

**OREGON ADMINISTRATIVE RULES  
DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION  
CHAPTER 333**

**DIVISION 80  
ORGAN PROCUREMENT ORGANIZATIONS  
TISSUE BANKS  
EYE BANKS**

**333-080-0040**

**Definitions**

(1) As used in this section of Oregon Administrative Rules:

(a) “Entity” means an individual, corporation, business trust, partnership, limited liability company, association, joint venture or an instrumentality of an entity.

(b) “Eye bank” means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes or parts of human eyes.

(c) “Health care facility” has the meaning given that term in ORS 442.015.

(d) “Organ procurement organization” means an entity designated by the United States Secretary of Health and Human Services as an organ procurement organization.

(e) “Tissue bank” means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of tissue for transplants.

(2) Tissue banks and eye banks must be registered with and regulated by the United States Food and Drug Administration.

(3) A health care facility that performs organ transplants must:

(a) Be a member of the Organ Procurement and Transplantation Network established by the National Organ Transplant Act of 1984;

(b) Be regulated by the United States Department of Health and Human Services; and

(c) Use an organ procurement organization to obtain organs for transplants.

(4) A health care facility that performs tissue or corneal transplants must obtain the tissue or corneas from a tissue bank or an eye bank that is registered with and regulated by the United States Food and Drug Administration.

Stat. Authority: ORS 441.015

Stats. Implemented: ORS 183.745, ORS 441.015, ORS 441.079, ORS 441.082

**333-080-0050**

**Registration and Civil Penalties**

(1) An organ procurement organization, tissue bank or eye bank may not do business in Oregon unless it has registered with the Department of Human Services. Registration with the Department must be completed within 30 days after the implementation of these rules on July 1, 2008.

(a) The Department shall develop a registration form and the transplant organizations shall, at least 30 days prior to implementation, obtain and mail the required form to the Department.

(2) Each organ procurement organization, tissue bank and eye bank shall provide to the Department, at least every three years, current documentation of designation, certification and

inspection as evidence of compliance with national standards and requirements under federal law.

(3) The Department may impose a civil penalty not to exceed \$1,000 against an organ procurement organization, tissue bank or eye bank doing business in this state for failure to:

- (a) Register with the Department;
  - (b) Report loss of designation, accreditation or certification within 60 days of the loss; or
  - (c) Supply the Department with requested current documentation of designation, certification and inspection.
  - (d) For the first violation the civil penalty shall be \$250;
  - (e) For the second violation the civil penalty shall be \$500;
  - (f) For the third and any subsequent violations, the civil penalty shall be \$1000.
- (4) Civil penalties under this section shall be imposed in the manner provided under ORS 183.745.

Stat. Authority: ORS 441.015

Stat. Implemented: ORS 183.745, ORS 441.015, ORS 441.079, ORS 441.082

## **DIVISION 520 HOSPITAL COMPLIANCE**

### **333-520-0110**

#### **Hospital Compliance**

(1) Hospitals shall demonstrate compliance by maintaining a file available for Health Division review, including the following:

- (a) Training curriculum;
- (b) Hospital policy and procedure regarding request and training for tissues, eyes, and organs;
- (c) If not included in policy and procedure, criteria for selection of requestor; and
- (d) Method by which 24-hour scheduling of requestor(s) is established.
- (e) Policies and procedures for communicating with procurement organizations regarding the availability of donor organs, tissues, and eyes.

(2) Hospitals may provide appropriate procurement organization personnel access to medical records of decedents on a periodic basis. The timing of this review will be mutually agreed to by both the hospital and procurement organizations. Procurement organizations will provide appropriate staff to conduct the review in the hospital. The purpose of this review will be to provide information to the hospital to assist in compliance with state and federal regulations related to organ, tissue and eye donation. If the hospital agrees to the review, all findings will remain strictly confidential.

(3) In the case of a hospital in which organ transplants are performed, the hospital must be a member of the Organ Procurement and Transplantation network established under Section 372 of the Public Health Service Act and abide by its rules and requirements.

(4) In the case of a hospital in which organ transplants are performed, the hospital must also comply with the requirements of OAR Division 80.

Stat. Auth.: ORS 441.015

Stats. Implemented: ORS 183.745, ORS 441.015, ORS 441.079, ORS 441.082