

Significant Analysis
For Rules Concerning Trauma Service Designation
New Sections of WAC 246-976-580, -700, and -800 and
Repealing WAC 246-976-485 through -887
(Repealed sections will be incorporated--with amendments--into the new, proposed sections)
August 5, 2009

Briefly describe the proposed rule.

The Department of Health (the department) proposes to repeal, update and revise Washington Administrative Code (WAC) relating to designated trauma centers. The rules being repealed are 246-976-485 through -887. New sections are proposed (New Sections WAC 246-976-580 through -800) that incorporate many of the same standards and language from the repealed Trauma Designation sections. These standards are moved into the new sections to provide better readability and organization. The intent of this revision is to make the department's rules about trauma designation easier to understand for trauma service stakeholders. Currently, stakeholders must go between multiple rules to be fully aware of the standards about designated trauma services. The proposed new sections ensure regulations and standards are clear, concise and reflect current standards of care and best practice for the benefit and safety of the public.

WAC 246-976-485 through 246-976-887 will be repealed.

The new proposed WAC-246-976-580 "Trauma Designation Process" replaces current WAC 246-976-485,-490 and a section of -885. This consolidates the process for applying as a designated trauma center into a single rule. Placing these requirements into a single rule makes the application process easier to understand. The new rule outlines the process for applying to become a designated trauma service for adult, pediatric and rehabilitation care.

Proposed WAC 246-976-700 "Trauma Service Standards" replaces multiple rule sections addressing trauma services. Standards that are currently in WAC 246-976-530, 535, 540, 620, 750, 755, 760, 870, 881, 886, 887 and a part of 885 are now consolidated in a single rule. This is accomplished by building a matrix of trauma service standards for all levels of designation, both adult and pediatric. Combining all of these standards into a single matrix provides clarity and ease of use for trauma service stakeholders. Currently, the stakeholder must move among the various rules to determine the standards to which they are held.

Proposed WAC 246-976-800 "Trauma Rehabilitation Service Standards" replaces current WAC 246-976-830, 840, 850 and 860. The proposed rule combines the standards for trauma rehabilitation services into a single rule. As with acute trauma service standards, combining the requirements into a single matrix provides clarity and ease of use for trauma rehabilitation service providers.

History

Trauma, defined as a major life-threatening injury, is a disease of epidemic proportions. Each year, over 140,000 people die from traumatic injuries in the United States. Thirty to forty percent of all trauma deaths occur within hours of the injury. Many deaths are avoided when an organized trauma system is in-place.

The state of Washington's trauma system has been in place since 1990. The goal of Washington's trauma system is to ensure that severely injured people arrive at the right hospital in the right amount of time. Washington State's Emergency Medical Services and Trauma System (EMS/TC) has an outstanding reputation for providing quality care to injured people. Part of that success is due, in part, to having high quality, designated trauma services that operate under a consistent set of standards and guidelines.

The standards included in the proposed rules reflect current best practices identified by experts in the field of trauma care. Standards for trauma services reflect the recommendations of the American College of Surgeons as well as experts in other focus areas including pediatric and rehabilitation. Trauma service providers from throughout the state provided input into the final standards adopted in rule.

In order for trauma services to be fully aware of the expectations, it is important to clearly define the standards and processes for designating trauma services. Revising the current rules, as proposed, provides clarity to trauma service stakeholders to ensure each designated trauma service delivers optimal care to injured people in Washington State.

Is a Significant Analysis required for this rule?

Yes.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

Authority for the adoption and revision of the Trauma Designation rules is established in RCW 70.168.060. The general goal of RCW 70.168.060 (1) is to "establish minimum standards for facility, equipment and personnel" in designated trauma services. This includes acute care adult, pediatric and trauma rehabilitation services at all levels. Additionally, RCW 70.168.070 calls for the department to establish standards and a process for designating trauma centers. The overarching goal of the trauma legislation is to establish an efficient and well coordinated statewide emergency medical services and trauma care system to minimize the human suffering and costs associated with preventable morbidity and mortality.

The objectives the proposed rules implement include (as identified in RCW 70.168.010):

- Providing optimal care to the trauma victim.
- Preventing unnecessary death and disability from trauma.
- Containing costs of trauma care.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

Chapter 70.168 RCW requires the department to designate health care facilities to provide acute and trauma rehabilitation care services. Chapter 246-976 WAC outlines how that is to be accomplished, clarifying the department's and each applicant's responsibilities, and listing the trauma care standards that must be met.

There are no alternatives available to allow for development of enforceable standards that provide for a fair and equitable process of designating health care facilities to provide trauma care services. The trauma system is a statewide multi-faceted program that provides for consistent care among designated facilities that would normally be competitive. Without the designation system, there would be no way to ensure that appropriate trauma care would be available where needed throughout the state.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The majority of proposed changes to the trauma designation rules document are the result of reorganization and clear rule writing. The following sections include proposed changes of substance that may include financial impact to trauma care stakeholders.

Department staff conducted two surveys to determine the potential financial impact of the proposed changes to rule. The first survey was distributed via email to trauma program managers in all currently designated trauma services. The questions primarily focused on proposed changes with possible financial impact and, in particular, proposed changes to training requirements for trauma care physicians and nurses. The sole level I responded, four out of five level IIs responded (80%), 11 out of 23 level IIIs responded (48%), nine out of 33 level IVs responded (27%), and three out of 15 level Vs responded (20%). Staff conducted a second survey to obtain a better response from level IV and V trauma services. The second survey focused solely on three proposed changes to training requirement rules that have the greatest potential financial impact on small, rural hospitals. Staff developed a series of questions and distributed them via email to trauma program managers and nursing administrators in a selected sampling of Level IV and V trauma services around the state – 23 in all. Staff then called each of the 23 trauma services to conduct the survey over the phone. Twenty-one of 23 completed the phone survey. The following analysis uses information from both surveys to estimate the financial impact of the proposed changes.

