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Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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SUBJECT: Revisions to the State Operations Manual (SOM) Appendix Y Organ Procurement Organizations

I. SUMMARY OF CHANGES: This transmittal includes revisions to the interpretive guidelines to strength surveyors' assessment of commpiance with the conditions for crtofocation for OPOs and to incorporate new regulations finalized Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization (CMS-3380-F).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: May 8, 2026
IMPLEMENTATION DATE:May 8, 2026

Or

MANUALIZATION/CLARIFICATION – EFFECTIVE/IMPLEMENTATION DATES: Not Applicable.

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix Y/Table of Contents - Part I – Survey Protocol for Organ Procurement Organizations
R	Appendix Y/Table of Contents - Part II – Survey Protocol for Organ Procurement Organizations
R	Appendix Y/Part I– Survey Protocol for Organ Procurement Organizations – I. Introduction
R	Appendix Y/Part I– Survey Protocol for Organ Procurement Organizations – II. Survey Procedures
N	Appendix Y/Part I– Survey Protocol for Organ Procurement Organizations – Survey Proceudres – Task III – Section III - Review of Protocols and Policies & Procedures
N	Appendix Y/Part I– Survey Protocol for Organ Procurement Organizations – Survey Proceudres – Task III – Section IV. Review of Donor Records

N	Appendix Y/Part I– Survey Protocol for Organ Procurement Organizations – Survey Proceudres – Task III – Section V. Review of Donor Records – 4. Family/Legally Authorized Representtive [Interview}
N	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486.302 – Definitions.
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486.303(a)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486.306(a)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486.308(d)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486.310(a)(1)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 310(a)(2)
N	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486.310(b)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 312(b)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 312(e)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 314(b)(2)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 314(b)(3)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 314(d)(1)(i)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 314(d)(1)(ii)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 314(d)(1)(iii)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 314(d)(1)(iv)
R	Appendix Y/Part II – Interpretive Guidelines for Organ Procurement Organizations - §486. 314(j)
R	Appendix Y/Part II – §486. 316(a) Re-certification of OPOs (text replaced)
R	Appendix Y/Part II – §486. 316(b) Re-certification of OPOs (text replaced)
R	Appendix Y/Part II – §486. 316(c) Re-certification of OPOs (text replaced)
N	Appendix Y/Part II – §486. 316(f) Re-certification of OPOs
N	Appendix Y/Part II – §486. 316(g) Re-certification of OPOs
R	Appendix Y/Z001- 486.318(a) deleted.
D	Appendix Y/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;
D	Appendix Y/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
D	Appendix Y/Z004-(Standard) §486.318(a)(3) The OPO data reports, averaged over the 4 years of the recertification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.
D	Appendix Y/Z005-(Standard) §486.318(a)(3)(i) The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following: (A) More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10); (B) A ratio of observed to expected yield less than 0.90; and (C) A two-sided p-value is less than 0.05.
D	Appendix Y/Z006-(Standard) §486.318(a)(3)(ii) The number of organs used for research per donor, including pancreata used for islet cell research.
D	Appendix Y/Z007-(Standard) §486.318(a)(3)(ii) The number of organs used for research per donor, including pancreata used for islet cell research.
D	Appendix Y/Z008-§486.318 (b) For OPOs operating exclusively in non-contiguous U.S. States, Commonwealths, Territories, or possessions, an OPO must meet two out of the three following outcome measures:
D	Appendix Y/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;
D	Appendix Y/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;
D	Appendix Y/Z011-(Standard) §486.318(b)(3) The OPO data reports, averaged over the 4 years of the recertification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.
D	Appendix Y/Z012-(Standard) §486.318(b)(3)(i) The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following: (A) More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10); (B) A ratio of observed to expected yield less than 0.90; and (C) A two-sided p-value is less than 0.05.
D	Appendix Y/Z013-(Standard) §486.318(b)(3)(ii) The number of or gans used for research per donor, including pancreata used for islet cell research.
D	Appendix Y/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
D	Appendix Y/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.
N	Appendix Y/Z018-(Standard) §486.318(d) An OPO is evaluated by measuring the donation rate and the organ transplantation rate in their DSA. (1) For all OPOs, except as set forth in paragraph (d)(2) of this section, for all OPOs: (i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential. (ii) The organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential…
N	Appendix Y/Z019--(Standard) §486.318(e) An OPO must demonstrate a success rate on the outcome measures in accordance with the following parameters and requirements:…
N	Appendix Y/Z020--(Standard) §486.318(f)(1) An OPO's performance on the outcome measures is based on an evaluation at least every 12 months, with the most recent 12 months of data available from the OPTN and state death certificates, beginning January 1 of the first year of the agreement cycle and ending December 31, prior to the end of the agreement cycle….
R	Appendix Y/ Z036-Interpretive Guidelines §486.320
R	Appendix Y/ Z036-Interpretive Guidelines §486.322(a)
R	Appendix Y/ Z058-Interpretive Guidelines §486.322(b)
R	Appendix Y/ Z059-Interpretive Guidelines §486.322(c)
R	Appendix Y/ Z060-Interpretive Guidelines §486.322(c)(1)(i)
R	Appendix Y/ Z061-Interpretive Guidelines §486. 322(c)(1)(ii)
R	Appendix Y/ Z085-Interpretive Guidelines §486.324(a)
R	Appendix Y/ Z089-Interpretive Guidelines §486.324(a)(4)
R	Appendix Y/ Z090-Interpretive Guidelines §486. 324(a)(5)
R	Appendix Y/ Z091-Interpretive Guidelines §486.324(a)(6)
R	Appendix Y/ Z092-Interpretive Guidelines §486.324(b)
R	Appendix Y/ Z093-Interpretive Guidelines §486.324(c)
R	Appendix Y/ Z146-Interpretive Guidelines §486.328(a)
R	Appendix Y/ Z160 Interpretive Guidelines §486.330(a)
R	Appendix Y/ Z161- §486.330(b)- (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 beneficiaries.
R	Appendix Y/ Z162-Interpretive Guidelines §486.330(c)

