salary/9 OPOs/12 plans	Per competi- tion burden hours	Per competi- tion cost esti- mate	Annual burden hours	Annual cost estimate
1 QAPI director* (RN) @ \$26.87/hr. × 30 hrs. × 9 competing OPOs for 12 plans	360	\$9,673.20	90	\$2,418.30
1 organ procurement coordinator (RN or SW)* @ \$26.87/hr. × 30 hrs. × 9 competing OPOs (preparing 12 plans)	360	9,673.20	90	2,418.30
1 OPO director** @ \$50.48/hr. × 30 hrs. × 9 competing OPOs (preparing 12 plans)	360	18,172.80	90	4,543.20
1 medical director ***@ \$84.14/hr. × 12 hrs. × 9 competing OPOs (preparing 12 plans)	144	12,116.16	36	3,029.04
1 secretary *@ \$16.11/hr. × 2 hrs. × 9 competing OPOs (preparing 12 plans)	24	386.64	6	96.66
Totals	1,248	50,022	312	12,505.50

* National Compensation Survey: Occupational Wages in the United States, July 2004; U.S. Department of Labor, U.S. Bureau of Labor Statistics, August 2005.

** Per OPO Consortium survey mean salary for OPO Director is \$105,000 annually (\$50.48 per hour) as stated in the proposed OPO rule (70 FR 6124).

*** http://swz.salary.com/salarywizard/layouthtmls/swzl_compresult_national_EX05000020.html.

The burden associated with this section is the time it takes to gather the required information and data, evaluate it, and prepare a plan to submit to CMS. While this requirement is subject to the PRA, we believe it is exempt because there are less than 10 respondents.

Section 486.322 Condition: Relationships With Hospitals, Critical Access Hospitals, and Tissue Banks

Section 486.322(a) requires an OPO to have a written agreement with 95 percent 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 this requirement is 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.

However, many OPOs will need to rewrite their agreements. In this case, 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 these hospitals to sign the standard agreement.

We believe an attorney would be key in this process. We estimate that it would take an attorney 8 hours to draft a new standard agreement that the OPO could present to each hospital. Thus, it would require 464.00 annual burden hours at an estimated annual cost of \$23,200.00 for all 58 OPOs to have a new standard agreement drafted.

Hours/est. salary/# of OPOs	Annual burden hours	Annual cost estimate
1 attorney × 8 hrs. × \$50/hr. × 58 OPOs	464.00	\$23,200.00
Totals	464.00	23,200.00

U.S. Department of Labor and salary.com.

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 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 require 116.00 burden hours at an estimated annual cost of \$5,000.00 per OPO.

Hours/est. salary/# of OPOs	Annual burden hours	Annual cost estimate
1 attorney × 2 hrs. × \$50/hr. × average of 50 hospitals/OPO	116.00	\$5,000.00
Totals	116.00	5,000.00

Thus, it would require 116.00 burden hours at an estimated annual cost of \$5,000.00 per OPO. It would require 6,728.00 burden hours at an estimated cost of \$290,000 for all of the 58 OPOs to make changes in their agreements with hospitals.

Hours/est. salary/# of OPOs	Annual burden hours	Annual cost estimate
1 attorney × 2 hrs. × \$50/hr. × average of 50 hospitals/OPO × 58 OPOs	6,728.00	\$290,000.00
Totals	6,728.00	290,000.00

Section 486.324 Condition: Administration and Governing Body

Section 486.324 states that the OPO must 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. While this requirement is subject to the PRA, we believe it is exempt as it is usual and customary business practice to have such bylaws, policies, and procedures.

Section 486.326 Condition: Human Resources

Section 486.326(a)(2) requires 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.

Section 486.326(a)(3) states that an OPO must maintain credentialing records for physicians who routinely recover organs in hospitals with which the OPO has an agreement.

While the burden associated with these requirements is subject to the PRA, we believe these requirements reflect usual and customary business practices and thus do not create any additional burden and are exempt from the PRA.

Section 486.328 Condition: Reporting of Data

Section 486.328(a) requires the OPO 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).

Sections 486.328(c) & (d) require 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 burden associated with these requirements is the time it would take the OPOs to report certain information. In this section, we proposed that this would take no more than 4 hours per OPO per year, or a national total of 236 hours. Based on comments, we are increasing this figure to 12 hours per OPO per year.

Hours/est. salary/# of OPOs	Annual burden hours	Annual cost estimate
1 data entry person @ \$19.25/hr. × 12 hrs. annually per 58 OPOs	696.00	\$13,398.00
Totals	696.00	13,398.00

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 approved #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 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.

Section 486.330 Condition: Information Management

Section 486.330 requires OPOs to include specific data elements in their records and to maintain their records in a human readable and reproducible paper or electronic format for 7 years. In support of public comment, we now will require that these records be maintained in electronic format. Additionally, we finalized the proposed requirement that these records be maintained for 7 years instead of 5 years.

We do not anticipate a significant burden associated with this requirement since we believe all OPOs are using computer systems due to the OPTN requirements. Additionally, because the final rule governing the operation of the OPTN states that OPOs must maintain donor records for 7 years, OPOs must already meet the proposed requirement. Otherwise, all other elements in this information management CoC will be finalized as proposed. While there is burden associated with these requirements we believe it is exempt under 5 CFR 1320.3.

Section 486.342 Condition: Requesting Consent

Sections 486.342 paragraphs (a) and (b) requires that an OPO have a written protocol to ensure that the individual(s) responsible for making the donation decision are informed of their options to donate organs and 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) The most likely uses for the donated organs or tissues.
- (3) A description of the screening and recovery processes.
- (4) Information about organizations that will recover, process, and distribute the tissue.
- (5) Information regarding access to and release of the donor's medical records.
- (6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.
- (7) Contact information for individual(s) with questions or concerns.

(8) A copy of the signed consent form if a donation is made.

(b) If an OPO does not request consent to donation because a potential donor

consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential donor's State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

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. We estimate that 10 percent of the 58 OPOs (that is, rounded to 6 OPOs) may have to add information to adequately meet this requirement. This requirement affects fewer than 10 OPOs that may need to make slight adjustments to information to adequately meet this requirement. Therefore, according to 5 CFR 1320.3(c), a "collection of information," the ICRs of this section are not subject to the PRA.

Section 486.344 Condition: Evaluation and Management of Potential Donors and Organ Placement Recovery

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

We have revised the proposed requirement that the OPO must implement a system to ensure that 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. Instead, we have lessened the potential burden by allowing a "qualified physician or other qualified individual" to meet this requirement. Also, we have removed reference to the term "best" practices in response to commenters' suggestions. Otherwise, only minor editorial and regulatory formatting changes have been made in this final rule.

We have finalized the proposed requirement that the OPO must include documentation in the donor's record of all test results, including blood type, prior to organ recovery. We are requiring that 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 finalized requirement is the same as the proposed burden. It includes the time it

would take to create the protocols. We believe that good business practices would dictate that an OPO have written protocols to address the requirements of this section. Therefore, there would be no additional burden and we believe this to be exempt from the PRA.

