



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-16-OPO

DATE: March 14, 2014

TO: Regional Offices

FROM: Director
Survey and Certification Group

SUBJECT: Interpretive Guidance for the Survey Process of the Organ Procurement Organization (OPO) Conditions for Coverage, published May 31, 2006, in the Federal Register – Interim Final

Memorandum Summary

This memorandum communicates an advanced copy of the Interpretive Guidance and associated revisions to Chapters 2 and 3 of the State Operations Manual (SOM) for the OPO Conditions for Coverage.

Background

Conditions for Coverage for OPOs were published on May 31, 2006. These conditions included outcome and process performance measures based on organ donor potential and other related factors in each service area of qualified OPOs.

The Interpretive Guidance communicated by this memo serves to interpret and clarify the Conditions for Coverage and do not impose any requirements that are not otherwise set forth in statute or regulation

Discussion

The Association of Organ Procurement Organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration were asked to review and provide comments on the draft guidance as well as the Regional Office OPO surveyors. All comments were considered and incorporated as appropriate. In addition, Chapters 2 & 3 of the SOM have been revised to reflect the OPO Conditions for Coverage and the Interpretive Guidance.

Questions regarding this memorandum should be sent to Melissa Rice at Melissa.Rice@cms.hhs.gov.

Effective Date: Immediately. This memorandum should be communicated with all survey and certification Regional Office OPO surveyors and their managers. This memorandum serves as information only to the State Survey Agency Directors.

/s/

Thomas E. Hamilton

Attachment (s)-

OPO Interpretive Guidance- Interim Final

SOM Chapter 2- OPO revisions

SOM Chapter 3- OPO revisions

cc: State Survey Agency Directors

Appendix Y - Organ Procurement Organization (OPO) Interpretive Guidance

Regulation

§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;
 - (3) The terms of the agreement with CMS and the basis for and the effect of de-certification; and
 - (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.

Guidance: The unintended transmission of a disease through organ transplantation would be considered an adverse event. There are limited instances where disease transmission may occur with the knowledge of the recovery personnel and the recipient. (See 486.344 (b)(2)).

§486.302 – Definitions. (con’t.)

Instances where the donor has a transmissible disease (e.g., Human Immune Deficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV)) and the recovered organ is transplanted into a recipient with the same transmissible disease with the informed consent of the recipient, would not be considered an adverse event.

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-heart beating 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).

Guidance: In Federal Register Notice Vol. 78, No. 128 published July 3, 2013 the U.S. Department of Health and Human Services announced that vascular composite allografts (VCAs) will be added to the definition of organs covered by federal regulation and legislation. This designation was effective July 3, 2013.

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) per §486.302 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. This definition differs from the OPTN definition of a standard criteria donor which is a donor that 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 non-compliance 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.**

Guidance: The term “Urgent Need” should be considered to be synonymous with the Survey and Certification definition of “Immediate Jeopardy.” (See §489.3) Follow procedures in the State Operations Manual (Appendix Q) for notification of the OPO and termination procedures when urgent need is identified.

§486.303 Requirements for certification. In order to be certified as a qualified organ procurement organization, an organ procurement organization must:

§486.303(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.

Interpretive Guidelines §486.303(a)

No on-site activity is necessary. The CMS Regional Office (RO) maintains a current signed copy of the Designation/Certification (Form CMS-576) for the OPO on file and should review this document before going on-site.

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

Interpretive Guidelines §486.303(b)

During the on-site review, check the organization’s most current IRS 501c approval documentation to validate non-profit status. This will usually be in the form of a letter from the IRS stating that the status is approved or renewed. The documentation should be no more than five years old as the Internal Revenue Service (IRS) reviews non-profit status every five years. If the approval is more than five years old, the OPO may produce IRS website information to indicate a more recent approval.

Deficient practice found at this regulation should be cited under §486.324(e).

§486.303(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.

Interpretive Guidelines §486.303(c)

The OPO must have written policies to ensure that fiscal affairs are conducted in accordance with generally accepted accounting procedures to maintain the fiscal stability of the organization. The policies should address the following:

- 1) Use of a balance sheet(s) which indicate assets, liabilities and fund balance(s);
- 2) The annual operating budget (*preparation and approval by the governing body*);
- 3) Cost report submission and responses from the fiscal intermediary/Medicare Administrative Contractor (MAC); and
- 4) Procedures to obtain payment for all renal and non-renal organs from transplant hospitals.

Verify that the organization's policies in regards to fiscal affairs address the above. Deficient practice found at this regulation should be cited at §486.324(e).

§486.303(d) Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under title XVIII for the procurement of kidneys.

Interpretive Guidelines §486.303(d)

See Interpretive Guidance for §486.303(a).

§486.303(e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.

§486.303(f) Have procedures to obtain payment for non-renal organs provided to transplant centers.

Interpretive Guidelines §486.303(f)

See Interpretive Guidance for §486.303(c).

§486.303(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.

The OPO must agree to enter into an agreement with any hospital/CAH that requests an agreement. However, in those instances where a hospital or CAH does not have an operating room or a ventilator, the agreement may address reporting of imminent death only. There would be no requirement for the agreement to include Designated Requestor training, death record reviews or periodic reports to the hospital/CAH as to how they are performing as regards reporting of potential donors.

§486.303(h) Meet the conditions for coverage for organ procurement organizations, which include both outcome and process performance measures.

Interpretive Guidelines §486.303(h)

This regulation should be co-cited with any citation of a condition for Coverage level finding

§486.303(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.

§486.304(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.

§486.304(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.

Interpretive Guidelines §486.304(b)

See Interpretive Guidance at §486.303(a)

§486.304(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.

Interpretive Guidelines §486.304(c)

This agreement with CMS is completed at each recertification cycle if the OPO meets or continues to meet all federal requirements. .

§486.306 OPO service area size designation and documentation requirements.

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

**subsection (d) referenced above is a misprint and should be (c) as there is no subsection (d).*

Interpretive Guidelines §486.306(a)

At the time of the on-site review, the surveyor, based upon documentation provided by the OPO, verifies that:

- a) The OPO's policies incorporate the information required by (§486.306 (b) and (c));
- b) The OPO is operating consistent with its written policies; and
- c) The OPO donation service area corresponds to the information regarding the OPO's service area on file at the applicable CMS Regional Office.

Deficient practice found at this regulation should be cited at §486.324(e).

§486.306(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.

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

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

§486.306(c) (2) Geographic boundaries of the service area.

§486.306(c) (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.

§486.308 (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.

§486.308 (b) Designation periods

§486.308 (b) (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.

§486.308 (b) (2) *Re-Certification.* Re-certification must occur not more frequently than once every 4 years.

Interpretive Guidelines §486.308(a) and (b)

A donation service area is only open for competition in the event of de-certification or voluntary withdrawal from the program. As a result, a current OPO may only change the boundaries of its donation service area (outside of re-designation by CMS resulting from an open competition) as a result of a merger, (approved in advance by CMS), with another OPO. OPOs must compete for an entire service area.

§486.308(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.

§486.308(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.

Interpretive Guidelines §486.308(d)

Requests for waiver should be submitted to:

Director of the Division of Technical Payment Policy

Chronic Care Policy Group

Center for Medicare

Centers for Medicare and Medicaid Services

7500 Security Blvd.

Baltimore, MD 21244

§486.308(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.
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§486.308(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.**

Interpretive Guidelines §486.308(e) and (f)

Waiver requests are processed by the Division of Technical Payment Policy, Chronic Care Policy Group, Center for Medicare.

§486.308(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.

§486.310(a) *OPO requirements.*

§486.310(a)(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.

Interpretive Guidelines §486.310(a)(1)

When the CMS RO receives notification of a prospective change in control or ownership for a designated OPO, the CMS RO must determine, based upon the documents and information submitted, that the operation of the OPO will continue uninterrupted during and following the changeover of ownership or control. Review all the documents submitted by the OPO in response to the elements on Form CMS-576. The OPO should show evidence of transition planning to ensure continuity. For any change of ownership a new CMS Form 576 must be signed. Confirm with the Fiscal Intermediary/MAC that the OPO has submitted a revised CMS Form-855 and that the information has been accepted by the Fiscal Intermediary/MAC.

Refer to Chapter 2 of the SOM, section 2814 - Organ Procurement Organizations (OPOs) – Change in Control/Ownership or Service Area.

§486.310(a) OPO requirements.

§486.310(a)(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.

Interpretive Guidelines §486.310(a)(2)

The OPO must have applicable policies and procedures in place to inform the applicable CMS RO of its intent to change the ownership of the designated OPO or participate in a merger with another OPO, which will require the re-designation of one or more current OPO donation service areas. This information must be submitted prior to the effective date of the change in ownership or merger and must include, at a minimum, all the information required by Form CMS-576.

If during the on-site visit it is discovered that the OPO completed a change of ownership, a change in control, or has merged or consolidated with another OPO and the CMS RO did not receive prior notification with submission of the required documents, cite a deficiency at §486.324(e). See §413.17(b)(3). Control exists if an individual or organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

§486.310(b) CMS requirements.

§486.310(b)(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.

Interpretive Guidelines §486.310 (b)

See State Operations Manual (SOM) Chapter 2, section 2812.3 for discussion regarding procedures for opening of a Donation Service Area for competition.

§486.310(b) CMS requirements

§486.310(b)(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.

§486.312 De-Certification.

§486.312(a) *Voluntary termination of agreement.*

If an OPO wishes to terminate its agreement, the OPO must send the applicable CMS RO written notice of its intention to terminate its agreement and the proposed effective date. The CMS RO 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 the CMS RO 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 the RO. The CMS RO will de-certify the OPO as of the effective date of the voluntary termination.

Interpretive Guidelines §486.312(a)

See SOM Chapter 2, section 2817 for discussion regarding the procedures for voluntary termination of an OPO.

§486.312(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.

Interpretive Guidelines §486.312(b)

If at any time during the 4 year certification period the OPO is determined by the CMS RO to be out of compliance with one or more of the conditions for coverage (CfC) or requirements for certification and fails to make corrections sufficient to regain compliance, the CMS RO will begin de-certification procedures per the SOM at Chapter 2 section 2818. For de-certification due to urgent need refer to §486.302.

§486.312(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.

Interpretive Guidelines §486.312(c)

If the OPO is found to be out of compliance with §486.318 or §486.303, provide the OPO the opportunity to develop and implement an acceptable plan of correction prior to the end of its current agreement. If the OPO is not able to regain compliance prior to the end of the current agreement begin non-renewal procedures per the SOM Chapter 2 section 2818.

§486.312 (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.

§486.312(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.

Interpretive Guidelines §486.312(e)

In cases where an OPO voluntarily terminates its agreement it must publish notification to the public in the local newspapers of its service area and on its website. The OPO must include the following information:

- a) Date the OPO will cease operation;
- b) The hospitals and CAHs located within the OPO's service area; and
- c) A telephone contact number for inquiries to the OPO's notice.

Request that the OPO provide CMS with copies of all published notifications and include the copies of the notices in the OPO's file.

Public notice is considered prompt when the notice of voluntary termination appears in local newspapers within three (3) business days of the date that CMS approved the OPO termination date.

§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.

Interpretive Guidelines §486.314

This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

See SOM Chapter 2, section 2819 for discussion regarding appeals.

§486.314(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.

Interpretive Guidelines §486.314(a)

See §486.312(d) above.

§486.314(b) *Reconsideration.*

§486.314(b)(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.

Interpretive Guidelines §486.314(b)(1)

The de-certification notice should be sent to the OPO by registered mail. Add three days (for mail delivery) to the date on the notice and then the OPO has until the close of 15 business days from that date to submit any written request for reconsideration of the de-certification notice.

General statements of disagreement with the final decision, concerns about the financial situation of the OPO, or general access concerns are not sufficient additional information to support reconsideration. The OPO must include specific, factual information concerning each finding with which it disagrees and reasons for disagreeing with the CMS determination, including any supporting evidence. The submitted information is then evaluated by CMS to determine if the de-certification decision is affirmed, modified or reversed in light of the additional information submitted.

§486.314(b)(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.

Interpretive Guidelines §486.314(b)(2)

When the CMS RO receives notice that the OPO has filed a request for hearing, inform the hearing officer. If the OPO failed to submit a request for reconsideration prior to its request for hearing or if it did not file the request for reconsideration timely (see §486.314(b)(1) above).

