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

Transmittal 180

Date: August 24, 2018

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix Y, Organ Procurement Organization (OPO) Interpretive Guidance

I. SUMMARY OF CHANGES: The SOM Appendix Y for OPOs is revised to add a survey protocol for OPOs under “Part I – Survey Protocol for OPOs”. In addition, revisions were also made to Appendix Y, “Part II – Interpretive Guidance for OPOs”. Changes to the Conditions for Coverage (CfCs) in the CY 2017 Medicare Program: Hospital Outpatient Prospective Payment (OPPS) final rule (81 FR 79562) for the definition of eligible death, outcome measure three, and organ transport documentation has been incorporated. The guidance at Z187 has been updated to provide better clarification to the surveyors.

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 24, 2018

IMPLEMENTATION: August 24, 2018

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
N	Appendix Y/Part I – Survey Protocol for Organ Procurement Organizations
R	Appendix Y/§486.302 Definitions
R	Appendix Y/Z004/§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.
R	Appendix Y/Z005/§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:
R	Appendix Y/Z006/§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/§486.318(a)(3)(iii) The number of organs used for research per donor, including pancreata used for islet cell research.

R	Appendix Y/Z011/§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.
R	Appendix Y/Z012/§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:
R	Appendix Y/Z013/§486.318(b)(3)(ii) The number of organs used for research per donor, including pancreata used for islet cell research.
D	Appendix Y/Z014/§486.318(b)(3)(iii) The number of organs used for research per donor, including pancreata used for islet cell research.
R	Appendix Y/Z187/§486.344(f)(1) Criteria for evaluating patients for donation after cardiac death;
R	Appendix Y/Z196/§486.346(b) (1)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
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	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

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***PART I – Survey Protocol for Organ Procurement Organizations
(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)***

I. Introduction

The Organ Procurement Organization (OPO) must meet the requirements of section 1138(b) of the Social Security Act (the Act) and is required to be in compliance with the Federal Conditions for Coverage (CfCs) set forth in 42 CFR Part 486, Subpart G. Certification of compliance with Federal requirements is accomplished through observations, interviews and document/record reviews. 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.

The general survey and certification requirements and authorities are located at 42 CFR Part 388, Subpart A and policies regarding survey and certification activities are addressed in the State Operations Manual (SOM).

This survey protocol represents instructions to surveyors by the Centers for Medicare & Medicaid Services (CMS) that promote consistency in the survey process and provide the surveyors with information to assist them in their review of an OPO's compliance with Federal requirements.

The Interpretive Guidelines (IGs) contain authoritative interpretations, clarifications of the regulatory requirements and examples to support the regulatory text. The IGs are an aide 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

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

The OPO survey protocol encompasses a full review of all the OPO CfCs and is for all re-certification surveys. The CMS Regional Office (RO) conducts recertification surveys every four years.

The Components of the Basic Survey

- A. Pre-Survey Preparation*
- B. Entrance*
- C. Task One – Administrative Review*
- D. Task Two – Donor Record Review*
- E. Task Three – Personnel Record Review and Interview*
- F. Task Four – Review of the Quality Assessment and Performance Improvement (QAPI) Program*
- G. Preparation for the Exit*
- H. Exit*

A. Pre Survey Preparation

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

Prior to each survey:

- Review the OPO's previous CMS-2567 forms;*
- Review any complaint information since the OPO's previous survey;*
- Verify the OPO's address;*
- Review for any changes in ownership or control since the last recertification survey;*
- Review a list of all the counties in the OPO's Donation Service Area (DSA); and*
- Review the most recent data report created by CMS.*

B. Entrance

(Rev.180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

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

Include the following activities in the entrance conference:

- Introduce the survey team members;*
- Explain the purpose of the survey and that the survey will include a review of donor records, a review of policies and procedures and interviews with staff;*
- 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 are clear about the request; and*
- Request a designated, secure place to work and access to any necessary facilities, such as copying and electronic medical records (if applicable);*

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 DSA;*
- c. Waivers (approved and pending);*
- d. OPO organizational chart;*
- e. Evidence of non-profit status, including most current approved tax exemption forms under section 501(c) of the Internal Revenue Code of 1986;*
- f. Information about any changes of ownership, if applicable;*
- g. List of all current OPO staff members and their titles (if not included in the OPO organizational chart requested above);*
- h. Advisory board by-laws/membership/credentials/meeting minutes from the previous four (4) years;*
- i. Governing body bylaws/membership/credentials/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 the OPO cases that progressed to donation for the last four (4) years recertification cycle (separated by brain death donation and donation after cardiac death);
- n. Death Record Report log of each hospital/CAH for the last three (3) months; and
- o. Quality Assessment and Performance Improvement (QAPI) plan/committee meeting minutes/reports (previous four (4) years);
- p. List of Transplant hospitals in the DSA; and
- q. Description of Medical Director position.