Section 486.346 Condition: Organ Preparation and Transport

We have finalized this COP with minor technical changes to the regulatory language. These changes have resulted in no additional associated burden.

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. 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 address the requirements of this section. Therefore, there would be no additional burden and we believe it is exempt from the PRA.

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

The ICRs under this section were published in the NPRM on February 4, 2005 and are being finalized in this rule. We require an 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.

The burden associated with these requirements would be the time and effort required to develop a QAPI program. While this burden is subject to the PRA, we believe the collection requirements are exempt as defined in 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (for example, in compiling and maintaining business records) will be excluded from the burden. We believe that a typical OPO would already have an established QAPI as part of its usual and customary business practices, thus, would not incur any associated burden.

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.: Melissa Musotto, CMS-3064-F, 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: Carolyn Lovett, CMS Desk Officer, CMS-3064-F, carolyn_lovett@omb.eop.gov. Fax (202)-395-6974.

V. Regulatory Impact Analysis

We have examined the impacts of this final 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 final rule is an economically significant rule 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 units of local government. 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. No such hospitals are significantly affected by this rule because none are either transplant centers or among those normally targeted for intensive organ donation efforts.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates may result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, or about \$120 million in 2006 dollars.

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 Public Law 106-505, which was passed by the Congress in 2000, requires us to publish 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 58 OPOs would be affected by the requirements in this final rule to a greater or lesser degree. Many OPOs have already put into practice many of the final rule requirements. Thus, while we do not believe the requirements in this final rule will 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 this 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 final rule would have a 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. Most of the costs of transplantation estimated later in this analysis fall upon hospitals. However, transplant hospitals are reimbursed for 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, the 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 re-certification process was actually interfering with the OPOs' effectiveness in increasing the level of organ donation.

c. The limitations noted in the DHHS' re-certification 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 re-certification 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 final rule.

The 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 final rule establishes certification and competition processes that will meet those goals.

1. Feasible Alternatives for Competition Among OPOs for Service Areas

This final rule allows OPOs to compete for another OPO's service area if the incumbent OPO has been de-certified by CMS. OPOs meeting certain criteria may compete for these OPO service areas at the end of each 4-year certification cycle. The competing OPO must meet the following criteria that is specified in § 486.316: (1) the OPO's performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; and (2) the OPO's donation rate is at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area.

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 competition is important to facilitate improvement in OPO performance.

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

a. *Full Competition.* All OPO service areas would be open for competition every 4 years. Every OPO that has met the conditions for coverage would be eligible to compete for another OPO's service area.

b. *Limited Competition.* All OPO service areas would be open for

competition every 4 years. Only those OPOs that meet the conditions for coverage, the outcome performance measure thresholds, and have at least a 15 percent higher donation rate in their own service area compared to the incumbent OPO would be allowed to compete for another OPO's service area. The incumbent OPO would be allowed to compete for its own service area unless it had been de-certified by CMS.

c. *Restricted Competition.*

Competition between OPOs would be allowed for the service areas of OPOs that had been de-certified by CMS and for service areas of OPOs that did not meet the outcome performance measure thresholds. The competing OPO would have met the conditions for coverage and the outcome performance measure thresholds. The incumbent OPO would not be allowed to compete.

In this final 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 final rule, we would select an OPO to replace an incumbent, de-certified OPO if, in our assessment, the OPO could significantly increase organ donation within that service area. This assessment would be based on the competing OPO's (1) performance on the outcome measures at § 486.318; (2) relative success in meeting the process performance measures at §§ 486.320 through 486.348; (3) contiguity to the open service area; and (4) submission of documentation detailing its success in identifying barriers to donation within its own service area. The competing OPO would have to submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

Although these criteria are more objective than those contained in the proposed rule, they will still give us the flexibility to exercise reasonable judgment in choosing between competing OPOs. When comparing competing OPOs, we will first consider each OPO's performance on the outcome measures and the degree to which the top-performing OPO's performance on the outcome measures exceeds the performance of other competitors. Although we may view small variations as relatively meaningless, if one OPO performed significantly better than its competitors on all three outcome measures, we will rank that OPO very high.

We will also take into account each competitor's relative success in meeting the process performance measures. By "relative success," we mean that we will judge whether the OPO simply satisfied the requirements necessary to meet the process performance measures or whether the OPO exceeded the requirements. In addition, we will take into consideration whether the competing OPO's service area is contiguous to the open area.

We will also carefully assess each OPO's experience and success in identifying and surmounting barriers to organ donation in its own donation service area and the relevance of those barriers to the barriers in the open service area. For this criterion, the competing OPO would have to submit information and data that described the barriers in its own service area, how they affected organ donation, what steps the OPO took to overcome them (such as, hospital development, training, or public education), and the results of the OPO's efforts. Although all OPOs face obstacles to organ donation in their donation service areas, the nature of the barriers and the degree to which they interfere with organ donation vary widely throughout the country.

When we select among competing OPOs, we will weight each of the first, second, and fourth criteria equally. We will use the third criterion, contiguity to the open area, as a deciding factor only if we determine that two or more competing OPOs are equally competent to take over an open 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 diseases that are incompatible with organ donation. Cultural, ethnic, or racial factors may also 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 is contemplating whether to compete for an open service area might need to perform significant research and data analysis to determine whether or not it wants to compete for a particular open service area. Once this analysis was completed, the OPO's staff would have to develop a document detailing its success in identifying barriers to donation within its own service area, as well as its success in developing and implementing processes to overcome barriers.

We received comments on the proposed rule that were critical of our cost analysis stating that we grossly

underestimated the cost of the new requirements. After further analysis of the multitude of tasks involved in meeting these requirements, we agree that the estimate of 16 hours is insufficient. We estimate that it would take a competing OPO approximately 104 hours to evaluate whether it wanted to compete for a particular open service area and, if it decided to compete, to prepare and submit the required written documentation to CMS to compete for the open service area. A competing OPO would likely need to include at least the following steps in its evaluation: collection of information and data for the potential new service area, analyses of the data and assessment of the incumbent OPO's service area, identification of the factors that affected

the incumbent's performance, analysis of the existing internal and external barriers to increasing organ donation in the service area, identification of the specific activities and interventions the competing OPO will have to perform to increase organ donation, and finally, preparation and submission of the required information and data that describe the barriers the competing OPO faced in its own service area, how those barriers affected organ donation, what steps it took to overcome them, and the results.

We would generally expect that 5 OPO staff members would participate in the evaluation and preparation and submission of the required documentation: The QAPI Director, Procurement Coordinator, Medical

Director, OPO Director, and a secretary. We have estimated the number of hours each staff person would need to spend developing an acceptable plan, based on the activities listed above, and calculated the cost using mean wage figures and added fringe benefit costs (see table 1). The mean physician hourly wage per the U.S. Department of Labor is \$57.90 and in the proposed rule we used a rate of \$60 per hour or \$125,000 annually. We received comment that wages for medical directors are significantly higher. We are now using a median pay rate that is unique to medical directors obtained from the salary.com Web site, a source of salary survey data reported only by human resource professionals.