§486.314(b)(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.

Interpretive Guidelines §486.414(b)(3)

If the reconsideration request is received timely by the RO, review the submitted information. The reconsideration process should be conducted by staff not involved in the original de-certification decision. Within 10 business days from the date of receipt of the reconsideration request, make a determination as to whether sufficient information and documentation was received to justify affirming, modifying or reversing the decision to de-certify (i.e., terminate) the OPO agreement. If the de-certification decision is reversed or modified notify the OPO in writing and forward a revised Form CMS- 2567 to reflect the revised findings.

If the de-certification decision is not reversed or modified, notify the OPO in writing of the decision including what materials were reviewed and why the materials did not provide substantive information to reverse or modify the initial decision. Inform the OPO that when the service area is “opened for competition” they will not be permitted to compete for that service area or any other service area in the future.

Incorporate all notifications to the OPO into the provider file. If the OPO seeks further administrative review (hearing officer review), provide the augmented administrative record which includes the reconsideration request and supporting documentation that was received from the OPO and the written reconsideration determination to the hearing officer.

§486.314(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.

Interpretive Guidelines §486.314(c)

See Interpretive Guidance at §486.314(b)(2) above.

§486.314(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. 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.

Interpretive Guidelines §486.314(d)(1)(i)

Upon notification that the OPO has requested an administrative hearing, forward the following information related to the survey in question to the hearing officer for inclusion into the administrative record:

- (a) Copies of Forms CMS-2567 (including any plans of correction);
- (b) Donation Service Area description;
- (c) OPTN membership status;
- (d) OPO staff qualifications as applicable;
- (e) Waivers granted;
- (f) List of hospitals and CAHs in the service area;
- (g) Member name(s) and position(s) represented on record for Advisory Board and Governing Body;
- (h) Evidence of compliance/non-compliance with OPTN regulations on reporting data (CMS OPO Database report).

§486.314(d)(1)(ii) Data from the outcome measures.

Interpretive Guidelines §486.314(d)(1)(ii)

Provide the hearing officer with a copy of the CMS OPO Database report, which includes the measurement of OPO performance with the three OPO regulatory data requirements. Provide sufficient historical Database information to encompass the survey period.

§486.314(d)(1)(iii) Rankings of OPOs based on the outcome data.

Interpretive Guidelines §486.314(d)(1)(iii)

Provide the hearing officer with a copy of the CMS OPO Database report ranking of all OPO(s) utilizing the most recent data collection period, based upon compliance with the regulatory data requirements at §486.318 and §486.328. The most recent data collection period will be the cumulative data for the three full years of the recertification cycle.

§486.314(d)(1)(iv) Correspondence between CMS and the affected OPO.

Interpretive Guidelines §486.314(d)(1)(iv)

Provide the hearing officer with:

- (a) Copies of all written correspondence between the OPO and the CMS RO relevant to the certification action under appeal;
- (b) All relevant e-mail correspondence between the OPO and the RO;
- (c) Any pertinent entries from a correspondence log if utilized; and
- (d) Relevant Survey and Certification Memoranda.

§486.314(d)(2) The administrative record will not include any privileged information.

Interpretive Guidelines §486.314(d)(2)

Privileged information includes those documents of communication between attorney and client. In this instance, all associated communications which were intended to be confidential between CMS and the Office of General Counsel are considered privileged and should not be included in the administrative record forwarded to the hearing officer.

§486.314(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.

Interpretive Guidelines §486.314(e)

This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

§486.314 (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.

Interpretive Guidelines §486.314(f)

This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

§486.314(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.**

Interpretive Guidelines §486.314(g)

This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

§486.314(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.**

Interpretive Guidelines §486.314(h)

This regulation addresses the reconsideration and appeal process. There is no pre-survey or on-site survey activity required by the surveyor. Do not make a compliance determination for this regulation as a component of the survey process.

§486.314(i) Hearing officer's decision.

The hearing officer renders a decision on the appeal of the notice of the 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.

§486.314 (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.

Interpretive Guidelines §486.314(j)

No extension will be granted to an OPO de-certified for an Urgent Need (Immediate Jeopardy) finding that has not been corrected by the time the current agreement ends. During any extension that is granted for non-urgent need findings, the applicable CMS RO must monitor the OPO's performance in the areas which resulted in the de-certification.

§486.314 (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).

Interpretive Guidelines §486.314(k)

See SOM Chapter 2, section 2812.3 for discussion regarding opening a donation service area for competition.

§486.316 Re-certification and competition processes.

§486.316(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:

§486.316(a)(1) Meets all 3 outcome measure requirements at §486.318; and

§486.316(a)(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.

Interpretive Guidelines §486.316(a)(2)

The OPO may not be re-certified with uncorrected deficiencies at the condition level. The OPO may be re-certified with standard level deficiencies only with an acceptable plan of correction.

§486.316(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.

§486.316(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 percent 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.**
-

§486.316(d) *Criteria for selection.* CMS will designate an OPO for an open service area based on the following criteria:

§486.316(d) (1) Performance on the outcome measures at §486.318;

Interpretive Guidelines §486.316(d)(1)

The applying OPO must currently be in compliance with all outcome measures at §486.318 and have been in compliance with all measures throughout the current certification cycle. For each data measure, consider the level of compliance (i.e., the position above the national mean). This data performance of the OPO should be considered as one of the factors for selection and should be utilized in association with the OPO's performance with the requirements of §486.316 (d)(2) through §486.316 (d)(4).

§486.316(d)(2) Relative success in meeting the process performance measures and other conditions at §486.320 through §486.348;

Interpretive Guidelines §486.316(d)(2)

“Relative success” is the compliance during the current re-certification cycle and the prior re-certification cycle with Conditions for Coverage §486.320-§486.348.

§486.316(d)(3) Contiguity to the open service area;

Interpretive Guidelines §486.316(d)(3)

Consider the proximity to and timely access of the applying OPO to the donor hospitals in the open service area.

§486.316(d)(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.

Interpretive Guidelines §486.316(d)(4)

Review the deficient practices that led to the opening of the service area. Review the information submitted by the applying OPO to determine what experiences that the applying OPO has had in addressing and successfully correcting similar concerns.

§486.316(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.

Interpretive Guidelines §486.316(e)

See SOM Chapter 2, Section 2812.3 for discussion regarding opening of a donation service area.

Z001

Organ Procurement Organization Outcome Requirements

(Condition) **§486.318 Condition: *Outcome measures.***

§486.318 (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:

Interpretive Guidelines §486.318(a)

Currently, the only OPOs in non-contiguous areas are located in Hawaii and Puerto Rico.

Z002

(Standard) **§486.318(a)(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;**

Interpretive Guidelines §486.318(a)(1)

Prior to going on site, refer to the most recent CMS OPO Database report. The database report will record the OPO's compliance level with this measurement as computed on an annual basis and then averaged over the three full calendar years of the re-certification cycle (aggregate 36 months) (see §486.318(c)(1)). Utilize the most recent calculated compliance results for the aggregate calculation. During the re-certification survey, inform the OPO of the report findings (compliance/non-compliance) and include any non-compliance in the exit interview.

Z003

(Standard) **§486.318(a)(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;**

The SRTR is the Scientific Registry of Transplant Recipients. Because CMS reviews OPOs on a four year cycle it is necessary to rely upon SRTR data to verify consistent compliance by the OPO with the requirements for "observed donation rate vs. expected donation rate." In order to verify consistent compliance with the requirements for observed donation rate vs. expected donation rate, CMS expects the OPO to show, at a minimum, 18 months of consecutive compliance within the 36 month period between re-certification cycles.

Prior to going on site, refer to the most recent CMS OPO Database report. Determine that the OPO has been in compliance with any 18 consecutive months of the 36 months of data utilized for the reports. CMS will use a rolling average methodology to calculate compliance.

Z004

(Standard) **§486.318(a)(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:**

Interpretive Guidelines §486.318(a)(3)

Prior to going on-site, refer to the CMS OPO Database report. The Database report will record the OPO level of compliance with §486.318 (a) (3) (i) – (iii) below for each full calendar year of the re-certification cycle as well as the aggregate compliance level for the three full years. Utilize the most recent calculated compliance results (36-month aggregate) to evaluate compliance with the Standard. During the re-certification survey, inform the OPO of the report findings (compliance/non-compliance) and include any non-compliance in the exit interview.

Z005

(Standard) **§486.318(a)(3)(i) The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;**

Z006

(Standard) **§486.318(a)(3)(ii) The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and**

Interpretive Guidelines §486.318(a)(3)(ii)

Expanded Criteria Donors (ECD) Donors who meet the expanded criteria are those over 60 years of age and those between 50 and 59 years of age meeting 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.

The OPO is not prohibited from the recovery of organs from ECD donors after cardiac death but DCD donors are only included in the CMS performance measure calculation at Measure 3 for organs for research.

Z007

(Standard) **§486.318(a)(3)(iii) The number of organs used for research per donor, including pancreata used for islet cell research.**

Interpretive Guidelines §486.318(a)(3)(iii)

Z008

(Standard) **§486.318(b) For OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions, the OPO outcome measures are as follows:**

Interpretive Guidelines §486.318(b)

Non-contiguous areas include the geographical areas of Hawaii and Puerto Rico.

Z009

(Standard) **§486.318(b)(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;

Interpretive Guidelines §486.318(b)(1)

See Interpretive Guidance for §486.318(a)(1) above.

Z010

(Standard) **§486.318(b)(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;

Interpretive Guidelines §486.318(b)(2)

See Interpretive Guidance for §486.318(a)(2) above.

Z011

(Standard) **§486.318(b)(3)** At least 2 out of the 3 following are no more than 1 standard deviation below the national mean:

Interpretive Guidelines §486.318(b)(3)

The data measured for §486.318(b)(3)(i) and (ii) are based exclusively on kidneys. However, the surveyor will follow the same Interpretive Guidance as for §486.318(a)(3).

Z012

(Standard) **§486.318(b)(3)(i)** The number of kidneys transplanted per standard criteria donor;

Interpretive Guidelines §486.318(b)(3)(i)

Z013

(Standard) **§486.318(b)(3)(ii)** The number of kidneys transplanted per expanded criteria donor; and

Interpretive Guidelines §486.318(b)(3)(ii)

Z014

(Standard) **§486.318(b)(3)(iii) The number of organs used for research per donor, including pancreata recovered for islet cell transplantation.**

Interpretive Guidelines §486.318(b)(3)(iii)

Z015

(Standard) **§486.318(c) Data for the outcomes measures.**

§486.318(c)(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.

Interpretive Guidelines §486.318(c)(1)

Z016

(Standard) **§486.318(c)(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 it's new service area, we will not hold the OPO accountable for it's performance in the new area until the end of the following re-certification cycle when 36 months of data are available.**

Interpretive Guideline §486.318(c)(2)

Z036

(Condition) **§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.

Interpretive Guidelines §486.320

Prior to going on-site, review the CMS OPO Database report to confirm that the OPO is a member of the OPTN. A membership status will be listed on the database report for the OPO. Only two OPTN membership statuses result in a non-compliance finding for this Condition. They are:

- 1) “Withdrawal of OPTN membership;” and
- 2) “Not an OPTN Member.”

If the OPO is currently listed as being in either of these two statuses, do not perform an on-site survey and notify the OPO that its Medicare certification will not be renewed.

Z056

(Condition) **§486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.**

Interpretive Guidelines §486.322

For review purposes the requirements of this Condition consider tissue banks and eye banks as separate entities.

Z057

(Standard) **§486.322(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.”

Interpretive Guidelines §486.322(a)

Request the written agreements for a percentage of the hospitals in the donation service area. Either create a list of all hospitals and CAHs in the service area prior to going on site or ask the OPO for a list of all hospitals and CAHs in their service area. Eliminate those hospitals/CAHs in the service area that currently have waivers to work with another OPO and ensure that the list of hospitals/CAHs for this OPO includes those facilities outside the service area that have waivers to work with this OPO. The surveyor should select the following sample size.

Less than 100 hospitals in the service areaSelect 10% at random;
More than 100 hospitals in the service area.....Select 05% at random.