WAC 246-976-580 Trauma Designation Process

Proposed Significant Changes

(1) Materials Required during a Trauma Designation Site Review.

The proposed rule clarifies and specifies the type of trauma-related documents the health care facility must make available to review team members if requested while at the facility during the on-site review.

Probable Costs

There are no appreciable cost increases resulting from these proposed changes. Direct costs to the health care facility will be in the form of document copying.

Probable Benefits

The benefit to implementing the proposed changes is providing clarity to the health care facility in regards to trauma-related documents that must be available upon request during site reviews. The specific list helps facilities prepare for the on-site review. The specific list provides on-site reviewers with all the information they need to conduct an effective evaluation of the trauma service.

(2) Educational Requirements for New Hires at a Designated Trauma Service

The proposed rule requires a health care facility to have all new hires meet trauma education requirements within the first 18 months of hire.

Probable Costs

Costs associated with this change are related to the higher cost output for training within an 18 month period. Because staffing levels fluctuate among hospitals and current economic conditions are resulting in lower attrition, the exact cost of this change cannot be calculated.

Probable Benefits

The proposed change requires physicians and nurses to be properly educated and prepared to provide care to trauma patients.

WAC 246-976-700 Trauma Service Standards

Proposed Significant Changes

(1) Trauma Medical Director

The proposed change requires the Trauma Medical Director (TMD) at level I and II trauma centers to be a board-certified general surgeon

Probable Costs

There is no incremental cost associated with this change. TMDs at the only level I and all level II trauma services are already board-certified general surgeons. The change clarifies the expectation and recognizes current practice.

Probable Benefits

The proposed change requires that TMDs, who provide leadership to trauma treatment teams, be adequately educated and trained to treat trauma patients within the expectations of the current standard of care.

(2) Trauma Medical Directors of Level III, IV & V Trauma Services

The proposed rule requires that TMDs in Level III services be current in Advanced Trauma Life Support (ATLS) certification if not board-certified in surgery. The TMD in level IV and V services must be current in ATLS if not board-certified in surgery or emergency medicine.

Probable Costs

The probable costs of this proposed change are associated with the requirement for maintaining ATLS certification for physicians not board-certified in surgery or emergency medicine. These costs vary depending upon who is conducting the educational course. Initial certification courses average \$800 and re-certification courses average \$450 every four years. The majority of level III TMDs are board-certified surgeons, so this proposed rule change will not impact them.

Approximately 85% of level IV and V TMDs are board-certified in surgery or emergency medicine and will not be impacted by the proposed rule. Of the 15% of level IV and V TMDs who are not board-certified, we know that some already maintain current certification in ATLS. So, it is estimated that less than 15% (fewer than seven) of level IV and V TMDs will be impacted by this proposed change and will be required to take ATLS every four years at the cost of \$800 for the initial certification and \$450 every four years thereafter.

Probable Benefits

The benefit of this proposed rule change is that the physician or physician extender (physician assistant or advanced registered nurse practitioner) serving in the trauma service leadership role will have the same or higher education and training as those care providers they oversee. The TMD is responsible for setting standards of care for the trauma service.

(3) Educational Requirements for Trauma Program Manager (TPM)

The proposed rule includes educational requirements for trauma program managers. Previously, there were no education requirements for the TPM. The proposed change clarifies the educational expectations for the TPM. New training requirements include:

- Advanced Cardiac Life Support (ACLS).
- Trauma Nurse Core Course (TNCC); after completing TNCC, they must then complete 12 hours of trauma related education every designation period.
- Pediatric Advanced Life Support (PALS) or Emergency Nurse Pediatric Course (ENPC) once and thereafter meets Pediatric Education Requirements (PER) outlined in rule.
- Attends the Trauma Program Manager Orientation course provided by the department.

Probable Costs

Based on a recent survey conducted by the department, the majority of TPMs currently meet the proposed education requirements. In many cases the TPM is an

instructor for the required courses. Of those who don't already meet the proposed requirement, the costs will vary depending upon the person conducting the various courses. The following is a breakdown of the cost for each of the required courses:

- ACLS: Average of \$215 per course; average of \$165 for a recertification course.
- TNCC: Average cost is \$200 for initial certification and \$180 for recertification course.
- PALS: Average cost is \$200 for initial certification and \$180 for recertification.
- ENPC: Average cost is \$260 for initial certification and \$180 for recertification.
- Trauma-specific contact hours (five hours every three years) to meet PER can be accomplished as part of the TPM's day-to-day responsibilities. Therefore, no incremental increase in cost.
- TPM Orientation course (one-time): The department does not charge a fee for conducting the course. Costs associated with this requirement are the result of individual hospitals paying per diem and travel expenses for TPM personnel. Only two of 31 survey respondents indicated that they currently don't meet the proposed requirement. For those two, one indicated a cost of \$153 and the other \$1,200 to meet the proposed requirement.

Probable Benefits

The benefit of this proposed rule change is that the nurse in the leadership role at a designated trauma center has equivalent or higher education and training than the nurses they oversee. As the leader of the nursing team, the TPM must have the necessary education and training to coordinate the trauma treatment team.

(4) Trauma Quality Improvement (QI) Program

The proposed rule clarifies expectations for the facility's quality improvement program. For example, the proposed rule requires the trauma QI program to have a reporting relationship to the facility's administrative team and the medical executive committee. The program must have a method to provide feedback to referring trauma services. And there must be a process to get information back on trauma cases referred to other QI programs in the facility. New language allows small volume level III-V trauma services (less than 100 trauma patients per year) to integrate the trauma QI program into the facility's overall QI program.