C. Task One –Administrative Review

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

This task pertains to the review of requirements under the following CfCs: Relationships with Hospitals/CAHs and tissue banks (§486.322); and Administration and governing body (§486.324).

1. Agreements with Donor Hospitals

A. Hospitals/CAHs:

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.

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 areaSelect 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 together collaboratively.

B. Agreements with Tissue Banks and Eye Banks:

The OPO should have written arrangements (e.g., a signed agreement or Memorandum of Understanding (MOU)) with each identified tissue bank and eye bank that have agreements with hospitals and CAHs that have agreements with the OPO. These arrangements should 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 also the designated tissue bank for a hospital, it is not necessary that the OPO and tissue bank have a written agreement or MOU with itself.

C. Agreements with Transplant programs:

The OPO should have a written agreement or Memorandum of Understanding (MOU) with transplant programs within the DSA. Such agreements or MOUs are usually separate from the agreements OPOs have with the hospital component of the transplant program. 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 should be reviewed annually by the OPO and the transplant hospitals to ensure they maximize organ donation and transplantation.

2. Records of Advisory and Governing Boards

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 of the advisory board to ensure it is comprised of individuals listed in §§486.324(a)(1)-(6); and*
- The minutes to ensure designated membership.*

B. Governing Board:

Review the following:

- The meeting minutes to verify the governing board's oversight activities regarding the development and implementation of policies/procedures, the annual budget, other fiscal concerns, the QAPI program and services furnished under contract or arrangement, including agreements for such services;*
- Verify that 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.*

D. Task Two – Review of the Donor Records

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

This task covers requirements pertaining to the following CfCs:

- Information Management (§486.330);*
- Staffing (§486.326);*
- Requesting Consent (§486.342); and*
- Evaluation and Management of Potential Donors and Organ Placement and Recovery (§486.344).*

1. Donor Evaluation and Management

The OPO must have written protocols for the following:

a. Donor Evaluation (per organ) which should address:

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

b. Donor Management (per organ) which should address:

- i. *Screening tests (such as cardiac);*
- ii. *Laboratory testing;*
- iii. *Drug administration parameters;*
- iv. *Ventilation management;*
- v. *Optimal vital signs; and*
- vi. *Fluid levels.*

c. Organ placement which should include:

- i. *UNET match list review; and*
- ii. *Communication with transplant hospitals.*

d. Organ recovery, which should include:

- i. *Scheduling;*
- ii. *Qualified staff;*
- iii. *Documentation of verification of blood type;*
- iv. *Documentation required during recovery;*
- v. *Organ packaging;*
- vi. *Organ transport; Documentation accompanying the organ; and*
- vii. *Any subsequent follow-up with transplant hospital.*

In addition to 1.a. through 1.d. above, the surveyor also reviews the following (in no particular order):

- *Review the OPO's written policy that addresses conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.*
- *Review the DCD protocols (if applicable).*
- *Review the policy/procedures for verification of credentials for recovery personnel.*
- *Review the OPO's written protocols to ensure that, in absence of a donor document, the 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:*
 - (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.*

- *Review the OPO's written protocols for contacting family or legally authorized representatives in the case of first person donation.*

2. Organ Donor Record Sample

Use the OPO log of cases for the last four years (recertification cycle) as the universe for sample selection to identify the records for review. Do not allow the OPO to select the sample. Select a minimum, random sample of 10 records from the total number of OPO records for the last four years, with five records representing brain death (BD) cases and five records representing DCD cases (if applicable). If the surveyor is unable to obtain five DCD records, then additional BD record 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, the type description of the document type, and the date and time the photocopy was made, for example, "Donor ABC123, Coordinator Notes, 01-31-18, 10:00a.m."

Review this sample of donor records for the following:

- *§486.326(a)(3) Note the name of the recovery surgeon(s) and time and date of each recovery in every record, and verify that the recovery surgeon credentials were verified before the organ recovery.*
- *§486.326(b)(1) Review the donor record for compliance with timely screening and evaluation.*
- *§486.342(a) Review the donor records to verify that in 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: The discussion regarding the individual's decision may not be included on the signed consent form. Documentation may appear elsewhere in the donor record.*
- *§486.342(b) For those donor records with first person consent, verify that such consent was made in a manner consistent with the applicable state law requirements.*
- *§486.344(a)(1) Review the donor record to verify that the OPO staff consistently followed their written protocols for donor management and that the Medical Director was notified promptly with any concerns.*
- *§486.344(b)(1) Review the donor record to verify that the OPO confirmed the pronouncement of brain death/DCD death as part of the evaluation of the donor.*
- *§486.344(b)(2) Review the donor record to verify that the OPO elimination criteria, screening and evaluation policies for a possible donor were followed.*
- *§486.344(b)(3) Verify that 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) Verify that the 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) Verify that vital signs and additional tests, as per protocol, were obtained during the evaluation as indicated.*
- *§486.344(c)(1) Verify that the OPO followed its policies for infectious disease testing.*
- *§486.344(c)(3) Verify that two separate ABO blood sample collections were documented by the OPO at two different times.*
- *§486.344(c)(4) Verify that the 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) Verify documentation that the OPO staff and another individual compared the donor and recipient blood type prior to recovery.*
- *§486.344(d)(2)(iii) Verify documentation that the donor blood type was forwarded to the transplant hospital with the organ.*

