

A-0369

§482.45 Condition of Participation: Organ, Tissue and Eye Procurement

A-0370

§482.45(a) Standard: Organ Procurement Responsibilities

The hospital must have and implement written protocols that:

Interpretive Guidelines §482.45(a)

The hospital must have written policies and procedures to address its organ procurement responsibilities.

A-0371

§482.45(a)(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

Interpretive Guidelines §482.45(a)(1)

The hospital must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the hospital;
- Includes a definition of “imminent death”;
- Includes a definition of “timely notification”;
- Addresses the OPO’s responsibility to determine medical suitability for organ donation;
- Specifies how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the hospital-designated tissue and eye bank(s);
- Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;
- Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the hospital;
- Permits the OPO, tissue bank, and eye bank access to the hospital’s death record information according to a designated schedule, e.g., monthly or quarterly;
- Includes that the hospital is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only “qualified, trained individuals” to perform organ recovery; and
- The interventions the hospital will utilize to maintain potential organ donor patients so that the patient organs remain viable.

Hospitals must notify the OPO of every death or imminent death in the hospital. When death is imminent, the hospital must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor’s organs are still viable. The hospital should have a written policy, developed in coordination with the OPO and approved by the hospital’s medical staff and governing body, to define “imminent death”. The definition for “imminent death” should

strike a balance between the needs of the OPO and the needs of the hospital's care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and hospitals will create a partnership that furthers donation, while respecting the perspective of hospital staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;
- Is in an intensive care unit (ICU) or emergency department; **AND**
- Exhibits clinical findings consistent with a Glasgow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**
- MD/DOs are evaluating a diagnosis of brain death; **or**
- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

Hospitals and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the hospital's OPO or organizations such as The Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the hospital and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each hospital.

Hospitals may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one hospital to another, it is the receiving hospital's responsibility to notify the OPO.

"Timely notification" means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a hospital must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the hospital does not consider an individual who is not on a ventilator to be a potential donor, the hospital must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a hospital to an OPO is timely if it is made:

- As soon as it is anticipated that a patient will meet the criteria for imminent death agreed to by the OPO and hospital or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the hospital (ideally, within one hour); **AND**
- Prior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), assures that the family is approached only if the patient is medically suitable for organ donation, and assures that an OPO representative is available to collaborate with the hospital staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for

tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.

Survey Procedures §482.45(a)(1)

- Review the hospital's written agreement with the OPO to verify that it addresses all required information.
 - Verify that the hospital's governing body has approved the hospital's organ procurement policies.
 - Review a sample of death records to verify that the hospital has implemented its organ procurement policies.
 - Interview the staff to verify that they are aware of the hospital's policies and procedures for organ, tissue and eye procurement.
 - Verify that the organ, tissue and eye donation program is integrated into the hospital's QAPI program.
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§482.45(a)(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretative Guidelines §482.45(a)(2)

The hospital must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every hospital death and should notify the tissue bank or eye bank chosen by the hospital about potential tissue and eye donors.

It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes".

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §482.45(a)(2)

Verify that the hospital has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all potential tissue and eye donors, or an agreement with an OPO that specifies the tissue bank and eye bank to which referrals will be made. The agreement should also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative agreement with a different tissue and/or eye bank.

A-0373

§482.45(a)(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate.

Interpretive Guidelines §482.45(a)(3)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached.

Survey Procedures §482.45(a)(3)

- Verify that the hospital ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.
- Does the hospital have QAPI mechanisms in place to ensure that the families of all potential donors are informed of their options to donate organs, tissues, or eyes, or to decline to donate?

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§482.45(a)(3) continued

The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guidelines §482.45(a)(3)

The individual designated by the hospital to initiate the request to a family must be an organ procurement representative, an **organizational representative of a tissue or eye bank**, or a designated requestor. Any individuals involved in a request for organ, tissue, and eye donation must be formally trained in the donation request process.

The individual designated by the hospital to initiate the request to the family must be an OPO, tissue bank, or eye bank representative or a designated requestor. A **“designated requestor”** is defined as a hospital-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached. If possible, the OPO representative and a designated requestor should approach the family together.

The hospital must ensure that any “designated requestor” for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §482.45(a)(3)

- Review training schedules and personnel files to verify that all designated requestors have completed the required training.
- How does the hospital ensure that only OPO, tissue bank, or eye bank staff or designated requestors are approaching families to ask them to donate?

A-0375

§482.45(a)(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

Interpretive Guidelines §482.45(a)(4)

Using discretion does not mean a judgment can be made by the hospital that certain families should not be approached about donation. Hospitals should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The hospital staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §482.45(a)(4)

- Interview a hospital-designated requestor regarding approaches to donation requests.

- Review the designated requestor training program to verify that it addresses the use of discretion.
 - Review the hospital's complaint file for any relevant complaints.
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A-0376

§482.45(a)(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues;

Interpretive Guidelines §482.45(a)(5)

Appropriate hospital staff, including all patient care staff, must be trained on donation issues. The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;
- Quality improvement activities; and
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the hospital's QAPI program.

Those hospital staff who may have to contact or work with the OPO, tissue bank and eye bank staff must have appropriate training on donation issues including their duties and roles.

Survey Procedures §482.45(a)(5)

- Review in-service training schedules and attendance sheets.
 - How does the hospital ensure that all appropriate staff has attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?
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A-0377

§482.45(a)(5) continued

Reviewing death records to improve identification of potential donors; and

Interpretive Guidelines §482.45(a)(5)

Hospitals must cooperate with the OPOs, tissue banks and eye banks in regularly or periodically reviewing death records. This means that the hospital must develop policies and procedures which permit the OPO, tissue bank, and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the hospital's donor potential, assure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the hospital, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

Survey Procedures §482.45(a)(5)

- Verify by review of policies and records that the hospital works with the OPO, tissue bank, and eye bank in reviewing death records.
- Verify that the effectiveness of any protocols and policies is monitored as part of the hospital's quality improvement program.
- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.

- Determine how confidentiality is ensured.
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A-0378

§482.45(a)(5) continued

Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

Interpretive Guidelines §482.45(a)(5)

The hospital must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintains the viability of their organs. The hospital must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §482.45(a)(5)

- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.
 - Verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.
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A-0379

§482.45(b) Standard: Organ Transplantation Responsibilities

(1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term “rules of the OPTN” means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term “organ” means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ transplant related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

Interpretive Guidelines §482.45(b)

If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.

Survey Procedures §482.45(b)

Verify by review, one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.
