

An Introduction: Federal Regulations

U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services

Conditions for Coverage (CfCs) & Conditions of Participations (CoPs)

CMS develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs / CfCs.

CoPs and CfCs apply to the following health care organizations:

- Ambulatory Surgical Centers (ASCs)
- Community Mental Health Centers (CMHCs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)
- End-Stage Renal Disease Facilities
- Federally Qualified Health Centers
- Home Health Agencies
- Hospices
- Hospitals
- Hospital Swing Beds
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
- **Organ Procurement Organizations (OPOs)**
- Portable X-Ray Suppliers
- Programs for All-Inclusive Care for the Elderly Organizations (PACE)
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Psychiatric Hospitals
- Religious Nonmedical Health Care Institutions
- Rural Health Clinics
- Long Term Care Facilities
- **Transplant Centers**

Hospital Death Notifications Organ & Tissue Donor Screening Organ Recovery Process

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

CMS Conditions of Participation for Hospitals

The Centers for Medicare and 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 with which OPO to work.

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 cast the wide net and 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 hospital staff notify the OPO of patients who are potential organ donors before death. Certain clinical signs are indicative of 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 family through this crucial and decision.*