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FED - Z0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline

FED - Z0001 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Condition

CFR 486.318

Regulation Definition

Interpretive Guideline

(a) With the exception of 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:

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

FED - Z0002 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(a)(1)

Regulation Definition

Interpretive Guideline

The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below

Prior to going on site, refer to the most recent CMS OPO Database report. The database report will record the OPO's compliance level with this measurement as computed on an annual basis and then averaged over the three full

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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;

calendar years of the re-certification cycle (aggregate 36 months) (see §486.318(c)(1)). Utilize the most recent calculated compliance results for the aggregate calculation. During the re-certification survey, inform the OPO of the report findings (compliance/non-compliance) and include any non-compliance in the exit interview.

FED - Z0003 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(a)(2)

Regulation Definition

The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

Interpretive Guideline

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

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

FED - Z0004 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(a)(3)

Regulation Definition

The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of

Interpretive Guideline

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

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the most current OPTN aggregate donor yield measure.

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.

FED - Z0005 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(a)(3)(i)

Regulation Definition

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 Guideline

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

FED - Z0006 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(a)(3)(ii)

Regulation Definition

The number of organs used for research per donor, including pancreata used for islet cell research.

Interpretive Guideline

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

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FED - Z0008 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(b)

Regulation Definition

For OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions, the OPO must meet two out of the three following outcome measures:

Interpretive Guideline

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

FED - Z0009 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(b)(1)

Regulation Definition

The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

Interpretive Guideline

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

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FED - Z0010 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(b)(2)

Regulation Definition

The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36-months of data used for re-certification, as calculated by the SRTR;

Interpretive Guideline

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

FED - Z0011 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(b)(3)

Regulation Definition

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 Guideline

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.

FED - Z0012 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(b)(3)(i)

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Regulation Definition

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 Guideline

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

FED - Z0013 - OUTCOME MEASURES

Title OUTCOME MEASURES

Type Standard

CFR 486.318(b)(3)(ii)

Regulation Definition

The number of organs used for research per donor, including pancreata used for islet cell research.

Interpretive Guideline

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

FED - Z0015 - DATA FOR THE OUTCOME MEASURES

Title DATA FOR THE OUTCOME MEASURES

Type Standard

CFR 486.318(c)(1)

Regulation Definition

An OPO's performance on the outcome measures is based on 36 months of data, beginning with January 1 of the first full year of the re-certification cycle and ending 36 months later on December 31, 7 months prior to the end of the re-certification cycle.

Interpretive Guideline

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FED - Z0016 - DATA FOR THE OUTCOME MEASURES

Title DATA FOR THE OUTCOME MEASURES

Type Standard

CFR 486.318(c)(2)

Regulation Definition

If an OPO takes over another OPO's service area on a date later than January 1, of the first full year of the re-certification cycle so that 36 months of data are not available to evaluate the OPO's performance in its new service area, we will not hold the OPO accountable for its performance in the new area until the end of the following re-certification cycle when 36 months of data are available.

Interpretive Guideline

FED - Z0036 - PART IN ORGAN PROCUREMENT/TRANSPLANT NETWORK

Title PART IN ORGAN PROCUREMENT/TRANSPLANT NETWORK

Type Condition

CFR 486.320

Regulation Definition

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

Interpretive Guideline

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

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

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

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sanctions under section 1138 only after such non-compliance has been determined in this manner.

FED - Z0056 - RELATIONSHIPS W HOSPITAL/CAH/TISSUE BANKS

Title RELATIONSHIPS W HOSPITAL/CAH/TISSUE BANKS

Type Condition

CFR 486.322

Regulation Definition

Relationships with Hospitals, Critical Access Hospitals, and Tissue Banks.