R	Appendix Y/ Z165-Interpretive Guidelines §486.342(a)
R	Appendix Y/ Z166-Interpretive Guidelines §486.342(b)
R	Appendix Y/ Z168-Interpretive Guidelines §486.344(a)
R	Appendix Y/ Z173 Interpretive Guidelines §486.344(b)(3)
R	Appendix Y/ Z174-Interpretive Guidelines §486.344(b)(4)
R	Appendix Y/ Z175-Interpretive Guidelines §486.344(b)(5)
R	Appendix Y/ Z176-Interpretive Guidelines §486.344(c)(1)
R	Appendix Y/ Z177-Interpretive Guidelines §486.344(c)(2)
R	Appendix Y/ Z180-Interpretive Guidelines §486.344(d)(1)
R	Appendix Y/ Z182-Interpretive Guidelines §486.344(d)(2)(ii)
R	Appendix Y/ Z187-Interpretive Guidelines §486.344(f)(1)
R	Appendix Y/ Z188-Interpretive Guidelines §486.344(f)(2)
R	Appendix Y/ Z189-Interpretive Guidelines §486.344(f)(3)
R	Appendix Y/ Z190-Interpretive Guidelines §486.344(f)(4)
R	Appendix Y/ Z191-Interpretive Guidelines §486.344(f)(5)
R	Appendix Y/ Z192-Interpretive Guidelines §486.344(g)
R	Appendix Y/ Z195-Interpretive Guidelines §486.346(a)
R	Appendix Y/ Z196-Interpretive Guidelines §486.346(b)
R	Appendix Y/ Z197-Interpretive Guidelines §486.346(c)
R	Appendix Y/ Z200-Interpretive Guidelines §486.348(a)
R	Appendix Y/ Z201-Interpretive Guidelines §486.348(b)
N	Appendix Y/ Z204-Interpretive Guidelines §486.348(d)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.
Or
Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Appendix Y – Organ Procurement Organization (OPO) Interpretive Guidance
Table of Contents
(Rev. 241; Issued: 05-08-26)

PART I – Survey Protocol for Organ Procurement Organizations

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

I. Introduction

The Organ Procurement Organization (OPO) *statutory provisions are set forth in S*ection 1138(b) of the Social Security Act (the Act). *Medicare participating OPOs are* required to *meet the Federal Requirements for Certification and Designation and* be in compliance with the Federal Conditions for Coverage (CfCs) set forth in 42 CFR Part 486, Subpart G. *We note that many of the Centers for Medicare and Medicaid Services (CMS) regulations are dependent on OPTN policies and bylaws. It can be helpful for surveyors to review current policies and bylaws for specific sections where noted.* The purpose of the survey process is to determine whether the OPO meets all applicable statutory and regulatory requirements. The survey is unannounced; no prior notice shall be given to the OPO. *Determination of compliance with Federal requirements is accomplished through both:*

- *an off-site review of the Final OPO Aggregate Performance Report (i.e., the final report in the 4-year survey cycle, which ends the year recertification surveys are conducted, e.g., the 2026 survey cycle covers performance during 2022-2026) to identify tier status; and*
- *an on-site survey using observation, interview and document/record review to assess compliance with the 'non-measure' CfCs*[1].

The general survey and certification requirements and authorities are located at 42 CFR Part *4*88, Subpart A and policies regarding survey and certification activities are addressed in the State Operations Manual (SOM), *Sections 2810 through 2821, and Appendix Y Organ Procurement Organization Interpretive Guidelines (IGs).*

This survey protocol presents instructions to surveyors by the CMS that promote consistency in the survey process and provide the surveyors with information to assist in their review of an OPO's compliance with Federal requirements.

The *IGs* contain authoritative interpretations *and* clarifications of the regulatory requirements*,* and examples to support the *interpretations of* regulatory text. The IGs are an aid and do not replace or supersede the law or regulations, and therefore, are not used as the basis for a deficiency citation.

II. Survey Procedures

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The OPO survey protocol encompasses a full review of all the OPO CfCs and is *used* for all re-certification surveys. The CMS *Federal surveyor(s)* conduct recertification

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[1] *§486.318 Condition: Outcome Measures is used for determining tier status; 'non-measure' CfCs refers to all other CfCs found in 486, i.e. 486.301-316, and 320-360.*

surveys every four years.

The Components of a Basic Survey:

Task One - Pre-Survey Preparation
Task Two - Entrance Conference
Task Three – Information Gathering
Task Four – Review of the Quality Assessment and Performance Improvement (QAPI) Program
Task Five – Preliminary Decision-making and Analysis of Findings
Task Six – Exit *Conference*

Task One—Pre-Survey Preparation
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General Objective

The objective of this task is to review information about the OPO in order to identify areas of potential focus during the survey, determine the size and composition of the survey team, and develop a preliminary survey plan.

Prior to each survey:

- Review the OPO's previous CMS-2567 *(Statement of Deficiencies and Plan of Correction)* forms;
- Review any complaint information since the OPO's *last recertification* survey;
- Verify the OPO's *physical* address;
- Review for any changes in ownership or control since the last certification survey;
- Review a list of all the counties *and any CMS-approved or pending hospital waivers* in the OPO's Donation Service Area (DSA) *(**Note:** This is published in the annual public OPO performance report on the Quality, Certification and Oversight Reports (QCOR))*;
- Review the most recent *performance outcome* report created by CMS.
- *Prior to going on-site, confirm with HRSA that the OPO is submitting data to the OPTN and SRTR as required by OPTN by-laws for the listed data elements §486.328 (a) (1)-(9) above. (Contact: OPTNMemberCompliance@hrsa.gov). CMS will consider a submission rate of 95 percent and above to meet the requirements of this standard.*

Survey Team Size and Composition:

Surveyors must successfully complete the CMS OPO Surveyor Training Course and any additional training specified by CMS (e.g., associated pre-requisites) before they serve on an OPO survey team (except as a trainee). Surveyor trainees may accompany the survey team under the supervision of an experienced surveyor. Each OPO survey team

should include at least one registered nurse (RN) with OPO survey experience. The CMS Location decides the size of the team. OPO surveys will vary in duration, dependent on the size of the survey team. The survey team size will vary depending on the size and characteristics of the OPO. The following factors may influence team size:

1. *The pattern of past deficiencies or complaints (e.g., more surveyors to review additional documents or conduct additional site visits/interviews);*
2. *Whether surveyor trainees are to accompany the surveyor.*

Task Two – Entrance Conference
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Objective:

The entrance conference should be brief and should begin as soon as possible following the surveyor*s'* entrance to the facility.

