

A-Engrossed
Senate Bill 341

Ordered by the Senate April 6
Including Senate Amendments dated April 6

Sponsored by Senators MONNES ANDERSON, WALKER; Senator MORRISETTE (Pre-session filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

[Requires that health care facility performing organ or tissue transplants be accredited by certain organization.]

[Requires that tissue banks be accredited by certain organization. Requires that tissue bank personnel be certified by certain organization.]

[Requires that health care facility use organ procurement organization.]

Requires tissue banks and eye banks to be registered and regulated by United States Food and Drug Administration.

Requires health care facility performing organ transplants to be member of Organ Procurement and Transplantation Network and to use organ procurement organization.

Requires health facility performing tissue or corneal transplants to obtain tissue or corneas from registered and regulated tissue bank or eye bank.

Requires Department of Human Services to adopt by rule standards and system of registration for organ procurement organizations, tissue banks and eye banks. Requires organizations and banks to register with department. Establishes civil penalties for noncompliance with standards or registration requirements.

A BILL FOR AN ACT

1
2 Relating to transplants.

3 **Be It Enacted by the People of the State of Oregon:**

4 **SECTION 1. (1) As used in this section and section 2 of this 2007 Act:**

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

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

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

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

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

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

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

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

NOTE: Matter in **boldfaced** type in an amended section is new; matter *[italic and bracketed]* is existing law to be omitted. New sections are in **boldfaced** type.

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

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

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

6 **SECTION 2.** (1) The Department of Human Services shall adopt by rule standards and a
7 system of registration for every organ procurement organization, tissue bank and eye bank
8 doing business in this state.

9 (2) An organ procurement organization, tissue bank or eye bank may not do business in
10 this state unless it has registered with the department.

11 (3) Each organ procurement organization, tissue bank and eye bank shall provide to the
12 department at least every three years current documentation of designation, certification
13 and inspection as evidence of compliance with national standards and requirements under
14 federal law.

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

18 (a) Register with the department;

19 (b) Report loss of designation, accreditation or certification within 60 days of the loss;

20 or

21 (c) Supply the department with requested current documentation of designation, certif-
22 ication and inspection.

23 (5) Civil penalties under this section shall be imposed in the manner provided under ORS
24 183.745.

25 **SECTION 3.** Each organ procurement organization, tissue bank and eye bank doing
26 business in this state must register with the Department of Human Services within 30 days
27 after the operative date of section 2 of this 2007 Act.

28 **SECTION 4.** Section 2 of this 2007 Act becomes operative on July 1, 2008.
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