

WSR 23-11-166

PROPOSED RULES

DEPARTMENT OF HEALTH

[Filed May 24, 2023, 11:19 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 21-03-011.

Title of Rule and Other Identifying Information: WAC 246-976-580 Trauma designation process; the department of health (department) is proposing to amend WAC 246-976-580 to establish clear requirements and criteria for assessing the need for additional level I and II trauma services in the state.

Hearing Location(s): On July 11, 2023, at 1:00 p.m. The department of health will hold a virtual public hearing. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_-7yZrJ1lSZOj-ibkP4UPOQ. After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: July 18, 2023.

Submit Written Comments to: Anthony Partridge, P.O. Box 47853, Olympia, WA 98504-7853, email TraumaDesignation@doh.wa.gov, by July 11, 2023.

Assistance for Persons with Disabilities: Contact Anthony Partridge, phone 360-584-6232, TTY 1-800-833-6388, email TraumaDesignation@doh.wa.gov, by June 27, 2023.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The department is proposing amendments to WAC 246-976-580 Trauma designation process, to establish clear requirements and criteria for assessing the need for additional level I and II trauma services in the state. The proposed amendments also include technical changes such as renumbering of subsections as the result of new subsections being added and reformatting spelled out numbers to numerals.

Reasons Supporting Proposal: Since the state trauma system's inception, there has not been a formalized process or set of criteria by which the department makes decisions about minimum and maximum numbers. As the trauma system continues to mature, trauma-designated facilities have expressed interest in applying for new level I or II designations. However, there is currently no formalized process or set of criteria that enables the objective evaluation of the need for additional higher levels of trauma service designations and the potential impact on the state trauma system.

The criteria outlined in the proposed rule will help ensure that Washingtonians have optimal access to trauma care services while maintaining a robust trauma system that balances access with other important considerations, such as maintenance of subspecialty volume and patient outcomes. Furthermore, the proposed amendments to the rule will ensure that trauma services are not overburdened or underutilized and are able to provide effective patient care that best supports the trauma system.

Statutory Authority for Adoption: RCW 70.168.050, 70.168.060, and 70.168.100.

Statute Being Implemented: RCW 70.168.060.

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: Anthony Partridge, 111 Israel Road S.E., Tumwater, WA 98501, 360-584-6232.

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 Anthony Partridge, P.O. Box 47853, Olympia, WA 98504-7853, phone 360-584-6232, TTY 1-800-833-6388, email anthony.partridge@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: The proposed rule does not impose any anticipated new costs on designated trauma service facilities unless they volunteer to change their designation level. The potentially impacted facilities do not meet the definition of a small business (50 or less employees). Thus, this rule making does not require a small business economic impact statement.

Scope of exemption for rule proposal:

Is fully exempt.

May 24, 2023
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary

OTS-4369.2

AMENDATORY SECTION (Amending WSR 18-24-082, filed 12/3/18, effective 1/3/19)

WAC 246-976-580 Trauma designation process. The department designates health care facilities to provide adult and pediatric acute care trauma services ("trauma services") and adult and pediatric trauma rehabilitation services ("trauma rehabilitation services") as part of the statewide emergency medical services and trauma care (EMS&TC) system. This section describes the designation process.

(1) The department must:

(a) Provide written notification to all licensed hospitals and to other health care facilities that a new designation period is beginning. The written notification and the EMS&TC regional plans are posted on the department's website;

(b) Provide a trauma designation application schedule outlining the steps and timeline requirements for a facility to apply for trauma service designation. The schedule must provide each facility at least ((ninety)) 90 days to complete an application for trauma designation. The application schedule is posted on the department's website;

(c) Provide an application for each level, type and combination of designation. Designation applications are released region by region, according to the established schedule;

(d) Conduct a site review for any hospital applying for level I, II, or III adult and pediatric trauma service designation to determine compliance with required standards;

(e) Initiate a three-year contract with successful applicants to authorize participation in the trauma system.

(2) To apply for ~~((trauma service designation the health care facility must do the following according to the application schedule:))~~ a new trauma service designation or a renewal for an existing trauma service designation, the health care facility must complete the steps in (a) through (d) of this subsection according to the application schedule. A health care facility applying for a new level I designation must meet the requirements of subsection (4) or (5) of this section. A health care facility applying for a new level II designation must meet the requirements of subsection (6) or (7) of this section.