Probable Costs

There are no incremental costs associated with this rule change. For low volume level III, IV, and V trauma services, this rule change may decrease their costs because they can now address trauma care in the hospital-wide quality improvement program, enabling them to reduce duplication of committees and personnel.

Probable Benefits

The clarification of expectations for trauma QI represent generally accepted principles and best practices by trauma care professionals. The clarifications will provide for more consistent and more effective trauma QI practices around the state.

(5) Diversion policy and procedure

The proposed rule clarifies expectations for the process to divert a trauma patient to another facility. The proposed rule requires the facility to describe how the facility will notify near-by trauma services and prehospital agencies of their divert status.

Probable Costs

The department conducted a survey of all designated facilities. We received completed surveys from 28 of 79 facilities. Of the surveys returned, only two facilities indicated that they would have any costs associated with meeting this new rule. All of the other facilities either indicated that this protocol is already in-place (many use a regional internet-accessible bed status program), or that there would be no new costs to add this step to their diversion protocol.

Probable Benefits

The proposed rule ensures that trauma providers in geographically close proximity are aware when a facility is temporarily unavailable to receive a trauma patient. This will reduce the chance that the patient is misdirected or sustains a delay in transport.

(6) Trauma Team Activation protocol

The proposed rule clarifies expectations for the facility's trauma team activation protocol.

Probable Costs

Trauma services are already required to have a trauma team activation protocol. The proposed rule simply clarifies existing language and expectations. There are no incremental costs associated with the proposed rule change.

Probable Benefits

Clear rule language and expectations will result in more consistent and effective trauma team activation protocols. The proposed rule may reduce the need for continual education and technical assistance from department staff regarding this important trauma service requirement.

(7) Emergency Department Medical Director for Level I, II and III Adult and Pediatric Trauma Services.

The proposed rule requires:

- For adult level I-III, the emergency medical director, if board-certified in a specialty other than emergency medicine or surgery, is expected to practice emergency medicine as their primary practice.

- For pediatric levels, the emergency medical director, if board-certified in a specialty other than pediatric emergency medicine, emergency medicine or surgery, is expected to practice emergency medicine as their primary practice.
- For pediatric levels, the emergency medical director, if not board-certified in pediatric emergency medicine, is expected to have special competence in the care of pediatric patients.

Probable Costs

Although this is new language, the requirement is current standard of care for all level I, II and III designated trauma services. Hospitals designated at this level meet and often exceed the minimum standard reflected in the proposed rule. Therefore, the cost for this requirement is negligible.

Probable Benefits

The benefit of adding the proposed language, particularly the pediatric requirements, provides that the physician providing leadership in the emergency department has the experience and training to fulfill the role. Having the proposed level of training and expertise provides for patient safety and quality trauma care.

(8) Certification and training requirements for emergency care physicians in level III (adult and pediatric), IV & V trauma services:

The proposed rule requires:

- For level III adult trauma services, emergency physicians must be current in ACLS and ATLS certification if they are not board-certified. Non board-certified physicians must practice emergency medicine as their primary practice.
- For level III pediatric trauma services, emergency physicians must be current in ATLS if they are not board certified. Non board-certified physicians must practice emergency medicine as their primary practice.
- For level IV facilities, physicians must be current in ACLS and ATLS if they are not board-certified. Physician assistants (PA) or advanced registered nurse practitioner (ARNP) who initiate care until the physician arrives must be current in ACLS and must audit ATLS every four years.
- For level V facilities, non board-certified physicians must have current certification in ACLS and ATLS. PAs and ARNPs must have current certification in ACLS and must audit ATLS every four years.

Probable Costs

The department conducted a survey of currently designated level I, II and III trauma services to determine the cost they might incur if they had to implement this rule. Though the survey did not specifically ask, the department knows--based on documentation submitted in their applications for trauma designation--that most level III and large IV facilities have board-certified physicians in the emergency department and so are exempt from the new requirement. Many facilities contract with an emergency physician organization to staff their emergency departments. These contracts voluntarily require physicians to have current certification in ACLS and ATLS. Of those that do not fit into either of the previously mentioned

categories, the providers that may be impacted by this rule are non board-certified physicians and physician extenders (PAs and ARNPs) primarily in rural level IV and V trauma services.

When the survey was released, the proposed rule would have required physicians to be current in ACLS and ATLS unless they were board-certified in emergency medicine, pediatric emergency medicine or surgery. Subsequently, a stakeholder meeting was convened and the proposed rule was relaxed to apply to only those physicians (and physician extenders) who are not board-certified in emergency medicine, pediatric emergency medicine or other relevant specialty and practicing emergency medicine as their primary practice. While the department doesn't know for sure how many more physicians would be exempt from the revised requirement, the department believes the revised new requirement will impact only those who will benefit most from the new training requirement. The second survey conducted with level IV and V trauma services indicated that approximately 30% of emergency physicians and physician extenders would be impacted by the proposed change. This is an estimate based on the information received from the survey hospitals. An estimate for the statewide impact is calculated. The following table illustrates the results of the survey:

Survey #2 Results on Impact of Educational Requirements for MDs and Mid-Level Providers

Trauma Svc. Type	Total Number of ED Physicians-Survey Results	Est. Cost for meeting Educational Requirements for all survey respondents	Total Number of Mid Level Providers-Survey Results	Est. Cost for Meeting Educational Requirements for all survey respondents
Level IV	83	(35 MDs @ (\$450 per): \$15,750	26	(20 mid-levels @ \$450 per): \$9,000
Level V	43	(36 MDs @ \$450 per): \$16,200	12	(2 mid-levels @ \$450 per): \$900

Based on the responses to the second survey, an analysis was performed in an attempt to estimate the cost of the proposed change statewide. The following table illustrates the estimated cost statewide for level IV and V trauma services.