If during the review of the sample, the surveyor determines that the OPO does not have a current agreement with one or more hospitals/CAHs in their service area, request additional information to determine whether the hospital/CAH has a ventilator and operating room or

whether the hospital/CAH has an approved waiver to work with another OPO. Disregard any hospital/CAH that does not meet the criteria or has an approved waiver in place. If the hospital(s) does meet these criteria or does not have an approved waiver in place, expand the sample to a 100% review to verify that the OPO has an agreement with at least 95% of the Medicare and Medicaid participating hospitals/CAHs in the donation service area that have both a ventilator and an operating room.

If the OPO for a donation service area has changed since the last survey, due to a CMS change of designation or CMS approval of a merger of two OPOs, verify that the OPO has effected new agreements with the Medicare certified hospitals and CAHs in the service area. In those instances where there is no agreement and there is no pending request for waiver (submitted within 30 days of the notice of change of designation), look for written documentation to show effort by the OPO to obtain a new agreement. If such documentation is available but the hospital or CAH refuses to enter into an agreement with the newly designated OPO and there is no waiver request pending, do not cite the OPO for a deficiency under this regulation but make a referral to the applicable State Survey Agency for possible hospital/CAH complaint investigation per §482.45/§485.643.

If the OPO has a written agreement with any hospital/CAH outside of its service area and cannot provide evidence of a waiver for that facility, either currently pending with CMS or approved by CMS, (see approval requirements at §486.308(e)), cite a deficiency under §486.322(a). Inform the OPO that the agreement must be terminated and the facility must be given any necessary assistance to secure an agreement with its designated OPO. Refer the finding to the applicable State Survey Agency for possible investigation under §482.45 or §485.643 as appropriate.

Prior to going on-site, check the CMS OPO Database report to identify:

1. any waiver denials issued, or
2. any pending hospital/CAH request to return to its designated OPO after a previous waiver approval.

During the on-site review, verify that there is a written agreement in place between the OPO and any hospital or CAH within the OPO's donation service area which requested a waiver and the waiver was subsequently denied by CMS.

Review the agreements to ensure that they include the responsibilities of both the OPO and the hospital/CAH and describe how they will work together collaboratively.

Deficiencies found at §486.303(g) should be cited at this regulation §486.322(a).

The hospital/CAH agreement should address:

- a) Appropriate hospital staff participation in training provided by or approved by the OPO;
- b) Staff roles/expectations for approaching the families regarding possible donation;

- c) Parameters for timely notification of the OPO of an imminent death (Agreement should define “timely referral” and the clinical triggers which would indicate an “imminent” death.)
- d) Access by the OPO to hospital services such as laboratory services, radiological services, operating room availability or anesthesia services on a 24/7 basis;
- e) OPO access to hospital medical records and the arrangements for copies to be made of the hospital medical records requested by the OPO;
- f) Hospital/CAH staff role/responsibilities for management of organ viability;
- g) Hospital/CAH staff role/responsibilities for procedures during Donation after Cardiac Death (DCD), if applicable. (The hospital may elect to opt out of DCD.);
- h) Hospital/CAH requirements for the qualifications that must be provided by the OPO for organ recovery team members upon request by the hospital;
- i) Notification of the OPO of any change in hospital privileges, which affect the privilege of organ recovery, for any surgeon or other recovery personnel from the hospital routinely recovering organs for the OPO; and
- k) Roles and responsibilities of surgeons and other personnel recovering for an OPO.

The OPO responsibilities should address:

- a) The provision of:
 - 1. timely communication and prompt response by the OPO on a 24/7 basis;
 - 2. orientation training for new Designated Requestors and annual training for all Designated Requestors;
 - 3. annual hospital specific organ donation data.
- b) The determination of the suitability of the donor;
- c) The parameters for OPO interaction with hospital/CAH staff and families or the legally authorized representative;
- d) Use of sensitivity in discussions with families or with the legally authorized representative;
- f) The notification to the hospital/CAH of any OPO policy changes that affect the role of the hospital/CAH in recovery, perfusion or transport;
- g) The assurance that:
 - 1. organ recovery teams are of the proper composition and qualifications;
 - 2. proper documentation is prepared for the transplant program about the recovered organ(s) including blood type and other identifying information;
- h) The role of the OPO staff:

1. in organ/tissue management within the hospital/CAH; and
 2. with the interactions with the family or the legally authorized representative in cases of first person consent.
- i) OPO roles, responsibilities and collaboration with the hospital staff on DCD, if applicable.

Z058

(Standard) **§486.322(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.**

Interpretive Guidelines §486.322(b)

According to the hospital regulations at 42CFR 482.45(a)(3), the individual designated by the hospital to initiate the request to the family or to the legally authorized representative must be an organ procurement representative **or** a Designated Requestor. According to regulations at 42CFR 485.643(c) for CAHs, the individual designated by the CAH to initiate the request to the family or to the legally authorized representative must be a Designated Requestor. However, the CAH may designate the OPO staff to function as the Designated Requestor. In both cases the Designated Requestors must have completed a training course provided or approved by the OPO. Hospital/CAH staff assigned to be Designated Requestor(s) must successfully complete an OPO approved training program prior to beginning their duties. The training course does not have to be presented in person by the OPO staff. The course may be presented by the hospital staff utilizing OPO approved materials.

Review any Designator Requestor training programs to evaluate the role of the OPO in the development or approval of the programs and whether the programs were developed in conjunction with the tissue bank and eye bank communities. If the Designated Requestor approaches the family or the legally authorized representative on behalf of the tissue banks or eye banks, the tissue banks or eye banks must participate directly in their training or indicate their approval of their training course.

Review the OPO training records for each hospital/CAH to ensure that training was provided or offered to Designated Requestors at each hospital/CAH on an annual basis. A hospital or CAH may provide its own Designated Requestor training. If the hospital/CAH provides the Designated Requestor training, the training content must be approved by the associated OPO per §482.45 (a)(3). The OPO should maintain records of these training presentations and evidence that they approved the programs. Training, offered by the OPO or hospital/CAH, must show participation by the tissue bank and eye bank communities or be approved by the tissue and/or eye bank if the OPO is performing recoveries for the banks

Designated Requester training programs should include, at a minimum, information on:

- a) Communication with the appropriate hospital staff to discuss the approach with the family or with the legally authorized representative of the potential donor;
- b) The appropriate timing for approaching the family;

- c) The appropriate method for initially approaching the family or the legally authorized representative including identification of the entity they represent (i.e., hospital, OPO, tissue bank);
- d) Sensitivity to varying family or legally authorized representative situations;
- e) Support staff that should be included when the family or the legally authorized representative is approached to ensure they receive adequate information;
- f) Accepting decisions by the family or the legally authorized representative to decline donation, in the absence of first person consent;
- g) 24/7 coverage;
- h) The process to obtain informed consent from the family or the legally authorized representative in the absence of first person consent if applicable;
- i) Interactions with OPO staff; and
- j) Any limitations of Designated Requesters.

In those instances where the hospital/CAH and OPO agree that the OPO will perform the Designated Requestor role exclusively in lieu of hospital/CAH staff, this arrangement must be stipulated in the agreement between the OPO and the hospital/CAH. OPO staff serving as a Designated Requestor at a CAH need not complete Designated Requestor training if they have completed other training by the OPO.

Z059

(Standard) **§486.322(c) Standard: Cooperation with tissue banks.**

§486.322(c) (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:

Interpretive Guidelines §486.322(c)(1)

Verify that the OPO has identified the eye bank and tissue bank agreements between each hospital/CAH located in the service area. The OPO should have written arrangements (either signed agreement or Memorandum of Understanding (MOU)) with each identified tissue bank and eye bank to address tissue recovery by the OPO in conjunction with organ recovery in the hospitals/CAHs (unless the OPO has written documentation that the tissue bank or eye bank refused to enter into a written arrangement); the arrangements must include the activities listed at §486.322(c)(1) (i)-(iv) below. The tissue bank and eye bank may elect to perform portions of the activities in §486.322(c)(1) (i) - (iv) themselves as delineated by the written arrangements. This coordination facilitates the recovery of usable tissues and eyes and limits the number of people who will approach the family or the legally authorized

representative regarding consent for donation and assures timely communication of safety related information among the OPO and the tissue and eye banks.

In those cases where the OPO is also the designated tissue bank for a hospital, it is not necessary that the OPO/tissue bank have a written agreement/MOU with itself. During the survey process, verify that the OPO is performing the activities of §486.322 (c) (1) (i)–(iv) consistent with tissue bank policies.

Z060

(Standard) **§486.322 (c)(1)(i) Screening and referral of potential tissue donors.**

Interpretive Guidelines §486.322 (c)(1)(i)

If the OPO has made arrangements to perform the screening for the tissue banks and eye banks, the arrangements between the two entities should include current written protocols for screening and referral procedures. Review the screening and referral protocols.

Tissue bank and eye bank screening criteria can vary from bank to bank and may change periodically. Therefore, the OPO should annually verify that they are using current screening criteria for its work for the tissue banks and eye banks.

The OPO must maintain documentation of all screening, referral and/or recovery activities performed for tissue banks and eye banks. Select a sample of donor records where screening and/or recovery was conducted by the OPO for a tissue bank or eye bank. Verify that the protocols agreed upon with the tissue banks and eye banks were followed.

Note: An OPO that performs tissue donor screening or tissue recovery must comply with the FDA regulations under 21 CFR Part 1271 applicable to the tissue manufacturing step it performs. These may be different from the requirements under the OPO CfCs. An example would be retention of records. Under 1271.270(d) an establishment performing a tissue manufacturing step must retain records for 10 years with some exceptions. Violations of the requirements under 1271.270 (d) should be reported to the FDA.

Z061

(Standard) **§486.322(c)(1)(ii) Obtaining informed consent from families of potential tissue donors.**

Interpretive Guidelines §486.322(c)(1)(ii)

The written agreement/MOU between the tissue banks and eye banks and the OPO for securing informed consent from the family or the legally authorized representative of the potential donor in the absence of a donor document (living will, advance directive, driver's license) must include the expectations for obtaining "informed consent." The arrangements should address the extent of information that should be shared with the family or the legally authorized representative regarding:

- a) What procedures will be performed;

- b) Where the procedures will be performed;
- c) Who will perform the procedures (generally);
- d) When the procedures will be performed (generally);
- e) What impact the procedures will have on the donor's body (e.g., disruption of funeral viewing); and
- f) The associated documentation requirements including specific requirements for telephone consents.

If the OPO utilizes the same informed consent form or procedure to obtain informed consent for both organs and tissue/eye, the documentation on the consent form must verify that the OPO provided information specific to tissue, eye or organ donation.

The OPO should have a written protocol in place with the tissue banks and eye banks regarding telephone consent. The telephone consent protocol should require a witness to all telephone consents unless the individual State law specifically allows a verbal record of the informed consent over the telephone without the need for a witness. In these cases, the consent recording should be maintained per medical record retention requirements. The telephone protocol should also address the OPO staff who may take the consent, persons who may provide consent, and how the OPO verifies the identity of the person providing consent.

Z062

(Standard) **§486.322(c)(1)(iii) Retrieval, processing, preservation, storage, and distribution of tissues.**

Interpretive Guidelines §486.322(c)(1)(iii)

The written arrangements between the OPO and the tissue banks and eye banks should delineate the specific procedures the OPO may perform as a representative of the tissue bank and/or eye bank in the retrieval of tissues, what measures the OPO must follow to preserve the tissues or eyes, and the role the OPO will play in the storage and distribution of tissues.

Z063

(Standard) **§486.322(c)(1)(iv) Providing designated requestor training.**

Interpretive Guidelines §486.322(c)(1)(iv)

The written arrangements between the OPO and the tissue banks and eye banks should specify whether the OPO or tissue or eye bank will provide Designated Requestor training (in those instances where a hospital has employees assigned as a Designated Requestors), what the training must include, and how the tissue banks and eye banks participate in training programs or approve any training programs presented by the OPO. See §486.322(b) for discussion of agreement requirements.

Z064

(Standard) **§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.**

Interpretive Guideline §486.322(c)(2)

Z084

(Condition) **§486.324 Condition: Administration and governing body.**

Z085

(Standard) **§486.324(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:**

Interpretive Guidelines §486.324(a)

Verify that there are written bylaws for the designated Advisory Board. The bylaws must grant the Advisory Board, as a minimum, the authority described in §486.324 (b) below and require (as a minimum) the membership of individuals listed in §486.324(a)(1)–(6) below. Review the written policies, which describe the process the OPO will follow for initial and/or annual verification of Advisory Board member qualifications. Request a list of the current Advisory Board members, their positions, professional qualifications and the corresponding OPO documentation verifying their qualifications.