A health care facility applying for trauma service designation must:

(a) Request an application;

(b) Submit a letter of intent to apply for trauma service designation indicating what level they are applying for;

(c) Submit a completed application(s);

(d) For health care facilities applying for level I, II, III adult and pediatric trauma service designation, the facility must complete a site review arranged and conducted by the department according to the following process:

(i) The department will contract with trauma surgeons and trauma nurses to conduct the site review. The review team members must:

(A) Work outside the state of Washington, for level I and II site reviews;

(B) Work outside the applicant's EMS&TC region, for level III site reviews;

(C) Maintain the confidentiality of all documents examined, in accordance with RCW 70.41.200 and 70.168.070. This includes, but is not limited to, all trauma patient data, staff discussions, patient, provider, and facility care outcomes, and any reports resulting from the site review;

(D) Present their preliminary findings to the health care facility at the end of the site review visit;

(ii) The department will provide the applicant the names of review team members prior to the site review. Any objections must be sent to the department within ~~((ten))~~ 10 days of receiving the department's notification of review team members;

(iii) A site review fee, as established in WAC 246-976-990, is charged and must be paid by the health care facility to the department prior to the site review. A standard fee schedule is posted on the department's website. For facilities applying for more than one type of designation or for joint designation, fee rates can be obtained by contacting the department;

(iv) The applicant must provide the department and the site review team full access to the facility, facility staff, and all records and documents concerning trauma care including trauma patient data, education, training and credentialing documentation, standards of care, policies, procedures, protocols, call schedules, medical records, quality improvement materials, receiving facility patient feedback, and other relevant documents;

(e) For health care facilities applying for level IV or V trauma service designation, level I or II trauma rehabilitation service designation or level I pediatric trauma rehabilitation service designa-

tion, the department may, at its discretion, conduct a site review as part of the application process to determine compliance with required standards. If a site review is conducted, the process will be the same as identified in (d) of this subsection, except a site review fee will not be charged.

(3) A trauma system assessment conducted by the department, including geospatial analysis conducted by the department, will be used to evaluate access to care at level I and II trauma services and identify areas where trauma services are needed. An optimal trauma system is one where level I and II trauma services are not overburdened or under-utilized and are able to provide effective patient care to best support the trauma system.

(4) A health care facility that is located in a geographic area where access to a level I trauma service is limited and cannot be reached within 60 minutes average ground transport time from the point of injury, may apply for a new designation as a level I trauma service in accordance with subsection (2) of this section.

(5) A health care facility that is not located within the geographic area described in subsection (4) of this section may apply for a new designation as a level I trauma service in accordance with subsection (2) of this section if:

(a) The facility is farther than 30 minutes average ground transport time from an existing level I service; and

(b) In accordance with its transfer-in and transfer-out guidelines required under WAC 246-976-700 (8) and (9), the facility has a minimum of 240 annual trauma patient admissions with an injury severity score of more than 15 or admits at least 1,200 trauma patients annually; and

(c) The facility meets all level I designation standards and has been fully designated and substantially in compliance as a level II trauma service for at least one full three-year designation period immediately prior to applying for a new level I designation.

(6) A health care facility that is located in a geographic area where access to a level II trauma service is limited and cannot be reached within 60 minutes average ground transport time from the point of injury, may apply for a new designation as a level II trauma service in accordance with subsection (2) of this section.

(7) A health care facility that is not located within the geographic area described in subsection (6) of this section may apply for a new designation as a level II trauma service under subsection (2) of this section if:

(a) The facility is farther than 30 minutes average ground transport time from an existing level I or II service; and

(b) The facility meets all level II designation standards and has been fully designated and substantially in compliance as a level III trauma service for at least one full three-year designation period immediately prior to applying for a new level II designation.