- §486.344(e) Verify that the UNET match run was included with the donor chart.
- §486.344(a)(1) & (f)(3) Verify that the 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) Verify that the donor record contains documentation listing all of the information that was transported with the organs.
- §486.346(c) Review the sample for cases in which an organ was packaged and shipped. Verify that all polices were followed and that documentation of the two individuals that verified the label information is present.

E. Task Three – Personnel Record Review and Interview

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

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

The surveyor should use the organizational chart and/or staff list of OPO staff to select a sample of full-time and contract personnel. Request the personnel records for the selected sample. The personnel interviews and personnel 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 employees in those positions. Expand the sample as necessary based on other survey findings.

1. Personnel Review

- a. *Review the personnel records of OPO employees and contract employees to ensure that the OPO is meeting all requirements in the OPO CfCs at §486.326.

 - i. *Review current licensure records, orientation records, position description, performance evaluations, conflict of interest evaluations, and training records for the staff.*
 - ii. *Verify that the staff are licensed and/or registered in their State.*
 - iii. *Verify that orientation and periodic in-service training are provided to the staff.**
- b. *Confirm that the OPO verified prior to recovery that recovery surgeons were currently credentialed.*
- c. *Review the file for the OPO medical director to 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. The 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.*

2. Personnel Interviews

The following are suggested interview questions.

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

Organ Procurement Coordinator Interview Guide:

- 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 and on-call coverage maintained?
- 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 are the procedures used for maintaining the donor? Who is responsible for this maintenance?

Organ Recovery Coordinator Interview Guide:

- 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 and on-call 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 this maintenance?

Medical Director Interview Guide:

- 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 suitability 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?

F. Task Four – Review of the Quality Assurance and Performance Improvement (QAPI) Program

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

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 actions that occurred in the OPO to ensure that it meets the requirements of the CfCs. QAPI in OPOs covers a wide range of areas and applications.

Review the QAPI program as the last task.

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;*
- c. Tracks performance to ensure that improvements are sustained;*
- d. Reviews donor, family and/or staff complaints; and*
- e. Records minutes of meetings, committees, and formal QAPI activities.*

Staff Interviews

QAPI Staff Interview Guide:

- 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?*

Review of 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 three month period.

Review the list of hospital deaths each month and the OPO documentation of the review.

G. Preparation for the Exit

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

Analyze all the information collected from the interviews 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, the supporting documentation of the decision and findings, 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 non-compliance. All supporting documentation must be gathered prior to the exit conference.

Determination of Compliance

A deficiency at a Condition 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.

H. Exit

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

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 found and provide the OPO with specific examples of any noncompliance (e.g., what the surveyor looked at, 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 a formal statement of deficiencies will be mailed to them.

***Part II – Interpretive Guidance for Organ Procurement Organizations
(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)***

§486.302 – Definitions.

As used in this subpart, the following definitions apply:

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

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

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

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

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

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

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

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

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the

OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

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

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

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heart beating or asystolic donor.

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

An eligible death for organ donation means the death of a person--

- (1) Who is 75 years old or younger;*
- (2) Who is legally declared dead by neurologic criteria in accordance with State or local law;*
- (3) Whose body weight is 5 kg or greater;*
- (4) Whose body mass Index (BMI) is 50 kg/m² or less;*
- (5) Who had at least one kidney, liver, heart, or lung that is deemed to meet the eligible data definition as follows:*

(i) The kidney would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

- (A) Is more than 70 years of age;*
- (B) Is age 50-69 years with history of Type 1 diabetes for more than 20 years;*
- (C) Has polycystic kidney disease;*
- (D) Has glomerulosclerosis equal to or more than 20 percent by kidney biopsy;*
- (E) Has terminal serum creatinine greater than 4.0 mg/dl;*
- (F) Has chronic renal failure; or*
- (G) Has no urine output for at least or more than 24 hours;*

(ii) The liver would be initially deemed to meet the eligible data definition unless the donor has one of the following:

- (A) Cirrhosis;*
- (B) Terminal total bilirubin equal to or more than 4 mg/dl;*
- (C) Portal hypertension;*
- (D) Macrosteatosis equal to or more than 50 percent or fibrosis equal to or more than stage II;*