Review the Advisory Board minutes to ensure that the designated membership is active. While there will always be instances when not all members are able to attend a meeting, the OPO should make every effort to schedule meetings at a time that the majority can attend. There should be written documentation that the members do attend most meetings. Consistently absent members should be replaced by the OPO per their written bylaws.

Z086

(Standard) **§486.324(a)(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.**

Interpretive Guidelines §486.324(a)(1)

There are four (4) individual kinds of members specifically listed within this Standard.

- (a) hospital administrator;
- (b) either intensive care or emergency room personnel;
- (c) tissue banks; if the OPO is the only tissue bank in its service area it may represent the tissue bank; and

(d) voluntary health associations in the OPO's service area.

Voluntary health associations are those organizations primarily engaged in raising funds for health related research such as disease prevention and treatment and providing health education and patient services.

The tissue bank representative may be from any tissue bank in the service area. This representative may be from a tissue recovery agency or tissue processor.

Z087

(Standard) **§486.324(a)(2) Individuals who represent the public residing in the OPO's service area.**

Interpretive Guidelines §486.324(a)(2)

This representative should not be the family member of a donor. This representative provides the "general public" perspective on organ donation to the Board.

Z088

(Standard) **§486.324(a)(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.**

Interpretive Guidelines §486.324(a)(3)

This individual should be an MD/DO with knowledge, experience or skill in the field of human histocompatibility or an individual with a PhD (in a science that studies living organisms) with knowledge and experience working with the genetics that influence acceptance or rejection of grafts.

Z089

(Standard) **§486.324(a)(4) A neurosurgeon or other physician with knowledge or skills in the neurosciences.**

Interpretive Guidelines §486.324(a)(4)

This position on the Advisory Board should be filled by a neurosurgeon or a neurologist.

Z090

(Standard) **§486.324(a)(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.**

Interpretive Guidelines §486.324(a)(5)

A transplant surgeon representing a transplant hospital may not simultaneously fulfill the requirements for any other role on the Advisory Board. Prior to going on-site, identify the transplant hospitals in the donation service area. During the on-site review, verify that the Advisory Board membership has transplant surgeon representation from each transplant hospital in the OPO service area and that the member has practicing privileges and is actively performing transplants at one of the transplant hospitals in the service area.

Z091

(Standard) **§486.324(a)(6) An organ donor family member.**

Interpretive Guidelines §486.324(a)(6)

The person fulfilling this role on the Advisory Board may be an organ donor's family member or a living organ donor.

Z092

(Standard) **§486.324(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.

Interpretive Guidelines §486.324(b)(1)-(12)

The Public Health Service Act limits the authority of the OPO Advisory Board to recommendations only. This regulation further limits the scope of recommendations appropriate for the Board to the activities listed in subsections (b) (1) through (12) above. Review the minutes of the Advisory Board for any 12 month period during the current re-certification cycle. Ensure that the topics placed before the Advisory Board and the recommendations from the Advisory Board are consistent with (1) through (12) above. Advisory Board recommendations should be made to the Governing Body of the OPO.

Z093

(Standard) §486.324(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.

Interpretive Guidelines §486.324(c)

Review the membership of the Governing Body or Board of Directors and the Advisory Board to ensure that these are separate and distinct bodies with no cross membership.

Review the bylaws of the Advisory Board for a notation disallowing cross membership and stipulating that the Advisory Board may make recommendations to the OPO Governing Body only on in the listed areas of §486.324 (b) (1)-(12) above but has no authority over other OPO activities (such as financial, administrative and personnel matters).

Review the minutes of all OPO boards other than the Advisory Board to ensure that if Advisory Board members are in attendance at other board meetings the minutes confirm that their attendance is purely in an advisory capacity (i.e., non-voting) and upon request. While OPO staff certainly are in attendance at Advisory Board meetings and respond to or provide additional information to the members, they should not be voting members.

Z094

(Standard) §486.324(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.

Interpretive Guidelines §486.324(d)

Ensure that the written bylaws for each of the currently operating boards of the OPO address as a minimum:

- a) Potential or appearance of conflict of interest for Board members (define conflict and measures to identify and prohibit conflicts);
- b) Length of terms for members; and
- c) Criteria for selecting and removing members.

Z095

(Standard) **§486.324(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.**

Interpretive Guidelines §486.324(e)

Review Governing Body minutes to verify their oversight activities regarding the development and implementation of policies, the annual budget, other fiscal concerns, the QAPI program and services furnished under contract or arrangement.

Verify that the OPO Governing Body has appointed an individual in writing to be responsible for the day-to-day operation of the OPO. This individual must have his/her role defined by the Governing Body and there should be written documentation that his/her activities are shared with or reported to the Governing Body on a routine basis. If the Governing Body has not defined the role of this individual and there are associated deficiencies with day to day operations of the OPO, cite a deficiency under this regulation.

Since the Governing Body is also responsible for the OPO's fiscal responsibilities, non-compliance with §486.303(b)(non-profit status) and §486.303 (c)(assuring fiscal stability) should be cited here.

Z096

(Standard) **§486.324(f) The OPO must have procedures to address potential conflicts of interest for the governing body described in paragraph (d) of this section.**

Interpretive Guidelines §486.324(f)

The OPO must develop written policies and procedures that address governing body potential conflict of interest. These policies should define /identify potential "conflicts of interest"

(both financial and personal), and include notification of the members of any real or potential conflict and the procedures which will be utilized to resolve the conflict. See Interpretive Guidance at §486.324(d) above.

Z097

(Standard) **§486.324(g) The OPO's policies must state whether the OPO recovers organs from donors after cardiac death.**

Interpretive Guidelines §486.324(g)

The OPO must include a statement in its policies as to whether or not it recovers organs from donors after cardiac death.

Z117

(Condition) **§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.

Z118

(Standard) **§486.326(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.

Interpretive Guidelines §486.326(a)(1)

Review the written position descriptions for clinical and family support positions. These descriptions should describe the requirements for licensure as applicable, educational background and work experience. Review the files for a sample of clinical and family support personnel (including those individuals providing services under arrangement) to determine:

- a) If employees meet the requirements of the position description within which they are working; and
- b) If licensure is applicable, whether the employee has a current license on file; and
- c) If employees participate in on-going training experiences to enable them to provide or supervise services effectively.

Z119

(Standard) **§486.326(a)(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.**

Interpretive Guidelines §486.326(a)(2)

The OPO must have written policies and procedures for the identification, investigation and resolution of potential conflicts of interest (financial or personal) for the OPO director, medical director, senior management, and procurement coordinators.

Confirm during review of employee files that potential conflict of interest is evaluated at the time of employment. Also, be alert in the employee files to any indication subsequent to employment of a potential conflict of interest (consistent with the OPO written policy). If noted, discuss the observation with the OPO Director to learn whether the situation was identified and what follow-up action was taken.

Z120

(Standard) **§486.326(a)(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.**

Interpretive Guidelines §486.326(a)(3)

The OPO should indicate in its operational policies what qualifications are required for recovery personnel who recover organs under contract or arrangement with the OPO. The OPO should also detail in its procedures how recovery personnel qualifications will be verified prior to any recovery.

For surgeons or other qualified practitioners who do not routinely recover organs on behalf of the OPO, the OPO must have protocols in place for quick verification of their qualifications and training prior to any recovery. Documentation of the verification must remain on file and confirm that verification was done before recovery.

Z121

(Standard) **§486.326(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.

Interpretive Guidelines §486.326(b)(1)

Review the OPO written policy on the screening of incoming hospital referral calls. Policies should include who may conduct the screening, the screening process to be followed, the time frame for completing the screening and the documentation that must be entered into the

intake record. Also, review the OPO written policy on the timeframes for subsequent OPO staff arrival at the hospital and evaluation.

As a part of the donor record review, verify that the OPO policies for screening are being followed.

Z122

(Standard) **§486.326(b)(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.**

Interpretive Guidelines §486.326(b)(2)

Review of donor records and results of QAPI activities should confirm that the OPO is:

- responding promptly (consistent with OPO policies) to the notification of a potential donor through screening and evaluation;
- performing optimal, clinical maintenance of the donor through correct use of management protocols;
- providing complete information to enable the donor's family or legally authorized representative to make an informed decision in the absence of a first person consent;
- initiating timely communication with the transplant community;
- facilitating an effective and timely recovery process; and
- transporting donated organs consistent with current OPTN requirements.

Verify that the staff performing QAPI review of a particular case did not actively participate in the recovery for that case. Verify that there is sufficient staff assigned to ensure that death record reviews conducted for the QAPI program are completed on a timely basis (monthly).

Z123

(Standard) **§486.326(b)(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.**

Interpretive Guidelines §486.326(b)(3)

If the OPO does not employ surgeons or other qualified practitioners to perform recoveries, it should have written arrangements in place with such personnel (most likely a group of surgeons from the transplant hospitals in its service area) who are available on call 24/7 to travel to the donor hospitals and recover organs for the OPO. Review these written agreements. Ensure that current call schedules are available from the hospitals. Review the sample of donor records to determine whether there were any unnecessary delays in organ recovery due to the unavailability of a recovery surgeon or other qualified practitioner. Review the minutes of the QAPI program to determine if there have been any aborted recoveries due to the lack of availability of a surgeon or other qualified practitioner.

When surgeons or other qualified practitioners are performing recoveries for the OPO they are functioning as OPO representatives and must follow the OPO policies and procedures. The OPO is ultimately responsible for ensuring that every surgeon or other qualified practitioner that performs a recovery is qualified and trained and has sufficient experience in recovery to preserve the organs properly. See also §486.326(a)(3).

Z124

(Standard) §486.326(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.**

Interpretive Guidelines §486.326(c)

Verify that there is a written position description for each OPO employee that includes the expectations for the employee. Review a minimum of five (5) employee files for the clinical and family support staff at the OPO including contract employees in those positions. Select the files at random from a list of all OPO employees and expand the samples as indicated to ensure that:

- a) A standardized orientation to the OPO mission, and an individualized orientation (per the OPO's performance expectations listed in its position descriptions including policies, procedures, and QAPI expectations) were provided and successfully completed;
- b) Training opportunities are provided for OPO employees who require continuing education credits (e.g., CEUs) to maintain their licensure/certification; and
- c) Periodic evaluations are conducted of employee performance and recommendations for improvement and plans to achieve that improvement are developed.

Verify that the OPO has an operational methodology for the identification of training needs for each employee and that these identified needs are addressed promptly.

Review the general training schedule and associated attendance logs for the OPO employees. Ensure that the training is appropriate (based upon the identified needs of employees, training requests from employees or updates on standards of community practice), occurs on a regular basis and includes all OPO staff and contract staff as applicable.

Z125

(Standard) §486.326 (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 and 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.

Interpretive Guidelines §486.326(d)

Review the administrative file for the OPO medical director to verify that:

- a) He/she is currently licensed as a physician in one of the States within the OPO donation service area or as required by State law (State laws of other States in the Donation Service Area may require that any physician practicing within that State be licensed by that State); and
- b) The position description for the medical director clearly delineates his/her role in the implementation of protocols for donor evaluation and management, determination of donor suitability for donation, organ recovery and placement in increased risk cases.

Interview the medical director to determine:

- a) His/her familiarity with the OPO protocols;
- b) The extent of his/her involvement in the implementation of protocols (especially protocols for the evaluation for suitability and donor management);
- c) His/her role in donor management (either on-site or consultation);
- d) His/her process for verifying whether the OPO is following its written protocols and ensuring the protocols are consistent with current standards of practice;
- e) Documentation of periodic evaluations of compliance with protocols (d above); and
- f) His/her role in the determination of donor suitability (e.g. donor of increased risk).

Generally, the OPO organ procurement coordinator performs donor management per protocols approved by the OPO medical director without his/her on-site participation. However, the OPO medical director must be available for consultation on any case where a procurement coordinator requires additional guidance. Verify through interview and review of donor records that the medical director is available for consultation 24/7 or has back-up coverage by another MD or DO.

Z145

(Condition) **§486.328 Condition: Reporting of data.**

Z146

(Standard) **§486.328(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.**

Interpretive Guidelines §486.328(a)

Prior to going on-site, review the CMS OPO Database report to ensure that the OPO is submitting data to the OPTN and SRTR as required by OPTN by-laws (7.0-7.9) for the listed data elements §486.328 (a) (1)-(9) above. No on-site review activity is required.