Include the following activities in the entrance conference:

- Introduce the survey team members;
- Explain the purpose of the survey;
- *Describe the methods and processes for* the survey, includ*ing* a review of *records (e.g.,* donor records, policies and procedures*, and various contracts and agreements),* and interviews with *a variety of key persons, including but not limited to, OPO* staff*, hospital personnel and board members;*
- Provide a general timeframe for the length of the survey and provide a projected date and time for the exit interview;
- Present a previously prepared list of documents that will be requested during the survey (see below for a list of the materials to be requested). Ensure that the OPO staff *understand* the request; and
- Request a designated, secure place to work*, with* access to necessary *equipment (such as a copier), paper and electronic records (such as medical records, staff training and education records, hospital referrals management and allocation records) and facility areas where tissue is prepared and organs are managed*.
- *Request the OPO to identify a point of contact, who is trained on the electronic record system and will assist with the medical record reviews.*

Material to be requested from the OPO during the entrance conference:

a. Map of DSA (including counties);
b. List of ***all*** donor hospitals and critical access hospitals (CAHs) located in *the* DSA *that have the potential to admit patients who may become organ donors and are therefore responsible for identifying and referring potential donors to the designated OPO.*

c. *Approved and pending hospital* waivers;
d. OPO organizational chart;
e. Evidence of non-profit status, *currently valid Internal Revenue Service* tax exemption *certificate* under section 501(c)*(3)* of the Internal Revenue Code of 1986;
f. Information about any changes of ownership or control *(CMS approval letter) under 42 CFR 486.310,* if applicable;
g. List of all current OPO staff members and their titles (if not included in the OPO organizational chart requested above). *(Once personnel have been selected for interview, personnel records and job descriptions will be requested, as noted below under Task 3, Section E)*;
h. Advisory board by-laws/members *with their* credentials *and* meeting minutes from the previous four (4) years;
i. Governing body bylaws/members *with their* credentials *and* meeting minutes from the previous four (4) years);
j. The OPO's conflict of interest policy;
k. Donor evaluation and management protocols;
l. Donor after cardiac death (DCD) protocols (if applicable);
m. A list of *all referrals that were evaluated for donation suitability for the previous* four (4) years. T*his list should include the following information for each referral:* brain death *or DCD*, *and final disposition of the donation process, including organ recovery or a reason for cessation of procurement. Reason(s) for cessation could include signs of life or other clinical indicators of unsuitability for donation. This list will be used to select donor records for review.*
n. Death Record Report *L*og/*list* of *three* hospital*s*/CAH*s* for *a selection of* three (3) months *(one within the past 12 months) since the last recertification survey to ensure that eligible deaths were assessed for potential procurement*;
o. Quality Assessment and Performance Improvement (QAPI) plan/committee meeting minutes/reports *from the* previous four (4) years;
p. List of *all* hospitals in the DSA *that are equipped for procurement (ventilator and operating room capacity)*; and
q. Copy of Medical Director *job description;*
r. Request the data reports that have been provided to the transplant hospitals by the OPO since the last re-certification visit.

Task *Three* – *Information Gathering*
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

Administrative Review

The OPO must establish written agreements, protocols, and policies and procedures as noted below.

I. Agreements

A. Hospitals/CAHs:
An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and *CAHs* in its *DSA(s)* that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO.

Request the written agreements for a percentage of the hospitals/CAHs in the OPO's DSA. The surveyor should select the following sample size for the agreements to be reviewed:
Less than 100 hospitals in the service area .....Select 10 percent at random;
More than 100 hospitals in the service area.....Select 5 percent at random.

Review the agreements in the sample to ensure that they specify the responsibilities of both the OPO and the hospital/CAH and describe how they will work collaboratively**.**

B. Agreements with Tissue Banks and Eye Banks:
The OPO *must* have written arrangements (*i.e.*, a signed agreement or Memorandum of Understanding (MOU)) with each identified tissue bank and eye bank that have agreements with hospitals and CAHs *with which the* OPO *has an agreement*. These arrangements *must* 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 with it. In those cases where the OPO is *a* designated tissue bank for a hospital, it is not necessary that the OPO and tissue bank have a written agreement or MOU with itself. *For more information see tag Z195.*

II. Records of Advisory and Governing *Body Structure and Activities*

A. Advisory Board:

Review the following:

- The bylaws to ensure that the advisory board is granted authority as described in §486.324(b) and that they address potential conflicts of interest, length of terms, and criteria for selecting and removing members of the advisory board;
- The membership *and credentials* of the advisory board *members* to ensure it is comprised of individuals listed in §§486.324(a)(1)-(6); and
- The minutes to ensure designated membership *and participation*.

B. Governing *Body*:

Review the following:

- The meeting minutes to verify the governing *body's* oversight activities regarding the development and implementation of policies/procedures, the

annual budget, fiscal concerns, the QAPI program, including agreements for such services;

- *Documentation t*hat the OPO governing body has appointed an individual in writing to be responsible for the day-to-day operation of the OPO; and
- The OPO's procedures to address potential conflicts of interest for the governing body.

III.Review of Protocols and Policies & Procedures

*(**Note:** The OPO may not have a separate policy/procedure/protocol for each requirement but should be able to tell the surveyor in which policy/procedure/protocol the requirement is located.)*

This *section* covers *some of the* requirements pertaining to the following CfCs:

- *§486.326 Human Resources*
- *§486.330 Information Management*
- *§486.342 Requesting Consent*
- *§486.344 Evaluation and Management of Potential Donors and Organ Placement and Recovery.*

Protocols

1. *Organ Specific* Donor Evaluation should *include*:
    a. Chart review requirements;
    b. *Laboratory testing requirements (standard and additional as indicated);*
    c. *Other testing as indicated (echocardiogram, chest x-ray, etc.);*
    d. *Required timeframes for donor protocol activities;*
    e. *Documentation requirements;*
    f. *OPO staff member interactions with family or legally authorized representatives to collect information; and*
    g. *OPO staff roles.*

2. *Organ Specific* Donor Management should *include:*
    a. *Screening tests (such as infectious disease);*
    b. *Laboratory testing (maintaining organ viability, such as O2 saturation);*
    c. *Drug administration parameters;*
    d. *Ventilation management;*
    e. *Optimal vital signs; and*
    f. *Fluid levels.*

3. Organ placement should include;
    a. *UNet*[2] *match list review; and*

[2] *UNet is the system wherein OPOs, transplant hospitals/programs and histocompatibility labs are connected to facilitate nationwide allocation of organs. https://unos.org/technology/*

b. Collaboration with transplant hospitals.

4. Organ recovery should include:

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

5. DCD

If there is no DCD protocol, the surveyor should document when the discussion occurred.

6. Collaborative Protocols with Transplant programs:

The OPO *must establish protocols in collaboration with transplant programs* within *its* DSA. Such *protocols* are usually separate from *organ procurement* agreements OPOs have with hospital*s where the* transplant program *is located*. These documents should describe the 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 *must* be reviewed annually by the OPO and the transplant hospitals to ensure they maximize organ donation and transplantation. *Surveyors should review documents for evidence of regular review. (See 42 CFR 486.344(d.)*

Policies and Procedures

1. Consent
*Review the OPO's written protocols for contacting family or legally authorized representatives in the case of first-person donation. In the absence of a donor document, **ensure that t**he individual(s) responsible for making the donation decision are informed of their options to donate organs or to decline to donate. The OPO must provide, at a minimum, the following to the next of kin or responsible party:*

- *A list of the organs and/or tissues that may be recovered.*
- *The most likely uses for the donated organs or tissues.*
- *A description of the screening and recovery processes.*
- *Information about the organizations that will recover, process, and distribute the tissue.*

- *Information regarding access to and release of the donor's medical records.*
- *An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.*
- *Contact information for individual(s) with questions or concerns. A copy of the signed consent form if a donation is made.*

2. *Verification of recovery personnel credentials*
   Review the policy/procedures for verification of credentials for recovery personnel.