TABLE 1.—OPO STAFF TIME REQUIRED TO COMPETE FOR AN OPEN SERVICE AREA

Staff person	Hourly wage	Hours of work	Total cost
QAPI Director (RN)	* \$26.87	30	\$ 806.10
Procurement Coordinator (RN or SW)	* \$26.87	30	\$ 806.10
OPO Director	** \$50.48	30	\$1514.40
Medical Director	*** \$84.14	12	\$1009.68
Secretary	* \$16.11	2	\$ 32.22
Subtotal		104	\$4168.50
Fringe Benefits: 30.8% total compensation	****		\$1855.34
Total Staff Costs			\$6023.84

* National Compensation Survey: Occupational Wages in the United States, July 2004; U.S. Department of Labor, U.S. Bureau of Labor Statistics, August 2005.

** Per OPO Consortium survey mean salary for OPO Director is \$105,000 annually (\$50.48 per hour) as stated in the proposed OPO rule (70 FR 6124).

*** http://swz.salary.com/salarywizard/layouthtmls/swzl_compresult_national_EX05000020.html.

**** Employer Costs for Employee Compensation, a Bureau of Labor Statistics compensation measure, Table 28, September 2005 data. (<http://www.bls.gov/ncs/ect/home.htm>)

The cost of evaluating whether or not to compete for an open service area and preparing and submitting the required documentation to CMS is estimated to be \$6,023.84 for each plan.

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. The full competition alternative we considered is described as alternative (a) above in which all OPOs who meet the conditions for coverage would be allowed to compete for any of the OPO 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 re-certification 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. We estimate that an OPO will expend \$6,023.84 to compete for an open service area. We analyzed the data that is currently available on the OPOs' performance. If the criteria in the final rule were applied to this data, we estimate that 9 OPOs would be de-certified. Based on this data and our prior experience with the OPOs, we believe this is a good estimate of how many OPOs would be de-certified using the criteria in this final rule. Based upon our previous experience, we estimate that 6 of those OPOs will either appeal or will choose not to appeal their de-certifications. Based upon historical data and our previous experience with the OPOs, of the 52 (the remaining 49

OPOs and the 3 OPO that had their de-certifications reversed), there may be 26 OPOs that would either elect to compete for other service areas or would have to defend their service area in a competition. Each of the 26 OPOs would have to develop and submit the documentation required to compete for the open service area. Some service areas may have more than one competing OPO and others might have only one. Since each competition would require at least 2 plans (one from the incumbent OPO and one from a competing OPO), we estimate that the OPOs would have to prepare and submit at least 52 plans to CMS. The cost to these 26 OPOs would be 52 x \$6,023.84 or \$313,239.68. Full competition is an adversarial process. This might 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 might be unable to improve donation in the service area. Therefore, we did not propose that OPO service areas be opened to competition from all OPOs.

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. Costs of this approach: Although limited competition would require fewer resources from OPOs overall, the competitive activities would require resources from OPOs that decide to compete for an open service area in the amount of \$6,023.84 per OPO for competition (see Table 1). Based upon the above discussion, we estimate that 9 OPOs would be de-certified at the end of the 4 year certification cycle. We believe that 3 would have their de-certifications reversed on appeal and 6 would either have their de-certifications upheld on appeal or chose not to appeal. Thus, there would be 6 open service areas. We expect that at least one OPO would compete for each newly open service area. Based upon both historical data and our previous experience with the OPOs, of the 29 top performing OPOs eligible to compete, there might be up to 9 OPOs that would elect to compete for other service areas. Of those 9 OPOs, we estimate that 3 would elect to compete for more than one service area. Thus, 12 plans would need to be developed and submitted to CMS. The

cost of developing these plans to compete is estimated to be \$72,286.08 (or $12 \times \$6,023.84$). 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 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 performing at a higher level 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. We estimate that 9 OPOs may be de-certified at the end of the 4-year certification cycle and 6 would have their de-certifications upheld on appeal or would choose not to appeal. Based upon our prior experience with the OPOs and historical data, we estimate that there are 9 OPOs that would want to compete for open service areas. We estimate that there would be at least one competitor for each open service area

and that 3 of the OPOs would choose to compete for more than one service area. Thus, we estimate that 9 plans would be prepared and submitted to CMS for the competition. The cost of developing these plans to compete is estimated to be $9 \times \$6,023.84$ or \$54,214.56. The service areas of minimally performing OPOs (that is, OPOs that met the requirements for re-certification but were not top performers) 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 Open Service Areas Under the Final Rule

Our method for competing the open service areas of de-certified OPOs is a modified limited competition, as we feel this option best balances the benefits and costs of the competitive process. We will not allow a de-certified OPO to compete. The competition would be limited to OPOs that met the requirements for re-certification in § 486.316(a), and that had donation rate and yield outcome measures at or above 100 percent of the mean nation rate averaged over the 4 years of the re-certification cycle and had a donation rate that is at least 15 percentage points higher than the OPO that is currently designated for the open service area. We would select an OPO for the service area based on its success in meeting the outcome and process performance measures, as well as the competing OPO's contiguity with the open service area and its submission of information and data that describes the barriers in its own service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

We are limiting competition to OPOs that have performed measurably better than the de-certified OPO. We believe such higher performing OPOs would have the expertise to take over such an OPO's service area and improve organ donation. We estimate that 9 OPOs would be de-certified on the basis of the criteria at § 486.316(a) (See also §§ 486.303, 486.312, and 486.318). We also estimate that 3 of those OPOs would have their de-certifications reversed during the appeals process. This would mean that potentially 6 service areas would be open for competition. The number of OPOs allowed to compete is restricted to those that meet the criteria at § 486.316 (c) which means perhaps less than half of the remaining 52 OPOs would be allowed to compete. We estimate that 9 OPOs that meet the criteria will elect to compete for the 6 de-certified OPOs'

service areas and that 3 of those OPOs will elect to compete for more than one open service area. This means that 12 plans would need to be developed by OPOs in order to compete. The cost of these 12 plans would be 12 x \$6,023.84 or \$72,286.08. OPOs will be required to declare whether they intend to compete for another service area very early in the process. If no OPO plans to apply for an open service area, § 486.316(f) states that CMS may select a single OPO to take over the entire service area or may adjust the service area boundaries of two or more OPOs to incorporate the open service area. CMS will base its decision on the same criteria used to determine which OPOs may compete for open service areas at § 486.316(c). Our preferred competition process would require fewer resources from the OPOs overall than full competition, ensure timely completion of the competitive process, and minimize disruption to operations in service areas.

Cost-Effectiveness and Cost-Benefit Analysis of Option Chosen

Our criteria for selecting a competing OPO are success in meeting the § 486.316(a) re-certification criteria, having a donation rate outcome measure and yield measures at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle, and a donation rate that is at least 15 percentage points higher than the donation rate of the OPO currently designated for the open service area. We estimate that the overall plan development cost of the modified limited competition option would total \$72,286.08 across all the OPOs once every 4 years. If we divide this figure by 4 to arrive at an annual dollar figure, the yearly cost would be \$18,071.52. We hope to see a benefit in terms of increased organ donation by as much as 3 percent per year, with up to a 15 percent increase over the new 4-year certification period in the new service area. Since the competing OPO would have at least a 15 percent higher rate of donation in its own service area, the expectation would be that this higher level of effectiveness would be transferred over to the newly acquired service area.

