Senate Bill 1515

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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 **as introduced.**

Requires nontransplant anatomical research and education recovery organization to be licensed by Oregon Health Authority, to have medical director and accreditation and to keep certain records. Authorizes authority to inspect premises of organization and to impose civil penalty for violation.

Exempts Oregon Health and Science University and persons who obtain waiver from authority from application of provisions of Act.

Applies to nontransplant anatomical research and education recovery organizations maintaining place of business in state on or after July 1, 2013.

A BILL FOR AN ACT

- 2 Relating to nontransplant anatomical research and education recovery organizations.
- 3 Be It Enacted by the People of the State of Oregon:
 - SECTION 1. As used in sections 1 to 5 of this 2012 Act:
 - (1) "Agent" has the meaning given that term in ORS 97.953.
- 6 (2) "Anatomical material" means a human body or human body part, including a cell or 7 group of cells.
 - (3) "Donor" has the meaning given that term in ORS 97.953.
 - (4) "Nontransplant anatomical research and education recovery organization" means a person that maintains a facility in this state for the recovery, storage or distribution of anatomical material from a donor for uses other than transplant or therapy.
 - (5) "Tissue bank" has the meaning given that term in ORS 97.953.
 - SECTION 2. (1) A person may not act as a nontransplant anatomical research and education recovery organization unless the organization is licensed as a nontransplant anatomical research and education recovery organization by the Oregon Health Authority.
 - (2) The authority may adopt rules setting forth the application process and fees for a nontransplant anatomical research and education recovery organization. The authority may not adopt rules imposing requirements that are in addition to or stricter than the requirements of this section and section 3 of this 2012 Act.
 - (3) A license issued pursuant to this section expires one year after the date of issuance and may be renewed annually by payment of a renewal fee and submission of a renewal application in the form and manner prescribed by the authority by rule.
 - (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 under ORS 413.101.
 - SECTION 3. (1) A nontransplant anatomical research and education recovery organiza-

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tion must have a medical director who is responsible for ensuring compliance with applicable laws and regulations and for maintaining records required under this section. The medical director must have an advanced degree in health care or a related field.

- (2) A nontransplant anatomical research and education recovery organization must be accredited by an accreditation organization for tissue banks.
- (3) A nontransplant anatomical research and education 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 the entity that had possession of the anatomical material immediately before the organization took possession of the anatomical material; and
- (c) A record of the disposition of the anatomical material by the organization, including the name and address of each entity that receives anatomical material from the organization.
 - (4) A nontransplant anatomical research and education recovery organization shall:
- (a) Require the donor or the donor's agent to have made an anatomical gift under ORS 97.951 to 97.982.
- (b) Notify the donor or the donor's agent that the donor's body may be dismembered and that body parts may be donated to different locations.
- (5) If a nontransplant anatomical research and education recovery organization returns any part of the remains of a deceased person to a friend or relative of the deceased person, the organization shall disclose to the friend or relative whether all or part of the deceased person's body is being returned.
- <u>SECTION 4.</u> The Oregon Health Authority may inspect premises and records of a nontransplant anatomical research and education recovery organization as is reasonably necessary to determine compliance with sections 2 and 3 of this 2012 Act.

SECTION 5. (1) In accordance with ORS chapter 183:

- (a) The Oregon Health Authority may impose a civil penalty in an amount not to exceed \$1,000 for each violation of section 2 or 3 of this 2012 Act.
- (b) In addition to the civil penalty allowed under paragraph (a) of this subsection, the authority may suspend or revoke a nontransplant anatomical research and education recovery organization license for violation of section 2 or 3 of this 2012 Act.
- (2) The authority shall deposit moneys received under this section into the Oregon Health Authority Fund established under ORS 413.101.

SECTION 6. Sections 1 to 5 of this 2012 Act do not apply to:

- (1) Oregon Health and Science University.
- (2) A person who has obtained a waiver from the Oregon Health Authority exempting the person from licensure on the basis that the person is licensed, accredited or regulated under federal or state law to recover or distribute anatomical material for transplant or therapy purposes.
- SECTION 7. Sections 1 to 5 of this 2012 Act apply to nontransplant anatomical research and education recovery organizations maintaining a place of business in this state on or after July 1, 2013.