

**FEDERAL AND INDUSTRY REGULATIONS**  
*Conditions of Participation for Hospitals*

**Hospital Death Notifications**  
**Organ and Tissue Donor Screening**  
**Organ Recovery Process**

*U.S. Department of Health and Human Services*  
*Centers for Medicare & Medicaid Services (CMS)*

There are numerous federal regulations impacting hospital deaths and how hospitals must work with organ procurement organizations. Most of these are contained within the Conditions of Participation for Hospitals, which are summarized below.

**CMS Conditions of Participation for Hospitals**

The Centers for Medicare & Medicaid Services (CMS) regulate all hospitals that receive any type of federal reimbursement for care provided. Virtually all 6,000 U.S. hospitals are impacted and must take certain actions to remain compliant with CMS regulations.

These regulations are described in rules called “CMS Conditions of Participation for Hospitals” which are published in the Federal Register.

Numerous regulations exist within the “Conditions of Participation for Hospitals Regarding Organ, Tissue and Eye Donation.” First published in 1998, current regulations make hospitals accountable to CMS for their donation programs in an effort to increase the number of organs and tissues available for transplantation.

Organ procurement organizations (OPOs) are assigned geographic service areas by CMS and are obligated to serve all hospitals in their assigned area. Under these regulations, hospitals must contract with their federally designated OPO. Hospitals may not choose which OPO to work with.

Hospitals also must have a contract with an eye bank and a tissue bank. If the OPO also recovers tissues, the hospital may prefer to work with a single agency and have a dual agreement with the OPO for organ and tissue donation. They also must have a separate contract with the eye bank in their area.

Key points of the Conditions of Participation for Hospitals regarding Organ, Tissue and Eye Donation include:

1. Hospitals must report **ALL** deaths to the OPO in a **timely** manner.
  - a. The purpose of this condition is to allow the OPO to screen ALL hospital deaths for the potential for organ, tissue and eye donation.

**Timeliness** is defined by the hospital. However, CMS recognizes that hospital notification of the OPO within one hour of cardiac death is ideal for preserving the opportunity for donation of tissues and eyes.

Timely notification of **imminent deaths** requires that hospital staff notify the OPO of patients who are potential organ donors before death. Certain clinical signs indicate impending neurological death and hospitals set parameters to notify their OPO within **one hour** of a patient meeting those criteria.
2. The OPO determines medical suitability. *No physician or nurse or any other caregiver in the hospital is allowed to make decisions about patient medical suitability for any type of organ, tissue or eye donation.*
3. Only an OPO staff member or a trained, designated requester may approach the family of a potential donor for consent for organ, tissue or eye donation. *This regulation recognizes that training and skill are required to guide a family through this crucial decision.*

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*Conditions of Participation for Hospitals*

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TITLE 42 – PUBLIC HEALTH [1]

CHAPTER IV – CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF  
HEALTH AND HUMAN SERVICES (CONTINUED)

PART 482: CONDITIONS OF PARTICIPATION FOR HOSPITALS – Table of Contents

Subpart C: Basic Hospital Functions

Sec. 482.45 Condition of participation: Organ, tissue and eye procurement.

- (a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:
- (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;
  - (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;
  - (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. 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;
  - (4) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors;
  - (5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues and eyes take place.
- (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.

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