	MD Cost Est. for State	Mid-Level Est. for State	Total Est. Cost-Statewide
Level IV	\$90,240	\$16,000	\$106,240
Level V	\$49,700	\$1,600	\$51,300
TOTAL	\$139,940	\$17,600	\$157,540

The cost of ACLS and ATLS is approximated below:

- The cost of an initial ACLS course is approximately \$215 per provider. An ACLS refresher course is estimated to be \$165. Costs to replace the work shift of some providers while attending ACLS certification courses must also be considered.
- The cost for an initial ATLS course is approximately \$800 per individual. A refresher course to maintain currency costs approximately \$450 per individual. If a physician is an employee of the facility (residents and physician extenders are usually facility employees), then the facility would pay the course costs and the physician or provider's salary for the number of course hours (an estimate of \$600 was given) or per diem expenses (an estimate of \$300-\$500 was given). Physician replacement costs do not appear to be a problem for any of the facilities.

Probable Benefits

The proposed language allows a provider who is not board-certified or a provider who is board-certified but not practicing emergency medicine as their primary practice to care for trauma patients as long as they maintain ACLS and ATLS certification. The overall benefit of requiring either board-certification or ACLS and/or ATLS certification is to ensure that physicians (and physician extenders) providing care in the emergency department have the education, credentials, and preparation needed to care for trauma patients. Board-certification demonstrates clinical currency in knowledge, as measured by a national specialty certifying committee. ACLS and ATLS certification demonstrates clinical currency in standard knowledge and skill as measured by a national specialty organization. Many emergency department physicians are already board-certified in emergency medicine or another relevant specialty (example: internal or family practice medicine) and practicing emergency medicine as their primary practice and are exempt from the proposed rule.

During discussions with stakeholders, the difference between educational requirements for nurses and physicians was apparent. Physicians, who are ultimately responsible for the care and outcome of patients, should be current in the skill and knowledge of caring for the acutely injured patient. As team leader, the physician's skill and knowledge should be equal to, or exceed, that of the members of the treatment team. This ensures that care provided to the trauma patient is consistent among all members of the treatment team.

(9) Emergency Department Nurse Requirements

The proposed rule requires:

- For level V services, a registered nurse must be in-house and available within five minutes of notification of the trauma patient's arrival (level V clinics are exempt from this proposed rule).
- For all adult trauma services (level I-V), emergency department registered nurses must have current ACLS certification.

- For all adult and/or pediatric trauma designation (level I, II, III, IV, V, I P, II P, & III P), emergency department registered nurses must be TNCC trained and thereafter receive 12 hours of trauma training every three-year designation period (except level V ED RNs are exempt from the ongoing trauma training requirement).

Probable Costs

The proposed requirement for level Vs to have a registered nurse in-house represents current standard of care. All level V (hospital based) trauma services currently have registered nurses in-house and available within the required time period. Therefore, the department assumes there is no incremental cost for this proposed requirement. Level V clinics are exempt from this requirement because they may not have staff in-house 24/7.

The department surveyed trauma services to determine the likely cost to implement the additional training requirements for ED RNs. Responses to the survey indicate the following:

- Twenty-eight of 31 facilities indicate they already require ED nurses to maintain currency in ACLS.
- For those facilities that currently do not meet the proposed rule, the cost for ACLS training is approximately \$215 per nurse for initial training and \$165 per nurse for recertification. The range of number of people needing to complete the training (of the three hospitals reporting that they don't meet the proposed rule) is 10-65. Therefore, the span of incremental increase to implement the proposed rule is \$2,150-\$13,975 for initial certification. For recertification, the incremental expense ranges from \$1,650-\$10,725.
- The cost of travel, lodging and per diem must also be considered. Each facility establishes policy for reimbursement of these expenses.
- Current rules require ED RNs in all levels (except level V) to have completed TNCC. The proposed rule would now require level V ED RNs to be TNCC trained. The three level V facilities that responded to the survey indicated they already require ED RNs to be TNCC trained. For those that don't already meet this requirement, the cost is estimated to be \$215 per nurse. Travel, lodging and per diem must also be considered.
- The proposed rule requires ongoing trauma training for ED RNs in all levels except level Vs. Facilities can meet the ongoing trauma training requirement by maintaining currency in TNCC. Alternatively, facilities can develop alternative, in-house methods for providing ED RNs with the proposed four hours/year trauma training.
- The second survey of level IV and V trauma services focused on the impact of the training requirements on these facilities. Most, if not all, level IV and V trauma services require ACLS certification of RNs. Additionally, most require TNCC for their nurses. Due to fluctuations in staffing as well as attrition of RNs, there will be an impact due to the

proposed change. A table summarizing the impact on these facilities follows:

	RNs requiring Training-Survey Results	RNs requiring Training-State Est.	Est. Cost to Provide Training (\$215 per Nurse), state- wide
Level IV	8	26	\$5,590
Level V	19	33	\$7,095
TOTAL	27	59	\$12,685

Probable Benefit

The benefit of the proposed educational changes is improvement in the clinical decisions and care provided to trauma patients. National professional nursing associations (Emergency Nurse Association, Society of Trauma Nurses, among others) recognize the value and importance of trauma training. TNCC is the national standard of education for nurses caring for trauma patients. The requirement also allows nurses to remain current in best practices relating to care of the trauma patient. The current standard of practice across the majority of the state already requires their nurses to have current ACLS certification, adopting this standard of practice into rule will help ensure consistent quality of care across the entire state.

(10) Emergency Department Equipment List.