Interpretive Guideline

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

FED - Z0057 - HOSPITAL AGREEMENTS

Title HOSPITAL AGREEMENTS

Type Standard

CFR 486.322(a)

Regulation Definition

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 Guideline

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

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

If during the review of the sample, the surveyor determines that the OPO does not have a current agreement with one or more hospitals/CAHs in their service area, request additional information to determine whether the hospital/CAH has a ventilator and operating room or whether the hospital/CAH has an approved waiver to work with another OPO. Disregard any hospital/CAH that does not meet the criteria or has an approved waiver in place. If the hospital(s) does meet these criteria or does not have an approved waiver in place, expand the sample to a 100% review to verify that

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the OPO has an agreement with at least 95% of the Medicare and Medicaid participating hospitals/CAHs in the donation service area that have both a ventilator and an operating room.

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

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

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

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

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

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

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

The hospital/CAH agreement should address:

- a) Appropriate hospital staff participation in training provided by or approved by the OPO;
- b) Staff roles/expectations for approaching the families regarding possible donation;
- c) Parameters for timely notification of the OPO of an imminent death (Agreement should define "timely referral" and the clinical triggers which would indicate an "imminent" death.)

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

The OPO responsibilities should address:

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

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FED - Z0058 - DESIGNATED REQUESTOR TRAINING - HOSP STAFF

Title DESIGNATED REQUESTOR TRAINING - HOSP STAFF

Type Standard

CFR 486.322(b)

Regulation Definition

The OPO must offer to provide designated requestor training on at least an annual basis for hospital and critical access hospital staff.

Interpretive Guideline

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

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

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

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

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

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

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

FED - Z0059 - COOPERATION WITH TISSUE BANKS

Title COOPERATION WITH TISSUE BANKS

Type Standard

CFR 486.322(c)

Regulation Definition

(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 Guideline

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

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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.

FED - Z0060 - COOPERATION WITH TISSUE BANKS

Title COOPERATION WITH TISSUE BANKS

Type Standard

CFR 486.322(c)(1)(i)

Regulation Definition

[The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:]

Screening and referral of potential tissue donors.

Interpretive Guideline

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.

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FED - Z0061 - COOPERATION WITH TISSUE BANKS

Title COOPERATION WITH TISSUE BANKS

Type Standard

CFR 486.322(c)(1)(ii)

Regulation Definition

[The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:]

Obtaining informed consent from families of potential tissue donors.

Interpretive Guideline

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

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

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

The OPO should have a written protocol in place with the tissue banks and eye banks regarding telephone consent. The telephone consent protocol should require a witness to all telephone consents unless the individual State law specifically allows a verbal record of the informed consent over the telephone without the need for a witness. In these cases, the consent recording should be maintained per medical record retention requirements.

The telephone protocol should also address the OPO staff who may take the consent, persons who may provide consent, and how the OPO verifies the identity of the person providing consent.

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FED - Z0062 - COOPERATION WITH TISSUE BANKS

Title COOPERATION WITH TISSUE BANKS

Type Standard

CFR 486.322(c)(1)(iii)

Regulation Definition

[The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:]

Retrieval, processing, preservation, storage, and distribution of tissues.

Interpretive Guideline

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

FED - Z0063 - COOPERATION WITH TISSUE BANKS

Title COOPERATION WITH TISSUE BANKS

Type Standard

CFR 486.322(c)(1)(iv)

Regulation Definition

[The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:]

Providing designated requestor training.

Interpretive Guideline

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

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FED - Z0064 - COOPERATION WITH TISSUE BANKS

Title COOPERATION WITH TISSUE BANKS

Type Standard

CFR 486.322(c)(2)

Regulation Definition

An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

Interpretive Guideline

FED - Z0084 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Condition

CFR 486.324

Regulation Definition

Administration and governing body.

Interpretive Guideline

FED - Z0085 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(a)

Regulation Definition

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 Guideline

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

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Board members, their positions, professional qualifications and the corresponding OPO documentation verifying their qualifications.

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

FED - Z0086 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(a)(1)

Regulation Definition

[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:]

Members who represent hospital administrators, either intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO's service area.

Interpretive Guideline

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

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

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

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

FED - Z0087 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(a)(2)

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Regulation Definition

[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:]

Individuals who represent the public residing in the OPO's service area.

Interpretive Guideline

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

FED - Z0088 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(a)(3)

Regulation Definition

[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:]

A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

Interpretive Guideline

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

FED - Z0089 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(a)(4)

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Regulation Definition

[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:]

A neurosurgeon or other physician with knowledge or skills in the neurosciences.

