

WSR 24-11-155

PROPOSED RULES

DEPARTMENT OF HEALTH

[Filed May 22, 2024, 10:08 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-17-070.

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 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): On June 25, 2024, at 9:00 a.m., at the Washington State Department of Health, 111 Israel Road S.E., Town Center 2, Room 166, Tumwater, WA 98501; or Zoom link. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_OnEZLx9lS8ulQb8iRa4F-A. After registering, you will receive a confirmation email containing information about joining the webinar. You may attend virtually or in person. You may also submit comments in writing.

Date of Intended Adoption: July 2, 2024.

Submit Written Comments to: Jason Norris, P.O. Box 47853, Olympia, WA 98504-7853, email <https://fortress.wa.gov/doh/policyreview/>, fax 360-236-2380, by 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, by 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 18.73.081.

Statute Being Implemented: SHB 1271 (chapter 290, Laws of 2023); RCW 43.70.040 and 18.73.290.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Jason Norris, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2851.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Jason Norris, 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.

Scope of exemption for rule proposal from Regulatory Fairness Act requirements:

Is not exempt.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated.

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 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 rule making 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 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:
 - o Standards for vehicle safety features such as tires, lighting, wipers, battery, brakes, and measures to secure items.
 - o 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 vehicle standards. The department was unable to quantify these costs due to variability but believes 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 WAC 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.

A copy of the detailed cost calculations may be obtained by contacting Jason Norris, 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.

May 22, 2024
 Todd Mountin, PMP
 Deputy Chief of Policy
 for Umair A. Shah, MD, MPH
 Secretary

OTS-5376.3

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.