The proposed rule simplifies the equipment required of designated trauma facility emergency departments. A representative group of clinicians reviewed the existing equipment requirements and recommended to the department the revised standards to better reflect current practice.

Probable Cost

There is no incremental increase in cost as a result of the proposed change. All hospitals currently maintain an equipment list consistent with the proposed revision.

Probable Benefit

The benefit to this change recognizes the advances made in equipment provided in emergency departments.

(11) Respiratory Therapists at Level III Facilities

The proposed rule requires facilities designated as level III trauma services to have a respiratory therapist available within five minutes of notification of the trauma patient’s arrival.

Probable Cost

Survey results report the following about the proposed change:

- Of the 11 responding level III facilities, 10 indicate that respiratory therapy (RT) services are already in place. Therefore, there is no incremental cost increase.
- While only 11 of the level III facilities responded to the survey, rules meetings suggest that the presence of an RT in house is the current practice among level III facilities. The department assumes that the incremental cost increase will be nominal if any.

Probable Benefit

The benefit to the proposed change is improved response time for RT services to severely injured patients. This resource is an essential part of caring for a severely injured person. Management of the patient's airway and ensuring optimal respiratory function is a key, if not primary factor in the outcome of the trauma patient. Implementing the proposed change will enhance patient safety and outcomes.

(12) Diagnostic Services

The proposed rule requires:

- Level V trauma services (except level V clinics), to provide basic diagnostic imaging services. These services include personnel able to perform routine radiological capabilities, on-call and available within 20 minutes of notification of the patient's arrival.
- Level I and II services to have magnetic Resonance Imaging (MRI) with a technologist on-call and available within 60 minutes of the trauma team leader's request.
- Level I and II services to have interventional radiology service on-call and available within 30 minutes of the trauma team leader's request.

Probable Costs

Based on survey results, the following information is provided relating to the probable cost of the proposed change.

- Three level V facilities responded indicating that diagnostic imaging services are available. The proposed change does not result in an incremental cost increase to these facilities. While this is a small sample of the level V facilities, all but one level V facilities currently designated are hospitals and already have basic diagnostic services available. Level V clinics are exempt from the proposed rule.
- The level I and all level II designated trauma facilities already have MRI and interventional radiology services available for trauma care.
- One level II trauma facility did indicate that having a technologist available within 20 minutes of the trauma team leader's request would result in an incremental increase in cost of \$27,300. At a subsequent stakeholder meeting, it was agreed to change the response time for MRI to 60 minutes and for interventional radiology to 30 minutes.
- Remaining respondents indicate they would not see an appreciable incremental increase in cost as a result of the proposed change.

Probable Benefits

The benefit to the proposed change aligns the rules with current best practice and reflects the resources currently available in licensed hospitals. This provides the best possible care and available services to an injured person.

(13) Clinical Laboratory Services

The proposed rule requires:

- Level V services (except for level V clinics) to provide basic clinical laboratory services.
- Level IV services to provide microbiology services.

Probable Costs

Responses to the survey suggest the following:

- Three level V facilities responded, indicating that clinical laboratory services are already available; therefore, no incremental increase in expense is anticipated. While this is a small sample, all but one of the level V trauma services are hospitals and have the services established. Level V clinics are exempt from the proposed change.
- Eleven level IV facilities responded to the survey and all indicate that microbiology services are available. Again, no incremental increase in cost as a result of implementing the change.

Probable Benefits

The proposed changes to clinical laboratory services align with current best practice and reflect the resources currently available in licensed hospitals. This provides the best possible care and available services for trauma patients.

(14) Provision of Blood and Blood Components

The proposed rule requires level V services (except level V clinics) to have blood and blood-component services available. The following services must be provided:

- Ability to obtain blood typing and crossmatching.
- Blood and blood components available from in-house or through community services to meet patient needs.
- Noncrossmatched blood available on patient arrival in the emergency department.

Probable Costs

Three level V trauma services responded to the first Department of Health survey. All report the services outlined in the proposed change currently are in-place. All but one of the level V services are hospitals with like resources. The level V clinic is exempt from the requirement. Based on this information, the department assumes that there will be no appreciable increase in costs resulting from the proposed rule.

Probable Benefits

The benefit of these changes is that they bring the trauma rules in line with standard practice, providing the best possible care and available services for trauma patients.

(15) Required back-up plan for General Surgery Coverage in Trauma Services

The proposed change requires levels I, II, and III general and/or pediatric designated facilities to have a written plan to provide general surgery coverage for trauma care when the general surgeon on-call for trauma is unavailable. The intent of this change is to ensure hospitals proactively address situations where the general surgeon is otherwise clinically engaged with another trauma patient or a non-trauma patient. The proposed rule does not require a formal back-up call schedule with committed physicians.

Probable Costs

At the time the survey was released, the proposed rule would have required the trauma service to have a formal back-up plan for general surgery coverage. When asked about the cost of implementing a back-up plan, responses ranged from \$0 to \$365,000. Subsequent to the survey, the department convened a stakeholder meeting to discuss the proposed rule. The expectation was clarified and the proposed rule was revised to remove the words “formal” and “back-up.” The intent and purpose of the proposed rule is for trauma services to have a written plan in-place to provide general surgery services when the general surgeon is otherwise clinically engaged and is unable to respond to a trauma patient. The plan could include transfer or diversion to another trauma service. Trauma services are not required to establish formal, back-up schedules and procedures. There is no incremental increase in cost associated with implementing this proposed rule.

Probable Benefits

The benefit of having this rule is that trauma services will have a predetermined plan in place to manage the rare times when the general surgeon on-call for trauma is unavailable. The plan will take into consideration the unique characteristics, resources and capabilities of each trauma service.