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. This rule requires that OPOs make available to CMS documentation verifying that the OPO meets the provisions of § 486.306 regarding service area location and characteristics to include specific

information. We believe that it would take an OPO an average of 1 hour (½ hour of organ procurement coordinator time and ½ hour of secretarial time) annually to make the information available. Using pay rates of \$26.87 for the organ procurement coordinator and \$16.11 for the secretary, the cost of 58 OPOs making the information available would be \$1,246.42.

Current OPO regulations require OPOs to have a board of directors or an advisory board with a specific membership composition. This final rule would 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 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 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 41 OPOs would need to develop bylaws addressing conflicts of interest, and approximately 13 would need to develop bylaws addressing length of terms and criteria for selection and removal of board members. Thus, under this final rule, OPOs would need to write 54 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 (\$50.48 per hour), it would cost an OPO \$403.84 to develop a set of bylaws, for a total of \$21,807.36 to develop 54 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 requires every OPO to have a medical director, although it does not specify that the medical director must be full time. We believe all OPOs have medical directors, because the OPTN standards state that OPOs must have medical directors who are licensed physicians and who are responsible for medical and clinical activities of the OPO. However, our final rule requires 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 final 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. As explained earlier in this regulatory impact analysis, we are using an annual salary of \$175,011 (or \$84.14 per hour) for OPO medical directors.

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 \$175,011 annually, it would cost each of these 6 OPOs \$87,505, and the total economic impact would be \$525,033.

We will require each 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 requires 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 appear to have sufficient staff. These two OPOs have added staff based on comparative data from successful OPOs and from the AOPO Annual Report have increased staffing over the past two years. 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. According to the U.S. Bureau of Labor Statistics report published in August 2005 the 2004 median annual income of an RN

was \$55,889.60 and the median annual income of medical and public health social workers was \$38,500. 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 2004, public relations managers had a median annual income of \$101,192. 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 2006, emergency medical technicians have a median annual income of \$24,600 according to *salary.com* data.

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 \$53,036 on average, the total economic impact would be \$636,432.

The human resources condition 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 \$5,000 per OPO. Some OPOs send

their procurement coordinators for training provided by the North American Transplant Coordinators Organization, which costs approximately \$1,000 to \$1,500 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 final 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 (\$50.48 per hour), the cost to the OPO would be approximately \$404. If 25 percent of OPOs (approximately 15 OPOs) needed to develop such bylaws, the total economic impact would be \$6,058.

The human resources condition requires 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 58 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 \$175,000 per year (\$84.14 per hour), the cost to the OPO for the medical director to spend 25 hours reviewing 100 records would be \$2,104. If we estimate that 10 percent of OPOs (approximately 6 OPOs) will need to perform this activity, the total cost would be \$12,621.

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 former OPO regulations required OPOs to maintain donor records with specific data elements, although there was no requirement for how long the records must be kept. The new information management condition requires 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 new 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 is required to provide data and other information directly to the Department as requested by the Secretary. The former regulations required 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 difficult 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.

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 58 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 58 OPOs of approximately \$13,398.

We have included provisions in this rule 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. In addition, the agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death, if the OPO has a protocol for donation after cardiac death. We expect that OPOs already have agreements with all Medicare and Medicaid participating 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 conditions of participation 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 are 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 will need 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 also expect that OPOs will develop an agreement concerning the responsibilities of both the OPO and the hospital concerning donation after cardiac death for those hospitals that have a donation after cardiac death protocol. 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 \$50 (Attorney II; per salary.com); therefore, the cost to the OPO would be \$400. The total cost for all 58 OPOs to have a new standard agreement drafted would be \$23,200.

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 \$5,000. The total cost for all OPOs to make changes in their agreements with hospitals would be \$290,000.

The condition also requires OPOs to offer annual designated requestor training to hospital and critical access hospital staffs. Although the hospital and critical access hospital conditions of participation 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 \$56,000 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 \$350. Based on our experience, we expect that nationwide, approximately 75 hospitals might request designated requestor training. Thus, the total economic impact would be approximately \$26,250, with an average of less than \$453 per OPO.

OPOs will be required to have arrangements to cooperate with tissue banks that have agreements with hospitals with which the OPO has agreements. OPOs will 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 proposed 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 area. 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 their 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 \$400 for preparing an agreement, and an additional cost of \$100 to make changes). However, unlike hospital agreements that 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 \$500, and the cost of preparing agreements with 15 tissue banks would be \$7,500.

For several reasons, we do not believe the requirement to have a QAPI program will have a significant impact on a large number of OPOs. First, 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 new 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 58 OPOs (12 OPOs) would need $\frac{1}{2}$ 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 \$56,000 annually. Thus, the cost to each of the 12 OPOs that would need to add $\frac{1}{2}$ of an FTE would be approximately \$28,000 per year, and the cost to each of the 9 OPOs that would need to add a full FTE would be \$56,000 per year, for a total cost of \$840,000.

In addition, the new requirement for QAPI will require an OPO to perform death record reviews at least monthly in every Medicare and Medicaid hospital in its service area that has a Level I or Level II trauma center or 150 or more beds, a ventilator, and an intensive care unit (unless the hospital has a waiver to work with another OPO), 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 this final 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 $\frac{1}{2}$ of an FTE in order to expand the number of hospitals in which it performs death record reviews or the number of hours needed to perform the death record reviews at least monthly. It is likely the death record reviews would be performed by RNs earning approximately \$56,000 per year, thus the cost to an OPO of adding $\frac{1}{2}$ of an FTE to perform death record reviews would be approximately \$28,000. The total economic impact for all 12 OPOs would be \$336,000.

The final 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 8 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 \$56,000 (approximately \$27 per hour) for a procurement coordinator, \$175,000 (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 \$54 per staff hour to develop an adverse event policy. Therefore, the cost to one OPO of developing an adverse event policy would be \$432 for 8 hours of work. The total cost to all 53 OPOs that would need to develop such policies would be \$22,896.

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 new conditions, some OPOs may have to broaden their informed consent policies, but there will be little resultant economic impact.

The final 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 final rule would take approximately 10 hours. There are approximately 824 transplant programs in the U.S.; therefore, each of the 58 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 \$175,000 annually (approximately \$84 per hour), it would cost an OPO \$840 for development of a single protocol and a total of \$11,760 to develop 14 protocols. (We assume that each protocol would be individualized.) If we assume that 70 percent of the 58 OPOs (41 OPOs) needed to develop protocols, the total economic impact would be \$482,160.

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 final rule are as follows.

- \$1,246 to make service area information available.
- \$21,807 to develop bylaws for OPO boards.
- \$525,033 annually for medical director salaries.
- \$636,432 annually for additional staff to meet human resources requirements.
- \$75,000 initial cost for staff training.
- \$6,058 to develop bylaws for OPO directors and other management staff.
- \$12,621 to develop credentialing records for recovery staff.
- \$13,398 annually to report data.
- \$23,200 to develop hospital agreements.
- \$290,000 to make changes to hospital agreements.
- \$26,250 for designated requestor training.