3. *For QAPI policies and procedures reference to Task Five below.*

4. *Conflict of Interest--Review the OPO's written policy that addresses conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.*

5. *Verification of recovery personnel credentials*

6. *Screening of referral calls.*

7. *Procedure for Medical Director review of donor records*

8. *Infectious disease testing*

IV. Review of Donor Records

A. Selecting the Sample of Organ Donor Record*s*

Use *the list of referrals evaluated for donation suitability requested during the Entrance Conference for sample selection to identify the records for review. Once it is determined how many records are needed, select records from each category: brain death (BD), DCD, and cases where procurement was stopped without recovery of organ(s).* Do not allow the OPO to select the sample. Select a minimum sample of 10 records from the list. *To the extent possible, select records from different hospitals, including records that reflect patients where the procurement process stopped prior to organ recovery.* If the surveyor is unable to obtain five DCD records, then additional BD record*s* may be added.

These records may be given to the surveyors in a combination of electronic and/or paper forms. The OPO is required to maintain records on an electronic information management system (EIMS) so a surveyor should ask OPO staff to assist in navigation through the electronic donor record if applicable.

Surveyors are to make photocopies of any documents needed to support the survey findings. If requested, the surveyor should provide the OPO with a copy of all items photocopied. The photocopies must be labeled to show total pages in each document

(for example, “page x of x”) and include the donor’s anonymous code, description of the document type, and the date and time the photocopy was made, for example, “Donor ABC123, Coordinator Notes, 01-31-18, 10:00 a.m.”

Review *selected* donor records for *evidence that*:

- §486.326(a)(3) *The* time and date of each recovery is in every record and that the recovery surgeon’s credentials were verified before the organ recovery.
- §486.326(b)(1) Screening and evaluation *of the donor was timely.*
- §486.342(a) *I*n each case the individual responsible for making the donation decision was provided with the information required in §§486.342(a)(1)-(8) and listed in 1-8 above during their conversation with the OPO and indicated an understanding of the information.
    - **NOTE**: *If t*he discussion regarding the individual’s decision *is* not included on the signed consent form*, check* elsewhere in the donor record.
- §486.342(b) For those donor records with first-person *(i.e. donor)* consent, that such consent was made in a manner consistent with the applicable state law requirements.
- §486.344(a)(1) *T*he OPO staff consistently followed their written protocols for donor management and that the *m*edical *d*irector was notified promptly with any concerns.
- §486.344(b)(1) *T*he OPO confirmed the hospital pronouncement of brain death/DCD death as part of the evaluation of the donor.
- §486.344(b)(2) *T*he OPO *acceptance* criteria, screening and evaluation policies for a possible donor were followed.
- §486.344(b)(3) *A* medical and social history were present, if possible, and contained sufficient information for the OPO to make a determination about the appropriateness for donation.
- §486.344(b)(4) *T*he donor physical examination for organ suitability was present and complete as a part of the evaluation. This physical exam is an external exam done by the OPO to determine potential barriers to donation. Ensure that all findings were documented and considered in the determination to proceed with donation.
- §486.344(b)(5) *V*ital signs and additional tests, as per protocol, were obtained during the evaluation.
- §486.344(c)(1) *T*he OPO followed its policies for infectious disease testing. *(Per OPTN policy, donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.)*
- §486.344(c)(3) *T*wo separate ABO blood sample collections were documented by the OPO at two different times.
- §486.344(c)(4) *T*he results of all tests ordered or performed by the OPO during its evaluation for donor suitability prior to recovery were included in the donor record.
- §486.344(d)(2)(ii) *T*he OPO staff and another individual compared the donor and recipient blood type prior to recovery.
- §486.344(d)(2)(iii) *T*he donor blood type was forwarded to the transplant *program* with the organ.
- §486.344(e) *An OPTN document that shows the intended organ beneficiary information. (See Guidance at 486.344(2), below.)*
- §486.344(a)(1) & (f)(3) *T*he use of medication and other interventions not related to

withdrawal of support (in brain death cases) were documented and administered per OPO policies and protocols.

- §486.346(b) *T*he donor record contains documentation listing all of the information that was transported with the organs.
- §486.346(c) *When* an organ was packaged and shipped*,* that all polices were followed and that documentation of the two individuals that verified the label information is present.

Particular attention should be made to whether actions were taken "timely" and "promptly".

V. Personnel Record Review and Interviews

This task covers requirements of the CfC on Human Resources (§486.326).

The surveyor should use the organizational chart and/or *OPO* staff list to select a sample of full-time and contract *staff*. Request the personnel records for the selected sample. The personnel interviews and file reviews should cover all staff positions. Review a minimum of five employee files for the clinical and family support staff at the OPO including contract *staff* in those positions. Expand the sample as necessary based on survey findings.

A. Personnel *Record* Review

1. Review the personnel records of OPO employees and contract *staff* to ensure that the OPO is meeting all requirements in the OPO CfCs at §486.326*, including*

    a. current licensure *as required by State or local law*
    b. position description
    c. performance evaluations
    d. conflict of interest evaluations
    e. orientation and periodic in-service training are provided to the staff.

2. Confirm that the OPO verified that recovery surgeons were currently credentialed *prior to recovery.*
3. *M*edical director—verify that he/she is currently licensed as a physician in one of the States within the OPO DSA or as required by State or local law *and that t*he position description for the medical director clearly delineates his/her roles and responsibilities for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement.

B. Interviews

The following are suggested interview questions.

NOTE: The titles for organ procurement staff may vary by OPO.