CMS will consider a submission rate of 95 percent and above to meet the requirements of this standard.

Z147

(Standard) **§486.328(b) An OPO must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.**

Interpretive Guidelines §486.328(b)

From the sample of transplant hospitals and CAHs selected in §486.322(a) request the reports that have been provided to the hospitals/CAHs by the OPO since the last re-certification visit. These reports should have provided information to the individual hospital or CAH for §486.328 (a) (1)-(9) above on an annual basis.

Z148

(Standard) **§486.328(c) Data to be used for OPO re-certification 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.**

Interpretive Guidelines §486.328(c)

Z149

(Standard) **§486.328(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.

Interpretive Guidelines §486.328(d)

See §486.328(a) above.

§486.328(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.

Interpretive Guidelines §486.328(e)

See §486.328(a) above.

Z159

(Condition) **§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.

Z160

(Standard) **§486.330(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.

Interpretive Guidelines §486.330(a)

For each donor the OPO maintains, in electronic format, a copy of the required minimum information and documentation of consent and family or legally authorized representative information.

Z161

(Standard) §486.330(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.

Interpretive Guidelines §486.330(b)

See Interpretive Guidelines for §486.330(a)

Z162

(Standard) §486.330(c) *Data retention.*

Donor and transplant recipient records must be maintained in a human readable and reproducible paper or electronic format for 7 years.

Interpretive Guidelines §486.330(c)

Verify that the OPO policies require that donor records will be maintained for a minimum of seven (7) years and that the records are in a human readable and reproducible paper or electronic format. Verify that the OPO policies are being followed through the donor record sample.

For purposes of this regulation, transplant recipient records are any transplant recipient information received from the transplant hospital and subsequently included in the donor record.

Request that the OPO locate the sampled donor records either electronically or in hard copy. If electronic records are located, verify that the entire record is maintained and that the record can be printed in a readable format. Ask the OPO to print one page to verify.

Z163

(Standard) §486.330(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.

Interpretive Guidelines §486.330(d)

The OPO should have written policies which outline the procedures which will be followed, if necessary, to make available its Electronic Information Management System (EIMS) software to allow a successor OPO to operate the program.

The policies and procedures of the OPO should also be in a format which can be forwarded electronically.

Other OPO operations (e.g., material budgets, governing body minutes, personnel files, QAPI minutes, etc.) may be transferred via paper or electronic format.

Z164

(Condition) **§486.342 Condition: Requesting consent.**

An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.

Interpretive Guidelines §486.342

Before going on-site, review the Aspen Complaint/Incident Tracking System (ACTS) to determine if any complaints have been filed against the OPO for inappropriate or insensitive behavior during the process of obtaining consent. If so, determine if there is any additional follow-up required or were the complaints resolved sufficiently?

In the absence of first person consent, while it may be assumed by the OPO that, in general, all persons, regardless of religious or personal beliefs, may be approached for organ donation, the OPO must be sensitive to any factors (from record review, hospital staff information, their own knowledge regarding religious beliefs or information received) which indicate that the OPO should not pursue consent. The OPO must respect the decisions by the family or the legally authorized representative as determined by State law. Declination must be respected if the family or legally authorized representative was approached by a trained requestor and declined donation. Review the staff orientation program for discussions on sensitivity with donor families and legally authorized representatives.

Review the QAPI documentation to determine if the OPO program conducted analysis on any complaints received from family members or legally authorized representatives reporting insensitive behavior or lack of discretion on the part of the OPO staff. Review OPO documentation of subsequent counseling and increased training that was provided to any staff member involved in such a complaint.

Z165

(Standard) **§486.342(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.**

Interpretive Guidelines §486.342(a)

In the absence of a donor document (e.g., living will, advance directive, driver's license declaration and State donor registries), the family or legally authorized representatives must give informed consent for the donation of organs.

Review the donor record sample (for donors without first person consent) to verify that in each case the family or legally authorized representatives was provide with the information listed in §486.342 (1)-(8) above and indicated an understanding of the information. The confirmation that the informer assessed the level of understanding by the family or legally authorized representatives may be incorporated into the consent form or may appear as a summary note by the informer in another part of the record. Any documentation of the level of understanding should include what information was provided, the method used to determine the level of understanding and the level of understanding expressed. The documentation should also include any specifics that were repeated for clarification.

At the time that informed consent is acquired, the OPO may not know definitively how the organ will be used. In these cases, informed consent must provide the family or legally authorized representatives with the range of most likely possibilities for usage (transplant or research).

The OPO should list its contact information on the consent form to include a specific point of contact at the OPO.

Copies of the consent are shared with the family or legally authorized representatives at the time the consent is signed. In instances where the recovery does not ultimately go forward, there would be no need to include a copy of the consent with any letter of explanation sent to the family or legally authorized representatives.

(Standard) **§486.342(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.

Interpretive Guidelines §486.342(b)

Request the OPO's written protocol for contacting family or legally authorized representatives in the case of first person donation. Ensure that the OPO is following its written protocol.

Review a sample of donor records where no family or legally authorized representative's consent was required (e.g., living will, advance directive, driver's license declaration with informed consent and State donor registries).

Verify that the OPO followed applicable State laws regarding first person consent. Documentation in the donor record should confirm that the OPO made every attempt to make contact with family or legally authorized representatives to provide additional information to them regarding the expected process of donation. Instances where the OPO attempted but was unable to make contact should be documented. Look for any instances where a donor family or legally authorized representatives requested additional information about the donation and verify that the OPO provided the information.

Z167

(Condition) **§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.

Interpretive Guidelines §486.344

The OPO should have written protocols for:

A. Donor Evaluation (per organ) which addresses;

- Chart review required;
- Laboratory testing required (standard and additional as indicated);
- Other testing as indicated (echocardiogram, chest x-ray, etc.);
- Required timeframes for donor protocol activities;
- Documentation required;
- OPO staff member interactions with family or legally authorized representatives to collect information; and
- OPO staff roles.

(Note: The above protocol is not developed to determine organ suitability for a certain recipient, but to determine the medical suitability of a potential donor.)

While the OPO may review the potential donor's hospital record without consent, in the absence of a donor document, consent from family or legally authorized representatives, or specific State law which allows invasive testing prior to consent, the OPO shall not conduct invasive testing prior to consent. Non-invasive testing would include procedures that involve no break in the skin and no contact with the mucosa or internal body cavities beyond natural body orifices.

B. Donor Management (per organ) to include:

- Testing (such as cardiac);
- Laboratory testing;
- Drug administration parameters;
- Ventilation management;
- Optimal vital signs; and
- Fluid levels;

C. Organ Placement to include:

- UNET match list review;
- Communication with transplant hospitals.

D. Organ Recovery to include:

- Scheduling;
- Qualified staff;
- Documentation of verification of blood type;
- Documentation required during recovery;
- Organ packaging;
- Organ transport; Documentation accompanying the organ; and
- Any subsequent follow-up with transplant hospital.

The above OPO protocols must be consistent with current standards of community practice for organ procurement.

As current clinical practices continue to evolve at a fairly rapid pace, advances are made in the science of organ procurement to improve the outcomes of transplantation. Therefore, the individual OPO is ultimately responsible for updating its own clinical policies and protocols as necessary but at least annually.

Z168

(Standard) **§486.344(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.

Interpretive Guidelines §486.344(a)

The OPO must have a written procedure for and must be able to provide evidence that the medical director reviews donor records (either periodically or in real time) to ensure that the OPO approved protocols for donor evaluation and management are being followed. Any failure by the OPO staff to follow the written OPO protocols should be documented by the medical director, promptly addressed and shared with the QAPI program. There must be evidence that the medical director is conducting periodic (consistent with OPO policy) reviews to ensure that staff are following the protocols.

Verify in the sample of donor records that:

- a) OPO staff consistently followed the written protocols for evaluation and management;
- b) Appropriately trained staff performed all procedures; and
- c) The medical director was notified promptly with any concerns.

Z169

(Standard) **§486.344(a)(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.**

Interpretive Guidelines §486.344(a)(2)

During the time period following the onset of brain death, it is critical that the potential donor's vital signs be maintained by aggressive medical management. This is a complex process that may involve a number of different recovery personnel in various capacities, including the OPO Procurement Coordinator, the OPO medical director, transplant surgeon(s), hospital critical care specialists, intensivists or anesthesiologists, and other OPO experts and consultants. Actual practice varies with individual OPOs and transplant surgeons. However, it is imperative for the OPO to make sure a qualified physician, physician's assistant, clinical nurse specialist or nurse practitioner (as allowed by State law) is readily available at all times to assist the primary OPO Coordinator with direct medical management of the potential donor as the transplant surgeon on call may not be immediately available.

The OPO may elect to utilize physicians in the donor hospital per its written agreement with the hospital or maintain a separate agreement with surgeons for call from one or more transplant hospitals in its service area.

Z170

(Standard) **§486.344(b) *Potential donor evaluation.***
The OPO must do the following:

Z171

(Standard) **§486.344(b)(1) Verify that death has been pronounced according to applicable local, State, and Federal laws.**

Interpretive Guidelines §486.344(b)(1)

The OPO does not make the actual determination of death (whether brain death or cardiac death). Rather, the OPO must verify and document that the potential donor has been pronounced dead in accordance with applicable legal requirements of local, State, and Federal laws with supporting documentation.

The OPO should be able to produce a copy of and have familiarity with the applicable, current State law on death pronouncement.

Review the sample of donor records (brain death) to verify that the OPO confirmed the pronouncement of death as part of the evaluation of the possible donor.

A copy of the death pronouncement must be included in the OPO donor record.

Z172

(Standard) **§486.344(b)(2) Determine whether there are conditions that may influence donor acceptance.**

Interpretive Guidelines §486.344(b)(2)

Ask the OPO for a list of those medical conditions which they consider as elimination criteria for a possible donor and which are included in its screening and evaluation processes. Verify during the review of donor records that the policies of the OPO are being followed.

The OPO must be alert to and identify those characteristics, findings, and conditions in the potential donor that may exclude consideration of that patient's solid organs for transplant (except in limited cases where risks outweigh the benefits).

In all instances where there are factors which result in the donor being designated as a donor with increased risk of disease transmission, the OPO must have documented evidence that they provided notification to the transplant surgeon/transplant coordinator that the organ was from a donor with increased risk and provided specific findings. The OPO must maintain additional information to confirm that the transplant surgeon or transplant coordinator was notified of all the pertinent information.

Z173

(Standard) **§486.344(b)(3) If possible, obtain the potential donor's medical and social history.**

Interpretive Guidelines §486.344(b)(3)

Due to the compressed time frame for deceased donor evaluation, there is a possibility that certain infections, such as HIV, HBV, and or HCV, may be present at an early stage, prior to the ability of an assay to detect the infection. Thus, considerable weight is placed on the donor's social and medical history in identifying potential risks that might not be reflected in blood test results. The potential donor's medical and social history provides invaluable information that might clarify or explain ambiguous and/or discordant diagnostic test results

that could eliminate an otherwise suitable organ donor or could include an otherwise unsuitable organ donor. It is crucial that the OPO closely review the medical and social history for the potential donor, identify any factors which may exclude the donor from donation or indicate extra restrictions on the type of recipient who may be allowed to receive the organ. The OPO considers the reliability of the informant for the social history and the likelihood the informant has sufficient knowledge of the potential donor to provide a definitive response to questions, especially questions associated with increased risk behavior.

In all instances on the social history where there are either questions answered in the affirmative regarding increased risk behavior or there is inadequate information to definitively respond on questions regarding increased risk behavior, confirm that the OPO immediately documented this information in DonorNet to provide sufficient information to transplant surgeons or transplant coordinators before proceeding with the donation.

In any instance where a social history or medical history revealed a condition or behavior that makes donation increased risk in most cases, there must be written documentation in the donor record to verify that the conditions and behaviors were completely discussed with the transplant surgeons at the time the organ offer was made.

In the absence of a social or medical history, the OPO should elevate the potential donor to an increased risk status and notify transplant surgeons of such evaluation.

Z174

(Standard) **§486.344(b)(4) Review the potential donor's medical chart and perform a physical examination of the donor.**

Interpretive Guidelines §486.344(b)(4)

The OPO Coordinator, or other appropriately qualified OPO staff, must review the hospital medical chart of the potential donor, perform a physical examination of the potential donor, and document all findings. Documentation from both reviews must be included in the OPO donor record. Simply charting that a record review was completed does not provide sufficient verification of a thorough review.