- \$7,500 to develop arrangements with tissue banks.
- \$840,000 annually for QAPI staff.
- \$336,000 annually to perform death record reviews.
- \$22,896 to develop an adverse event policy.
- \$482,160 to develop protocols with transplant centers.
- \$18,071 annual cost for competition (includes fringe benefits).

Fringe benefit costs have been added to the annual cost for competition, if fringe benefit costs were added to the remaining items at a rate of 30.8 percent of total compensation we need to add in \$1,477,510. We have added fringe benefit costs in response to comments that salary costs are not realistic when fringe benefits are omitted.

Summary of Direct Cost

The first-year economic impact of implementing the requirements in this final rule would be \$4,815,182, and the average first-year cost to each of the 58 OPOs would be \$83,000. This figure includes the fringe benefits for all of the staff hours that were calculated.

Benefits

The primary economic impact of this final rule would lie with its potential to increase organ donation. However, it is difficult to predict precisely what that impact will be. In 1998, the year in which the hospital conditions of participation went into effect, organ donation increased by nearly 6 percent. During the first year of the Organ Donation Breakthrough Collaborative (2003–2004), organ donation increased by nearly 11 percent, and rates continue to increase. A 6 percent increase was seen in 2005, and the first quarter of 2006 shows a 3 percent increase. We believe that the Breakthrough Collaborative has been the driving force behind the most recent increases in organ donation. Further, the Collaborative has helped achieve some of the goals envisioned by this rule. Thus, we estimate that future growth in organ donations as a result of this rule will be lower than immediate past experience.

Absent the impact of this rule, the number of organ donors is expected to remain stable in 2006. We estimate that by increasing OPOs' efficiency and adherence to continuous quality improvement measures, the provisions of this final rule could increase the number of organ donors by an additional 1 to 3 percent per year, resulting in up to 180 additional donors in the regulation's first year. Based on 2000 data for the average number of organs transplanted per donor (2.87), a

1 to 3 percent increase would result in approximately 172 to 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) were kidney transplants. If this regulation results in up to 571 additional transplants in the first year, 241 lives (46.7 percent of 517 transplants) could be vastly improved by kidney transplants and 276 lives (53.3 percent of 517) could be 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 final 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.

Since private payers generally base their payments on Medicare payment rates, and since Medicare is the primary

payor for the majority of transplants, the discussion of costs of increased transplants will use Medicare payment estimates. It is estimated that Medicare will pay for 55.3 percent of all transplants occurring in 2006 based on historical data. A 1 to 3 percent increase in transplants would result in 95 to 286 additional Medicare transplants. Based on a median increase of 2 percent, this would result in 161 additional kidney transplants and 163 additional transplants of other organs nationally.

Kidney transplantation costs are offset by reductions in other medical costs over time, primarily dialysis costs. The 2003 average per person per year primary payor cost for dialysis patients was \$63,723 while the cost for end-stage renal disease patients with a functioning kidney graft was \$15,357 (United States Renal Data System (USRDS): 2005 Annual Data Report: Atlas of End-Stage Renal Disease in the United States pages 674 and 680). During the year of kidney transplantation, the 2003 average per person per year primary payor cost was \$95,567 according to the USRDS. Therefore, during the first two years of kidney transplantation, the potential net health care cost savings would be \$16,522 per patient with annual savings of \$48,366 thereafter. The projected 2007 cost savings for the 2 percent increase in kidney transplants is \$13 million annually.

Below, based on Milliman projections, are the 5-year estimated national costs resulting from a 2 percent increase in organ transplants. The chart does not include heart-lung, kidney-pancreas, and other multi-organ transplants, since complete data are not available for these transplants. We believe the figures below underestimate the economic impact of an increase in the number of transplants by approximately 6 percent because multi-organ transplants are not included.

We expect that the increase in organ transplants will be sustained over the years so that every year this rule is in

effect, it would result in an increase of up to 517 (or more) additional transplants being performed every year. It is difficult to project the total cost savings that will result from this rule, but we do expect to see some significant cost saving benefits.

In order to estimate the costs of providing transplantation and to supplement the CMS payment data, we turned to the 2006 projections of Milliman USA Consultants and Actuaries (authored by Nickolas J. Ortner, and peer reviewed by Richard H. Hauboldt). In their report table 2 shows the "Estimated U.S. Average 2006 First-Year Charges Per Transplant" broken out according to the type of organ transplanted, including the estimated charges for the transplant and the outpatient immunosuppressant medication during the initial year. The estimated charges for the actual transplantation are broken into 3 categories: procurement, hospital, and physician. In order to compare the Milliman figures to what Medicare actually pays out, we compared 2004 CMS claims data for procurement to the 2006 figures developed by Milliman. We found that in 2004 Medicare paid between 31 and 72 percent of the estimated 2006 Milliman charges for procurement. To allow for some inflation and to be sure we are not underestimating the costs, we are not applying a factor between 31 to 72 percent, but are estimating that in 2006 Medicare would pay 80 percent of the 2006 Milliman estimated charges for each of the additional transplants resulting from this rule. The estimated first year total transplant costs of the 324 additional transplants (a 2 percent increase) resulting from this rule is \$87,066,414. Since the table below was based on 2006 data, the figure of \$85,125,338 was adjusted for inflation to obtain a 2007 projection for the estimated total first year transplant costs.

ESTIMATED FIRST YEAR TRANSPLANT COSTS

Total transplant year costs	Milliman	Cases	Total
Heart	399,595	44	17,582,180
Liver	352,874	91	32,229,159
Lung	262,645	19	4,902,707
Pancreas	266,433	9	2,309,086
Kidney	174,910	161	28,102,207
Total	291,291	85,125,338

Note: The table above is derived from the 2006 Milliman estimates using a factor of 0.8. These costs include procurement, hospital, physician, follow-up, immunosuppressive medications, and evaluation costs.

Transplant patients incur certain health care costs in the years following transplantation. The Milliman data includes projections for the immunosuppressant charges during the first year of transplantation (which are included in the estimated first year figures above). Milliman does not

estimate transplant related charges after the first year following the transplant “due to a lack of data and a lack of general interest in these values.” Milliman drug charges are calculated at 100 percent of 2006 average wholesale prices. In keeping with section 303(c) of the Medicare Modernization Act,

Medicare pays for drugs at a lower rate of 106 percent of the average sales price. Therefore, we adjusted the Milliman figures to arrive at a dollar figure that reflects the estimated annual amount Medicare would actually pay for immunosuppressant therapy after the first year of transplantation.

ON-GOING ESTIMATED ANNUAL IMMUNOSUPPRESSIVE DRUG COSTS*

	Milliman	Cases	Total
Heart	15,675	44	689,700
Liver	16,074	91	1,468,092
Lung	16,245	19	303,240
Pancreas	18,753	9	162,526
Kidney	15,390	161	2,472,660
Total			3,631,055

*For a 2 percent increase in the number of transplanted patients.