1. Organ Procurement Coordinator:

    a. When did you start as an organ procurement coordinator with this OPO?
    b. Please discuss your role as an organ procurement coordinator.
    c. How are staff training needs determined and how often are staff trained?
    d. How are staff skills and competencies assessed and maintained?
    e. How is 24/7 coverage maintained? *What happens if the surgeon is not immediately available to medically manage the potential donor?*
    f. When a call is received for a potential donor, how are you notified and what is your role?
    g. Once a referral is made, what are the processes for obtaining consent?
    h. *What is the process if family/LAR declines to donate?*
    i. What are the procedures used for maintaining the donor? Who is responsible for *donor* maintenance?
    j. *What is your role in the QAPI process? (See other QAPI questions in Task Four.)*

2. Organ Recovery Coordinator:

    a. When did you start as an organ recovery coordinator with this OPO?
    b. Please discuss your role as an organ recovery coordinator.
    c. How are staff training needs determined and how often are staff trained?
    d. How are staff skills and competencies assessed and maintained?
    e. How is 24/7 coverage maintained?
    f. When a call is received for a potential donor, how are you notified and what is your role?
    g. What are the procedures used for maintaining the donor? Who is responsible for *donor* maintenance?
    h. *What is your role in the QAPI process? (See other QAPI questions in Task Four.)*

3. Medical Director:

    a. When did you start as a medical director with this OPO?
    b. Please discuss your role as the medical director.
    c. Discuss the extent of your involvement in the development and revision of all of the protocols, especially protocols for the evaluation for suitability and donor management.
    d. Discuss your role in donor management.
    e. Discuss your role in determination of donor *eligibility* in the case of a potentially high-risk donor.
    f. Discuss your role in donor management when the surgeon on call is unavailable.
    g. What is the process used to verify that the OPO is following its written protocols for donor management?
    h. *What is your role in the QAPI process? (See other QAPI questions in Task*

Four.)

4. *Family/Legally Authorized Representative:*
   When feasible and appropriate (i.e. there is a family identified by the OPO or hospital that is known to be receptive to discussing their loved-one's donation), surveyors should take the opportunity to interview families or LARs (in-person or by phone) about their experience. This especially includes issues around gaining consent and information provided to help them understand and make a decision about donation. Situations involving consent issues or allegations of misinformation or coercion, especially if complaints or grievances were initiated by the family, are appropriate cases to follow. Surveyors should not approach families who are actively grieving or who decline to speak with the surveyor.

Task Four - Review of the Quality Assurance and Performance Improvement (QAPI) Program
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

This task covers requirements of the CfC on QAPI (§486.348).

Review the OPO's QAPI program plan, QAPI minutes, and the analysis of any adverse *events* that occurred in the OPO*, since its last survey,* to ensure that it meets the requirements of the CfCs.

Complete information gathering ***by*** **review*ing* the QAPI** *plan, minutes, adverse event policy and procedure and logs.*

Review the OPO's QAPI program to determine whether the OPO:

a. Has comprehensive policies and procedures in place;
b. Monitors processes to ensure compliance with policies *and procedures*;
c. Tracks performance to ensure that improvements are sustained;
d. Reviews donor, family and/or staff complaints *made to the OPO directly and to the hospital regarding the organ procurement process;* and
e. Records minutes *and attendance* of meetings, committees, and formal QAPI activities.

1. Staff Interviews

QAPI Staff Interview Guide *(select general staff members to assess awareness of QAPI)*:

a. Please discuss your roles and responsibilities for the QAPI program.
b. How does the QAPI program operate?
c. How are quality improvement decisions made based on data from the QAPI program?
d. How are quality improvement decisions made if there are competing priorities?
e. What aspects of care does the OPO monitor in its QAPI program?

f. What evidence is there that the OPO carries out components of a QAPI program?

2. Death Record Review Reports

Select a sample of three of the hospitals/CAHs within the OPO DSA. Review the Death Record Review reports for the hospitals as performed by the OPO for *a selection of three months (one within the past 12 months) since the last recertification survey*.

Review the list of hospital deaths each month and the OPO documentation of the review *to evaluate potential for organ donation. This includes all deaths with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1– Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.*

Task Five: Preliminary Decision-making and Analysis of Findings
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

Analyze all the information collected from the interviews*, observations* and record reviews to determine whether the OPO meets the CfCs at 42 CFR Part 486, Subpart G.

The surveyor should document his/her decision*(s)*, and the number of cases impacted in order to determine the extent of the OPO's noncompliance. This evidence should include photocopies of records and any additional documentation or evidence needed to support identified noncompliance. All supporting documentation must be gathered prior to the exit conference.

Determination of Compliance

A deficiency at a *c*ondition level may be due to noncompliance with requirements in a single standard or several standards within the condition or based upon a single finding representing a severe or critical health or safety violation. *(See 42 CFR 488.26(b), where it states, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a particular standard within the CfC is noted, the determination of whether the non-compliance is at the standard- or condition-level depends upon the nature of the noncompliance – i.e., how serious is the non-compliance in terms of its potential or actual harm to patients, the extent of non-compliance, e.g., how many different regulatory requirements within a CfC are being cited for non-compliance, or how widespread it was, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is sufficient to find condition-level noncompliance.*

Task Six*—Exit *Conference
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

Provide the OPO Administrator (and/or designated contact(s)) with an overview of the survey findings.

During the exit conference, the surveyor should accomplish the following:

- Identify each deficiency and provide the OPO with specific examples of any noncompliance (e.g., what the surveyor *observed,* why it did not meet the requirements of the regulation, and how the surveyor confirmed the finding); and
- Provide an opportunity for the OPO to present additional information.

When you have completed the exit conference, inform the OPO representative that *CMS will send* a formal statement of deficiencies. *See SOM Chapter 2, Section 2724, for additional information.*

Part II – Interpretive Guid*elines* for Organ Procurement Organizations
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

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

§486.301 Basis and Scope
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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.

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 *beneficiary*.**

***Guidelines*:** 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)).

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 *Agreement cycle*

refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Assessment period is a 12-month period in which an OPO's outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

***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.**

Death that is consistent with organ donation means all deaths from the state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1– Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

***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**

adverse event.

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 rate is the number of donors as a percentage of the donor potential.

Donation service are (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** ***transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell 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.**

Donor potential is the number of inpatient deaths within the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

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.**

Kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

Lowest rate among the top 25 percent will be calculated by taking the number of total DSAs in the time period identified for establishing the threshold rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked, and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

***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). *The pancreas counts as an organ even if it is used for research or islet cell transplantation.

Organ type	*Number of organs transplanted*
(1) Right or Left Kidney	*1*
(2) Right and Left Kidney	*2*
(3) Double/En-Bloc Kidney	*2*
(4) Heart	*1*
(5) Intestine	*1*
(6) Intestine Segment 1 or Segment 2	*1*
(7) Intestine Segment 1 and Segment 2	*2*
(8) Liver	*1*
(9) Liver Segment 1 or Segment 2	*1*
(10) Liver Segments 1 and Segment 2	*2*
(11) Right or Left Lung	*1*
(12) Right and Left Lung	*2*

Organ type	*Number of organs transplanted*
(13) Double/En-bloc Lung	*2*
(14) Pancreas (transplanted whole, research, islet transplant)	*1*
(15) Pancreas Segment 1 or Segment 2	*1*
(16) Pancreas Segment 1 and Segment 2	*2*

***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.**

Organ transplantation rate is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. The organ transplantation rate will be risk-adjusted for the average age of the donor potential using the following methodology:

(1) The age groups used for the adjusted transplantation rates are: <1, 1-5, 6-11, 12-17, 18-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-75.