Interpretive Guideline

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

FED - Z0090 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(a)(5)

Regulation Definition

[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:]

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 Guideline

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

FED - Z0091 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(a)(6)

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Regulation Definition

[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:]

An organ donor family member.

Interpretive Guideline

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

FED - Z0092 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(b)

Regulation Definition

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).

Interpretive Guideline

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

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- (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.

FED - Z0093 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(c)

Regulation Definition

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.

Interpretive Guideline

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

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Members of the advisory board described in paragraph (a) of this section are prohibited from serving on any other OPO board.

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

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

FED - Z0094 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(d)

Regulation Definition

The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.

Interpretive Guideline

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

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

FED - Z0095 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(e)

Regulation Definition

A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of

Interpretive Guideline

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

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policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

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

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

FED - Z0096 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(f)

Regulation Definition

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

Interpretive Guideline

The OPO must develop written policies and procedures that address governing body potential conflict of interest. These policies should define /identify potential "conflicts of interest" (both financial and personal), and include notification of the members of any real or potential conflict and the procedures which will be utilized to resolve the conflict. See Interpretive Guidance at §486.324(d) above.

FED - Z0097 - ADMINISTRATION AND GOVERNING BODY

Title ADMINISTRATION AND GOVERNING BODY

Type Standard

CFR 486.324(g)

Regulation Definition

The OPO's policies must state whether the OPO recovers organs from donors after cardiac death.

Interpretive Guideline

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

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FED - Z0117 - HUMAN RESOURCES

Title HUMAN RESOURCES

Type Condition

CFR 486.326

Regulation Definition

All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

Interpretive Guideline

FED - Z0118 - QUALIFICATIONS

Title QUALIFICATIONS

Type Standard

CFR 486.326(a)

Regulation Definition

(1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services.

Interpretive Guideline

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

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

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FED - Z0119 - QUALIFICATIONS

Title QUALIFICATIONS

Type Standard

CFR 486.326(a)(2)

Regulation Definition

The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.

Interpretive Guideline

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

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

FED - Z0120 - QUALIFICATIONS

Title QUALIFICATIONS

Type Standard

CFR 486.326(a)(3)

Regulation Definition

The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.

Interpretive Guideline

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

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

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FED - Z0121 - STAFFING

Title STAFFING

Type Standard

CFR 486.326(b)(1)

Regulation Definition

The OPO must provide sufficient coverage, either by its own staff or under contract or arrangement, to assure both that hospital referral calls are screened for donor potential and that potential donors are evaluated for medical suitability for organ and/or tissue donation in a timely manner.

Interpretive Guideline

Review the OPO written policy on the screening of incoming hospital referral calls. Policies should include who may conduct the screening, the screening process to be followed, the time frame for completing the screening and the documentation that must be entered into the intake record. Also, review the OPO written policy on the timeframes for subsequent OPO staff arrival at the hospital and evaluation.

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

FED - Z0122 - STAFFING

Title STAFFING

Type Standard

CFR 486.326(b)(2)

Regulation Definition

The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development.

Interpretive Guideline

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

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

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- o facilitating an effective and timely recovery process; and
- o transporting donated organs consistent with current OPTN requirements.

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

FED - Z0123 - STAFFING

Title STAFFING

Type Standard

CFR 486.326(b)(3)

Regulation Definition

The OPO must provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation.

Interpretive Guideline

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

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

FED - Z0124 - EDUCATION, TRAINING, & PERFORMANCE EVALUATION

Title EDUCATION, TRAINING, & PERFORMANCE EVALUATION

Type Standard

CFR 486.326(c)

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Regulation Definition

The OPO must provide its staff with the education, training, and supervision necessary to furnish required services. Training must include but is not limited to performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. OPOs must evaluate the performance of their staffs and provide training, as needed, to improve individual and overall staff performance and effectiveness.