Chart reviews should include at a minimum:

- a) Social history, if possible;
- b) Physical examination;
- c) Medical history;
- d) Laboratory results;
- e) Physician progress notes;
- f) Death pronouncement (e.g.; DCD case); and
- g) Donor documents.

The donor physical examination performed by the OPO should not be confused with the physical examination performed by the hospital physician. The OPO examination is primarily performed to determine if there are any conditions that may indicate a compromised organ (e.g., masses or observations that could indicate the possibility of infection such as tattoos, track marks, etc. and which require additional investigation).

The hospital medical chart review is conducted not only to gain information from the medical and social history but also to review the course of the hospitalization. Events occurring throughout the hospitalization could impact the suitability for organ donation.

Review the sample of donor records to confirm that the OPO completed a physical examination and medical record review as a part of its evaluation for organ suitability. Ensure that all findings were documented and considered in the determination to proceed with donation.

Z175

(Standard) **§486.344(b)(5) Obtain the potential donor's vital signs and perform all pertinent tests.**

Interpretive Guidelines §486.344(b)(5)

The OPO must have written protocols for the required laboratory and other clinical testing required per organ to enable the OPO to make a determination on donor suitability. (See §486.344(a))

Review the sample of donor records to confirm that the potential donor's vital signs (e.g., temperature, oxygen saturation, blood pressure, heart rate, respiratory rate) were obtained during the evaluation and additional testing as required by OPO protocol was performed and utilized in the evaluation process.

§486.344(c) Testing. The OPO must do the following:

Z176

(Standard) **§486.344(c)(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.**

Interpretive Guidelines §486.344(c)(1)

The goals of pre-transplant infectious disease screening are:

- a) To identify conditions and possible conditions which assess the risk of disease transmission from the potential donor;
- b) To identify and treat active infection pre-transplant; and
- c) To define the level of infection risk in order to determine strategies for preventing or reducing post-transplant infection in recipients.

The timeframe for deceased donor evaluation is typically hours. Because of the short timeframe, there is a possibility that certain infections, such as HIV, HBV, and/or HCV, may be present at an early stage, prior to the ability of an assay to detect the infection. Thus, considerable weight must be placed on the donor's social and medical history in identifying potential risks that might not be reflected in blood testing.

Also, certain infections (e.g., donor bacteremia) may come to light only after the transplant has been performed.

The OPO must have arrangements in place to perform the necessary screening and testing for infectious diseases on a 24/7 basis. The arrangements must be with a Clinical Laboratory Improvement Amendments (CLIA) approved laboratory willing to perform STAT testing. See §486.344 (c)(2).

OPTN Rules Policy Number 2.2.3.2 states, “All potential donors are to be tested by use of a serological screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (Anti-HIV-1 and Anti-HIV-2).

If the sample is qualified, the screening test for HIV is negative, and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary.”

The OPO must develop and implement procedures for the types and the number of tests that will be performed for HIV, HBV and HCV using the FDA’s most sensitive approved test available, for potential donors who:

- a) Test positive on the initial HIV, HBV, and/or HCV assay;
- b) Received transfusions during the current hospitalization and for whom there is insufficient pre-transfusion blood to perform an initial HIV, HBV, and/or HCV screening test; (donors with only a hemodiluted sample available for testing are considered “increased risk.”)

or

- c) Have a social history that reveals increased risk.

The OPO must make full disclosure of the results of all HIV, HBV, and HCV screening tests and subsequent confirmation tests with relevant parties to include transplant surgeons, eye banks and tissue banks. This disclosure is crucial to enable the transplant surgeon to request additional testing of the donor and/or to allow the potential transplant recipient to give informed consent for transplantation.

Review the OPO policies for infectious disease testing to ensure that they are consistent with current standards of practice (e.g., HIV, HBV, and HCV). Verify in the sample of donor records that the OPO follows its policies for testing.

If the OPO makes print screen copies of laboratory results, including blood typing results, from the donor hospital, those copies should be appropriately identified for inclusion in the donor record with the patient name, medical record number and the date of the test.

Z177

(Standard) §486.344(c)(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.

Interpretive Guidelines §486.344(c)(2)

The OPO may accomplish laboratory testing in one of three ways.

- a) The hospital laboratory of the donor hospital;
- b) An agreement with an off-site laboratory;
- c) Point of Care Testing (POCT); and/or

Verify through the Regional CLIA staff that all laboratories performing tests for the OPO are appropriately CLIA certified. Ensure that if the OPO uses POCT (as identified in donor records) the testing is performed by an OPO staff member who has received training from laboratory personnel.

Z178

(Standard) **§486.344(c)(3) Ensure that the potential donor’s blood is typed using two separate blood samples.**

Interpretive Guidelines §486.344(c)(3)

Verify through the sample of donor records that two distinct samples of blood (e.g., during current patient admission and/or OPO evaluation) were collected from the donor at two different times and submitted as separate specimens for ABO blood typing. If one test was already performed by the hospital, then the OPO need only perform one additional test. “Split samples” (that is, submitting two specimens from a common sample derived from a single blood sample collection) do not meet this requirement.

Z179

(Standard) **§486.344(c)(4) Document potential donor’s record with all test results, including blood type, before organ recovery.**

Interpretive Guidelines §488.344 (c) (4)

Review the sample of donor records to confirm that the results of all tests ordered or performed by the OPO during its evaluation for donor suitability are included in the donor record. The documentation may be in the form of actual laboratory or test reports or the results may be documented in narrative in the OPO Coordinator notes.

Z180

(Standard) **§486.344(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.

Interpretive Guidelines §486.344(d)(1)

The OPO should have a written agreement or Memorandum of Understanding (MOU) in place with every Medicare certified transplant program in its donation service area (separate from its agreement with the hospital portion of the transplant program). These documents should describe the type of collaboration that will occur between the two entities on an on-going basis as well as protocols for any assistance the transplant program will provide for donor management and organ recovery. Protocols should be reviewed annually by the OPO and the transplant hospitals to ensure they maximize organ donation and transplantation.

Z181

§486.344(d)(2) The protocol must ensure that:

(Standard) **§486.344(d)(2) (i) The OPO is responsible for two separate determinations of the donor's blood type;**

Interpretive Guidelines §486.344(d)(2)(i)

See § 486.344(c)(3)

Z182

(Standard) **§486.344(d)(2)(ii) If the *identify (sic) 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; (*identify is a misprint in the regulation text and should be identity.)**

Interpretive Guidelines §486.344(d)(2)(ii)

The OPO must have policies in place for compliance with OPTN requirements that, in cases where the recipient is known, two separate persons must compare the blood type of the donor and the blood type of the recipient. At least one verification must be performed by an OPO staff person.

Z183

(Standard) **§486.344(d)(2)(iii) Documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.**

Interpretive Guidelines §486.344(d)(2)(iii)

Review the sample of the donor records to confirm that the OPO forwarded documentation of the donor blood type to the transplant hospital with the organ. This documentation should use an assigned identification number in lieu of the donor's name.

Z184

(Standard) **§486.344(d)(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.**

Interpretive Guidelines §486.344(d)(3)

See §486.344(d)(1)

Z185

(Standard) **§486.344(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.

Interpretive Guidelines §486.344(e)

In most instances, the OPO will have information about the intended recipient prior to organ recovery. Review the sample of donor records for a copy of the UNET match run showing the organ recipient's identification number, blood type and ranking in relation to other suitable candidates. If the recipient has not yet been identified, the OPO cannot obtain such documentation.

Z186

(Standard) **§486.344(f) *Donation after cardiac death.***
If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:

Interpretive Guidelines §486.344(f)

If it is the OPO's policy to recover DCD organs, it must have written protocols specifically for the evaluation of the donor, management of the organs, and recovery of the organs for DCD donors as these procedures may need to be carried out somewhat differently from those utilized with brain death donation. These protocols should clearly delineate how the OPO will work with the donor's hospital to maintain the donor until recovery.

Z187

(Standard) **§486.344(f)(1) *Criteria for evaluating patients for donation after cardiac death;***

Interpretive Guidelines §486.344(f)(1)

The criteria for the evaluation of organ suitability for DCD donors is the same as the evaluation of brain death donors. However there is a need for additional evaluation of organ suitability in the operating room post-extubation for the DCD donor. The OPO protocols must address what evaluations will be done during this period (from extubation to declaration of death) and at what frequency.

The OPO should include documentation in its donor record of WIT; and the OPO should include documentation in the DCD donor records of declaration of death in accordance with State and local laws.

Z188

(Standard) **§486.344(f)(2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;**

Interpretive Guidelines §486.344(f)(2)

Once informed donation consent is obtained, or in the case of first person consent, the OPO should work in collaboration with the donor hospital staff to prepare the family or the legally authorized representative for withdrawal of support and honor the family's or the legally authorized representative's desire to be included as much as possible consistent with hospital policies and protocols.

The OPO must have written protocols for its collaboration with the donor hospital staff regarding withdrawal of life support including clear directives as to the responsibilities of the donor hospital staff and the OPO staff in the period of time between extubation and declaration of death. The protocol should state that recovery personnel (surgeons and other recovery practitioners) may enter the operating room to prep and drape the donor, but then must leave the operating room until declaration of death. OPO personnel may be in the operating room prior to the actual recovery pursuant to OPTN policy 2.1 and 2.3 which requires that they maintain complete information on any and all organs recovered.

Z189

(Standard) **§486.344(f)(3) Use of medications and interventions not related to withdrawal of support;**

Interpretive Guidelines §486.344(f)(3)

Medications and interventions may be used to maintain perfusion of organs until the time of transplant. The OPO must have written protocols on the types of drugs that may be used, the dosages and frequency of administration, the persons who may administer the drugs and collaboration with the hospital staff on the administration of medications. The protocol should be consistent with current standards of practice and should include those situations that would require notification of the OPO medical director.

Review the sample of donor records to verify that the OPO followed its approved protocols for these administrations.

Z190

(Standard) **§486.344(f)(4) Involvement of family members prior to organ recovery;**

Interpretive Guidelines §486.344(f)(4)

The OPO must have written protocols for its involvement with families (either first person consent or consent by next of kin or legally authorized representative) prior to the organ recovery. The protocol should indicate that the OPO is not involved in the family's or the legally authorized representative's decision to withdraw life support. Throughout the informed consent process the OPO should work in tandem with the donor hospital staff to support the family or the legally authorized representative by allowing them the opportunity to ask questions and to make decisions such as when the withdrawal will occur, who will be present for the withdrawal and whether there are any specific needs or requests by the family that may be accommodated by the OPO.

Z191

(Standard) **§486.344(f)(5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.**

Interpretive Guidelines §486.344(f)(5)

The OPO staff cannot make a death pronouncement. The person making the declaration must be a person authorized to do so by the donor hospital and applicable State laws. The declaration must be made in conformance with State laws and the OPO must include a copy of the declaration in the donor record. The OPO must have written protocols that discuss the wait time between declaration and the beginning of recovery (consistent with current expert recommendations).

Review the sample of DCD donor records to verify that the OPO followed its protocols.

Z192

(Standard) **§486.344(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.**

Interpretive Guidelines §486.344(g)

If the OPO is a member in good standing with the OPTN (per the CMS OPO Database report) then this requirement is met.

Z193

(Standard) **§486.344(h) *Organ placement.* The OPO must develop and implement a protocol to maximize placement of organs for transplantation.**

Interpretive Guidelines §486.344(h)

As timing is crucial to the donation process, the OPO written protocols must ensure there is no unnecessary delay of the process from the time that consent is received or confirmed for organ donation to the time of transport.

The components of the protocol should include as a minimum, timeliness for entering information into UNET, responsibilities of each staff member throughout the process,

timeframes for each process and the documentation that is required to verify that each process was completed.

Z194

(Condition) **§486.346 Condition: Organ preparation and transport.**

Z195

(Standard) **§486.346(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.**

Interpretive Guidelines §486.346(a)

See §486.344(c)

Z196

(Standard) **§486.346(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.**

Interpretive Guidelines §486.346(b)

Review the sample of donor records to verify OPO documentation, consistent with OPTN policy, that the following information was transported with each organ:

- (a) ABO typing source documents;
- (b) Serology results;
- (c) Medical/social history form;
- (d) Donor evaluation (documentation that donor met the OPO donation criteria);
- (e) Records of donor management (monitoring, drug administration, testing etc. done by the OPO from the time of death to recovery);
- (f) Copy of signed informed consent form or documentation of first person consent;
- (g) Documentation of organ quality (size, appearance, etc).

