

Enrolled
House Bill 3345

Sponsored by Representative HOYLE

CHAPTER

AN ACT

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

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

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

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

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

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

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

(A) A hospital or other health care facility, as those terms are defined in ORS 442.015;

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

(C) A public or private institution of higher education; or

(D) A clinical laboratory, as defined in ORS 438.010, that is:

(i) Licensed under ORS 438.010 to 438.510; and

(ii) Owned or controlled by, or under common ownership with, a hospital described in subparagraph (A) of this paragraph.

SECTION 2. (1) A person may not act as a nontransplant anatomical research recovery organization unless the person is licensed as a nontransplant anatomical research recovery organization by the Oregon Health Authority.

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

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

(4) The license required by this section is in addition to and not in lieu of any other license required by law.

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

SECTION 3. (1) A nontransplant anatomical research recovery organization shall maintain a record of each donor from whom the organization obtains anatomical material. The record must include:

(a) Documentation showing that the donor donated the anatomical material for the purpose of research or education;

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

(c) Documentation of the disposition of the anatomical material by the organization, including the name and address of each person that receives anatomical material from the organization.

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

(3) A nontransplant anatomical research recovery organization shall dispose of any anatomical material not returned to a relative or personal representative of the donor in accordance with all laws pertaining to the disposition of human remains.

(4) If a nontransplant anatomical research recovery organization accepts an offer from an individual to donate anatomical material to the organization, the organization shall provide to the individual clear notice as to whether or not the organization guarantees the coverage of a cost related to transporting and disposing of the individual's anatomical material, including coverage of costs in instances in which the individual or a relative or personal representative of the individual subsequently rescinds, or the organization later rejects, the offer of anatomical material.

SECTION 4. (1) The Oregon Health Authority may:

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

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

(c) In lieu of conducting inspections authorized under paragraph (b) of this subsection, accept accreditation from an accrediting body approved by the authority.

(2) To be approved under subsection (1)(c) of this section, an accrediting body must:

(a) Require a nontransplant anatomical research recovery organization to document processes related to the recovery, handling and distribution of anatomical material and submit to the accrediting body that documentation.

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

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

(A) Donor intake;

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

(C) Any inspection of a facility owned or operated by the nontransplant anatomical research recovery organization.

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

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

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

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

SECTION 6. Notwithstanding section 2 (1) of this 2013 Act, a person acting as a nontransplant anatomical research recovery organization, as defined in section 1 of this 2013 Act, before July 1, 2013, is not required to be licensed under section 2 (1) of this 2013 Act before July 1, 2014.

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

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

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

Passed by House April 25, 2013

Received by Governor:

Repassed by House June 3, 2013

.....M.,....., 2013

Approved:

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Ramona J. Line, Chief Clerk of House

.....M.,....., 2013

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Tina Kotek, Speaker of House

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John Kitzhaber, Governor

Passed by Senate May 29, 2013

Filed in Office of Secretary of State:

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Peter Courtney, President of Senate

.....M.,....., 2013

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Kate Brown, Secretary of State