Interpretive Guideline

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

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

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

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

FED - Z0125 - MEDICAL DIRECTOR

Title MEDICAL DIRECTOR

Type Standard

CFR 483.326(d)

Regulation Definition

The OPO's medical director is a physician licensed in at least one of the States or territories within the OPO 's service area or as required by State or territory law or by the jurisdiction in which the OPO is located. The medical director is responsible for implementation of the OPO's protocols for donor

Interpretive Guideline

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

- a) He/she is currently licensed as a physician in one of the States within the OPO donation service area or as required by State law (State laws of other States in the Donation Service Area may require that any physician practicing within that State be licensed by that State); and
- b) The position description for the medical director clearly delineates his/her role in the implementation of

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evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

protocols for donor evaluation and management, determination of donor suitability for donation, organ recovery and placement in increased risk cases.

Interview the medical director to determine:

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

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

FED - Z0145 - REPORTING OF DATA

Title REPORTING OF DATA

Type Condition

CFR 486.328

Regulation Definition

Interpretive Guideline

FED - Z0146 - REPORTING OF DATA

Title REPORTING OF DATA

Type Standard

CFR 486.328(a)

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Regulation Definition

An OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and DHHS, as requested by the Secretary. The data may include, but are not limited to:

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

Interpretive Guideline

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

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

FED - Z0147 - REPORTING OF DATA

Title REPORTING OF DATA

Type Standard

CFR 486.328(b)

Regulation Definition

An OPO must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.

Interpretive Guideline

From the sample of transplant hospitals selected in §486.322(a) request the reports that have been provided to the hospitals by the OPO since the last re-certification visit. These reports may include, but are not limited to §486.328 (a) (1)-(9) above.

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FED - Z0148 - REPORTING OF DATA

Title REPORTING OF DATA

Type Standard

CFR 486.328(c)

Regulation Definition

Data to be used for OPO re-certification purposes must be reported to the OPTN and must include data for all deaths in all hospitals and critical access hospitals in the OPO's donation service area, unless a hospital or critical access hospital has been granted a waiver to work with a different OPO.

Interpretive Guideline

FED - Z0149 - REPORTING OF DATA

Title REPORTING OF DATA

Type Standard

CFR 486.328(d)

Regulation Definition

Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the error is identified.

Interpretive Guideline

See §486.328(a) above.

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FED - Z0159 - INFORMATION MANAGEMENT

Title INFORMATION MANAGEMENT

Type Condition

CFR 486.330

Regulation Definition

An OPO must establish and use an electronic information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

Interpretive Guideline

FED - Z0160 - DONOR INFORMATION

Title DONOR INFORMATION

Type Standard

CFR 486.330(a)

Regulation Definition

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 Guideline

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

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FED - Z0161 - DISPOSITION OF ORGANS

Title DISPOSITION OF ORGANS

Type Standard

CFR 486.330(b)

Regulation Definition

The OPO must maintain records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant recipients.

Interpretive Guideline

See Interpretive Guidelines for §486.330(a)

FED - Z0162 - DATA RETENTION

Title DATA RETENTION

Type Standard

CFR 486.330(c)

Regulation Definition

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

Interpretive Guideline

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

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

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

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FED - Z0163 - FORMAT OF RECORDS

Title FORMAT OF RECORDS

Type Standard

CFR 486.330(d)

Regulation Definition

The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant recipient records and procedural manuals and other materials used in conducting OPO operations.

Interpretive Guideline

The OPO should have written policies which outline the procedures which will be followed, if necessary, to make available its Electronic Information Management System (EIMS) software to allow a successor OPO to operate the program.
The policies and procedures of the OPO should also be in a format which can be forwarded electronically.
Other OPO operations (e.g., material budgets, governing body minutes, personnel files, QAPI minutes, etc.) may be transferred via paper or electronic format.

FED - Z0164 - REQUESTING CONSENT

Title REQUESTING CONSENT

Type Condition

CFR 486.342

Regulation Definition

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

Interpretive Guideline

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

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

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program for discussions on sensitivity with donor families and legally authorized representatives.