(2) Calculate a national age-specific transplantation rate for each age group.

*An expected transplantation rate for each OPO is calculated as ∑(g=1)Gdg*Rg/∑gdg, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and ∑gdg is the OPO's total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.*

*(3) Calculate the age-adjusted organ transplantation rate as (O/E)*P, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.*

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's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.**

Guidelines: **The term "Urgent Need" should be considered 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.**

Requirements for Certification and Designation

§486.303 Requirements for Certification.

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

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 *Location* 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 regard 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 Guidelines 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 Guidelines 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.

§486.306 OPO Service Area Size Designation and Documentation Requirements.

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

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 *Location*.

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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

§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)

When mailing waiver requests, those requests should be mailed to CMS at:

Centers for Medicare and Medicaid Services
ATTN: Chronic Care Policy Group/Division of Technical Payment Policy;
Mailstop: C4-25-02
7500 Security Blvd
Baltimore, MD 21044

If sending waiver requests electronically via email, please email those requests to: OPOWaiverRequests@cms.hhs.gov.

§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.**

§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.

§486.310 Changes in Control or Ownership or Service Area.

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

§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 *Location* receives notification of a prospective change in control or ownership for a designated OPO, the CMS *Location* 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 *or control (e.g., executive director)* 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 *Location* 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 *Location* 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.

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)(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.

§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.

Re-Certification and De-Certification

§486.312 De-certification.

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

§486.312(a) Voluntary termination of agreement.

If an OPO wishes to terminate its agreement, the OPO must send the applicable CMS written notice of its intention to terminate its agreement and the proposed effective date. The CMS may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area. If CMS determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by the CMS. CMS 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 *Location* 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 *Location* 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 in the service area of the date of de-certification and such other information as CMS may require. In the case of involuntary termination or nonrenewal of an agreement, CMS also provides notice to the public in the service area of the date of de-certification. 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 *prompt* notification to the public of its service area. 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 *is available to the public* within three (3) business days of the date that CMS approved the OPO termination date.

§486.314 Appeals.

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

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 *Location* 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.*3*14(b)(3)

If the reconsideration request is received timely by the *CMS Location,* 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 Guidelines 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. ***(1)*** **The administrative record consists of, but is not limited to the following:**

(i) **Factual findings from the survey(s) on the OPO conditions for coverage.**

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 *the a*dvisory *b*oard and Governing Body;
(h) Evidence of compliance/noncompliance with OPTN regulations on reporting data.

§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 *most recent* CMS OPO *Annual Public Aggregated Performance Report,* which includes the measurement of OPO performance with the *two* OPO regulatory *outcome* requirements. Provide sufficient historical 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 *most recent* CMS OPO *Annual Public Aggregated*

Performance Report which ranks OPO(s), utilizing the most recent data collection period, based upon compliance with the regulatory data requirements at §486.318*(d)* and §486.328.

§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 *Location* relevant to the certification action under appeal;
(b) All relevant e-mail correspondence between the OPO and the *CMS Location*
(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.
(2) 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 *Location* must monitor the OPO's performance in the areas that 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.
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

§486.316(a) Re-certification of OPOs.

Based upon performance on the outcome measures set forth in § 486.318 and the re-certification survey, each OPO will be designated into either Tier 1, Tier 2, or Tier 3. The tier in which the OPO is designated will determine whether the OPO is re-certified (Tier 1), must compete to retain its DSA (Tier 2), or will receive an initial de-certification determination (Tier 3).

(1) Tier 1. An OPO is re-certified for at least an additional 4 years, the OPO's DSA is not opened for competition, and the OPO can compete for any open DSA if it meets all of the following:

> ***(i) It 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***

486.360; and

(ii) It meets the outcome requirements as described in § 486.318(e)(4) for the final assessment period of the agreement cycle.

(2) Tier 2. An OPO's DSA is open for competition and the OPO is eligible to compete to retain its DSA and for any open DSA if it meets all of the following:

(i) It 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 486.360; and

(ii) It meets the outcome requirements as described in § 486.318(e)(5) at the final assessment period of the agreement cycle.

(3) Tier 3. An OPO will receive a notice of de-certification determination under § 486.314 and cannot compete for any open DSA if it meets either of the following:

(i) Has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; or

(ii) Has outcome requirements as described in § 486.318(e)(6) at the final assessment period of the agreement cycle.

§486.316(b) De-certification and competition.

If an OPO fails to meet the outcome measures set forth in § 486.318(e)(6) at the final assessment period prior to the end of the agreement cycle, or it meets the requirements described in paragraph (a)(3) of this section:

(1) CMS will send the OPO a notice of its initial de-certification determination and the OPO has the right to appeal as established in § 486.314;

(2) 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 that qualify to compete for open service areas as set forth in paragraph (c) of this section. The de-certified OPO is not permitted to compete for its open area or any other open area.

(3) The OPO competing for the 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 DSA, an OPO must meet the performance requirements of the outcome measures for Tier 1 or Tier 2 at § 486.318(e)(4) and (5), and the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 at the most recent routine survey. The OPO must compete for the entire DSA.

§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.

§486.316(f) Extension of the agreement cycle for extraordinary circumstances.

OPOs can seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPOs that has affected the data of the final assessment period so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than the last day of the final assessment period.

§486.316(g) Exception.

For the 2022 recertification cycle only, an OPO is recertified for an additional 4 years and its service area is not opened for competition when the OPO meets one out of the two outcome measure requirements described in § 486.318(a)(1) and (3) for OPOs not operating exclusively in the noncontiguous States, Commonwealths, Territories, or possessions; or § 486.318(b)(1) and (3) for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions. An OPO is not required to meet the second outcome measure described in § 486.318(a)(2) or (b)(2) for the 2022 recertification cycle. If an OPO does not meet one of the outcome measures as described in paragraphs § 486.318(a)(1), (a)(3), (b)(1), or (b)(3), or has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, 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.

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

Note: Z001 text for 486.318(a) and interpretive guidance through Z0017 expired July 31, 2022.

Z018
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) ***§486.318(d) An OPO is evaluated by measuring the donation rate and the organ transplantation rate in their DSA.***

(1) For all OPOs, except as set forth in paragraph (d)(2) of this section, for all OPOs:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. The numbers of donors and organs transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation. The data is obtained from the most recent 12-months data from state death certificates.

(2) For the OPO representing the Hawaii DSA:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The kidney transplantation rate is calculated as the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA. The numbers of donors and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on

inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation. The data is obtained from the most recent 12-months data from state death certificates.