- (E) Fulminant hepatic failure; or*
- (F) Terminal AST/ALT of more than 700 U/L.*

(iii) The heart would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

- (A) Is more than 60 years of age;*
- (B) Is at least or more than 45 years of age with a history of at least or more than 10 years of HTN or at least or more than 10 years of type 1 diabetes;*
- (C) Has a history of Coronary Artery Bypass Graft (CABG);*
- (D) Has a history of coronary stent/intervention;*
- (E) Has a current or past medical history of myocardial infarction (MI);*
- (F) Has a severe vessel diagnosis as supported by cardiac catheterization (that is more than 50 percent occlusion or 2+ vessel disease);*
- (G) Has acute myocarditis and/or endocarditis;*
- (H) Has heart failure due to cardiomyopathy;*
- (I) Has an internal defibrillator or pacemaker;*
- (J) Has moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair;*
- (K) Has serial echo results showing severe global hypokinesis;*
- (L) Has myxoma; or*
- (M) Has congenital defects (whether surgically corrected or not).*

(iv) The lung would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

- (A) Is more than 65 years of age;*
- (B) Is diagnosed with coronary obstructive pulmonary disease (COPD) (for example, emphysema);*
- (C) Has terminal PaO₂/FiO₂ less than 250 mmHg;*
- (D) Has asthma (with daily prescription);*
- (E) Asthma is the cause of death;*
- (F) Has pulmonary fibrosis;*
- (G) Has previous lobectomy;*
- (H) Has multiple blebs documented on a Computed Axial Tomography (CAT) Scan;*
- (I) Has pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures;*
- (J) Has bilateral severe pulmonary contusions as per CT.*

(6) If a deceased person meets the criteria specified in paragraphs (1) through (5) of this definition, the death of the person would be classified as an eligible death, unless the donor meets any of the following criteria:

(i) The donor was taken to the operating room with the intent for the OPO to recover organs for transplant and all organs were deemed not medically suitable for transplantation; or

(ii) The donor exhibits any of the following active infections (specific diagnoses) of--

(A) Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel or intra-abdominal sepsis;

(B) Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including Viral Encephalitis or Meningitis, Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile (c) Virus infection, SARS, except as provided in paragraph (8) of this definition.

(C) Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides, Active candidemia or invasive yeast infection;

(D) Parasites: Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.); or

(E) Prion: Creutzfeldt-Jacob Disease.

(7) The following are general exclusions:

(i) Aplastic anemia, Agranulocytosis;

(ii) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease;

(iii) Previous malignant neoplasms with current evident metastatic disease;

(iv) A history of melanoma;

(v) Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma;

(vi) Active Fungal, Parasitic, Viral, or Bacterial Meningitis or Encephalitis; and

(vii) No discernable cause of death.

(8) Notwithstanding paragraph (6)(ii)(B) of this definition, an HIV positive organ procured for the purpose of transplantation into an HIV positive recipient would be an exception to an active infection rule out, consistent with the HIV Organ Policy Equity Act (the Hope Act).

Eligible donor means any donor that meets the eligible death criteria. The number of eligible donors is the numerator of the donation rate outcome performance measure.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan Area Data Book published by the U.S.

Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Expected donation rate means the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, CMS Case Mix Index, total bed size, number of intensive care unit (ICU) beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

Observed donation rate is the number of donors meeting the eligibility criteria per 100 deaths.

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

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

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

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

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

Standard criteria donor (SCD) per §486.302 means a donor that meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor. This definition differs from the OPTN definition of a standard criteria donor, which is a donor that does not meet the criteria to be a donor after cardiac death or expanded criteria donor.

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

Urgent need occurs when an OPO's non-compliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

Guidance: The term “Urgent Need” should be considered 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.

Z004

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

(Standard) **§486.318(a)(3)** *The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.*

Interpretive Guidelines §486.318(a)(3)

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

Z005

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

(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.*

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

See the interpretive guidance for §486.318(a)(3).

Z006

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

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

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

See the interpretive guidance for §486.318(a)(3).

Z011

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

(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.*

Interpretive Guidelines §486.318(b)(3)

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

Z012

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

(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.*

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

See the interpretive guidance for §486.318(b)(3).

Z013

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

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

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

See the interpretive guidance for §486.318(b)(3).

Z187

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

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

Interpretive Guidelines §486.344(f)(1)

The criteria for the evaluation of organ suitability for DCD donors is the same as the evaluation of brain death donors. 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 protocol should also 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 should consistently follow the protocol and should 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 hospital will have their own policies for the length of time the hospital physician must wait after asystole before pronouncement. This is not the same as the length of time that the OPO will wait, per their protocol, post pronouncement of death before beginning recovery of the organs.

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

Z196

(Rev. 180, Issued: 08-24-18, Effective: 08-24-18, Implementation: 08-24-18)

(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)

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.