



PROPOSED RULE MAKING

CR-102 (July 2022) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: May 22, 2024

TIME: 10:08 AM

WSR 24-11-155

Agency: Department of Health

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

- Preproposal Statement of Inquiry was filed as WSR 23-17-070 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or
- Proposal is exempt under RCW _____.

Title of rule and other identifying information: Creating licensing requirements for organ transport services and vehicles. The Department of Health (department) is proposing a new rule in response to legislative requirements under Substitute House Bill (SHB) 1271 (chapter 290, Laws of 2023) to establish the minimum standards for organ transport vehicles and equipment in WAC 246-976-360.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
June 25, 2024	9:00 am.	In-Person: WA State Department of Health 111 Israel Rd SE Town Center 2 Room 166 Tumwater, Washington 98501 Zoom Link: Register in advance for this webinar: https://us02web.zoom.us/webinar/register/WN_OnEZLx9IS8ulQb8iRa4F-A After registering, you will receive a confirmation email containing information about joining the webinar.	The Department of Health will be offering a hybrid hearing. You may attend virtually or in person. You may also submit comments in writing.

Date of intended adoption: July 2, 2024 (Note: This is NOT the effective date)

Submit written comments to:

Name: Jason Norris
 Address: P.O Box 47853, Olympia, WA 98504-7853
 Email: <https://fortress.wa.gov/doh/policyreview/>
 Fax: 360-236-2380
 Other:
 By (date) June 25, 2024

Assistance for persons with disabilities:

Contact Jill Hayes
 Phone: 360-236-2838
 Fax: 360-236-2380
 TTY: 800-833-6388 or 711
 Email: jill.hayes@doh.wa.gov
 Other:
 By (date) June 18, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: SHB 1271 Organ Transport Vehicles and Services directs the department to issue a license to organ transport services that meet minimum licensing standards. The department must create rules establishing minimum licensing standards for organ transport vehicles

and equipment. This proposed new rule establishes minimum requirements for vehicle and equipment standards, as well as establishes the licensing process to obtain an organ transport license. The law and the proposed rules will allow licensed organ transport vehicles to use lights and sirens, high occupancy vehicle (HOV) lanes, and signal preemptive devices to transport time critical organs and tissues within Washington State without compromising public health and safety.

Reasons supporting proposal: SHB 1271 directs the department to issue a license to organ transport services that meet the licensing standards established in the law and the minimum standards established by the department. The proposed rules establish minimum standards for the issuance, suspension, and revocation of organ transport vehicles and service licenses to implement SHB 1271.

Statutory authority for adoption: SHB 1271 (chapter 290, Laws of 2023), RCW 43.70.040 and RCW 18.73.081

Statute being implemented: SHB 1271 (chapter 290, Laws of 2023), RCW 43.70.040 and RCW 18.73.290

Is rule necessary because of a:

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: Private Public Governmental

Name of proponent: (person or organization) Department of Health

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Jason Norris	111 Israel Road SE, Tumwater, WA 98501	360-236-2851
Implementation:	Jason Norris	111 Israel Road SE, Tumwater, WA 98501	360-236-2851
Enforcement:	Jason Norris	111 Israel Road SE, Tumwater, WA 98501	360-236-2851

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Jason Norris
Address: P.O. Box 47853, Olympia, WA 98504-7853
Phone: 360-236-2851
Fax: 360-236-2830
TTY: 800-833-6388 or 711
Email: jason.norris@doh.wa.gov
Other:

No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

[RCW 34.05.310](#) (4)(b)
(Internal government operations)

[RCW 34.05.310](#) (4)(e)
(Dictated by statute)

[RCW 34.05.310](#) (4)(c)
(Incorporation by reference)

[RCW 34.05.310](#) (4)(f)
(Set or adjust fees)

[RCW 34.05.310](#) (4)(d)
(Correct or clarify language)

[RCW 34.05.310](#) (4)(g)
((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.

The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

Brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

As directed by Substitute House Bill (SHB) 1271 (chapter 290, Laws of 2023) – Organ Transport Vehicles, the department must establish minimum standards for organ transport vehicles and equipment. Additionally, the legislation requires the department to issue a license to organ transport vehicles and organ transport services.

This is a new rule, and there are no other states in the United States or any current federal laws around organ transport vehicles or organ transport services. By establishing this rule, the department will satisfy the requirements of SHB 1271. The department will be able to enforce minimum standards through the effect of rule.

It is anticipated that the rulemaking will ensure regulations and standards are clear, concise, and reflect current standards and best practices for organ transport vehicles and services for the benefit and safety of the public.

The probable compliance requirements for a small business to comply with the proposed rule would include the additional requirements of adding a fire extinguisher to the vehicle and requiring the organ transport vehicle to have the ability to secure the equipment, organs, and tissue donors in the vehicle to prevent items from sliding, rolling, and any vertical movement.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
621991	Blood and Organ Banks	7	\$27,571.15
621999	All Other Miscellaneous Ambulatory Health Care Services	60	\$5,446.13

Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

New Section - WAC 246-976-360 Organ Transport Service and Vehicle License.

Description: This new rule describes how to obtain a license for an organ transport service and an organ transport vehicle.