(8) The department will designate the health care facilities it considers most qualified to provide trauma care services including when there is competition for trauma service designation ((within a region)). There is competition for designation ((within a region)) when the number of applications for a level and type of designation is more than the maximum number of trauma services identified by the department and in the approved EMS&TC regional plan. The department will evaluate, at a minimum, the following in making its decisions:

(a) The quality of the health care facility's performance based on:

- (i) The submitted application, attachments, and any other information the department requests from the facility to verify compliance, or the ability to comply with trauma standards;
- (ii) Recommendations from the site review team;
- (iii) Trauma patient outcomes during the previous designation period, if applicable;
- (iv) Compliance with the contract during the previous designation period, if applicable;
- (b) The health care facility's conformity with the EMS&TC regional and state plans, based on:
 - (i) The impact of the facility's designation on the effectiveness of the trauma system;
 - (ii) Patient volumes for the area;
 - (iii) The number, level, and distribution of trauma services identified in the state and approved regional plans;
 - (iv) The facility's ability to comply with state and regional EMS&TC plan goals.
- ~~((4))~~ (9) After trauma service designation decisions are made in a region, the department will:
 - (a) Notify each applicant in writing of the department's designation decision;
 - (b) Send each applicant a written report summarizing the department's findings, recommendations and additional requirements to maintain designation. If a site review was conducted as part of the application process, the review team findings and recommendations are also included in the written report. Reports are sent:
 - (i) Within ~~((sixty))~~ 60 days of announcing designation decisions for level IV and V trauma services and trauma rehabilitation services;
 - (ii) Within ~~((one hundred twenty))~~ 120 days of the site review for level I, II and III adult and pediatric trauma services and any other facility that received a site review as part of the application process;
 - (c) Notify the EMS&TC regional council of designation decisions within the region and all subsequent changes in designation status;
 - (d) Initiate a trauma designation contract with successful applicants. The contract will include:
 - (i) Authority from the department to participate in the state trauma system, receive trauma patients from EMS agencies, and provide trauma care services for a three-year period;
 - (ii) The contractual and financial requirements and responsibilities of the department and the trauma service;
 - (iii) A provision to allow the department to monitor compliance with trauma service standards;
 - (iv) A provision to allow the department to have full access to trauma patient data, the facility, equipment, staff and their credentials, education, training documentation, and all trauma care documents such as: Standards of care, policies, procedures, protocols, call schedules, medical records, quality improvement documents, receiving facility patient feedback, and other relevant documents;
 - (v) The requirement to maintain confidentiality of information relating to individual patient's, provider's and facility's care outcomes under RCW 70.41.200 and 70.168.070;
 - (e) Notify the designated trauma service and other interested parties in the region of the next trauma designation application process at least ~~((one hundred fifty))~~ 150 days before the contract expires.

~~((5))~~ (10) Designated trauma services may ask the department to conduct a site review for technical assistance at any time during the designation period. The department has the right to require reimbursement for the costs of conducting the site review.

~~((6))~~ (11) The department will not approve an application for trauma service designation if the applicant:

(a) Is not the most qualified, when there is competition for designation; or

(b) Does not meet the trauma care standards for the level applied for; or

(c) Does not meet the requirements of the approved EMS&TC regional plan; or

(d) Has made a false statement about a material fact in its designation application; or

(e) Refuses to permit the department to examine any part of the facility that relates to the delivery of trauma care services ~~((7))~~ including, but not limited to, records, documentation, or files.

~~((7))~~ (12) If the department denies an application, the department will send the facility a written notice to explain the reasons for denial and to explain the facility's right to appeal the department's decision in accordance with chapters 34.05 RCW and 246-10 WAC.

~~((8))~~ (13) To ensure adequate trauma care in the state, the department may:

(a) Provisionally designate health care facilities that are not able to meet all the requirements of this chapter. The provisional designation will not be for more than two years. A department-approved plan of correction must be prepared by the health care facility specifying steps necessary to bring the facility into compliance and an expected date of compliance. The department may conduct a site review to verify compliance with required standards. If a site review is conducted, the department has the right to require reimbursement for the cost of conducting the site review;

(b) Consider additional applications at any time, regardless of the established schedule, if necessary to attain the numbers and levels of trauma services identified by the department and in the approved EMS&TC regional and state plan;

(c) Consider applications from hospitals located and licensed in adjacent states. The department will evaluate an out-of-state application in the same manner as all other applications. However, if the out-of-state applicant is designated as a trauma service in an adjacent state with an established trauma system whose standards meet or exceed Washington's standards and there is no competition for designation at that level, then the department may use the administrative findings, conclusions, and decisions of the adjacent state's designation evaluation to make the decision to designate. Additional information may be requested by the department to make a final decision.