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

FED - Z0165 - REQUESTING CONSENT

Title REQUESTING CONSENT

Type Standard

CFR 486.342(a)

Regulation Definition

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

Interpretive Guideline

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

Review the donor record sample (for donors without first person consent) to verify that in each case the family or legally authorized representatives was provide with the information listed in §486.342 (1)-(8) above and indicated an understanding of the information. The confirmation that the informer assessed the level of understanding by the family or legally authorized representatives may be incorporated into the consent form or may appear as a summary note by the informer in another part of the record.

Any documentation of the level of understanding should include what information was provided, the method used to determine the level of understanding and the level of understanding expressed. The documentation should also include any specifics that were repeated for clarification.

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

The OPO should list its contact information on the consent form to include a specific point of contact at the OPO. Copies of the consent are shared with the family or legally authorized representatives at the time the consent is signed. In instances where the recovery does not ultimately go forward, there would be no need to include a copy of the consent with any letter of explanation sent to the family or legally authorized representatives.

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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.

FED - Z0166 - REQUESTING CONSENT

Title REQUESTING CONSENT

Type Standard

CFR 486.342(b)

Regulation Definition

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 Guideline

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.

FED - Z0167 - EVAL/MGT OF PTNTL DONORS/ORG PLCMNT & RCVRY

Title EVAL/MGT OF PTNTL DONORS/ORG PLCMNT & RCVRY

Type Condition

CFR 486.344

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Regulation Definition

The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

Interpretive Guideline

The OPO should have written protocols for:

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

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

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

- B. Donor Management (per organ) to include:
 - o Testing (such as cardiac);
 - o Laboratory testing;
 - o Drug administration parameters;
 - o Ventilation management;
 - o Optimal vital signs; and
 - o Fluid levels;
- C. Organ Placement to include:
 - o UNET match list review;
 - o Communication with transplant hospitals.
- D. Organ Recovery to include:
 - o Scheduling;
 - o Qualified staff;
 - o Documentation of verification of blood type;
 - o Documentation required during recovery;
 - o Organ packaging;

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- o Organ transport; Documentation accompanying the organ; and
- o Any subsequent follow-up with transplant hospital.

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

FED - Z0168 - POTENTIAL DONOR PROTOCOL MANAGEMENT

Title POTENTIAL DONOR PROTOCOL MANAGEMENT

Type Standard

CFR 486.344(a)(1)

Regulation Definition

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 Guideline

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

Verify in the sample of donor records that:

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

FED - Z0169 - POTENTIAL DONOR PROTOCOL MANAGEMENT

Title POTENTIAL DONOR PROTOCOL MANAGEMENT

Type Standard

CFR 486.344(a)(2)

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Regulation Definition

The OPO must implement a system that ensures that a qualified physician or other qualified individual is available to assist in the medical management of a potential donor when the surgeon on call is unavailable.

Interpretive Guideline

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

FED - Z0170 - POTENTIAL DONOR EVALUATION

Title POTENTIAL DONOR EVALUATION

Type Standard

CFR 486.344(b)

Regulation Definition

The OPO must do the following:

Interpretive Guideline

FED - Z0171 - POTENTIAL DONOR EVALUATION

Title POTENTIAL DONOR EVALUATION

Type Standard

CFR 486.344(b)(1)

Regulation Definition

[The OPO must do the following:]

Verify that death has been pronounced according to applicable

Interpretive Guideline

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

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local, State, and Federal laws.

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

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

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

FED - Z0172 - POTENTIAL DONOR EVALUATION

Title POTENTIAL DONOR EVALUATION

Type Standard

CFR 486.344(b)(2)

Regulation Definition

[The OPO must do the following:]

Determine whether there are conditions that may influence donor acceptance.

Interpretive Guideline

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

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

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

FED - Z0173 - POTENTIAL DONOR EVALUATION

Title POTENTIAL DONOR EVALUATION

Type Standard

CFR 486.344(b)(3)

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Regulation Definition

[The OPO must do the following:]

If possible, obtain the potential donor's medical and social history.