We are projecting 5-year costs of the additional transplants resulting from this rule by adding the first year costs and the immunosuppressant therapy

costs for years 2 through 5 as shown on the table below. The cost for the immunosuppressant medication associated with a 2 percent increase in

organ transplantation is estimated to be \$3,631,055 annually starting with the second year after transplantation.

ESTIMATED 5-YEAR COSTS FOR A 2 PERCENT INCREASE IN TRANSPLANTS

	2007	2008	2009	2010	2011	Total
Inflation	1.02	1.04	1.03	1.03	1.03
Transplant Costs	87,066,414	90,438,902	93,515,336	96,439,428	99,623,603	467,083,683
Follow-Up Therapy For:						
2007 Patients		3,857,708	3,988,934	4,113,662	4,249,485	16,209,789
2008 Patients			3,988,934	4,113,662	4,249,485	12,352,081
2009 Patients				4,113,662	4,249,485	8,363,147
2010 Patients					4,249,485	4,249,485
Total	87,066,414	94,296,610	101,493,204	108,780,415	116,621,542	508,258,184

In our earlier discussion, we outlined the potential costs savings of the additional 2 percent median increase in kidney transplants that would be realized from the cost savings of dialysis. Other benefits of organ transplants include:

- Increase in years of life gained.

- Improvements in quality of life, particularly for chronic kidney disease patients.
- Resumption of work/volunteerism/productivity for some patients.
- An increase in the number of taxpayers (patients who return to work).
- An increase in access to dialysis as more patients receive kidney transplants.

• In addition, we have calculated a benefit resulting from this rule in terms of life years saved in the amount of up to \$1.38 billion that is not included in this cost analysis.

The table below shows the estimated costs savings from the kidney transplant patients who would no longer need dialysis.

ESTIMATED COST SAVINGS—RENAL

	2007	2008	2009	2010	2011	Total
Renal Savings For New Kidney Transplants	80,976	84,113	86,974	89,694	92,655
New Kidney Transplants	161	161	161	161	161
2007 Patients	13,010,200	13,514,145	13,973,852	14,410,795	14,886,601
2008 Patients		13,514,145	13,973,852	14,410,795	14,886,601
2009 Patients			13,973,852	14,410,795	14,886,601
2010 Patients				14,410,795	14,886,601
2011 Patients					14,886,601
Total Savings	13,010,200	27,028,291	41,921,556	57,643,179	74,433,005	214,036,230

The tables below show the estimated costs savings from the non-renal

transplant patients who would no longer need end-of-life care. We

developed this table based upon data from the SRTR databank.

END-OF-LIFE SAVINGS

	2007	2008	2009	2010	2011	Total
End of Life Savings for:						
2007 Patients	12,854,904
2008 Patients	13,352,834
2009 Patients	13,807,053
2010 Patients	14,238,781
2011 Patients	14,708,907
Total Savings	12,854,904	13,352,834	13,807,053	14,238,781	14,708,907	68,962,479

The final step in our 5-year cost estimate requires that we subtract the estimated cost savings from the costs of

transplantation shown above and add in the estimated costs of implementing the processes required by this rule. The

table below reflects a projected 2 percent increase in transplants and shows this calculation.

TOTAL NET COSTS YEAR

	2007	2008	2009	2010	2011	Total
Costs of Additional Transplants*	61,201,310	53,915,485	45,764,594	36,898,456	27,479,629	225,259,476
Costs of Complying with Final Rule	4,815,182	3,887,394	4,081,764	4,285,852	4,500,144	21,570,336
Totals	66,016,492	57,802,879	49,846,358	41,184,308	31,979,773	246,829,812

*Includes both renal and non-renal transplants.

*Includes savings from dialysis and end-of-life care costs.

The total estimated impact of this rule, assuming a 2 percent increase in organ transplants, is \$66 million in the first year and \$247 million over 5 years. Assuming that Medicare transplants comprise 55.3 percent of all transplants, the estimated impact of this rule on the Medicare program is \$37 million in the first year and \$136 million over 5 years.

Formal Uncertainty Analysis

As discussed elsewhere in this preamble, our best estimate of the impact of this final rule is a benefit of more than \$1 billion each year, based on the number of lives we expect would be saved and the decrease in dialysis-associated costs by increasing organ donation and transplantation due to increased OPO performance.

There are uncertainties associated with many of the projected costs of this final rule. Many of the processes required by this final rule have been put into place by OPOs in varying degrees. Current events, as well as the publication of the proposed OPO conditions for coverage, highlighted the need to make improvements in the organ procurement and distribution process. OPOs have implemented processes over the last year in response, and it is difficult to assess how close current OPO practices have come to the requirements in this final rule. We have estimated the additional human resources necessary to meet these

requirements based on data we received from the OPO coordinators and our assessment of reasonable amounts of time required to complete tasks. There is, however, uncertainty as to whether OPOs will implement efficiencies that allow these requirements to be met by existing staff or a by a smaller increase in full-time equivalents than we predicted. We projected the cost of developing and updating agreements with hospitals and arrangements with tissue banks. We are uncertain as to whether OPOs would use templates for these documents that could serve to reduce the costs.

This final rule implements a new competition process. We have predicted and calculated the associated costs of this competition process based on our estimation of the number of OPOs that would: be de-certified; be qualified to compete; and choose to compete for a service area. We used historical OPO data to devise a reasonable estimate of the number of OPOs falling into each category. Although we utilized the information currently available to us to make this prediction, there is some uncertainty as to how many OPOs will actually compete. Further, the OPOs have flexibility to decide how many resources each would expend on the competition process, so there is some uncertainty as to the cost of competition.

We calculated the costs of a one-time increase in the number of transplanted organs that we predict would result from the implementation of this rule. Over the last few years, there have been significant increases in the number of procured organs due primarily to the effort of the Breakthrough Collaborative described earlier in this preamble. Due to these recent notable improvements in organ donation rates, we are cautiously predicting a further increase of up to 3 percent. There is uncertainty as to what percent increase in transplanted organs can be expected. While this rule is expected to have a positive effect, there are a number of other factors that could affect the donation rate such as the population demographics over the years, natural disasters, technological advances, and donation initiatives that may effect organ donation. There could also be incremental increases in the number of organs procured over the next several years that we did not predict.

We have calculated the costs associated with this rule using the data and information we currently have available to formulate a reasonable burden statement. There are uncertainties that may impact the costs; however, we have performed an analysis of the predicted costs and described the associated uncertainties.

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 amends 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, 1320b-8(b), 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395vv).

§ 413.200 [Amended]

■ 2. Section 413.200(f) is amended by removing the phrase “part 485, subpart D” and by adding “part 486, subpart G” 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-8, 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), 1871 of the Social Security Act, section 371(b) of the Public Health Service Act—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 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.

486.309 Re-certification from August 1, 2006 through July 31, 2010.

486.310 Changes in control or 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: Evaluation and management of potential donors 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.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations as may be necessary to carry out the administration of the Medicare program under title XVIII.

(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 de-certification.

(4) The requirements for an OPO to be re-certified.

