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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

PH 45-2023

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED

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ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Permitting human pathological waste removal from a health care facility (SB 189, 2023)

EFFECTIVE DATE: 09/24/2023 THROUGH 03/21/2024

AGENCY APPROVED DATE: 09/22/2023

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Filed By:
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NEED FOR THE RULE(S):

Senate Bill 189 (Oregon Laws 2023, chapter 269) will go into effect on September 24, 2023; it permits pathological waste removal from a health care facility. In order to ensure that health care facilities that wish to, can release pathological waste, the Oregon Health Authority (OHA) must have temporary rules in place. The OHA will obtain input from Tribal leaders and other interested parties and communities during the permanent rulemaking process to follow, to ensure the rules are appropriate and comply with legislative intent.

JUSTIFICATION OF TEMPORARY FILING:

Pathological waste includes "biopsy materials and all human tissues and anatomical parts that emanate from surgeries, autopsies and obstetrical and laboratory procedures; 'pathological waste' does not include teeth or formaldehyde or other preservative agents." Failure to immediately adopt this temporary rule would have negative consequences on individuals, including American Indians/Alaska Natives who may have specialized burial or interment practices that require receipt of their anatomical parts after removal. Failure to immediately amend this rule would cause immeasurable harm to communities whose cultural practice requires receipt of removed anatomical parts; temporarily amending this rule will assure that such communities are able to practice their customs with respect to the final disposition of their anatomical parts.

The Oregon Health Authority (OHA) finds that failure to act promptly will result in serious prejudice to the public interest, OHA, and members of communities, including American Indian/Alaska Natives (4% of Oregon's total population according to the 2020 U.S. Census), whose cultural practices may require receipt of their removed anatomical parts. Thus, these rules need to be adopted promptly in order to allow cultural practices without hinderance.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

SB 189 (Oregon Laws 2023, chapter 269):

RULES:

333-056-0020, 333-056-0045

AMEND: 333-056-0020

RULE SUMMARY: Amend OAR 333-056-0020: Definitions have been added for freestanding birthing center and health care facility center as defined in ORS 442.015; and for pathological waste as defined in ORS 459.386.

CHANGES TO RULE:

333-056-0020

Definitions Relating to Infectious Waste ¶¶

As used in OAR 333-056-0010 through 333-056-0050, unless the context requires otherwise, the following definitions apply:¶¶

(1) "Act" means chapter 763, Oregon Laws, 1989, codified as ORS 459.386 to 459.405.¶¶

(2) "Disposal" has the meaning given that term in ORS 459.386.¶¶

(3) "Disposal site" has the meaning given that term in ORS 459.005.¶¶

(4) "Division" means the Oregon Health Authority, Public Health Division.¶¶

(5) "Freestanding birthing center" has the meaning given that term in ORS 442.015.¶¶

(6) "Health care facility" has the meaning given that term in ORS 442.015 ¶¶

(7) "Incineration" has the meaning given that term in ORS 459.395.¶¶

(8) "Infectious waste" means biological waste, cultures and stocks, pathological waste, or sharps, as those terms are defined in ORS 459.386; or syringes.¶¶

(9) "Landfill" means a facility for the disposal of solid waste involving the placement of solid waste on or beneath the land surface.¶¶

(10) "Noninfectious" means a state in which a disease causing agent is not capable of causing an infection to occur.¶¶

(11) "Pathological waste" has the meaning given that term in ORS 459.386.¶¶

(12) "Saturated waste" means waste that contains enough body fluid that it would cause dripping of the body fluid from the waste container, with or without compaction.¶¶

(13) "Sterilization" means, for purposes of these rules, any process which changes infectious waste so that disease causing agents contained within it are rendered non-infectious at the time the process is completed.¶¶

(14) "Storage" has the meaning given that term in ORS 459.386.¶¶

(15) "Syringe" means an instrument for the injection of medicine or the withdrawal of body fluids that consists of a hollow barrel fitted with a plunger and a hollow needle.¶¶

(16) "Transportation" has the meaning given that term in ORS 459.386.¶¶

(17) "Treatment" means incineration, sterilization or other method, technique or process approved by the Oregon Health Authority, Public Health Division that changes the character or composition of any infectious waste so as to render the waste noninfectious. Treatment also includes methods of rendering waste noninfectious, which are approved by the Environmental Quality Commission.