(16) Orthopedic surgery services.

The proposed rule requires level III trauma services to have orthopedic surgeons on-call and available within 30 minutes of the trauma team leader’s request.

Probable Costs

The department’s survey received 11 responses from the 25 level III trauma services in the state. Six of the respondents report no incremental cost increase as a result of the proposed language. Four respondents do anticipate a cost increase due to the proposed change. The remaining respondent did not address this specific issue. Current rule already requires level IIIs to have orthopedic surgery services on-call and available for consultation. The proposed rule adds a specific response time of 30 minutes when requested by the team leader. When calculating any expected additional costs, the department considered that the only time the orthopedic surgeon will be required to respond will be at the trauma team leader’s request. According to stakeholders, it is not often that an orthopedic surgeon will be called to respond and provide care on an emergent basis, within the first 24 hours of a patient’s injury. However, the new response time requirement may prompt orthopedic surgeons to request on-call or trauma team activation stipends. It is difficult to predict and

quantify these costs. Two facilities provided increased cost estimates of \$185,000 and \$365,000.

Probable Benefits

Many times, severely injured patients require the care of an orthopedic surgeon. Implementing this proposed rule creates consistent availability of orthopedic surgeons in all level III hospitals throughout the state. This enhances patient care and aligns with current best practice. This is a national standard of care for level III trauma services (American College of Surgeons).

(17) Anesthesia Services

The proposed rule allows a CRNA to provide anesthesia services in all trauma service levels. Previously, level I and II trauma services were required to use anesthesiologists only.

Probable Costs

There is no incremental cost increase from this proposed rule. The proposed rule may save some trauma service money through lower salary costs.

Probable Benefits

The proposed rule provides trauma services with flexibility in how they provide anesthesiology services. The proposed rule reflects current standard of practice and does not compromise patient safety.

(18) Ongoing Trauma Training for Critical Care RN's.

The proposed rule requires:

- For level I and II trauma services, critical care RNs to have at least six contact hours of trauma training every three-year designation period.
- For level III designated facilities, critical care RNs to have at least three contact hours of trauma training every three-year designation period.

Probable Costs

In all level I-III designated facilities, critical care nurses are currently required to have trauma training once in their career. All facilities providing critical care services for trauma patients will be financially impacted by the proposed rule requiring ongoing trauma training. Facility costs will vary depending on whether a facility conducts an in-house training or chooses an outside course or an alternative training option. In the survey the department conducted, a facility provided an estimate of their expected costs to meet this requirement; for example, with 60 nurses, a typical \$200 course, salary/per diem costs paid at \$30/hour for eight hours, the facility's costs would be \$26,400 every three years. Sending nurses to an outside course is expensive and the majority of facilities look for alternative methods. The department is unable to provide estimates of the cost using alternative methods to meet the requirement.

Probable Benefits

The benefit of the proposed educational changes is improvement in the clinical decisions and care provided to trauma patients in the critical care unit. National professional nursing associations (including the Society of Trauma Nurses) recognize the value and importance of trauma training. The Trauma Nursing Core Course is the national standard of education for nurses caring for trauma patients.

(19) Critical Care General Surgery Consults and Use of Intensivists.

The proposed rule requires level I, II, and III general and/or pediatric designated facilities to either provide general surgeon consults to trauma patients admitted to the critical care unit or if an intensivist is the primary admitting physician, the intensivist must have four hours per year or 12 hours every three years of trauma specific continuing medical education (CME).

Probable Costs

There were 17 surveys returned, showing varied responses to this proposed rule. Eight facilities indicated they would not have additional expenses, four indicated that their surgeons are always involved, one indicated that the costs would be deferred to the intensivists, and three did not provide rationale for their response of no cost increase. Reported costs associated with the proposed rule range from \$960 for four intensivists to \$48,000 for eight intensivists.

Probable Benefits

The intent and benefit of this rule is to ensure that intensivists caring for trauma patients are prepared to care for critically injured patients. Surgeons are turning care of trauma patients over to intensivists earlier in their course of care so intensivists' skills need to be current. Some trauma patients may even be admitted directly to an intensivist, because hospitals have hired them to provide critical care. Requiring intensivists to have trauma-specific CME will improve the care provided.

(20) Level V Auxiliary Services

The proposed rule requires level V designated facilities, including clinics, to make sure the following services are available or that patients have access to them:

- Adult protective services.
- Child protective services.
- Pastoral or spiritual care.
- Pharmacy services.

Probable Costs

Three level V designated facilities returned completed surveys and indicated that they would not have any additional costs. While this is a small sample of the level V facilities, the proposed required services are basic in nature. These services are not required to be in-house but simply made available to trauma patients. Adult and child protective services are already requirements of another state agency, the Department of Social and Health Services. The department assumes no additional costs are associated with the proposed requirements.

Probable Benefits

The proposed requirement ensures that key ancillary services are available to patients cared for by level V trauma facilities. The proposed rule aligns with current best practice.

(21) Participation in Community and Regional Injury Prevention Activities.

The proposed rule requires:

- For level I – III services, to have a public injury prevention education program AND participate in regional injury prevention activities.
- For level IV and V, to participate in community or regional injury prevention activities.
- For all levels, to have a written plan for drug and alcohol screening and brief intervention and referral.