For organ transport **services and vehicles**, the proposed new rule:

- Directs the applicant to comply with the requirements in statute and submit an application for licensure. Proposed rule language directing the applicant to comply with requirements in statute is exempt under RCW 34.05.328 (5)(b)(iii) as it incorporates by reference without material change Washington state statutes. The application process outlined in the proposed rule is not considered a Significant Legislative rule, by definition in RCW 34.05.328 (5)(c)(i), this is considered a “procedural rule” and therefore a cost/benefit analysis is not required.
- Outlines the vehicle and driver equipment standards that an applicant must meet in order to obtain an organ transport vehicle license. These include:
 - Standards for vehicle safety features such as tires, lighting, wipers, battery, brakes, and measures to secure items.
 - Requirements for equipment such as seat belts, mirrors, fire extinguisher, and smooth surfaces.

These requirements are incorporated by reference to RCW 18.73.290. These requirements are exempt from analysis under RCW 34.05.328(5)(c)(i).

Cost(s): For both current vehicles providing organ transport services and new vehicles seeking to operate this service, the proposed rule establishes minimum vehicle standards that the industry understands are necessary to provide safe vehicles. The department anticipates there may be costs for vehicles that are either not in compliance with these vehicle standards or need repair in which to continue to meet vehicles standards. The department was unable to quantify these costs due to variability but believe that vehicles currently providing service already adhere to basic vehicle safety features, such as tires, lighting, wipers, battery, brakes, etc. These vehicle standards are common for basic vehicle safety.

To allow for safe organ transport, the department anticipates that some vehicles may need to be retrofitted to adhere to the proposed rule. These include measures to secure items and fire extinguishers. SBEIS Table 2 below outlines the range of estimated additional costs to adhere to the proposed rule. The department produced the estimates with the following assumptions:

- There is not a set type of vehicle required for transportation. Vehicle types could widely range in make and model.
- The type of equipment necessary will depend on the type of services provided.
- The proposed rules do not require a specific way to secure the items as long as they are secure. This could range from securing the item in a seat using a seatbelt or using a ratchet strap to hold a container down, to installing gurney mount hardware.
- The proposed rule requires all service vehicles be required to have a fire extinguisher.

The department does not anticipate compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

Summary of all Cost(s)

SBEIS Table 2. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)	Description
New section 246-976-360 Organ transport service and vehicle license	One-time equipment cost range: \$0 to \$3,112	Securing equipment, gurney mount hardware.
	Initial cost range: \$50- \$100	Fire extinguisher
Total	Up to \$3212	

The department does not anticipate that the proposed rule may impose more than minor costs for businesses in the industry. The costs of the proposed rule, \$3,212 are less than the minor cost threshold \$5,446.13 (as calculated above).

Summary of how the costs were calculated

The costs of the proposed rules were calculated by reaching out to a subject matter expert in fleet maintenance to determine the additional equipment that is being required from the current standards of the current services that are providing organ transport services. Those items were a fire extinguisher and securing devices for equipment and gurneys.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name: Jason Norris

Address: P.O. Box 47853, Olympia, WA 98504-7853

Phone: 360-236-2851

Fax: 360-236-2830

TTY: 800-833-6388 or 711

Email: jason.norris@doh.wa.gov

Other:

Date: 5/22/24

Name: Todd Mountin, PMP, for Umair A. Shah, MD, MPH

Title: Deputy Chief of Policy for Secretary of Health

Signature:



NEW SECTION

WAC 246-976-360 Organ transport service and vehicle license.

(1) The secretary licenses organ transport services and vehicles. To become licensed an applicant shall:

(a) Comply with RCW 18.73.290;

(b) Submit a completed application on forms provided by the department; and

(c) Meet the minimum organ transport vehicle standards in subsection (2) of this section.

(2) A licensed organ transport vehicle must meet the following standards:

(a) Essential equipment for driver and passenger safety and comfort must be in good working order;

(b) A paper copy of current state organ transport vehicle license must be made immediately available upon request;

(c) Tires must be in good condition;

(d) Electrical system. All regular and special electrical equipment must be functional at all times:

(i) Interior lighting in the driver compartment must be designed and located so that no glare is reflected from surrounding areas to the driver's eyes or line of vision from the instrument panel, switch panel, or other areas which may require illumination while the vehicle is in motion;

(ii) Exterior lights must be fully operational;

(iii) Emergency warning lights must be provided in accordance with RCW 46.37.190, as administered by the state patrol; and

(iv) Emergency audible warning signals may be used in accordance with RCW 46.37.380;

(e) Windshield wipers and washers must be dual, electric, multi-speed, and functional at all times;

(f) Battery system. The battery must be capable of sustaining all systems. It must be located in a ventilated area sealed off from the vehicle interior, and completely accessible for checking and removal;

(g) Vehicle brakes, heating and cooling units, and window glass, must be functional at all times;

(h) Equipment, organs, and tissue donors must be secured in the vehicle to prevent items from sliding, rolling, and vertical movement;

(i) Functioning seat belts that comply with Federal Motor Vehicle Safety Standards 207, 208, 209, and 210. Restraints must be provided in all seat positions in the vehicle;

(j) Mirrors on the left side and right side of the vehicle. The location of mounting must provide maximum rear vision from the driver's seated position;

(k) One 5-B:C fire extinguisher must be secured in a manner that prevents sliding, rolling, and vertical movement; and

(l) Exterior surfaces must be smooth, with appurtenances kept to a minimum.

(3) Drivers of organ transport vehicles must comply with RCW 18.73.290.

(4) Licenses for organ transport services and vehicles must be renewed every two years. To renew a license, an applicant shall submit an application to the department at least 30 days prior to expiration.