Statutory/Other Authority: ORS 431.110, 433.004, 459.395

Statutes/Other Implemented: ORS 431.110, 433.004, 459.395, 459.386

AMEND: 333-056-0045

RULE SUMMARY: Amend OAR 333-056-0045: Amendments have been made to allow human pathological waste, such as removed anatomical parts, to be received by the donor or their representative for the purposes of cremation, interment, or other final disposition in accordance with ORS chapter 97 and SB 189 (Oregon Laws 2023, chapter 269). Minor changes around gender nomenclature, deleting redundant text and re-ordering of subsections are made to the rule related to the release of placentas, without changing the substance of the rule.

CHANGES TO RULE:

333-056-0045

Exemptions for Placenta Removal ~~Removal of Human Pathological Waste, Including Placentas, From a Health Care Facility-~~

~~(1) Notwithstanding any other provision in these rules, a health care facility or freestanding birthing center, as those terms are defined in ORS 442.015, may release a placenta to the woman from whom the placenta originated, or to her designee.~~ OAR chapter 333, division 56, a health care facility may release human pathological waste to the donor of the pathological waste or an authorized representative of the donor, if:

~~(a) The facility or birthing center has a written policy and procedure to ensure the safe recipient attests in writing that the pathological waste will be disposed of by cremation, interment, or other management and transport of placentas;~~

~~(b) The woman tested negative for infection by hepatitis B and human immunodeficiency viruses by testing obtained since the beginning of the pregnancy; and~~

~~(c) The woman, in accordance with ORS chapter 97; and~~

~~(b) The pathological waste does not contain hazardous preservatives, such as formaldehyde or formalin.~~

(2) Notwithstanding any other provision in OAR chapter 333, division 56, a health care facility or freestanding birthing center may release a placenta to the individual from whom the placenta originated, or to their designee, if the individual or their designee, and the woman/individual's health care provider sign a form that contains at least the following:

~~(Aa) The woman/individual's name, date of birth, address and the name of the health care provider;~~

~~(Bb) An attestation by the woman/individual or their designee that the placenta will not be used for commercial purposes; and~~

~~(Cc) An attestation by the health care provider that:~~

~~(iA) Since the beginning of the pregnancy the woman/individual tested negative for infection by hepatitis B and human immunodeficiency viruses;~~

~~(iiB) The woman/individual either tested negative for hepatitis C virus since the beginning of the pregnancy or is not at risk for hepatitis C; and~~

~~(iiiC) To the health care provider's knowledge, the woman/individual has no infection that poses a threat to persons who handle the placenta.~~

(23) The health care facility or freestanding birthing center must keep a copy of the signed release form described in subsection (1)(c) of this rule in the individual's medical record.

(4) In addition to the requirements in sections (1) through (3) of this rule, health care facilities and freestanding birthing centers must have a written policy and procedure that:

(a) Specifies whether and when pathological waste and placentas will be released;

(b) If they will be released, specifies how that release will occur in order to ensure compliance with this rule; and

(c) Ensures the safe management and transport of pathological waste and placentas.

(35) Health care facilities and freestanding birthing centers shall make policies and procedures developed in accordance with subsection (1)(a4) of this rule available to the Division upon request.

(46) Nothing in this rule prohibits a health care facility or freestanding birthing center from having additional requirements for the removal of a placenta from the facility or center.

Statutory/Other Authority: ORS 431.110, 433.004, 459.400, 97.010, 97.745

Statutes/Other Implemented: ORS 431.110, 433.004, 459.400, 97.010, 97.745