§ 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 time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Certification means a CMS determination that an OPO meets the requirements for certification at § 486.303.

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

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at § 486.303.

Designated requestor or effective 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.

Donation service area (DSA) 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.

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 after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heartbeating or asystolic donor.

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

Eligible death for organ donation means the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

- (1) Active infections (specific diagnoses).
 - (i) Bacterial:
 - (A) Tuberculosis.
 - (B) Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.
 - (ii) Viral:
 - (A) HIV infection by serologic or molecular detection.
 - (B) Rabies.
 - (C) Reactive Hepatitis B Surface Antigen.
 - (D) Retroviral infections including HTLV I/II.
 - (E) Viral Encephalitis or Meningitis.
 - (F) Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia.
 - (G) Acute Epstein Barr Virus (mononucleosis).
 - (H) West Nile Virus infection.
 - (I) Severe acute respiratory syndrome (SARS).
 - (iii) Fungal:
 - (A) Active infection with *Cryptococcus*, *Aspergillus*, *Histoplasma*, *Coccidioides*.
 - (B) Active candidemia or invasive yeast infection.
 - (iv) Parasites: active infection with *Trypanosoma cruzi* (Chagas'), *Leishmania*, *Strongyloides*, or *Malaria* (*Plasmodium* sp.).
 - (v) Prion: Creutzfeldt-Jacob Disease.
- (2) General:
 - (i) Aplastic Anemia.
 - (ii) Agranulocytosis.
 - (iii) Extreme Immaturity (<500 grams or gestational age of <32 weeks).
 - (iv) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease.
 - (v) Previous malignant neoplasms with current evident metastatic disease.
 - (vi) A history of melanoma.
 - (vii) Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma.
 - (viii) Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or

more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation.

(ix) Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis.

(3) The number of eligible deaths is the denominator for the donation rate outcome performance measure as described at § 486.318(a)(1).

Eligible donor means any donor that meets the eligible death criteria. The number of eligible donors is the numerator of the donation rate outcome performance measure.

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.

Expected donation rate means the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, CMS Case Mix Index, total bed size, number of intensive care unit (ICU) beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

Observed donation rate is the number of donors meeting the eligibility criteria per 100 deaths.

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 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.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Standard criteria donor (SCD) means a donor that meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor.

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.

Urgent need occurs when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

Requirements for Certification and Designation

§ 486.303 Requirements for certification.

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

(a) Have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO.

(b) Be a non-profit entity that is exempt from Federal income taxation under section 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 CMS, as the Secretary's designated representative, 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 the conditions for coverage for organ procurement organizations, which include both outcome and process performance measures.

(i) Meet the provisions of titles XI, XVIII, and XIX of the Act, section 371(b) of the Public Health Services Act, and any other applicable Federal regulations.

§ 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 CMS as an OPO.

(b) An OPO must be certified as a qualified OPO by CMS under 42 U.S.C.

273(b) and § 486.303 to be eligible for designation.

(c) An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid.

§ 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 and the names of all hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

§ 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 when the OPO for the service area is de-certified and all administrative appeals under § 486.314 are exhausted.

(b) Designation periods—

(1) *General.* An OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, 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-Certification.* Re-certification must occur not more frequently than once every 4 years.

(c) 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.

(d) 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 (e) of this section within 30 days of notice of the change in designation.

(e) 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.

(f) 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.

(g) 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.

§ 486.309 Re-certification from August 1, 2006 through July 31, 2010.

An OPO will be considered to be re-certified for the period of August 1, 2006 through July 31, 2010 if an OPO met the standards to be a qualified OPO within a 4-year period ending December 31, 2001 and has an agreement with the Secretary that is scheduled to terminate on July 31, 2006. Agreements based on the August 1, 2006 through July 31, 2010 re-certification cycle will end on January 31, 2011.

§ 486.310 Changes in control or ownership or service area.

(a) *OPO requirements.*

(1) A designated OPO considering a change in control (see § 413.17(b)(3)) or

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 control or 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 control or 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 administrative 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 requirements for certification at § 486.303 throughout the remaining period.

Re-Certification and De-Certification

§ 486.312 De-certification.

(a) *Voluntary termination of agreement.* If an OPO wishes to terminate its agreement, the OPO must send CMS written notice of its intention to terminate its agreement and the proposed effective date. 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. 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) *Involuntary termination of agreement.* During the term of the agreement, CMS may terminate an agreement with an OPO if the OPO no longer meets the requirements for certification at § 486.303. 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) *Non-renewal of agreement.* CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at § 486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at § 486.303. 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 to an OPO at least 3 calendar days prior to the effective date of the de-certification. The notice of de-certification states the reasons 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 titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.

§ 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 and procedural grounds.

(a) *Notice of initial determination.* CMS mails notice to the OPO of an initial de-certification determination. The notice contains the reasons for the determination, the effect of the

determination, and the OPO's right to seek reconsideration.

(b) *Reconsideration.* (1) Filing request. If the OPO is dissatisfied with the de-certification determination, it has 15 business days from receipt of the notice of de-certification to seek reconsideration from CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for disagreement.

(2) An OPO must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.

(3) *Reconsideration determination.* CMS makes a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination and the findings on which it was based. CMS augments the administrative record to include any additional materials submitted by the OPO, and a copy of the reconsideration decision and sends the supplemented administrative record to the CMS hearing officer.

(c) *Request for hearing.* An OPO dissatisfied with the CMS reconsideration decision, must file a request for a hearing before a CMS hearing officer within 40 business days of receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review.

(d) *Administrative record.* The hearing officer sends the administrative record to both parties within 10 business days of receipt of the request for a hearing.

(1) The administrative record consists of, but is not limited to, the following:

- (i) Factual findings from the survey(s) on the OPO conditions for coverage.
- (ii) Data from the outcome measures.
- (iii) Rankings of OPOs based on the outcome data.
- (iv) Correspondence between CMS and the affected OPO.

(2) The administrative record will not include any privileged information.

(e) *Pre-Hearing conference.* At any time before the hearing, the CMS hearing officer may call a pre-hearing conference if he or she believes that a conference would more clearly define the issues. At the pre-hearing conference, the hearing officer may establish the briefing schedule, sets the hearing date, and addresses other

administrative matters. The hearing officer will issue an order reflecting the results of the pre-hearing conference.

(f) *Date of hearing.* The hearing officer sets a date for the hearing that is no more than 60 calendar days following the receipt of the request for a hearing.

(g) *Conduct of hearing.* (1) The hearing is open to both parties, CMS and the OPO.

(2) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(3) The hearing officer provides the parties with an opportunity to enter an objection to the inclusion of any document. The hearing officer will consider the objection and will rule on the document's admissibility.

(4) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(5) The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

(6) The hearing officer rules on motions and other procedural items.

(7) The hearing officer regulates the course of the hearing and conduct of counsel.

(8) The hearing officer may examine witnesses.

(9) The hearing officer takes any action authorized by the rules in this subpart.

(h) Parties' rights. CMS and the OPO may:

(1) Appear by counsel or other authorized representative, in all hearing proceedings.