The records must include a notation that all the information that was sent with the organ was confirmed by two individuals. One of the individuals must be an OPO employee.

These activities should also be completed in those cases where an organ is recovered and transplanted within the same hospital.

Z197

(Standard) **§486.346(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.**

Interpretive Guidelines §486.346(c)

The OPO should develop its written protocols for packaging, labeling, handling and shipping organs and the protocols should be consistent with OPTN rule 5.0 Standardized Packaging and Transporting of Organ and Tissue Typing Materials.

The protocols must also require that an OPO staff member verify in writing that the ABO indicated on the container label and the donor information documents being sent with the organ are accurate. A second person, other than the person originally performing verification of the labeling and documentation requirements, must also verify their accuracy in writing.

Review the sample of donor records to verify that the OPO has documentation to confirm that this double confirmation occurred and was documented.

Z198

(Standard) **§486.346(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.**

Interpretive Guidelines §486.346(d)

See §486.346(c)

Z199

(Condition) **§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.

Interpretive Guidelines §486.348

A focus on continual improvement of procedures, processes, responsibilities, and approaches to care and the provision of services typically involves system level changes to promote sustained improvement. A comprehensive, data-driven program should include the following:

1. A mechanism by which the OPO identifies events (such as complaints or adverse events) that need to be investigated to determine the underlying causes and:
 - develops an action plan,
 - implements the action plan,
 - evaluates the effectiveness of the plan utilizing a data driven system, and

- revises the plan or continues with the plan based on the outcomes of the evaluation.
- 2. Performance indicators that are monitored on an on-going basis. These performance indicators are measured against established benchmarks or thresholds. Results from the on-going monitoring and evaluation of these performance measures will determine whether the OPO has met its goals or require some type of corrective action plan.
- 3. A governance or leadership function (e.g., a steering committee, QA committee, and/or senior leadership) that ensures that the OPO has a QAPI program, a written QAPI plan, and appropriate resources to carry out QAPI activities. The role of this function is to establish priorities for the QAPI program, authorize performance improvement projects and action plans, and assure there is a designated, qualified QAPI program coordinator.

See also §486.348(a).

Z200

(Standard) **§486.348(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.

Interpretive Guidelines §486.348(a)

The OPO QAPI program must include a comprehensive plan that encompasses each phase of an organ procurement process (i.e., pre-organ procurement, procurement of the organ(s), and post-organ procurement).

This plan should include:

- a. QAPI Committee or organizational structure (the plan should delineate lines of communication, committee composition, roles and responsibilities);
- b. Objective measures by which the quality-related data will be collected and analyzed;
- c. Established frequencies for review of program performance and reporting to the QAPI Committee or governance/leadership structure;
- d. Designation of person or persons responsible for monitoring the QAPI program and description of their role(s) and responsibilities;
- e. Evidence of systemic approaches that are focused on changes and promote sustained improvements;

- f. Evidence of implementation of recommendations and continuing compliance for improvement;
- g. Evaluation of missed opportunities for donation identified through death record reviews;
- h. Analysis of complaints/investigations;
- i. Measurement of the level of compliance with OPTN policies;
- j. Evaluation of infectious disease;
- k. Staff training requirements (sensitivity and family interactions);
- l. Measurement of effectiveness with relationships to tissue banks and eye banks;
- m. Measurement of effectiveness with relationships to hospitals;
- n. Data collection, analysis, and reporting;
- o. Evaluation of potential for Advisory Board, Governing Body conflicts of interest;
- p. Evaluation of staff compliance with approved protocols; and
- q. Analysis of adverse events reported to the OPO by a transplant center.

Z201

(Standard) §486.348(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.

Interpretive Guidelines §486.348(b)

OPO Policies must address the components that will be included in the monthly death record review (including how records are identified for each hospital) and the timeframes for summarization of the reviews and submission of summarization to the QAPI Committee. The policies must delineate how these findings will be shared with the involved hospital/CAH.

For a sample of Medicare and Medicaid participating hospitals hospitals in the service area (meeting the above criteria) select a consecutive three (3) month period within the previous four (4) years and request the following information *for each* hospital in the sample:

- a) A list of hospital deaths each of the three months;
- b) A sample of the completed OPO reviews from each hospital in the sample each of the months; and
- c) OPO documentation for each review.

Look for evidence that death record review findings are reported to the Governing Body, corrective actions are implemented, as appropriate, and there is evidence that corrective actions are tracked for compliance (consistent with §486.324 (e)).

Z202

(Standard) §486.348(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.

Interpretive Guidelines §486.348(c)(1)

The OPO policies should address as a minimum:

- a) Procedure for OPO reporting of adverse events to OPTN/ /CMS/ public health authorities (as indicated) including the hierarchy for reporting in accordance with State requirements and applicable eye bank or tissue bank if the eyes or tissues were donated by the donor;
- b) The required time frame for reporting, investigating and analyzing adverse events;
- c) The timeframes for corrective action following the analysis and recommendations; and
- d) Use of analysis in prevention of future adverse events.

Z203

(Standard) §486.348(c)(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.**

Interpretive Guidelines §486.348(c)(2)

Request the OPO's log of all adverse events occurring over the current re-certification cycle. Verify that the program followed its written procedures for timely investigation, reporting and analysis and utilized the findings to effect changes in its operation as indicated.

During the review of donor records, be alert to any adverse event incidents. Verify that these events were investigated promptly and appropriate follow-up action was taken including OPO policy changes, if indicated.

INTERIM FINAL

State Operations Manual

Chapter 2 - The Certification Process

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Organ Procurement Organizations

2810 - Organ Procurement Organizations (OPOs) – Citations - Statutory Authority

(Rev.)

Section §1138 (b)(1) of the Social Security Act (the Act) authorizes the Secretary to provide payment under Medicare or Medicaid to hospitals/CAHs and transplant centers for the cost of organs procured from organ procurement organizations (OPOs) only if the organization:

- *Is a qualified OPO operating under a grant made under §371(a) of the Public Health Service Act (PHSA), or has been certified or recertified by the Secretary within the previous four years as meeting the standards to be a qualified OPO;*
- *Meets applicable requirements of Medicare or Medicaid for OPOs;*
- *Meets performance-related standards prescribed by the Secretary;*
- *Is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) designated by the Secretary pursuant to §372 of the PHSA. (The United Network for Organ Sharing (UNOS) operates the OPTN under a contract with the PHS);*
- *Allocates organs, within its service area and nationally, in accordance with medical criteria and the policies of the OPTN; and*
- *Is designated or re-designated by the Secretary as an OPO under §1138 of the Act.*

To be designated as the OPO for a service area, an organization must at the time of application and throughout the period of designation meet these statutory requirements. Further, the Act requires that the Secretary may not designate more than one OPO for each service area, as described in §371 (b)(1)(E) of the PHSA and §1138 (b)(2) of the Act.

2810.1 – Definitions

(Rev.)

***Certification** means a CMS determination that an OPO meets the requirements for certification at 42 CFR 486.303.*

***Decertification** means a CMS determination that an OPO no longer meets the requirements for certification at 42 CFR 486.303.*

***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.*

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

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 beneficiaries for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

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 is non-compliant with one or more conditions for coverage and this has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

2811 - OPO Requirements for Certification

(Rev.)

42 CFR 486.303 details the following requirements that an OPO must meet in order to be certified by CMS. A qualified OPO:

1. 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;
2. Be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986;
3. Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals;
4. Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under Title XVIII for the procurement of kidneys;
5. Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005;
6. Have procedures to obtain payment for non-renal organs provided to transplant centers;
7. Agree to enter into an agreement with any hospital or CAH in the OPO's service area, including a transplant hospital that requests an agreement;
8. Meet or have met the conditions for coverage for OPOs, including both the outcome measures and the process performance measures; and
9. Meet the provisions of Titles XI, XVIII, and XIX of the Act, section 371(b) of the PHSA, and any other applicable Federal regulations.

2812 – OPO Designation Requirements

(Rev.)

An OPO must be designated by CMS and must enter into an agreement with CMS in order for the OPO to be reimbursed under Medicare and Medicaid for the costs of organ procurement.

42 CFR 486.306(b) and (c) details the requirements that an OPO must meet for service area designation, service area location, and characteristics.

42 CFR 486.308 specifies that CMS designates only one OPO per service area and that the service area is only **open for competition** after the OPO designated for that area is de-certified and all administrative appeals have been completed under §486.314, or the OPO voluntarily withdraws from the program. A designated OPO may only change its service area boundaries as a result of a merger or consolidation with another OPO after advance approval by CMS as noted in §486.310 (a). An OPO must compete for an entire service area according to §486.316(c)(3).

An OPO is normally designated for a 4-year agreement cycle. In the case of a voluntary termination of its agreement, CMS will open the service area for competition to fill the remaining term of the 4-year agreement cycle. A designation period may be longer than the 4-year agreement cycle in instances where CMS requires a longer period of time to select a successor to an OPO that has been de-certified or has voluntarily terminated.

2812.2 - Waivers

(Rev.)

A certified hospital/CAH must enter into an agreement only with the OPO designated for the service area in which the hospital/CAH is located, unless CMS has granted the hospital/CAH a **waiver** under §486.308(e). A hospital/CAH may request and CMS may grant a waiver allowing the hospital to have an agreement with a designated OPO outside of its service area. To qualify for a waiver, the hospital must submit data to CMS as detailed in **42 CFR 486.308(e)(1) and (2)**. In making a determination on waiver requests, CMS considers the requirement under **42 CFR 486.308 (f)(1)-(4)**:

- Cost effectiveness;
- Improvements in quality;
- Changes in a hospital's designated OPO due to changes in the definition of metropolitan statistical areas, if applicable; and
- The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

A hospital/CAH may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If the waiver is denied by CMS, the hospital/CAH must enter into an agreement with the OPO designated for its service area within 30 days of notification of the final determination as noted in §486.308(g).

2812.3 - Open Competition

(Rev.)

To assure that the **CMS** RO is not designating more than one OPO per service area, it should plot the proposed service areas of all applicants prior to taking any certification action. Under the statute, it is critical that the service areas of OPOs not overlap. If an

applicant designates a service area that crosses **CMS** RO boundaries, the physical location of the OPO's main office determines which **CMS** RO controls the review of the application. In these situations, coordinate certification action between the appropriate **CMS** RO(s).

If there is no competition within a given service area and the applicant meets the statutory and regulatory requirements, the **CMS** RO sends the organization the Model OPO Approval Letter (see Exhibit 172). If the OPO is not hospital-based, assign a provider number with an alpha "P" in the third position of the provider number. For example, the **CMS** RO inputs the information 21P001 into the Online Survey Certification and Reporting System/Online Data Input and Edit (OSCAR/ODIE) systems.

NOTE: If the OPO is hospital-based, the hospital's Fiscal Intermediary/Medicare Administrative Contractor will service the OPO and no special provider number is needed.

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 §486.316 (d).

2812.4 - Criteria to Compete: (Rev.)

In order for an OPO to compete for an open service area, it must meet the following specific criteria:

- *The criteria in §486.316(a);*
- *A donation rate and yield outcome rate measure that is at or above 100 per cent of the mean national rate averaged over the 4 years of the re-certification cycle; A donation rate at least 15 percentage points above the donation rate of the OPO currently designated for the service area for which it is competing; and compete for the entire service area.*

An OPO in competition for an open service area must submit the following information:

- *Data and information that describes the barriers (e.g., geographical, cultural, religious, financial) in its service area;*
- *How the barriers affected organ donation;*
- *What steps the OPO took to overcome the barriers; and*
The results of the OPO's actions to overcome the barriers.

2812.5 - Criteria for Selection of an OPO in an Open Service Area: (Rev.)

CMS designation for an open service area is based on the following criteria:

- *Performance on the outcome measures detailed at 42 CFR 486.318;*

- *Relative success in meeting the process performance measures and compliance with the other conditions at **42 CFR 486.320** through **42 CFR 486.348**;*
- *Contiguity to the open service area; and*
- *Success in identifying and overcoming barriers (e.g., geographical, cultural, religious, financial) to donation within its current service area and the relevance of those barriers to barriers in the open service area.*

2813 - Re-Certification Cycle (42 CFR 486.309)

(Rev.)

An OPO is considered re-certified if it meets the standards of a qualified OPO within the 4-year period beginning from August 1, 2006 through July 31, 2010; August 1, 2010 through July 31, 2014; August 1, 2014 through July 31, 2018; August 1, 2018 through July 31, 2022; and onwards.

An OPO is surveyed once every four years and its service area is not opened for competition when the OPO:

- *Meets all 3 outcome measure requirements at **42 CFR 486.318**; and*
- *Has been shown by the results of a survey to be in compliance with the certification requirements at **42 CFR 486.303**, including the conditions for coverage at **42 CFR 486.320 through 486.348**.*

2814 - Change in Control/Ownership or Service Area (42 CFR 486.310)

(Rev.)

*The applicable CMS RO must be notified **before** a designated OPO implements a change in either ownership or control or in its service area. The OPO must provide information to the CMS RO that is specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation the CMS RO determines to be necessary for designation. A designated OPO considering a change in its service area must obtain prior CMS RO approval.*

*If an OPO's change of ownership or control is of such an extent that it no longer meets the requirements for designation as an OPO, as determined on **Form CMS-576**, CMS may de-certify the OPO and designate its service area an open area. The OPO may appeal such a de-certification under §486.314. The service area is not opened for competition until the conclusion of the administrative appeals process. The OPO must submit a revised **Form CMS-855** (Medicare Enrollment Application) to the FI/MAC with any change of control or ownership.*

*** See 2812.3 Open Competition**

When the CMS RO receives notification of a prospective change in control or ownership for a designated OPO, the CMS RO must determine, based upon the documents submitted, that the operation of the OPO will continue uninterrupted and continue to

satisfy Medicare and Medicaid requirements during and following the changeover of ownership or control. The CMS RO will review all the documents submitted by the OPO, including its responses to the elements on Form CMS-576. If the RO approves the CHOW/change of control and the OPO proceeds with change of ownership a new CMS Form 576 must be signed by the person designated by the governing body to be responsible for operations. The OPO should show evidence of transition planning to ensure continuity. Confirm with the Fiscal Intermediary/MAC that the OPO has submitted a revised CMS Form-855 and that the information has been accepted.

De-certification (42 CFR 486.312)

2815 - De-certification and Competition:

(Rev.)

*If an OPO does not meet all 3 outcome measures as outlined in **42 CFR 486.318** or if it has been shown by survey to be out of compliance with the requirements described in **42 CFR 486.320 through 486.348**, the OPO is de-certified. If the OPO does not appeal the de-certification, or if the OPO appeals and the reconsideration official and the CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The OPO that has been de-certified is not permitted to compete for its open area or any other open service area.*

2817 - Voluntary Termination of an Agreement:

(Rev.)

The OPO must submit to the applicable CMS RO a written notice of its intention to terminate its agreement and include a stated proposed effective date. CMS has the option to agree to the proposed effective date or set another termination date no later than six months from the OPO requested date, or set a different date less than six months after the proposed effective date if it determines a different date would not disrupt services in that area. If CMS determines that the OPO has ceased providing services to its donation service area, then that cessation of services is considered a voluntary termination by the OPO, with the effective date to be determined by CMS.

*After approval from CMS of the date for voluntary termination, the OPO must provide public notice of its voluntary termination in local newspapers within three (3) business days from the approval date. The notice should include the date the OPO will cease operations and services, a list of hospitals and CAHs in the OPOs service area, and the OPO telephone contact numbers for inquiries. The OPO must provide the CMS RO with copies of each public notice within **seven (7) business days** of CMS's approval of voluntary termination. No further payments under Title XVIII or XIX of the Act will be made with respect to costs attributable to the OPO on or after the effective date of de-certification.*

** See also **2812.3 Open Competition***

2818 - Involuntary Termination and Non-renewal of an Agreement:

(Rev.)

*During the term of an OPO agreement, CMS may terminate an agreement with an OPO at any time the OPO no longer meets the requirements for certification at **42 CFR 486.303**. Additionally, 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. If CMS determines that the OPO is out of compliance with one or more Conditions for Coverage and the OPO does not implement an approved plan of correction that re-establishes compliance prior to the end of a designated period of time, CMS will begin the process of de-certification. CMS may also immediately terminate an agreement in cases of urgent need as defined in **42 CFR 486.302**. CMS will decertify the OPO as of the effective date of the involuntary termination or as of the ending date of the agreement in the case of non-renewals.*

** See also **2812.3 Open Competition***

*Except in cases of urgent need, CMS will give the OPO written notice of the intent to de-certify at least **90 days** before the effective date of de-certification. CMS provides public notice of the effective date of de-certification in local newspapers in the OPO's service area. The notice will state the reasons for de-certification and the effective date. No further payments under Title XVIII or XIX of the Act will be made with respect to costs attributable to the OPO on or after the effective date of the de-certification. In cases of urgent need, follow the procedures found in **Appendix Q: Immediate Jeopardy**.*

2819 Appeals (§486.314)

(Rev.)

Involuntary Termination/Non-Renewal of Agreement:

An OPO may appeal an involuntary termination or non-renewal of an agreement on substantive and procedural grounds. CMS sends a notice of initial de-certification determination to the OPO which contains the reasons for the determination, the effect of the determination, and the OPO's right to seek reconsideration. The notice letter informing the OPO of de-certification and impending termination must include the appropriate appeal rights as well as instructions on how to file a request for reconsideration.

Reconsideration of a De-certification:

*An OPO has **15 business days** from receipt of CMS' notice of de-certification to seek reconsideration from CMS if it is dissatisfied with the de-certification determination. The OPO reconsideration request must state the issues or findings of fact with which the OPO disagrees, the reasons for disagreement and factual support for each finding with which they disagree, and the reasons for disagreement. The OPO may submit factual support for each findings with which they disagree as well as additional information and arguments as to why it should not be decertified. CMS then evaluates the submitted information to determine if the de-certification decision is upheld or reversed. An OPO*

must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If the OPO does not request reconsideration from CMS, or fails to submit its request timely to CMS, the OPO has no right to further administrative review and the de-certification is final.

CMS Reconsideration Determination:

*A written reconsidered determination is made by CMS within **10 business days** of the request for reconsideration. This determination will affirm, reverse or modify the initial de-certification determination and the findings on which it was based and will determine whether the submitted documentation and information was sufficient to support a change in the initial decision. If the determination decision is reversed or modified, CMS notifies the OPO in writing with a revised Form **CMS-2567** to reflect the revised findings. If the decision is not reversed or modified, but is affirmed, CMS notifies the OPO in writing of the decision, including what materials CMS reviewed and why the submitted documentation did not justify a reversal or modification in the initial decision to de-certify. Additionally, CMS informs the OPO that it will not be eligible to compete for the current service area or any other service area opened for competition. CMS will augment 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. If the OPO timely seeks further administrative review (hearing), CMS forwards the initial request for reconsideration and all supporting documentation to the hearing officer.*

Administrative Hearing:

*An OPO that wishes to appeal the reconsideration decision of CMS must file a written hearing request within **forty (40) business days** of the receipt of the notice of CMS reconsideration decision. If a hearing request is not submitted or received timely by CMS, than the OPO has no further right to appeal or other administrative review. The Administrative Appeal Process is handled through the Office of Medicare Hearings and Appeals.*

Administrative Record:

The administrative record consists of, but is not limited to, (1) factual findings from the survey(s) on the OPO conditions for coverage; (2) data from outcome measures; (3) rankings of OPOs based on the outcome data; and (4) correspondence between CMS and the affected OPO. The hearing officer sends the administrative record to both parties within ten (10) business days of receipt of the OPO's written request for hearing.

2820 - Outcome Measures/Data Reporting (§486.318, 486.328): NOT REVIEWED ON SITE

(Rev.)

Data measures as calculated by University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) utilizing the Scientific Registry of Transplant Recipients (SRTR) data

and OPTN reporting data are entered into the OPO database for CMS CO/RO review for regulatory compliance.

2821 - Information Management (§486.330):
(Rev.)

*The OPO is required to keep and maintain donor and transplant recipient records in a human readable and reproducible paper or electronic format for a minimum of **seven (7)** years.*

State Operations Manual

Chapter 3 - Additional Program Activities

(Rev.)

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Adverse Actions

3012.2 - Termination of Organ Procurement Organizations (OPO) *(Rev.)*

If an OPO voluntarily terminates its agreement, it must send a written notice *to the CMS RO* with the proposed effective date. The *CMS RO* approves the proposed termination date or sets a different date no later than 6 months after the proposed effective date *or sets a date less than 6 months after the proposed effective date if it determines that a different date would prevent a disruption of services to the service area.* When an OPO ceases organ procurement services in its service area, this *will be considered* a voluntary termination by the OPO. The *CMS RO* determines the effective date and notifies the OPO.

OPOs are involuntarily terminated when they fail to meet the *requirements of certification at 42 CFR 486.303, including one or more conditions for coverage (CfC) or when they are not in substantial compliance with and any other applicable Federal regulations or provisions of titles XI, XVIII, or XIX of the Social Security Act (the Act).*

The *provider agreement between the OPO and the Secretary may be involuntarily terminated at anytime during the 4-year certification cycle or at the end of a cycle may not be renewed (re-certified) for another 4 year cycle.* The *CMS RO* notifies CO, the *FI/MAC* and the Organ Procurement Transplantation Network (OPTN) that the OPO has been terminated and the *effective* date of the termination. The *CMS RO* follows the termination procedures detailed below.

3012.2A - Termination Procedures *(Rev)*

- 1. If the OPO is determined to be out of compliance with one or more CfCs, initiate termination of the provider agreement. CMS RO notifies the OPO of the pending termination date and the timeframes for submitting any additional information to support that appropriate corrections have been made and compliance achieved.*
- 2. If the OPO achieves compliance, as determined through an onsite or desk review, send Model Letter: Organ Procurement Organization Approval. (See Exhibit 172.)*
- 3. If the OPO fails to achieve compliance, send Model Letter: Organ Procurement Organization Notice of Termination. (See Exhibit 173.) The letter informs the OPO of:*

- a. *Reasons for the determination;*
 - b. The effective date of the determination;
 - c. The deficiencies cited and the requirements not met;
 - d. *The OPOs right to seek reconsideration;* and
 - e. *The timeframe for submitting additional data.*
4. Open the service area for competition. (See §2817.3 and Exhibit 175.)
 5. Publish a public notice in the newspapers.
 6. Send copies of the *public* notice with a cover letter to:
 - a. Association of Organ Procurement Organizations
1364 Beverly Road, Suite 100
McLean, VA 22101;
 - b. Current Organ Procurement and Transplantation Network (OPTN)

The current OPTN is:
UNOS
Post Office Box 2484
Richmond, VA 23225;
 - c. *CMS Central Office*
 - d. Hospitals that have a working relationship and agreements with the OPO;
 - e. Bordering OPOs;
 - f. Medicaid/Medicare State Agencies; and
 - g. *FI/MAC* of the terminated OPO.

3012.2B - Reconsideration Procedures
(Rev.)

The OPO may appeal the termination decision under 42 CFR 486.314.

The CMS RO mails notice to the OPO of a termination initial determination. The notice contains the reasons for the termination action, the effective date of the termination, and

the OPO's right to seek reconsideration. If the OPO is dissatisfied with the termination action, it has 15 business days from receipt of the notice of the termination action to submit its request in writing to the appropriate CMS RO to seek reconsideration of that determination from CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for the disagreement.

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.

The CMS RO will make a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination.

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.

3012.2C - Appeal Procedures

If the OPO submits a request for a formal hearing, the CMS RO sends a complete administrative record that includes any additional materials submitted by the OPO, and a copy of the reconsideration decision and sends the supplemental administrative record to the CMS hearing officer.

CMS will provide the hearing officer with:

- a) A copy of the CMS OPO Database report ranking of all OPO(s) utilizing the most recent data collection period, based upon compliance with the regulatory data requirements at §486.318 through §486.328.*
- b) Copies of all written correspondence between the OPO and the CMS RO relevant to the certification action under appeal;*
- c) All relevant e-mail correspondence between the OPO and the RO;*
- d) Any pertinent entries from a correspondence log if utilized; and*
- e) Relevant Survey and Certification Memoranda and guidance.*