Probable Costs

- Current rule requires level I-III trauma services to have a public injury prevention education program **OR** to participate in community or regional injury prevention programs. The proposed rule requires level I-IIIs to have an injury prevention program **AND** participate in regional injury prevention programs. All level I-III trauma services have public education/injury prevention programs in-place (previous rule). They also either coordinate efforts with their EMS/TC regional council or are involved in community events injury prevention activities such as health fairs and school assembly presentations. The proposed rule adds no incremental cost to level I-III trauma services.
- Survey responses from 15 level IV and V facilities were received. Responses regarding this topic identified costs ranging from \$1,000 to \$8,000. Five facilities didn't complete the question, two indicated "unknown," two already have a program in place so no expected increased costs, and six provided cost estimates as identified earlier. Trauma system participation grant funds provide by the department can be used to sponsor injury prevention activities.
- The proposed rule requires all levels to have a written plan for drug and alcohol screening and brief intervention and referral. The completed surveys showed multiple responses: 12 provided cost estimates, 10 indicated there would be no additional costs as a program is already in place, six indicated "unknown" and three did not answer the question. Estimated costs are largely driven by the interpretation of the proposed change. There is a broad spectrum of programs available. Elaborate models exist that are extremely costly to operate and maintain. The minimum requirement outlined in the proposed rule allows a very basic program with minimal costs associated.

Probable Benefits

The benefit of requiring facilities to be involved in injury prevention activities is immeasurable. Many hospitals are already doing these activities even if not directly coordinated by the trauma service. The designation application process has shown that this is the case. For example, the birthing center may be giving away bicycle

helmets and car seats for newborns, and doing seatbelt checks. All injury prevention related activities provided by the facility count towards meeting this standard.

Benefits of a Drug and Alcohol Screening and Brief Intervention Program provide additional support to injured people. Research has shown there is an actual measurable decrease in the drug and alcohol related trauma recidivism when individuals are given a brief intervention.

(22) Pediatric Education Requirement (PER)

The proposed rule requires:

- Level V emergency department physicians, nurses and PAs and ARNPs to complete the PER.
- Level IV surgeons and anesthesia providers to complete the PER if the facility's scope of trauma care includes general surgery services.
- The proposed rule removes the exception to PER for physicians who are board-certified in pediatric emergency medicine or in emergency medicine (level IV only).
- The proposed rule modifies the methods to meet the PER. Providers must complete at least five contact hours of pediatric trauma specific education every three years. One-time PALS or equivalent certification is no longer an option.

Probable Costs

With the proposed change, it is difficult to quantify the economic impact of the requirement. The survey analysis attempts to quantify the actual number of health care providers who currently are not compliant with the requirement. However, because the methods available to meet the requirement are broad, calculating the net impact is difficult. The proposed language clarifies that an individual may opt to take a PALS course (approximately \$200), though it is not a requirement, to meet the intent of the proposed rule. Health care providers are able to comply with the rules through a number of no or low-cost options. This includes web-based training that is provided at no cost. Therefore, attempts to estimate the potential economic impact will be inaccurate. Many of the survey respondents stated that they provide such training in-house or require their personnel to maintain currency in PALS.

Probable Benefits

Care of pediatric trauma patients differs from that of adult trauma patients. The unique physiologic response to trauma that a child has, makes caring for the pediatric patient challenging. Many rural communities experience minimal exposure to traumatized pediatric patients so experience and exposure becomes problematic. In many cases, these facilities are the only available health care resource and must be competent in the care of the pediatric patient. The training required in the proposed rule highlights the importance of pediatric-specific trauma training. Implementing the proposed change ensures that pediatric patients receive quality care in every area of the state. It is interesting to note that the respondents to the level IV and V survey recognize the importance of such training and many have already committed resources to provide such training to their staff.

WAC 246-976-800 Trauma Rehabilitation Service Standards

Proposed Significant Changes

(1) Level I trauma rehab services must be a licensed hospital

The proposed rule clarifies that level I rehabilitation and level I pediatric rehabilitation services must be licensed hospitals.

Proposed Cost

There is no incremental cost to the proposed rule. The rule simply clarifies existing rule and helps to distinguish the requirement differences between level I and level II services. Designated level II trauma rehabilitation services do not have to be licensed hospitals.

Proposed Benefit

The proposed rule provides clarity and will ensure correct interpretation of the requirement.

(2) Trauma rehabilitation service Medical Director

The proposed rule clarifies the role and responsibility of the medical director for all levels including participation in the trauma rehabilitation quality improvement program.

Proposed Cost

There is no incremental cost to the proposed rule. The rule separates the medical director responsibility from the patient management responsibilities.

Proposed Benefit

The proposed rule provides clear expectations for the medical director responsibility. It provides more flexibility to trauma rehabilitation services in terms of how they meet the administrative and patient management responsibilities.

(3) Psychiatrist in-house or on-call

The proposed rule clarifies that a psychiatrist, who may or may not be the medical director, must be in-house or on-call twenty-four hours every day and responsible for the day-to-day clinical management and the treatment plan of trauma patients.

Proposed Cost

There is no incremental cost to the proposed rule. The rule separates the medical director responsibility from the patient management responsibilities.

Proposed Benefit

The proposed rule provides trauma rehabilitation services with more flexibility in terms of how they meet the administrative and patient management responsibilities.

(4) Anesthesia services

The proposed rule clarifies that either an anesthesiologist or a Certified Registered Nurse Anesthetist (CRNA) can provide anesthesia services.

Proposed Cost

There is no incremental cost to the proposed rule. The rule simply clarifies the expectation.

Proposed Benefit

The proposed rule provides trauma rehab services with more flexibility in terms of how they provide anesthesia services.

(5) Pharmaceutical services

The proposed rule allows pharmacy services in level I pediatric rehabilitation services to be provided by a pharmacist in-house or on-call with immediate access to pharmaceuticals and patient medical records and pharmacy databases. Previously, a pharmacist in level I pediatric services was required to be in-house.

Proposed Cost

There is no incremental cost to the proposed rule. In fact, the proposed rule may provide financial relief to hospitals since they would not be required to maintain a pharmacist in house 24/7 but rather have the option to have the pharmacist available from a remote location with immediate access to electronic information with personnel available to dispense pharmaceuticals in-house.