(2) Participate in any pre-hearing conference held by the hearing officer.

(3) Agree to stipulations as to facts which will be made a part of the record.

(4) Make opening statements at the hearing.

(5) Present relevant evidence on the issues at the hearing.

(6) Present witnesses, who then must be available for cross-examination, and cross-examine witnesses presented by the other party.

(7) Present oral arguments at the hearing.

(i) Hearing officer's decision. The hearing officer renders a decision on the appeal of the notice of de-certification within 20 business days of the hearing.

(1) *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.

(2) *De-certification is upheld.* If the de-certification determination is upheld by the hearing officer, the OPO is de-certified and it has no further administrative appeal rights.

(j) *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.

(k) *Effects of de-certification.* Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. CMS will then open the de-certified OPO's service area for competition as set forth in § 486.316(c).

§ 486.316 Re-certification and competition processes.

(a) *Re-Certification of OPOs.* An OPO is re-certified for an additional 4 years and its service area is not opened for competition when the OPO:

(1) Meets all 3 outcome measure requirements at § 486.318; and

(2) Has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at § 486.320 through § 486.348.

(b) *De-certification and competition.* If an OPO does not meet all 3 outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open service area, an OPO must meet the criteria in paragraph (a) of this section and the following additional criteria:

(1) The OPO's performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; and

(2) The OPO's donation rate is at least 15 percentage points higher than the

donation rate of the OPO currently designated for the service area.

(3) The OPO must compete for the entire service area.

(d) *Criteria for selection.* CMS will designate an OPO for an open service area based on the following criteria:

(1) Performance on the outcome measures at § 486.318;

(2) Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.348;

(3) Contiguity to the open service area.

(4) Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(e) *No OPO applies.* If no OPO applies to compete for a de-certified OPO's 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 criteria in paragraph (d) of this section.

Organ Procurement Organization Outcome Requirements

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, or possessions, an OPO must meet all 3 of the following outcome measures:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:

(i) The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;

(ii) The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and

(iii) The number of organs used for research per donor, including pancreata used for islet cell research.

(b) For OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions, the OPO outcome measures are as follows:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following are no more than 1 standard deviation below the national mean:

(i) The number of kidneys transplanted per standard criteria donor;

(ii) The number of kidneys transplanted per expanded criteria donor; and

(iii) The number of organs used for research per donor, including pancreata recovered for islet cell transplantation.

(c) Data for the outcome measures.

(1) An OPO's performance on the outcome measures is based on 36 months of data, beginning with January 1 of the first full year of the re-certification cycle and ending 36 months later on December 31, 7 months prior to the end of the re-certification cycle.

(2) If an OPO takes over another OPO's service area on a date later than January 1 of the first full year of the re-certification cycle so that 36 months of data are not available to evaluate the OPO's performance in its new service area, we will not hold the OPO accountable for its performance in the new area until the end of the following re-certification cycle when 36 months of data are available.

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, participate in, 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 a 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 Medicare and Medicaid participating 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 donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms "timely referral" and "imminent death."

(b) *Standard:* Designated requestor training for hospital staff. The OPO must offer to provide 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.

(iv) Providing designated requestor training.

(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, either intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO's service area.

(2) Individuals who represent the public residing in the OPO's service area.

(3) 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.

(4) A neurosurgeon or other physician with knowledge or skills in the neurosciences.

(5) 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.

(6) An organ donor family member.

(b) The OPO 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 immunodeficiency syndrome (AIDS).

(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.

(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 procedures to address potential conflicts of interest for the governing body described in paragraph (d) of this section.

(g) The OPO's policies must state whether the OPO recovers organs from donors after cardiac death.

§ 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, 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 for organ and/or tissue donation 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 a physician licensed in at least one of the States or territories within the OPO's service area or as required by State or territory law or by the jurisdiction in which the OPO is located. The 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) An OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and DHHS, as requested by the Secretary. The data may include, but are not limited to:

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

(b) An OPO must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.

(c) Data to be used for OPO recertification purposes must be reported to the OPTN and must include data for all deaths in all hospitals and critical access hospitals in the OPO's donation service area, unless a hospital or critical access hospital has been granted a waiver to work with a different OPO.

(d) Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the error is identified.

(e) For the purpose of determining the information to be collected under

paragraph (a) of this section, the following definitions apply:

(1) *Kidneys procured.* Each kidney recovered will be counted individually. En bloc kidneys recovered will count as two kidneys procured.

(2) *Kidneys transplanted.* Each kidney transplanted will be counted individually. En bloc kidney transplants will be counted as two kidneys transplanted.

(3) *Extra-renal organs procured.* Each organ recovered is counted individually.

(4) *Extra-renal organs transplanted.* Each organ or part thereof transplanted will be counted individually. For example, a single liver is counted as one organ procured and each portion that is transplanted will count as one transplant. Further, a heart and double lung transplant will be counted as three organs transplanted. A kidney/pancreas transplant will count as one kidney transplanted and one extra-renal organ transplanted.

§ 486.330 Condition: Information management.

An OPO must establish and use an electronic information management system to maintain the required medical, social and identifying information for every donor and transplant 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 and/or tissues that may be recovered.

(2) The most likely uses for the donated organs or tissues.

(3) A description of the screening and recovery processes.

(4) Information about the organizations that will recover, process, and distribute the tissue.

(5) Information regarding access to and release of the donor's medical records.

(6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.

(7) Contact information for individual(s) with questions or concerns.

(8) A copy of the signed consent form if a donation is made.

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

§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.

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

(a) *Potential donor protocol management.* (1) The medical director is responsible for ensuring that potential donor evaluation and management

protocols are implemented correctly and appropriately to ensure that potential donors are thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

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

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

(1) Verify that death has been pronounced according to applicable local, State, and Federal laws.

(2) Determine whether there are conditions that may influence donor acceptance.

(3) If possible, obtain the potential donor's medical and social history.

(4) Review the potential donor's medical chart and perform a physical examination of the donor.

(5) Obtain the potential donor's vital signs and perform all pertinent tests.

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

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

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

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

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

(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 the evaluation and management of potential donors, organ recovery, and organ placement, including donation after cardiac death, if the OPO has implemented a protocol for donation after cardiac death.

(2) The protocol must ensure that:

(i) The OPO is responsible for two separate determinations of the donor's blood type;

(ii) If the identity of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the

donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual;

(iii) Documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.

(3) The established protocols must be reviewed regularly with the transplant programs to incorporate practices that have been shown to maximize organ donation and transplantation.

(e) *Documentation of recipient information.* If the intended recipient has been identified prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended organ recipient's ranking in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

(f) *Donation after cardiac death.* If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:

(1) Criteria for evaluating patients for donation after cardiac death;

(2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

(3) Use of medications and interventions not related to withdrawal of support;

(4) Involvement of family members prior to organ recovery;

(5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.

(g) *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.

(h) *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 individuals, one of whom must be an OPO employee, 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. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, 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 at least monthly 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, a ventilator, and an intensive care unit (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 written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process.

(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.

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: Sections 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)

Dated: May 11, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 19, 2006.

Michael O. Leavitt,

Secretary.

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