Interpretive Guideline

Due to the compressed time frame for deceased donor evaluation, there is a possibility that certain infections, such as HIV, HBV, and or HCV, may be present at an early stage, prior to the ability of an assay to detect the infection. Thus, considerable weight is placed on the donor's social and medical history in identifying potential risks that might not be reflected in blood test results. The potential donor's medical and social history provides invaluable information that might clarify or explain ambiguous and/or discordant diagnostic test results that could eliminate an otherwise suitable organ donor or could include an otherwise unsuitable organ donor. It is crucial that the OPO closely review the medical and social history for the potential donor, identify any factors which may exclude the donor from donation or indicate extra restrictions on the type of recipient who may be allowed to receive the organ. The OPO considers the reliability of the informant for the social history and the likelihood the informant has sufficient knowledge of the potential donor to provide a definitive response to questions, especially questions associated with increased risk behavior.

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

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

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

FED - Z0174 - POTENTIAL DONOR EVALUATION

Title POTENTIAL DONOR EVALUATION

Type Standard

CFR 486.344(b)(4)

Regulation Definition

[The OPO must do the following:]

Review the potential donor's medical chart and perform a physical examination of the donor.

Interpretive Guideline

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

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verification of a thorough review.

Chart reviews should include at a minimum:

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

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

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

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

FED - Z0175 - POTENTIAL DONOR EVALUATION

Title POTENTIAL DONOR EVALUATION

Type Standard

CFR 486.344(b)(5)

Regulation Definition

[The OPO must do the following:]

Obtain the potential donor's vital signs and perform all pertinent tests.

Interpretive Guideline

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

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

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required by OPO protocol was performed and utilized in the evaluation process.

FED - Z0176 - TESTING

Title TESTING

Type Standard

CFR 486.344(c)(1)

Regulation Definition

The OPO must do the following:

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 Guideline

The goals of pre-transplant infectious disease screening are:

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

The timeframe for deceased donor evaluation is typically hours. Because of the short timeframe, there is a possibility that certain infections, such as HIV, HBV, and/or HCV, may be present at an early stage, prior to the ability of an assay to detect the infection.

Thus, considerable weight must be placed on the donor's social and medical history in identifying potential risks that might not be reflected in blood testing.

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

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

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

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

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

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

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testing are considered "increased risk.")

or

c) Have a social history that reveals increased risk.

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

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

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

FED - Z0177 - TESTING

Title TESTING

Type Standard

CFR 486.344(c)(2)

Regulation Definition

[The OPO must do the following:]

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 Guideline

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

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

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

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FED - Z0178 - TESTING

Title TESTING

Type Standard

CFR 486.344(c)(3)

Regulation Definition

[The OPO must do the following:]

Ensure that the potential donor's blood is typed using two separate blood samples.

Interpretive Guideline

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

FED - Z0179 - TESTING

Title TESTING

Type Standard

CFR 486.344(c)(4)

Regulation Definition

[The OPO must do the following:]

Document potential donor's record with all test results, including blood type, before organ recovery.

Interpretive Guideline

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

FED - Z0180 - COLLABORATION WITH TRANSPLANT PROGRAMS

Title COLLABORATION WITH TRANSPLANT PROGRAMS

Type Standard

CFR 486.344(d)(1)

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Regulation Definition

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 Guideline

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

FED - Z0181 - COLLABORATION WITH TRANSPLANT PROGRAMS

Title COLLABORATION WITH TRANSPLANT PROGRAMS

Type Standard

CFR 486.344(d)(2)(i)

Regulation Definition

[The protocol must ensure that:]

See § 486.344(c)(3)

The OPO is responsible for two separate determinations of the donor's blood type;

Interpretive Guideline

FED - Z0182 - COLLABORATION WITH TRANSPLANT PROGRAMS

Title COLLABORATION WITH TRANSPLANT PROGRAMS

Type Standard

CFR 486.344(d)(2)(ii)

Regulation Definition

[The protocol must ensure that:]

If the *identify* (sic) of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an

Interpretive Guideline

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.

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individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual;

(*identify is a misprint in the regulation text and should be identity.)