Proposed Benefit

The proposed rule provides trauma rehab services with more flexibility in terms of how they provide pharmaceutical services.

(6) Lists of services and providers that must be available to the trauma rehabilitation service.

The proposed rule reorganizes various lists of services and providers that must be available by type of service (medical, rehab, social) and by the expectation for response (example: in-house vs. through affiliation).

Proposed Cost

There is no incremental cost to the proposed rule. The rule simply clarifies the expectation.

Proposed Benefit

The proposed rule provides clarification and consistency between levels of designation.

(7) Special competence in pediatric rehabilitation care for level I pediatric rehabilitation care.

All trauma rehabilitation service providers in level I pediatric trauma rehabilitation services must have special competence in pediatric rehabilitation care.

Proposed Cost

There is no incremental cost to the proposed rule. Pediatric CARF accreditation requires personnel who serve children/adolescents to demonstrate competencies in pediatric care. The proposed rule simply reinforces the requirement in CARF and inserts our trauma designation language to have “special competence” in pediatric rehabilitation. By definition, “special competence” is determined by the appropriate specialty area within each facility.

Proposed Benefit

The proposed rule provides clarification and consistency between levels of designation. The special competence language provides flexibility for each facility to determine the education, training, and experience required to meet the competency requirement by specialty type.

Cost Benefit Summary

Based on input received from stakeholders during meetings, through emails and phone calls, and through the financial impact surveys, the department’s assumption is that a majority of trauma services already comply with a majority of the requirements in this proposed rule. Some trauma services, however, may face costs to satisfy these requirements. In those cases where trauma services have indicated that they will have to complete additional or new tasks (e.g., specified training and minimum qualifications for staff, establishing policies and procedures, providing additional services and programs), the analysis estimates the cost implications of completing these various tasks. Collectively, although there will be individual trauma services that will have to complete these tasks and incur the costs of these actions, the benefit of an improved statewide trauma system, which helps to ensure severely injured people arrive at a hospital prepared to meet their needs, exceed these costs. Therefore, the probable benefits of this proposed rule exceeds the probable costs. The department believes that the proposed rules mirror the current standard of practice for trauma care.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

Department staff worked closely with trauma care stakeholders to review and propose revised rules to meet the overall goals of the system and at the same time minimize the burden on providers. Several meetings and teleconferences, a video conference, and an iLink workshop were conducted over a 10 month period to involve stakeholders around the state in the designation rules revision process. Many ideas were proposed, vetted, and then accepted or rejected throughout the lengthy review process. Rules that were proposed but ultimately rejected because the cost implications exceeded the benefit include:

- (1) A proposal to expand the pediatric education and training requirement (PER) was considered but rejected because of concerns from providers about the cost implications.

The proposed rule would have required many more providers to meet the PER; it would have changed one of the options for meeting the PER from one-time PALS certification to currency in PALS certification; and it removed an exception to the rule for physicians who are board-certified in pediatric emergency medicine. A survey conducted by the department indicated that the cost of the proposed rule was significant. For example, the average cost to meet the new requirement for a level V trauma service (previously exempt from PER) was approximately \$40,000. The department received numerous verbal and written concerns about the impact of the proposed rule. Several stakeholders indicated that they would have to drop out of the trauma system if the rule was adopted. Based on these concerns, the department worked with the Governor's EMS and Trauma Steering Committee to develop compromise language that accomplishes the goal of providing pediatric trauma specific education without the potential for burdensome cost.

(2) A proposal to require ongoing trauma training for emergency department RNs was considered and accepted with a couple of modifications. The department opted not to require emergency department (ED) RNs in level V trauma services to meet the ongoing trauma training requirement at this time. Previously, ED RNs in level Vs were not even required to have one-time trauma training. The proposed rules will require ED RNs in level Vs to take trauma nurse training at least once. The department decided that adding a currency requirement at the same time imposed an unreasonable financial burden on these small, rural hospitals. The proposed rule was also modified to require that level I-IV nurses complete 12 hours of trauma-related training in each three-year designation period rather than maintain currency in a department-approved course. This change offers flexibility in how the training is provided in each trauma service to include education programs developed in-house.

(3) A proposal to require physicians (and physician extenders) not board-certified in emergency medicine or surgery to have current ACLS and ATLS certification was modified. The revised proposed rule now requires physicians (and physician extenders) not board-certified in emergency medicine or surgery or other relevant specialty and practicing emergency medicine as their primary practice to have current ACLS and ATLS certification. This reduces the number of providers required to be current in ACLS and ATLS and targets the requirement to those providers who will most benefit from it.

(4) A proposal to require a back-up plan for general surgery coverage was modified. Stakeholders interpreted the proposal to mean a formal, published back-up call schedule that would essentially require more than one surgeon to be on-call for trauma at the same time. Stakeholder estimates of the cost to implement the proposed rule ranged from \$0 to almost \$400,000. At a later stakeholder meeting, the proposed rule was discussed and revised to require a "written plan for general surgery coverage, if the general surgeon on-call for trauma is otherwise clinically-engaged." The written plan may specify a surgeon back-up schedule or an alternative method of ensuring general surgery services including transfer or diversion to a neighboring trauma service. The plan must take into consideration the facility's unique characteristics, resources and geographic location. The plan must be monitored through the facility's trauma QI program.

(5) A proposal to require all new hires to meet the trauma training requirements within the first year of employment was revised to within the first 18 months of employment.

(6) A proposal to require level I and II trauma services to provide angiography and magnetic resonance imaging (MRI) within twenty minutes was revised to require angiography within 30 minutes and MRI within 60 minutes.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.