

OFFICE OF THE SECRETARY OF STATE

LAVONNE GRIFFIN-VALADE  
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CHERYL MYERS  
DEPUTY SECRETARY OF STATE  
AND TRIBAL LIAISON



ARCHIVES DIVISION

STEPHANIE CLARK  
DIRECTOR

800 SUMMER STREET NE  
SALEM, OR 97310  
503-373-0701

**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333  
OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

**FILED**

01/30/2024 4:30 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Permitting human pathological waste removal from a health care facility

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 02/21/2024 5:00 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

CONTACT: Acute & Communicable Disease Prevention  
971-673-1111  
publichealth.rules@odhsoha.oregon.gov

800 NE Oregon St. Suite 772  
Portland, OR 97232

Filed By:  
Public Health Division  
Rules Coordinator

HEARING(S)

*Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.*

DATE: 02/15/2024

TIME: 2:00 PM

OFFICER: Staff

REMOTE HEARING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 971-277-2343

CONFERENCE ID: 901100402

SPECIAL INSTRUCTIONS:

This hearing is being held remotely via Microsoft Teams. To provide oral testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register and receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971-277-2343, Phone Conference ID 901 100 402# for audio only.

The hearing will remain open until all persons who have signed up to testify have had a chance to provide their comments but may close as early as 2:30 PM if everyone who has signed up to testify has provided their testimony.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

## NEED FOR THE RULE(S)

Senate Bill 189 (Oregon Laws 2023, chapter 269), which took effect September 24, 2023, permits pathological waste removal from a health care facility “in accordance with rules adopted by the Oregon Health Authority” (OHA). To ensure that health care facilities that wish to do so may release pathological waste, OHA temporarily amended OAR 333-056-0020 and 333-056-0045, effective September 24, 2023, through March 21, 2024. To continue to comply with the statute, OHA must amend those rules permanently, permitting removal of pathological waste from health care facilities while minimizing potential health hazards.

These rules define health care facility and freestanding birthing center in accordance with Oregon Revised Statutes (ORS) 442.015 and allow human pathological waste (defined by reference to ORS 459.386), 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. Minor changes are made to the rule related to the release of placentas without changing the substance of the rule.

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## DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Padmanabhan KK, Barik B. Health Hazards of Medical Waste and its Disposal. In: Barik D, ed. Energy from Toxic Organic Waste for Heat and Power Generation. Woodhead Publishing 2019:99–118. Available at [www.sciencedirect.com/science/article/pii/B9780081025284000080](http://www.sciencedirect.com/science/article/pii/B9780081025284000080).

SB 189 (Oregon Laws 2023, chapter 269):

<https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB189>

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## STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

OHA recognizes the cultural significance and importance of this change for many individuals and their families, which were the impetus behind SB 189. This rule change represents a positive impact on cultural communities, for example, Tribal Communities, who will be able to honor their burial practices by respectfully disposing of their anatomical body parts in accordance with their beliefs and traditions. In addition to a Tribal Consultation meeting (held on January 24, 2024), two representatives of the Tribal Communities also participated in the RAC on January 9, 2024.

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## FISCAL AND ECONOMIC IMPACT:

No fiscal or revenue impact was determined by Senate Committee on Health Care

<https://olis.oregonlegislature.gov/liz/2023R1/Measures/Overview/SB189>. Impact on state or local agencies would be trivial. The financial impact associated with specimen release would be administrative and time consuming with an estimated 40% increase staff time to educate patients around the rule and policies.

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## COST OF COMPLIANCE:

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

(1) Neither the statute nor the proposed rule amendments impose any requirements on state agencies; however, it's possible that units of local government, for example health districts, might experience an increase in administrative costs.

(2)(a) The Acute and Communicable Disease Prevention section does not collect data on the number of staff each agency employs and therefore cannot estimate with accuracy how many agencies may be small businesses. There are about 100 ambulatory surgery centers in Oregon; it is assumed that some might employ 50 or fewer persons and thus would be impacted by these rules.

(b) Under the statute and the proposed permanent rule amendments, releasing pathological waste is voluntary for health care facilities. Those that choose to do so will incur the administrative costs associated with developing a written policy and procedure regarding release of pathological waste; of obtaining and preserving signed patient attestations; and of making their policies and procedures available to the OHA Public Health Division upon request.

(c) See 2.b. above regarding administration and labor required of health care facilities that choose to participate. No equipment will be required.

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DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were represented on the Rules Advisory Committee.

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WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

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RULES PROPOSED:

333-056-0020, 333-056-0045

AMEND: 333-056-0020

RULE SUMMARY: OAR 333-056-0020 is amended to reference statutory definitions used in OAR 333-056-0045, namely "Health care facility" (ORS 442.015) and "Pathological waste" (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.¶¶

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

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

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

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

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

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

(10) "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.¶¶

(10) "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.¶¶

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

(12) ~~"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.~~¶¶

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

(14) "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, 459.400

AMEND: 333-056-0045

RULE SUMMARY: OAR 333-056-0045 is amended to authorize release of pathological waste other than a placenta to the donor of the pathological waste or to an authorized representative of the donor.

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~~ OAR chapter 333, division 56 or ORS 459.386 to 459.405, a health care facility is authorized to release pathological waste other than a placenta to the woman from whom the placenta originated, or to her designee, if:

~~(a) The facility or birthing center has a written policy and procedure to ensure the safe 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, donor of the pathological waste or to an authorized representative of the donor, if the recipient attests in writing that the pathological waste will be disposed of by cremation, interment, or other means in accordance with ORS chapter 97, and the facility complies with sections (4) and (5) of this rule.~~

(2) Notwithstanding any other provision in OAR chapter 333, division 56 or ORS 459.386 to 459.405, a health care facility may release a placenta to the individual from whom the placenta originated, or to their designee, if the facility complies with sections (3) to (5) of this rule, and 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 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/attestations described in subsection (1)(e2) of this rule in the mother/individual's medical record.

(34) Health care facilities and freestanding birthing center that release placentas or other pathological waste must have and implement a written policy and procedure that:

(a) Specify when placentas or other pathological waste will be released;

(b) Specify how the release will occur in order to ensure compliance with this rule;

(c) Ensure the safe management and transport of placentas or other pathological waste; and

(d) Identify a procedure for patients to submit complaints about the facility's process for releasing pathological waste or about the implementation of that process.

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

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

(7) Nothing birthing center from having additional requirements for the removal of a placenta from the facility or center in this rule exempts facilities from other state or federal laws, including but not limited to the Resource Conservation and Recovery Act, regarding handling of pathological waste.

(8) The Oregon Health Authority recognizes that facilities that release pathological waste in accordance with these rules may help to support the final disposition of body parts in accordance with an individual's traditions, cultural beliefs, customs, and ceremonies.

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, 459.386, 459.395