FED - Z0183 - COLLABORATION WITH TRANSPLANT PROGRAMS

Title COLLABORATION WITH TRANSPLANT PROGRAMS

Type Standard

CFR 486.344(d)(2)(iii)

Regulation Definition

[The protocol must ensure that:]

Documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.

Interpretive Guideline

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

FED - Z0184 - COLLABORATION WITH TRANSPLANT PROGRAMS

Title COLLABORATION WITH TRANSPLANT PROGRAMS

Type Standard

CFR 486.344(d)(3)

Regulation Definition

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 Guideline

See §486.344(d)(1)

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FED - Z0185 - DOCUMENTATION OF RECIPIENT INFORMATION

Title DOCUMENTATION OF RECIPIENT INFORMATION

Type Standard

CFR 486.344(e)

Regulation Definition

If the intended recipient has been identified prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended organ recipient's ranking in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

Interpretive Guideline

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

FED - Z0186 - DONATION AFTER CARDIAC DEATH

Title DONATION AFTER CARDIAC DEATH

Type Standard

CFR 486.344(f)

Regulation Definition

If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:

Interpretive Guideline

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

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FED - Z0187 - DONATION AFTER CARDIAC DEATH

Title DONATION AFTER CARDIAC DEATH

Type Standard

CFR 486.344(f)(1)

Regulation Definition

[If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:]

Criteria for evaluating patients for donation after cardiac death;

Interpretive Guideline

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.

FED - Z0188 - DONATION AFTER CARDIAC DEATH

Title DONATION AFTER CARDIAC DEATH

Type Standard

CFR 486.344(f)(2)

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Regulation Definition

[If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:]

Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

Interpretive Guideline

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

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

FED - Z0189 - DONATION AFTER CARDIAC DEATH

Title DONATION AFTER CARDIAC DEATH

Type Standard

CFR 486.344(f)(3)

Regulation Definition

[If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:]

Use of medications and interventions not related to withdrawal of support;

Interpretive Guideline

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

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

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FED - Z0190 - DONATION AFTER CARDIAC DEATH

Title DONATION AFTER CARDIAC DEATH

Type Standard

CFR 486.344(f)(4)

Regulation Definition

[If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:]

Involvement of family members prior to organ recovery;

Interpretive Guideline

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.

FED - Z0191 - DONATION AFTER CARDIAC DEATH

Title DONATION AFTER CARDIAC DEATH

Type Standard

CFR 486.344(f)(5)

Regulation Definition

[If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:]

Criteria for declaration of death and the time period that must elapse prior to organ recovery.

Interpretive Guideline

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

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FED - Z0192 - ORGAN ALLOCATION

Title ORGAN ALLOCATION

Type Standard

CFR 486.344(g)

Regulation Definition

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 Guideline

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

FED - Z0193 - ORGAN PLACEMENT

Title ORGAN PLACEMENT

Type Standard

CFR 486.344(h)

Regulation Definition

The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

Interpretive Guideline

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

The components of the protocol should include as a minimum, timeliness for entering information into UNET, responsibilities of each staff member throughout the process, timeframes for each process and the documentation that is required to verify that each process was completed.

FED - Z0194 - ORGAN PREPARATION AND TRANSPORT

Title ORGAN PREPARATION AND TRANSPORT

Type Condition

CFR 486.346

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Regulation Definition

Organ Preparation and Transport.

Interpretive Guideline

FED - Z0195 - ORGAN PREPARATION AND TRANSPORT

Title ORGAN PREPARATION AND TRANSPORT

Type Standard

CFR 486.346(a)

Regulation Definition

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.

See §486.344(c)

Interpretive Guideline

FED - Z0196 - ORGAN PREPARATION AND TRANSPORT

Title ORGAN PREPARATION AND TRANSPORT

Type Standard

CFR 486.346(b)

Regulation Definition

(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.

Interpretive Guideline

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

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(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.

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.

FED - Z0197 - ORGAN PREPARATION AND TRANSPORT

Title ORGAN PREPARATION AND TRANSPORT

Type Standard

CFR 486.346(c)

Regulation Definition

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 Guideline

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

The protocols must also require that an OPO staff member verify in writing that the ABO indicated on the container label and the donor information documents being sent with the organ are accurate. A second person, other than the person originally performing verification of the labeling and documentation requirements, must also verify their accuracy in writing. Review the sample of donor records to verify that the OPO has documentation to confirm that this double confirmation occurred and was documented.