Z019

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) ***§486.318(e) An OPO must demonstrate a success rate on the outcome measures in accordance with the following parameters and requirements:***

(1) For each assessment period, threshold rates will be established based on donation rates during the 12-month period immediately prior to the period being evaluated:

Interpretive Guidelines 486.381(e)(1)

Mortality data for the performance score calculation comes from the annual Multiple Cause of Death file produced by the Centers for Disease Control. This calendar year data is available at the end of the subsequent year, so that January 1, 2024 through December 31, 2024 (the 2024 calendar year) is not available to produce the 2026 report until December 2025.

(i) The lowest rate among the top 25 percent in DSAs, and

(ii) The median rate among the DSAs.

(2) For each assessment period, threshold rates will be established based on the organ transplantation or kidney transplantation rates during the 12- month period prior to the period being evaluated:

(i) The lowest rate among the top 25 percent, and

(ii) The median rate among the DSAs

(3) The 95 percent confidence interval for each DSA's donation and organ transplantation rates will be calculated using a one-sided test.

Interpretive Guidelines 486.318(e)(3)

Tier placement is based on achieving a threshold established at the median (Tier 2 cutoff) and top 25% (Tier 1 cutoff) levels based on the distribution of the prior year's scores. Using the prior year's scores sets a benchmark for improvement where an OPO must do better than the prior year's median to be at or above the median.
The upper limit of the confidence interval for the rate is used rather than the rate itself making it easier to meet the threshold. The current year's scores are then similarly used to establish tiers (and achievement expectations for the subsequent year.
Notably, the thresholds for each donation and transplant rate have increased from year to year.

(4) Tier 1—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

(5) Tier 2—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but is not in Tier 1 as described in paragraph (e)(4) of this section will be identified at each assessment period.

(6) Tier 3—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established for their DSA will be identified at each assessment period. OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

(7) For the OPO exclusively serving the DSA that includes the noncontiguous state of Hawaii and surrounding territories, the kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a Tier will be the same as in paragraphs (e)(4), (5), and (6) of this section except kidney transplantation rates will be used.

Interpretive Guidelines §486.318(e)(2), (4)-(7)

The report will list outcome scores and tier status for each OPO.
The highest performing OPOs are those that are ranked in the top 25 percent. Any OPO whose performance is not statistically different than the lowest performer in the top 25 percent will be assigned to Tier 1. Tier 2 OPOs are the next highest performing OPOs, where performance on both measures meets or exceeds the median but does not reach Tier 1. Tier 3 OPOs are the lowest-performing OPOs that have one or both measures below the median.

Z020

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) ***§486.318(f)(1) An OPO's performance on the outcome measures is based on an evaluation at least every 12 months, with the most recent 12 months of data available from the OPTN and state death certificates, beginning January 1 of the first year of the agreement cycle and ending December 31, prior to the end of the agreement cycle.***

(2) An assessment period is the most recent 12 months prior to the evaluation of the outcome measures in which data is available.

(3) If an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available.

Z036

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(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 noncompliance has been determined in this manner.

Interpretive Guidelines §486.320

Prior to going on-site, confirm the OPO's *current membership status by searching for public notice of OPTN probation or not being a member in good standing, or contacting the HRSA Division of Transplantation (OPTNMemberCompliance@hrsa.gov).* Only two OPTN membership statuses result in a noncompliance 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.

Z057

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) **§486.322(a) 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 area..... Select 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 *established* 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. *A*ny waiver denials issued, or
2. *A*ny 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 the OPO has a protocol for donation after cardiac death.
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.

OPO responsibilities should address:

a) The provision of:

    1. *T*imely communication and prompt response by the OPO on a 24/7 basis;
    2. *O*rientation training for new Designated Requestors and annual training for all Designated Requestors;
    3. *A*nnual 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. *O*rgan recovery teams are of the proper composition and qualifications;
    2. *P*roper 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. *I*n organ/tissue management within the hospital/CAH; and
    2. *W*ith 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) **§486.322(b) 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 42 CFR 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 Designat*ed* Requestor training programs *used by the OPO* 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; *note: the hospital should be able to demonstrate the availability of a designated or effective requestor at all times.*
h) The process to obtain informed consent from the 29bor 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) **§486.322(c) 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *at* *OCOD@fda.hhs.gov*.

Z061

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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.

Note: Also see list for family legally authorized representative information Z165.

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.

Z085

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *a*dvisory *b*oard. The bylaws must grant the *a*dvisory *b*oard, 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 *a*dvisory *b*oard member qualifications. Request a list of the current *a*dvisory *b*oard members, their positions, professional qualifications and the corresponding OPO documentation verifying their qualifications.

Review the *a*dvisory *b*oard 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 *(more than 50 percent)* 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.

Z089

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *a*dvisory *b*oard should be filled by a neurosurgeon or a neurologist.

Z090

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *a*dvisory *b*oard. Prior to going on-site, identify the transplant hospitals in the donation service area. During the on-site review, verify that the *a*dvisory *b*oard 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

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

Interpretive Guidelines §486.324(a)(6)

The person fulfilling this role on the *a*dvisory *b*oard may be an organ donor's family member or a living organ donor.

Z092

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *a*dvisory *b*oard 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 *a*dvisory *b*oard for any 12-month period during the current re-certification cycle. Ensure that the topics placed before the *a*dvisory *b*oard and the recommendations from the *a*dvisory *b*oard are consistent with (1) through (12) above. *A*dvisory *b*oard recommendations should be made to the *g*overning *b*ody of the OPO.

Z093

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *a*dvisory *b*oard to ensure that these are separate and distinct bodies with no cross membership.

Review the bylaws of the *a*dvisory *b*oard 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 *a*dvisory *b*oard to ensure that if *a*dvisory *b*oard 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 *a*dvisory *b*oard meetings and respond to or provide additional information to the members, they should not be voting members.

Z146

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 HHS, 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) *[Reserved]***
- **(5) Data related to non-recovery of organs;**
- **(6) Data about consents for donation;**
- **(7) Number of donors;**
- **(8) Number of organs recovered, by type of organ; and**
- **(9) Number of organs transplanted, by type of organ.**

Interpretive Guidelines §486.328(a)

Prior to going on-site, *confirm with HRSA* that the OPO is submitting data to the OPTN and SRTR as required by OPTN by-laws for the listed data elements §486.328 (a) (1)-(9) above. *(Contact: OPTNMemberCompliance@hrsa.gov)*. CMS will consider a submission rate of 95 percent and above to meet the requirements of this standard.

Z160

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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)

*During donor record review, f*or each donor the OPO maintains in electronic format, *the surveyor should confirm that* a copy of the required minimum information and documentation of consent and family or legally authorized representative information *is documented.*

Z161

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *beneficiaries*.

Interpretive Guidelines §486.330(b)

See Interpretive Guidelines for **§486.330(a)**

Z162

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

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

Donor and transplant beneficiary 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 *that includes typed and handwritten text* to verify.

Z165

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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.

Note: Also see list at Z061.

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*d* with the information listed in §486.342(1)-(8) above *(including those organs declined for donation, if any)* and indicated an understanding of the information. *Verify that only the organs for which consent was given were procured.* 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.

Z166

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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. *Consent requirements should be confirmed during donor record review.*

Z168
(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 reviews*, consistent with OPO policy*, to ensure that staff are following the protocols *(reference medical director interview question regarding donor management)*.

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.

Z173

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *limited* time 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *suggestive of intravenous drug use*, 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *vital signs,* 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *in the potential donor* 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. *Per OPTN policies, donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.*

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).

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*'s* name, medical record number and the date of the test.

Z177

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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).

Verify *that the lab performing tests for the OPO is a CLIA certified lab using the Quality, Certification & Oversight Reports (QCOR) website.* 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.

Z180

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) **§486.344(d) 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 *must establish protocols in collaboration with transplant programs within the DSA.* (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.

Z182

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) **§486.344(d)(2)(ii) If the *identity* of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual;**

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. *Review the OPO policy and verify policy compliance during donor record review.*

Z184

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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)

Z187

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 are the same as the evaluation of brain death donors. The OPO must have written protocols for its collaboration with the

hospital staff regarding withdrawal of life support for the DCD donor, including clear directives as to the responsibilities of the hospital staff and the OPO staff in the period of time between extubation and declaration of death. During this period of time, the OPO staff may be present in the operating room to observe the patient's vital signs, which are recorded by the hospital staff. This is to determine if the interim length of time between extubation and declaration may have been so extended as to have impacted organ suitability. The OPO may obtain a copy of the anesthesia record for their records, but are not required to document all vital signs during this interim period.

The OPO protocol must be clear that the OPO staff will not be involved in the administration of care for the patient prior to the attending physician's pronouncement of death or involved in the declaration of death. See also §486.326(a)(2).

The hospital will have their own policies for the length of time the hospital physician must wait after asystole before pronouncement.

The *OPO* protocol *must* address what period of time the OPO will wait after pronouncement of death before commencing recovery of the organs and what observations they will make during that time. The OPO *must* consistently follow the protocol and document in their clinical record both the time declaration of death (in compliance with State and Local laws) occurred and the time they commenced recovery of organs. *The OPO protocol should also reflect current requirements of the OPTN.*

Agreements between hospitals and OPOs should be aligned to prevent these policies and procedures from having contradictory elements, especially related to timing of pronouncement/declaration of death and initiating organ recovery.

Z188

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *may allow* recovery personnel (surgeons and other recovery practitioners) *to* 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 which requires that they maintain complete information on any and all organs recovered.

Z189

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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, *especially the use of sedatives, anxiolytics and paralytics* 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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.

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

Z191

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *standards of practice*). *The protocol should reference sources. If the protocol does not, questions may be asked during survey.*

Review the sample of DCD donor records to verify that the OPO followed its protocols. *For example, review operative report. Surveyors should be looking for time of death versus recovery time and the vital signs to support compliance with waiting period identified in OPO's written protocol.*

Z192

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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)

Determine that the OPO is a member in good standing with the OPTN. *Contact HRSA at (OPTNMemberCompliance@hrsa.gov).*

Z194

(Rev. 115, Issued: 05-23-14, Effective: 05-23-14, Implementation: 05-23-14)

(Condition) **§486.346 Condition: Organ Preparation and Transport.**

Z195

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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)

The OPO should establish a written agreement with a histocompatibility laboratory that includes

specific details of the minimum tissue typing material, type of specimen, medium, and shipping requirements for these items. Extra vessels recovered for transplantation are excluded from minimum tissue typing material requirements.

(Condition) §486.346 Condition: Organ Preparation and Transport.

Z196

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) **§486.346(b)**

(1) 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.

This information is available to the transplant center electronically.

(2) The OPO must physically send a paper copy of the following documentation with each organ:

- **(i) Blood type;**
- **(ii) Blood subtype, if used for allocation; and**
- **(iii) Infectious disease testing results available at the time of organ packaging.**

(3) The source documentation must be placed in a watertight container in either of the following:

- **(i) A location specifically designed for documentation; or**
- **(ii) Between the inner and external transport materials.**

(4) 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)(1)-(4)

Review the sample of donor records to verify OPO documentation, consistent with OPTN policy, that the following information was physically sent in paper form with each organ:

(a) Blood type;
(b) Blood subtype, if used for allocation; and
(c) Infectious disease testing results available at the time of organ packaging.

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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(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 *policies on organ and vessel packaging, labeling, shipping, and storage*.

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.

Z200

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) §486.348(a) 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*, data-driven* plan that encompasses each phase of an organ procurement process (i.e., pre-organ procurement, procurement of the organ(s), and post-organ procurement).

The OPO's QAPI program must include

a. *Objective measures to evaluate and demonstrate:*
    a. *Improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management; and*
    b. *Timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport.*

b. Actions that result in performance improvements and track performance to ensure that improvements are sustained.

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 *a*dvisory *b*oard, *g*overning *b*ody 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

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) **§486.348(b) 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 *p*olicies 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.

Interviews should be conducted to ensure staff are following death record review policies and procedures.

Look for evidence that all potentially eligible deaths were:
1. Referred by the hospital to the OPO
2. Timely and appropriate follow-through by the OPO.

Select three Medicare and Medicaid participating hospitals in the service area (meeting the above criteria) select three (3) months *since the OPO's last recertification survey (one within the last 12 months)* and request the following information for each hospital in the sample:
a) A list of hospital deaths *from the selected months*
b) Review *the documentation a* sample of *five* completed OPO reviews from each hospital in the *selected* months.

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)).

Z204

(Rev. 241: Issued 05-08-26: Effective 05-08-26: Implementation 05-08-26)

(Standard) ***§486.348(d) Standard: Review of outcome measures.***

(1) An OPO must include a process to review its performance on the outcome measure requirements at § 486.318. The process must be a continuous activity to improve performance.

(2) An OPO must incorporate data on the outcome measures into their QAPI program.

(3) If the outcome measure at each assessment period during the recertification cycle is statistically significantly lower than the top 25 percent of donation rates or organ or kidney transplantation (Tier 2 and Tier 3 OPOs) rates as described in § 486.318(e)(5) and (6), the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

REFER TO E-TAGS (Appendix Z)

§486.360 Condition of participation: Emergency preparedness.

Interpretive Guidelines: §486.360

OPOs must comply with the applicable emergency preparedness requirements in §486.360 which is referenced in Appendix Z of the State Operations Manual. For all applicable requirements and associated guidelines for Emergency Preparedness, please refer to Appendix Z. We note that compliance with the emergency preparedness requirements is assessed in accordance with the survey protocol outlined within Appendix Z.