~~((9))~~ (14) The department may suspend or revoke a trauma designation if the facility or any owner, officer, director, or managing employee:

(a) Is substantially out of compliance with trauma care standards WAC 246-976-700 through 246-976-800 or chapter 70.168 RCW and has refused or is unwilling to comply after a reasonable period of time;

(b) Makes a false statement of a material fact in the designation application, or in any document required or requested by the department, or in a matter under investigation;

(c) Prevents, interferes with, or attempts to impede in any way, the work of a department representative in the lawful enforcement of chapter 246-976 WAC, 34.05 RCW, 246-10 WAC, or 70.168 RCW;

(d) Uses false, fraudulent, or misleading advertising, or makes any public claims regarding the facility's ability to care for non-trauma patients based on its trauma designation status;

(e) Misrepresents or is fraudulent in any aspect of conducting business.

~~((10))~~ (15) The Administrative Procedure Act, chapter 34.05 RCW, and chapter 246-10 WAC govern the suspension and revocation process. The department will use the following process to suspend or revoke a facility's trauma designation:

(a) The department will send the facility a written notice to explain the reasons it intends to suspend or revoke the designation and to explain the facility's right to a hearing to contest the department's intended action under WAC 246-10-201 through 246-10-205;

(b) The notice will be sent at least ~~((twenty-eight))~~ 28 days before the department takes action, unless it is a summary suspension, as provided for in the Administrative Procedure Act, chapter 34.05 RCW and WAC 246-10-301 through 246-10-306;

(c) If a facility requests a hearing within ~~((twenty-eight))~~ 28 days of the date the notice was mailed, a hearing before a health law judge will be scheduled. If the department does not receive the facility's request for a hearing within ~~((twenty-eight))~~ 28 days of the date the notice was mailed, the facility will be considered in default under WAC 246-10-204;

(d) For nonsummary suspensions, in addition to its request for a hearing, the facility may submit a plan within ~~((twenty-eight))~~ 28 days of receiving the notice of the department's intent to suspend, describing how it will correct deficiencies:

(i) The department will approve or disapprove the plan within ~~((thirty))~~ 30 days of receipt;

(ii) If the department approves the plan, the facility must begin to implement it within ~~((thirty))~~ 30 days;

(iii) The facility must notify the department when the problems are corrected;

(iv) If, prior to ~~((sixty))~~ 60 days before the scheduled hearing, the facility is able to successfully demonstrate to the department that it is meeting the requirements of chapters 246-976 WAC and 70.168 RCW, which may require a site review at the facility's expense, the department will withdraw its notice of intent to suspend designation;

(e) The department will notify the regional EMS&TC council of the actions it has taken.

~~((11))~~ (16) A facility may seek judicial review of the department's final decision under the Administrative Procedure Act, RCW 34.05.510 through 34.05.598.

~~((12))~~ (17) A newly designated or upgraded trauma service must meet education requirements for all applicable personnel according to the following schedule:

(a) At the time of the new designation, ~~((twenty-five))~~ 25 percent of all personnel must meet the education and training requirements in WAC 246-976-700 through 246-976-800;

(b) At the end of the first year of designation, ~~((fifty))~~ 50 percent of all personnel must meet the education and training requirements in WAC 246-976-700 through 246-976-800;

(c) At the end of the second year of designation, (~~seventy-five~~) 75 percent of all personnel must meet the education and training requirements defined in WAC 246-976-700 through 246-976-800;

(d) At the end of the third year of designation, and all subsequent designation periods, (~~ninety~~) 90 percent of all personnel must meet the education and training requirements defined in WAC 246-976-700 through 246-976-800.

(~~(13)~~) 18 All currently designated trauma services must have a written education plan with a process for tracking and assuring that new physicians and staff meet all trauma education requirements within the first (~~eighteen~~) 18 months of employment.

[Statutory Authority: RCW 70.168.060 and 70.168.070. WSR 18-24-082, § 246-976-580, filed 12/3/18, effective 1/3/19. Statutory Authority: RCW 70.168.050, 70.168.060, and 70.168.070. WSR 09-23-085, § 246-976-580, filed 11/16/09, effective 12/17/09.]