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FED - Z0198 - ORGAN PREPARATION AND TRANSPORT

Title ORGAN PREPARATION AND TRANSPORT

Type Standard

CFR 486.346(d)

Regulation Definition

All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.

Interpretive Guideline

See §486.346(c)

FED - Z0199 - QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT

Title QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT

Type Condition

CFR 486.348

Regulation Definition

The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement.

Interpretive Guideline

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

1. A mechanism by which the OPO identifies events (such as complaints or adverse events) that need to be investigated to determine the underlying causes and:
 - o develops an action plan,
 - o implements the action plan,
 - o evaluates the effectiveness of the plan utilizing a data driven system, and
 - o revises the plan or continues with the plan based on the outcomes of the evaluation.
2. Performance indicators that are monitored on an on-going basis. These performance indicators are measured against established benchmarks or thresholds. Results from the on-going monitoring and evaluation of these performance measures will determine whether the OPO has met its goals or require some type of corrective action plan.

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3. A governance or leadership function (e.g., a steering committee, QA committee, and/or senior leadership) that ensures that the OPO has a QAPI program, a written QAPI plan, and appropriate resources to carry out QAPI activities. The role of this function is to establish priorities for the QAPI program, authorize performance improvement projects and action plans, and assure there is a designated, qualified QAPI program coordinator.

See also §486.348(a).

FED - Z0200 - COMPONENTS OF A QAPI PROGRAM

Title COMPONENTS OF A QAPI PROGRAM

Type Standard

CFR 486.348(a)

Regulation Definition

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 Guideline

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

This plan should include:

- a. QAPI Committee or organizational structure (the plan should delineate lines of communication, committee composition, roles and responsibilities);
- b. Objective measures by which the quality-related data will be collected and analyzed;
- c. Established frequencies for review of program performance and reporting to the QAPI Committee or governance/leadership structure;
- d. Designation of person or persons responsible for monitoring the QAPI program and description of their role(s) and responsibilities;
- e. Evidence of systemic approaches that are focused on changes and promote sustained improvements;
- f. Evidence of implementation of recommendations and continuing compliance for improvement;
- g. Evaluation of missed opportunities for donation identified through death record reviews;
- h. Analysis of complaints/investigations;
- i. Measurement of the level of compliance with OPTN policies;
- j. Evaluation of infectious disease;
- k. Staff training requirements (sensitivity and family interactions);
- l. Measurement of effectiveness with relationships to tissue banks and eye banks;
- m. Measurement of effectiveness with relationships to hospitals;
- n. Data collection, analysis, and reporting;

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- o. Evaluation of potential for Advisory Board, Governing Body conflicts of interest;
- p. Evaluation of staff compliance with approved protocols; and
- q. Analysis of adverse events reported to the OPO by a transplant center.

FED - Z0201 - DEATH RECORD REVIEWS

Title DEATH RECORD REVIEWS

Type Standard

CFR 486.348(b)

Regulation Definition

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 Guideline

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

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

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

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

FED - Z0202 - ADVERSE EVENTS

Title ADVERSE EVENTS

Type Standard

CFR 486.348(c)(1)

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Regulation Definition

An OPO must establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process.

Interpretive Guideline

The OPO policies should address as a minimum:

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

FED - Z0203 - ADVERSE EVENTS

Title ADVERSE EVENTS

Type Standard

CFR 486.348(c)(2)

Regulation Definition

The OPO must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO's policies and practices to prevent repeat incidents.

Interpretive Guideline

Request the OPO's log of all adverse events occurring over the current re-certification cycle. Verify that the program followed its written procedures for timely investigation, reporting and analysis and utilized the findings to effect changes in its operation as indicated.
During the review of donor records, be alert to any adverse event incidents. Verify that these events were investigated promptly and appropriate follow-up action was taken including OPO policy changes, if indicated.

FED - Z9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline