

A-Engrossed
House Bill 3345

Ordered by the House April 19
Including House Amendments dated April 19

Sponsored by Representative HOYLE

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.

Provides for regulation of persons that engage in recovery or distribution of anatomical material from donors **for research or education purposes other than transplanting anatomical material or therapy.**

Continuously appropriates moneys to Oregon Health Authority for purposes of Act.
Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to anatomical material; appropriating money; and declaring an emergency.

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

4 **SECTION 1. As used in sections 1 to 5 of this 2013 Act:**

5 (1) **"Anatomical material" means the body of a dead human or a cell, group of cells or**
6 **body part taken from the body of a dead human.**

7 (2) **"Donor" has the meaning given that term in ORS 97.953.**

8 (3)(a) **"Nontransplant anatomical research recovery organization" means a person that**
9 **engages in the recovery or distribution of anatomical material from a donor for research or**
10 **education purposes other than transplanting the anatomical material or therapy.**

11 (b) **"Nontransplant anatomical research recovery organization" does not include:**

12 (A) **A hospital or other health care facility;**

13 (B) **A public corporation, as defined in ORS 353.010; or**

14 (C) **A public or private institution of higher education.**

15 **SECTION 2. (1) A person may not act as a nontransplant anatomical research recovery**
16 **organization unless the person:**

17 (a) **Is licensed as a nontransplant anatomical research recovery organization by the**
18 **Oregon Health Authority;**

19 (b) **Obtains a waiver from the authority that exempts the person from licensure on the**
20 **basis that the person is regulated under federal law to recover or distribute anatomical ma-**
21 **terial for transplant or therapy purposes; or**

22 (c) **Is accredited by an organization that accredits nontransplant anatomical research**
23 **recovery organizations and that meets the qualifications described in subsection (2) of this**
24 **section.**

25 (2) **The organization that accredits nontransplant anatomical research recovery organ-**
26 **izations under this section must, at a minimum:**

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 (a) Require a nontransplant anatomical research recovery organization to document
2 processes related to the recovery, handling and distribution of anatomical material and sub-
3 mit to the organization that documentation.

4 (b) Require a nontransplant anatomical research recovery organization to keep and
5 maintain all records related to the recovery or distribution of anatomical material for at
6 least 10 years.

7 (c) Conduct, or have a designee conduct, regular onsite compliance inspections of a
8 nontransplant anatomical research recovery organization's records, processes and materials
9 relating to:

10 (A) Donor intake;

11 (B) Acquisition, preparation, labeling, packaging, storage and distribution of anatomical
12 material; and

13 (C) Any inspection of a facility owned or operated by the nontransplant anatomical re-
14 search recovery organization.

15 (3) The authority shall adopt rules establishing an application process and fees for ob-
16 taining and renewing a nontransplant anatomical research recovery organization license.
17 The fee for obtaining or renewing a license under this subsection may not exceed \$1,750.

18 (4) A license issued or renewed under this section expires two years after the date of
19 issuance or renewal.

20 (5) The license required by this section is in addition to and not in lieu of any other li-
21 cense required by law.

22 (6) The authority shall deposit fees collected under this section into the Oregon Health
23 Authority Fund established in ORS 413.101. Moneys deposited in the fund under this sub-
24 section are continuously appropriated to the authority for the purposes of carrying out the
25 duties, functions and powers of the authority under sections 1 to 5 of this 2013 Act.

26 **SECTION 3.** (1) A nontransplant anatomical research recovery organization shall main-
27 tain a record of each donor from whom the organization obtains anatomical material. The
28 record must include:

29 (a) Documentation showing that the donor donated the anatomical material for the pur-
30 pose of research or education;

31 (b) The name and address of each person that had possession of the anatomical material
32 before the organization took possession of the anatomical material; and

33 (c) Documentation of the disposition of the anatomical material by the organization, in-
34 cluding the name and address of each person that receives anatomical material from the
35 organization.

36 (2) If a nontransplant anatomical research recovery organization returns any anatomical
37 material to a relative or personal representative of a donor, the organization shall disclose
38 to the relative or personal representative whether all or part of the donor's body is being
39 returned.

40 (3) A nontransplant anatomical research recovery organization shall dispose of any ana-
41 tomical material not returned to a relative or personal representative of the donor in ac-
42 cordance with all laws pertaining to the disposition of human remains.

43 (4) If a nontransplant anatomical research recovery organization accepts an offer from
44 an individual to donate anatomical material to the organization, the organization shall pro-
45 vide to the individual clear notice as to whether or not the organization guarantees the

1 coverage of a cost related to transporting and disposing of the individual's anatomical ma-
2 terial, including coverage of costs in instances in which the individual or a relative or per-
3 sonal representative of the individual subsequently rescinds, or the organization later
4 rejects, the offer of anatomical material.

5 **SECTION 4.** The Oregon Health Authority may:

6 (1) Adopt rules to implement sections 1 to 5 of this 2013 Act; and

7 (2) Inspect the premises and records of a nontransplant anatomical research recovery
8 organization as is reasonably necessary to determine compliance with sections 2 and 3 of this
9 2013 Act.

10 **SECTION 5.** (1) In accordance with ORS chapter 183, the Oregon Health Authority may:

11 (a) Impose a civil penalty in an amount not to exceed \$1,000 for each violation of section
12 2 or 3 of this 2013 Act; and

13 (b) Suspend or revoke a license issued or renewed under section 2 of this 2013 Act for a
14 violation of section 3 of this 2013 Act.

15 (2) The authority shall deposit penalties collected under this section into the Oregon
16 Health Authority Fund established in ORS 413.101. Moneys deposited in the fund under this
17 subsection are continuously appropriated to the authority for the purposes of carrying out
18 the duties, functions and powers of the authority under sections 1 to 5 of this 2013 Act.

19 **SECTION 6.** Notwithstanding section 2 (1) of this 2013 Act, a person acting as a
20 nontransplant anatomical research recovery organization, as defined in section 1 of this 2013
21 Act, before July 1, 2013, is not required to be licensed or accredited or have obtained a waiver
22 under section 2 (1) of this 2013 Act before July 1, 2014.

23 **SECTION 7.** (1) Sections 1 to 5 of this 2013 Act become operative on January 1, 2014.

24 (2) The Oregon Health Authority may take any action before the operative date specified
25 in subsection (1) of this section that is necessary to enable the authority to exercise, on and
26 after the operative date specified in subsection (1) of this section, all the duties, functions
27 and powers conferred on the authority by sections 1 to 5 of this 2013 Act.

28 **SECTION 8.** This 2013 Act being necessary for the immediate preservation of the public
29 peace, health and safety, an emergency is declared to exist, and this 2013 Act takes effect
30 on its passage.

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