Significant Legislative Rule Analysis

For WAC 246-976-580 and -700
Rules Concerning Trauma Designation Standards

July 6, 2018
SECTON 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

The Department of Health (department) proposes to update and revise Washington Administrative Code (WAC) 246-976-580 and -700 relating to designated trauma centers. Revisions to the rules are proposed in order to incorporate current national standard of care and minimum standards established by the American College of Surgeons Committee on Trauma (ACS-COT).

Nationally, ACS-COT is widely considered the leading authority on trauma care and trauma care standards. The ACS-COT publishes their designation criteria in a book titled, Resources for Optimal Care for the Injured Patient. The newest version of this publication (referred to as the Orange Book), outlines the most current minimum standards in the function and evaluation of trauma systems. In an effort to maintain current minimum standards and ensure the optimal care of the injured patient in Washington, it is important that the department look closely at the Orange Book to scrutinize and adopt these current minimum standards, where applicable.

The current rules (WAC 246-976-580 and -700) have not been updated since 2009. Since then, the ACS-COT has made substantial changes to the criteria used in the verification of ACS-COT designated trauma centers. Through a stakeholder gap analysis, the department has found that this proposing updated rules to more closely align with the Orange Book criteria could help ensure the department is evaluating trauma services to current and nationally recognized standards, and therefore ensuring the provision of optimal care to injured Washingtonians by designated trauma centers.

SECTION 2:

Is a Significant Analysis required for this rule?

Yes, the proposed rules require a significant analysis. Consistent with RCW 34.05.328(5)(c) (iii), the proposed rules amend requirements that adopt substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction.

The department has determined that no significant analysis is required for the following portions of the rule:
<table>
<thead>
<tr>
<th>#</th>
<th>WAC Section</th>
<th>Section Title</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>WAC 246-976-580(2)(e)</td>
<td>Trauma Designation Process</td>
<td>The proposed changes eliminate language no longer used or relevant for stakeholders. The proposed changes do not meet the definition of a significant legislative rule under RCW 34.05.328(5)(c)(iii).</td>
</tr>
<tr>
<td>2</td>
<td>WAC 246-976-700(4)(f); WAC 246-976-700(7);</td>
<td>Trauma Quality Improvement</td>
<td>The department is proposing to reorganize this section, leaving the standard language and intent unchanged.</td>
</tr>
<tr>
<td>3</td>
<td>WAC 246-976-700(13); WAC 246-976-700(7);</td>
<td>Trauma Registry</td>
<td>Rule only clarifies language without changing its effect per RCW 34.05.328(5)(b)(iv).</td>
</tr>
<tr>
<td>4</td>
<td>WAC 246-976-700(13);</td>
<td>Trauma Team Activation Protocol</td>
<td>The proposed standard clarifies the intent of the current rule and what is already widely in practice without changing its effective meaning, per RCW 34.05.328(5)(b)(iv).</td>
</tr>
<tr>
<td>5</td>
<td>WAC 246-976-700(14)(e)(v)-(vi)</td>
<td>Emergency Care Services</td>
<td>The proposed changes eliminate language no longer used or relevant for stakeholders. The proposed changes do not meet the definition of a significant legislative rule under RCW 34.05.328(5)(c)(iii).</td>
</tr>
<tr>
<td>6</td>
<td>WAC 246-976-700(14)(e)(xv);</td>
<td>Emergency Care Services</td>
<td>Rule only clarifies language without changing its effect per RCW 34.05.328(5)(b)(iv).</td>
</tr>
<tr>
<td>7</td>
<td>WAC 246-976-700(14)(e)(xvi);</td>
<td>Emergency Care Services</td>
<td>Rule only clarifies language without changing its effect per RCW 34.05.328(5)(b)(iv).</td>
</tr>
<tr>
<td>8</td>
<td>WAC 246-976-700(16);</td>
<td>Diagnostic Imaging Services</td>
<td>Rule only clarifies language without changing its effect per RCW 34.05.328(5)(b)(iv).</td>
</tr>
<tr>
<td>9</td>
<td>WAC 246-976-700(19)(a)(xii);</td>
<td>General Surgery Services</td>
<td>Rule only clarifies language without changing its effect per RCW 34.05.328(5)(b)(iv).</td>
</tr>
<tr>
<td>10</td>
<td>WAC 246-976-700(25);</td>
<td>Post Anesthesia Care Unit</td>
<td>Rule only clarifies language without changing its effect per RCW 34.05.328(5)(b)(iv).</td>
</tr>
<tr>
<td>11</td>
<td>WAC 246-976-700(33)(a)(ii)</td>
<td>Injury Prevention Education Program</td>
<td>Rule only clarifies language without changing its effect per RCW 34.05.328(5)(b)(iv).</td>
</tr>
</tbody>
</table>
SECTION 3:

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

Authority for the adoption and revision of Trauma Designation rules is established in RCW 70.168.070: Provision of Trauma Care Service—Designation. The general goal of RCW 70.168.060(1) is to “establish minimum standards for facility, equipment, and personnel” in designated trauma services. The intent of this statute is to also mandate that any healthcare facility that desires to be authorized to provide a designated trauma care service shall agree to maintain a level of commitment and resources sufficient to meet the responsibilities and standards required by the state-wide emergency medical services and trauma care system. The proposed rules meet this intent by accomplishing the following:

1. Updating designation standards to maintain current minimum standards and ensure the optimal care of the injured patient in Washington; and
2. Supporting the overarching goal of chapter 70.168 RCW by updating designation standards to ensure designated facilities and providers meet the minimum requirements to provide accessible, quality trauma services to injured Washingtonians.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. 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 departments and each applicant’s responsibilities, and listing the trauma care standards that must be met.

There are no feasible alternatives to rulemaking that would allow for development of enforceable standards for designated health care facilities providing 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 for trauma designation status by the department. Without the designation system and the rules enforcing it, there would be no way to ensure that appropriate trauma care would be available where needed throughout the state.
SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the Probable Costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

To determine that the probable benefits of the proposed rule revisions are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs, department staff requested feedback and data from trauma services providers regarding the fiscal impact expected as a result of the proposed changes to rule. The fiscal impact data request was sent to all designated trauma services in the state. Thirteen of the 81 designated trauma services (16%) responded. Of these thirteen facilities, nine (69%) provided quantitative fiscal cost estimates of the proposed standards. These fiscal impact comments were quantified, collated, and categorized to identify which section and its corresponding subsection standards resulted in a fiscal impact.

The submitted fiscal impact comments were then discussed with stakeholders during the last two formal rule making meetings, which resulted in a consensus on the proposed standards where a fiscal impact is expected. The cost estimates submitted ranged from zero dollars to $269,920.

A supplemental program analysis was done to identify the potential fiscal impact of the proposed standards. Cost estimates were achieved using state data, such as provider estimates from 2014-2018 trauma designation applications, as well as national and professional program data, such as education course costs. The program’s fiscal impact summary estimates a potential fiscal impact ranging from zero dollars to $282,300 per hospital. The proposed standards as a whole were determined to be the least costly alternative for affected hospitals and the least burdensome alternative to comply with.

The following is a breakdown of the proposed standard revisions, the probable benefits for each proposed standard revision, and the identified fiscal impacts:

1. **Proposed amendments to WAC 246-976-700(2): Trauma Medical Director:** The proposed Trauma Medical Director (TMD) standards:
   - (2)(a) Require Advanced Trauma Life Support (ATLS) currency for TMDs in level I, II, and III trauma services.
   - (2)(h) Expand the current continuing medical education (CME) requirement to twelve hours annually or thirty-six hours every three years of trauma-specific CME. This requirement can also be met through an internal education process based on practice-based learning and QI efforts.
• (2)(j) Clarifies the TMD’s responsibility and authority in the trauma service to determine each general surgeon’s ability to participate on the trauma call panel based on an annual review, in conjunction with medical staffing.

(2)(k) Requires membership and participation in regional or national trauma organizations for TMDs in level I and II trauma services

**Probable Costs**-

The proposed changes would require the TMD in level I, II, and III adult and pediatric designated facilities to maintain ATLS certification through training. The current designation standards do not require ATLS for TMDs who are board-certified, working in level I, II, or III trauma services. Current WAC requires the TMDs in level III, IV and V trauma services to be ATLS current if they are not board-certified. This expanded standard is not likely to affect lower level trauma services or smaller hospitals since they are already meeting the ATLS requirement. The larger hospitals designated as a level I, II, or III with a board certified TMD will see an estimated cost burden of $800-1,000 for initial ATLS training and certification and $350-600 for renewal, every four years.

The proposed standards also increase the amount of continuing medical education (CME) that is required to thirty-six hours every three years or twelve hours annually. This proposed standard only applies to TMDs in level I and II trauma services. This increase in CME aligns with the nationally recognized current minimum standards of the ACS-COT. Conferences offering CME provide anywhere from 10-15 CME credits, meaning a TMD would have to attend two or three conferences in three years. The costs of these conferences, plus travel expenses, is estimated to be $1,000-$2,600 each. These providers are also able to meet the CME requirement utilizing an internal education process. The cost of the internal education program is difficult to quantify—as many programs currently provide education or have access to content that would meet the intent of the proposed standard (i.e., medical case reviews, journal article reviews, etc.). The internal education option is likely to be a low or no cost alternative to traditional external CME options.

As regional and state leaders in trauma, the level I and II TMDs are already actively involved in regional and national trauma organizations, including the American College of Surgeons, as well as regional quality improvement forums. No fiscal impact was identified for requiring the TMD’s participation in regional or national trauma organizations.

As the director of trauma care, the TMD must have the authority to determine a provider’s ability to participate on the trauma team. This is already a current practice and there were no public comments or submitted fiscal impacts with regards to this proposed standard.

**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 developing clinical policies and reviewing the clinical practice of other providers. In higher level trauma services, the TMDs also often serve as a resource for other
trauma services within their trauma care region. By mandating participation in regional and national organizations, the TMDs at level I and II trauma services will be knowledgeable in current minimum standards of trauma patient care, as well as the clinical and system issues pertinent to trauma. These providers educate not only the providers within their facility, but those within their trauma care region and even the state. Trauma services in the state will benefit from highly trained clinical leadership, resulting in more effective and efficient trauma service delivery.

2. Proposed amendments to WAC 246-976-700(3): Trauma Program Manager

The proposed Trauma Program Manager (TPM) standards:

- (3)(c) Expand the CME requirement from twelve hours every three years to twelve hours annually, or thirty-six hours every three years of external trauma-specific CME or demonstrated participation in an internal educational process.
- (3)(g) Require a full-time position dedicated to the trauma service if annual trauma registry volume is greater than five hundred and less than seven hundred fifty inclusions annually.
- (3)(h) Require the TPM to be responsible for the quality of data and overall supervision of the trauma registry.

Probable Costs -

CME Requirements:

The proposed standards increase the amount of CME that is required from twelve hours every three years to thirty-six hours every three years or twelve hours annually. The current standards require that the TPM maintain currency in the Trauma Nurse Core Course (TNCC) or achieve twelve hours of trauma-related CME every three years. While this proposal is a large increase in CME hours, it aligns with the nationally recognized minimum standard of the ACS-COT. Conferences offering CME provide anywhere from 10-15 CME credits, meaning a TPM would have to attend a minimum of two additional conferences in three years. The costs of these conferences, plus travel expenses, are estimated to be $1,000-$2,600 each. The TPM is also able to meet the CME requirement utilizing an internal education process. The cost of the internal education program is difficult to quantify—as many programs currently provide education or have access to content that would meet the intent of the proposed standard (i.e., medical case reviews, journal article reviews, online education modules, etc.). The internal education option is likely to be a low or no cost alternative to traditional external CME options.

TPM full-time equivalent (FTE) and program oversight:

The proposed standards would require a 1.0 FTE for the TPM position in trauma services with an annual trauma registry volume of five hundred patients or more, who currently are not providing this level of staffing. This would align with the nationally recognized ACS-COT standard for program manager staffing. The position also potentially increases the workload through the
supervision of the trauma registry. Cost estimates submitted for the increase in TPM FTE and program oversight range from $30,000-$52,000 annually.

**Probable Benefits**

CME Requirements:
The benefit of this proposed rule change is that the nurse in the leadership role at a designated trauma service 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. Trauma services in the state will benefit from highly trained clinical leadership, resulting in more effective and efficient trauma service delivery.

TPM FTE and program oversight:
The TPM role is a dynamic position consisting of administrative, clinical, educational, and supervisory duties. To ensure that the trauma program receives the support necessary to function properly, it is important that the TPM has enough time dedicated to the duties of the position. Since quality improvement is a major component of the TPM position, proper staffing allows for the timely identification and resolution of issues that impact patients. TPM’s who are staffed appropriately are able to maintain a more robust program and are much more successful during re-designation.

3. Proposed amendments to WAC 246-976-700(4): Trauma Quality Improvement Program

The proposed Trauma Quality Improvement standards:

- (4)(a)(i) Establish a fifty percent attendance requirement for the TMD to attend the Multidisciplinary Trauma Quality Improvement Committee (MTQIC) meetings.
- (4)(a)(ii), (b), (d) Clarifies the intent of the current standards.
- (4)(e) Expand the requirement requiring the hospital give authority to the trauma service to establish trauma care standards, guidelines, and protocols by mandating the use of clinical practice guidelines, protocols, and algorithms derived from evidence-based validated sources.
- (4)(g) Specify the minimum audit filter requirements for monitoring and tracking compliance with trauma care standards.
- (4)(h) Expands current standards to include a minimum set of outcome measures and clarifies the intent of the current standards.
- (4)(i) Require the use of outcome measures and specifies the minimum outcome measures that must be measured by the trauma service through the written quality improvement program plan.
- (4)(l) Clarifies the intent of the current standards and expands current standards by requiring a quarterly monitoring and review process for under triage.
• (4)(m) Expands current standards by establishing peer review and mortality review process requirements.

• (4)(q) Require a separate pediatric-specific trauma quality improvement program for a trauma service admitting at least one hundred pediatric trauma patients annually.

• (4)(r) Require appointed liaisons from emergency medicine, orthopedics, neurosurgery, anesthesiology, critical care, and radiology to actively participate in the trauma QI program, with at least a fifty percent attendance requirement for the MTQIC.

• (4)(s) Require the use of risk-adjusted data for benchmarking and performance improvement purposes, mandating level I and II trauma services to participate in the American College of Surgeons Trauma Quality Improvement Program (TQIP) data collection and benchmarking system.

**Probable Costs**

**TQIP:**

TQIP comes with initial costs as well as annual renewal/maintenance costs. Currently, two of the eight level II trauma services in the state are already participating in TQIP. TQIP requires an annual renewal cost at a total expense of $13,000. Trauma service staff are also required to attend an annual TQIP conference, which is free to attend, but travel expenses are not covered. The state registry software vendor, DiCorp, also requires a separate module to make submitting data to TQIP possible. This comes with an initial cost of $3,000, plus $500 for training. Thereafter, the cost is $1,000 annually to maintain TQIP. Specifics of the TQIP costs are as follows:

- **TQIP:**
  - $13,000 per year, per designation (adult or pediatric. A hospital with an adult and pediatric TQIP program would have an annual cost of $26,000 per year).
  - Flight and hotel costs for TQIP conference (varies, estimated at $1,000-$2,600)

- **DiCorp trauma registry software TQIP module:**
  - $3,000 initial; $1,000 annual renewal
  - $500 initial training costs

**Rule Expansion/clarification for audit filter, protocol development, and outcome measure standards:**

- The expanded quality improvement standards are intended to produce a more robust quality improvement process. To quantify the increase in time needed to meet the data monitoring, analysis, protocol development, and reporting requirements would be difficult—as these specific proposed standards do not add any additional requirements, but instead expand and clarify what is already the
intent of the current designation standards. Stakeholder input suggests that with the proposed standard specifics, the workload for a program manager or registrar might increase, but since the proposed changes only clarify expectations and intent, most programs are already doing this work and thus would not be likely to incur any additional costs. The total expected increase in costs, based on estimates submitted by stakeholders (which includes $13,000 for TQIP participation and $3,500 for the DiCorp TQIP trauma registry module), is $15,000-$70,000 a year. This includes a potential estimated increase in program manager and trauma registrar full time equivalent (FTE) of up to a .5 FTE. Some of the level II trauma programs have already been participating in TQIP and thus have already incurred costs, meaning that no additional costs would be expected.

### Probable Benefits-

**TQIP:**

Since there are not enough level I and II trauma services in the state to appropriately benchmark, TQIP provides a method for these higher level trauma services to be risk-adjusted and benchmarked with similar sized facilities across the nation. Without this, there is no reliable way to benchmark trauma program performance for these higher level trauma programs.

**Rule expansion:**

The clarification and expansion of standards for trauma quality improvement represent generally accepted principles and current minimum standards by trauma care professionals. The clarifications will provide for more consistent and more effective trauma QI practices around the state. In most cases, these expansions align WAC with the current practice in the majority of trauma centers in the state.

### 4. Proposed amendments to WAC 246-976-700(9): Transfer-out guidelines

The transfer-out guidelines section clarifies the current standards by including a provision specifying collaboration among higher-level trauma centers in the development of transfer guidelines. It also includes a provision to transfer patients to a care destination based on the needs of the patient and not on the requirements of the provider network. Lastly, the clarified standard specifies the requirement to make acute transfers-out subject to case review, with the trauma service monitoring those transfers for appropriateness.

### Probable Costs-

No public comments were submitted for this section, nor were any fiscal impacts identified. The proposed changes clarify what is already in practice.
**Probable Benefits**-
Tracking the timeliness and appropriateness of trauma patient transfer is an essential component of system quality assurance. For years the designation application has asked for this transfer information, so by clarifying these standards we are aligning the application with what is in rule.

5. **Proposed amendments to WAC 246-976-700(12): Written Diversion Protocol**
The proposed standards expand and clarify the current requirements by including a provision that will mandate the surgeon on-call be included in the decision to divert a trauma patient (level I and II) or at least be notified of the decision to divert (level III). The proposed standards also include a requirement for trauma services to be on divert no more than five percent of the time, with a mechanism in place to monitor and document instances of diversion, with a method to document and report the reason for initiating the diversion.

**Probable Costs**-
No public comments were submitted and no fiscal impact has been identified. The infrastructure for monitoring divert (WATRAC) has been in use by the majority of the state and is available to all trauma services. There are also other facility-specific methods of monitoring divert. Regardless, there is no new cost associated with the infrastructure or process to monitor divert.

**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 and ensures that a surgeon is either involved in the decision to divert or at least is aware of the decision to divert. This will reduce the chance that the patient is misdirected to a hospital out of the trauma system or sustains a delay in transport to a higher level trauma service.

6. **Proposed amendments to WAC 246-976-700(14): Emergency Care Services**
The proposed emergency care standards:

- (e)(xii-xiii) Expand the CME requirements for emergency medicine physicians who participate on the trauma team (level I and II trauma services only) to twelve hours annually or thirty-six hours every three years of trauma-related CME.
- (e)(xiv) Clarify the ATLS education requirements for advanced practitioners participating in the resuscitative care of trauma patients.
- (g) Update the required standard emergency room equipment to include bedside ultrasound.
Probable Costs-

Expanded physician and advanced practitioner education:

Current WAC does not require CME for board-certified physicians outside of the requirements for their board-certification/recertification. It also does not specify the education requirements for advanced practitioners and non-board-certified physicians who participate in trauma care, outside of the lower level IV and V trauma services. The proposed WAC would require advanced practitioners and non-board certified physicians to maintain currency in ATLS and would require thirty-six hours of CME every three years for physicians who participate on the trauma team.

A secondary survey was sent to stakeholders to gauge the number of physicians and advanced practitioners who would likely be affected by the increased ATLS requirements. The purpose of this was to establish an estimated number of providers who would need to take ATLS annually. Twenty-five of the eighty-one trauma services replied to this survey (30%). Based on these survey results and the proposed WAC changes, facility estimates range from no providers meeting this requirement to up to thirty six. With an average cost of $800-1,000 for initial ATLS certification and $350-600 for renewal, the average expected fiscal impact of the expanded ATLS requirement ranges from $0-$36,000 per facility, or $350-$1,000 per physician or advanced practitioner.

Increased CME:

The increase in CME for physicians, while large, better aligns WAC with the nationally recognized current minimum standards of the ACS-COT. Conferences offering CME provide anywhere from 10-15 CME credits, meaning a physician would have to attend a minimum of three conferences in three years. The costs of these conferences, plus travel expenses, is estimated (by trauma services who submitted fiscal impact estimates) to be $1,000-$2,600 per physician. Current emergency department (ED) physician numbers provided in each hospital designation application (2014-2018) was used to obtain current physician counts. These counts were used to determine a cost estimate if all ED physicians chose to meet the increased CME requirement using external CME. This yielded a minimum of zero and a maximum of 57 physicians who would need to meet the expanded CME requirements. The total estimated cost for an external CME option ranges from $0-$148,200.

These providers are also able to meet the CME requirement utilizing an internal education process. The cost of the internal education program is difficult to quantify—as many programs currently provide education or have access to content that would meet the intent of the proposed standard (i.e., medical case reviews, journal article reviews, online education modules, trauma grand rounds, etc.). The internal education option is likely to be a low or no cost alternative to traditional external CME options. The fiscal impact estimate for ED provider CME can range from $0-148,200.
Emergency Equipment:
While the majority of emergency departments utilize ultrasound technology, it has not been explicitly required in rule. The proposed standards would require ultrasound equipment to be available in the ED. With this standard, there is a potential for costs associated with training providers to use this technology, as well as a potential equipment cost for emergency departments not already using this technology. Only one of the eighty-one facilities submitted comments that the proposed standards would result in any costs associated with the purchase of an ultrasound machine or the training of providers. The total costs estimated from this single hospital for equipment and training totaled $30,000. The estimated cost ranges from $0-$30,000.

Probable Benefits:
The benefit of adding the proposed standards, particularly the expanded CME and ATLS requirements, ensures that the physicians and advanced practitioners providing leadership and care in the emergency department will have the experience and training to fulfill the role and provide leadership to the trauma team. Expanding the training and education requirements will help improve clinical decision making. ATLS certification demonstrates clinical currency in standard knowledge and skill as measured by a national specialty organization. ATLS is considered a current minimum standard of care.

Expanding the ATLS requirements for advanced practitioners provides clarification for a portion of the current rules that are not clear. Current rules or standards only identify the education requirements for advanced practitioners providing initial resuscitative care at level IV and V trauma services. Advanced practitioners have a role in trauma care at higher level trauma services as well. The proposed standards provide the education requirements for advanced practitioners providing care to trauma patients at level I, II, and III trauma services.

7. Proposed amendments to WAC 246-976-700(19): General Surgery Services
The proposed general surgery standards:
  - (a)(i-iv) Change the surgeon response time to activations from twenty minutes to fifteen minutes.
  - (a)(xi) Require an eighty percent documentation threshold for surgeon attendance at activations.
  - (a)(xiii) Requires a surgeon from the trauma call panel to participate in the hospitals disaster planning process.
  - (a)(xiv-xv) Create a fifty percent attendance requirement for all trauma surgeons at the MTQIC or a method in place to communicate information from the meetings to the group of surgeons.
  - (b) Clarify requirements for surgical commitment, mandating a published schedule for first call and a written backup plan for when the surgeon on call is clinically engaged.
• (b)(iii-iv) For level I and II trauma services, create a CME requirement for all general surgeons who take trauma call to accrue an average of twelve hours annually or thirty-six hours every three years of trauma-specific CME.

**Probable Costs-**

CME requirement:
The proposed increase in CME for general surgeons, while large, better aligns WAC with the nationally recognized current minimum standards of the ACS-COT. Conferences offering CME provide anywhere from 10-15 CME credits, meaning a surgeon would have to attend a minimum of three conferences in three years. The costs of these conferences, plus travel expenses, is estimated (by trauma services who submitted fiscal impact estimates) to be $1,000-$2,600 per surgeon. A range of general surgeons was determined, using the level I and II 2014-2018 trauma designation applications to estimate the overall cost estimate if all general surgeons chose to meet the increased CME requirement using only external CME. This yielded a range of zero to 12 surgeons who would need to meet the expanded CME requirements. The total estimated cost for an external CME option based on this estimate ranges from $0-31,200.

These providers are also able to meet the CME requirement utilizing an internal education process. The cost of the internal education program is difficult to quantify—as many programs currently provide education or have access to content that would meet the intent of the proposed standard (i.e., medical case reviews, journal article reviews, online education modules, etc.). The internal education option is likely to be a low or no cost alternative to traditional external CME options. The estimate for general surgeon CME can range from $0-31,200 per hospital.

Surgeon Response Times:
One of the hallmarks of a trauma system is the mandated prompt response of the surgeon to trauma activations. The proposed standards reduce the surgeon’s response time at level I and II trauma services from twenty minutes to fifteen minutes. This better aligns WAC with the ACS-COT current minimum standards. There are a total of eight trauma services who would be subject to this new standard. Seven of the eight facilities provide in-house surgical coverage and are not affected by the proposed change.

Surgeon backup and activation attendance documentation changes:
There is no expected or identified fiscal impact with the other proposed changes in this subsection regarding surgical commitment or documentation threshold standards. Trauma services are currently meeting these requirements. The proposed WAC simply clarifies the expectation of the standards. 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.
Surgeon participation in disaster planning:
There is no expected or identified fiscal impact with the other proposed changes in this subsection regarding surgeon participation in disaster planning. The expectation is not for a surgeon to attend every disaster planning meeting, but only that they are involved, when necessary, in disaster planning as it pertains to surgical intervention.

**Probable Benefits**

The benefit of the proposed educational changes is improvement in the clinical decisions and care provided to trauma patients. This CME requirement is in alignment with the nationally recognized ACS-COT current minimum standards. Expanding and clarifying the response and attendance requirements ensures that there is a mechanism in place to provide consistent resources to trauma patients as well as a pre-determined contingency plan to get patients to timely and definitive care in the scenario of surgeon encumbrance.

There is a need for surgical involvement in the disaster planning process. Surgical involvement in the disaster planning process (and the mass casualty incident itself) can help to establish a system where, amongst other things, over triage (getting patients with non-critical injuries to immediate treatment) is avoided. This can help to ensure the appropriate provision of vital and often limited medical resources. The proposed standards ensure a comprehensive response to any potential disaster.

8. **Proposed amendments to WAC 246-976-700(20): Neurosurgery services**

The proposed neurosurgery standards:

- (d, e) Requires neurosurgeons who take trauma call to accrue twelve hours annually or thirty-six hours every three-years of trauma-related CME.
- (f) The proposed standards also require a predefined neurotrauma diversion plan and a contingency plan for neurosurgeons who cover two trauma services within the same limited geographic area.
- (g) Clarifies requirements for neurosurgical commitment, mandating a published schedule for first call and a written backup plan for when the neurosurgeon on call is clinically engaged. (h) Clarifies the intent of the current standards and aligns with nationally recognized current minimum standards.

**Probable Costs**

Neurosurgeon Backup and diversion:

The proposed rule would expand on the current neurosurgery standards for level I and II trauma services by requiring a published schedule for first call and a written plan for neurosurgery backup. The proposed rule does not require a formal back-up call schedule with committed physicians. The plan could include transfer or diversion to another trauma service, and because of this, a predefined diversion plan is required. There is no expected incremental increase in cost associated with implementing this proposed rule—as trauma services already maintain a first call
schedule that is, in many cases, just an informal call tree. The proposed schedule mandates a formalized version of this schedule to ensure dedicated first call coverage is clearly communicated and that there is a contingency for when these services are unavailable. The intent of this change is to ensure hospitals proactively address situations where the neurosurgeon is otherwise clinically engaged with another trauma patient or a non-trauma patient.

Neurosurgeon CME:

The increase in CME for neurosurgeons, while large, better aligns WAC with the nationally recognized current minimum standards of the ACS-COT. Conferences offering CME provide anywhere from 10-15 CME credits, meaning a neurosurgeon would have to attend a minimum of three conferences in three years. The costs of these conferences, plus travel expenses, is estimated (by trauma services who submitted fiscal impact estimates) to be $1,000-$2,600 per surgeon. A range of neurosurgeons was determined, using the level I and II 2014-2018 trauma designation applications to estimate the overall cost estimate if all neurosurgeons chose to meet the increased CME requirement using only external CME. This yielded a range of zero to 10 surgeons who would need to meet the expanded CME requirements. The total estimated cost for an external CME option based on this estimate ranges from $0-26,000.

These providers are also able to meet the CME requirement utilizing an internal education process. The cost of the internal education program is difficult to quantify—as many programs currently provide education or have access to content that would meet the intent of the proposed standard (i.e., medical case reviews, journal article reviews, online education modules, etc.). The internal education option is likely to be a low or no cost alternative to traditional external CME options. The fiscal impact estimate for neurosurgeon CME can range from $0-$26,000.

**Probable Benefits—**

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

The benefit of the proposed educational changes is improvement in the clinical decisions and care provided to trauma patients requiring neurosurgical intervention. This CME requirement is in alignment with the nationally recognized ACS-COT current minimum standards.

9. **Proposed amendments to WAC 246-976-700(21): Surgical Services On-Call**

The proposed on-call surgical services standards:

- (d)(i-iii) Requires dedicated call or an effective backup system for orthopedic surgery services.
- (d)(iv) Requires a published first call schedule for orthopedic surgery with a written plan for backup orthopedic surgery coverage.
- (d)(v-vi) At level I and II trauma services, requires twelve hours annually or thirty-six hours every three years of trauma-specific CME, or participation in an internal education
program, for orthopedic surgeons who take trauma call. This standard applies to level I and II trauma services only.

**Probable Costs**

Backup Call:

Current rule already requires level IIIs to have orthopedic surgery services on-call and available for consultation. The proposed rule would expand on the current orthopedic surgery standards for level I, II, and III trauma services by requiring a published schedule for first call and a written plan for orthopedic surgery backup. The proposed rule does not require a formal back-up call schedule with committed physicians. The plan could include transfer or diversion to another trauma service. There is no expected incremental increase in cost associated with implementing this proposed rule. These proposed standards help to ensure that there is a mechanism in place to provide consistent orthopedic resources to trauma patients as well as a pre-determined contingency plan to get patients to timely and definitive care in the scenario of orthopedic surgeon encumbrance.

Surgeon CME:

The increase in CME for orthopedic surgeons, while large, better aligns WAC with the nationally recognized current minimum standards of the ACS-COT. Conferences offering CME provide anywhere from 10-15 CME credits, meaning an orthopedic surgeon would have to attend a minimum of three conferences in three years. The costs of these conferences, plus travel expenses, is estimated (by trauma services who submitted fiscal impact estimates) to be $1,000-$2,600 per surgeon. A range of orthopedic surgeons was determined, using the level I and II 2014-2018 trauma designation applications to estimate the overall cost estimate if all orthopedic surgeons chose to meet the increased CME requirement using only external CME. This yielded a range of zero to 16 surgeons who would need to meet the expanded CME requirements. The total estimated cost for an external CME option based on this estimate ranges from $0-$41,600.

These providers are also able to meet the CME requirement utilizing an internal education process. The cost of the internal education program is difficult to quantify—as many programs currently provide education or have access to content that would meet the intent of the proposed standard (i.e., medical case reviews, journal article reviews, online education modules, etc.). The internal education option is likely to be a low or no cost alternative to traditional external CME options. The fiscal impact estimate for orthopedic surgeon CME can range from $0-$41,600.

**Probable Benefits**

The benefit of the proposed educational changes is improvement in the clinical decisions and care provided to trauma patients. This CME requirement is in alignment with the nationally recognized ACS-COT current minimum standards.

The benefit of requiring dedicated first call and establishing a backup plan is that trauma services will have a predetermined plan in place to manage the rare times when the orthopedic surgeon on-call for trauma is unavailable. The plan will take into consideration the unique characteristics, resources and capabilities of each trauma service.
10. WAC 246-976-700(22): Surgical Services On-Call for Patient Consultation

There are no proposed changes to this subsection.

11. Proposed amendments to WAC 246-976-700(23): Anesthesiology Services

The proposed anesthesiology standards expand and clarify the current standards by requiring a published schedule for first call, with a written plan for anesthesia coverage if the on-call provider is otherwise clinically engaged. The proposed standards also require a dedicated liaison from anesthesiology to the MTQIC.

_Probable Costs_

No public comments were submitted and no fiscal impact has been identified. Current practices are not expected to change. Since the proposed WAC in subsection 4 (quality improvement) requires an anesthesiology liaison to the trauma MTQIC, there may be some increased cost associated with that pre-determined liaisons participation in the MTQIC, but no stakeholders were able to directly identify any quantifiable costs. Anesthesiology participation in the MTQIC is already required in trauma programs who provide anesthesia services to trauma patients.

_Probable Benefits_

The proposed change aligns the rules with current minimum standards and appropriately reflects the resources currently available in licensed hospitals. This ensures the best possible care and available services to an injured person. The robust backup plan requirement ensures efficient and appropriate treatment or transfer of the patient in the instance the anesthesia provider is otherwise clinically engaged.

The proposed standards will ensure that specific anesthesiology-related issues can be addressed in the QI program and that the liaison to the anesthesia department can communicate, on behalf of the committee, back to the other anesthesia providers. This will improve the overall quality improvement program and process, ultimately improving overall trauma care.

12. Proposed amendments to WAC 246-976-700(24): Operating Room Services

The proposed standards reduce the operating room staff response time for level II hospitals from twenty minutes to fifteen minutes. The proposed standards also requires delays in operating room availability to be reviewed in the QI committee for opportunities for improvement. The proposal also updates medical and medical equipment terminology.

_Probable Costs_

No public comments were submitted and no fiscal impact has been identified. Current practices are not expected to change.
Probable Benefits -
The proposed WAC aligns operating room staff response time with the ACS-COT current minimum standards and clarifies the expectation for the current standards regarding the QI case review of operating room delays.

13. Proposed amendments to WAC 246-976-700(26): Critical Care Services
The proposed critical care standards:

- (b) Mandate coverage of critically ill patients in the intensive care unit (ICU) by appropriately trained physicians.
- (b-d) Establish a response time for physicians providing coverage in the ICU.
- (e) Require a predetermined liaison to the ICU to participate in the MTQIC, with at least fifty percent attendance.
- (f-g) Establish an education requirement for ICU physicians and the liaison who participate on the trauma team to accrue twelve hours annually or thirty-six hours every three years of trauma-related CME. This requirement can also be met by participation on an internal education process.
- (n) Require surgical collaboration with implementing policies and administrative decisions that impact trauma patients admitted to the ICU.

Probable Costs -
Liaison to MTQIC:
No public comments were submitted and no fiscal impact has been identified. Since the proposed WAC in subsection 4 (quality improvement) requires an ICU liaison to the trauma MTQIC, there may be some increased cost associated with that pre-determined liaisons participation in the MTQIC, but no stakeholders were able to directly identify any quantifiable costs. While the current standards do not explicitly require a dedicated liaison to the ICU to participate in the trauma programs MTQIC, ICU participation in the MTQIC is already required for trauma programs that provide critical care services for trauma patients.

Physician Coverage/Response Time in the ICU:
No public comments were submitted and no fiscal impact has been identified.

Probable Benefits -
Liaison to MTQIC:
The proposed standards will ensure that specific ICU issues can be addressed in the QI program and that the liaison to the ICU can communicate, on behalf of the committee, back to the ICU
providers. This will improve the overall quality improvement program and process, ultimately improving overall trauma care.

Physician coverage/Response Time:

The physician coverage and response time standards clarify the intent of the current rule. The current ICU standards do not provide detail on the responsibility for coordinating with an attending physician for trauma patient care. This will clarify the timeliness of care as well as the level of critical care physician involvement for trauma services level I, II, and III. This will ensure the right resources are available for trauma patient care in the ICU.

CME:

The intent and benefit of this rule is to ensure that critical care physicians caring for trauma patients are prepared to care for critically injured patients. Surgeons are turning care of trauma patients over to these physicians earlier in their course of care so it is crucial that the critical care physician’s skills need to be current. Requiring these physicians to have trauma-specific CME will improve the care provided to the trauma patient in the ICU. This also aligns with the ACS-COT current minimum standards.

14. Proposed amendments to WAC 246-976-700(27): Pediatric Education Requirements

The proposed standards expand the pediatric education requirements (PER) only for the TMD and the liaisons to neurosurgery, orthopedic surgery, emergency medicine, and critical care within level I and II pediatric trauma centers. This education is expanded from seven hours every three years to twelve hours annually or thirty-six hours every three years of trauma-related CME.

Probable Costs—

Conferences offering CME provide anywhere from 10-15 CME credits, meaning a TMD or liaison would have to attend two or three conferences in three years. The costs of these conferences, plus travel expenses, are estimated to be $1,000-$2,600 each. These providers are also able to meet the CME requirement utilizing an internal education process. The cost of the internal education program is difficult to quantify—as many programs currently provide education or have access to content that would meet the intent of the proposed standard (i.e., medical case reviews, journal article reviews, etc.). The internal education option is likely to be a low or no cost alternative to traditional external CME options. The cost estimate for the TMD and each liaison to meet the proposed CME requirement is $0-$13,000 per level I or II pediatric trauma service.

Probable Benefits—

The benefit of this proposed rule change is that surgeons serving in the trauma service leadership role and the liaisons will have the same or higher education and training as those trauma care providers they oversee. The TMD is responsible for setting standards of care for the trauma services, and in higher level pediatric trauma services, these providers often serve as a resource for other trauma services within their trauma care region. This CME requirement ensures that
these providers are competent in the care of pediatric trauma patients. This increase in CME aligns with the current minimum standards of the ACS-COT.

15. Proposed amendments to WAC 246-976-700(33): Injury Prevention Education Program

The proposed injury prevention standards:

- (a)(i) Require someone in a leadership position that has injury prevention as part of their job description.
- (a)(iii) Clarifies intent of the current standards and aligns with what is recommended by the department in the application and final report out process.
- (b) Clarifies current intent and aligns with what is already largely in practice.
- (d) Require screening and brief intervention and referral to treatment (SBIRT). Specifically, the proposed rule expands on current SBIRT requirements by requiring screening to occur and patients who screen positive for drugs or alcohol must receive an intervention by appropriately trained staff.

Probable Costs-

Injury Prevention leadership and registry data:

There is no cost associated with the use of registry data to identify injury prevention priorities. All trauma services are required to submit data to the state trauma registry. This data submitted includes all of the specific data points necessary to identify these top mechanisms of injury that should be targeted in injury prevention initiatives. The inclusion of injury prevention in a leadership position is current practice in many trauma services. There was one level IV trauma service who submitted fiscal impact comments that the injury prevention leadership standards would result in increased costs estimated at $8,320. These cost estimates were based on perceived costs necessary to maintain an injury prevention program, including program management, data collection, and education. No other trauma services submitted comments or fiscal impact data on the proposed injury prevention leadership and registry data standards.

SBIRT Screening:

Current standards only require that a trauma service have a written SBIRT policy in place. There has been no requirement to screen patients or monitor screening activities. The expectation has been that trauma services are screening patients and providing interventions to patients who screen positive for drugs or alcohol. Trauma centers who have written policies for SBIRT in place would be expected to have the appropriately trained staff to administer an intervention as well as the resources necessary for screening. The proposed standards would require screening and the intervention of all patients who test positive for drugs or alcohol by an appropriately trained staff member. Two trauma services (one level III and one level IV) did submit comments and fiscal impact estimates associated with the expanded SBIRT requirements. The average of these estimates submitted is $11,320 to cover the training and increased employee FTE necessary to screen patients, provide interventions, and to provide education to staff.
**Probable Benefits**

The proposed injury prevention standards clarify and expand the current requirements. These changes ensure that injury prevention initiatives are relevant, using facility-specific data on patient populations that would benefit the most from injury prevention initiatives. The majority of trauma patients are being saved and the area with the biggest potential impact on reducing morbidity and mortality is injury prevention. By clarifying the rules and expanding the leadership requirements, we can ensure that each trauma center provides injury prevention services relevant to their community. The proposed standards are also directly aligned with the ACS-COT current minimum standards.

**SBIRT:**

SBIRT Programs 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.

**16. Proposed amendments to WAC 246-976-700(37): Trauma Research**

The proposed trauma research standards require a trauma research program with twenty peer-reviewed articles published every three years. The standards also establish specific requirements for neurosurgery, emergency medicine, orthopedic surgery, radiology, anesthesia, and other departments that impact trauma to participate in publications.

**Probable Costs**

No public comments were submitted and no fiscal impact has been identified. The proposed standards are aligned with the ACS-COT established current minimum standards regarding the trauma service research requirements for level I trauma centers. The state’s sole level I trauma center was consulted on the proposed standards. The level I hospital currently exceeds all proposed standards and is in support of the proposed standards.

**Probable Benefits**

Trauma research provides valuable information on the care of the injured patient, providing validation of current treatment and helps to advance our knowledge of innovative ways to treat patients. Trauma research requirements are one of the main differentiating factors that separates a level I trauma service from a level II. Even though trauma research has been an integral component of our state’s level I trauma service, by expanding the standards to include specific requirements for level I trauma centers, we provide an objective mechanism to validate the research work being done at the level I trauma center or potential future level I trauma centers. These standards, as written, are also aligned with the ACS-COT current minimum standards for level I adult and pediatric trauma service designation.
17. Proposed amendments to WAC 246-976-700(39): Disaster Planning and Management
The proposed disaster planning and management standards require trauma services to meet the disaster-related requirements of the facility’s accrediting agency.

*Probable Costs*-  
No public comments were submitted and no fiscal impact has been identified. Hospitals are already required to meet disaster planning requirements for their hospital licensure accreditation.

*Probable Benefits*-  
As a state, Washington is at risk for serious and widespread natural disasters, including tsunamis, earthquakes, and volcanic eruptions as well as man-made, multiple casualty incidents, such as mass shooter events. Meeting the accrediting agency’s disaster planning requirements helps to ensure the facility is prepared to care for patients in the event of a disaster or mass casualty event.

18. Proposed amendments to WAC 246-976-700(40): Organ Procurement Activities
The proposed standards would include a provision for requiring trauma services to establish a relationship with a recognized Organ Procurement Organization (OPO) and to develop a written policy for notification of an OPO when a viable organ is available. The proposed standards would also require written protocols defining the clinical criteria and confirmatory tests for the diagnosis of brain death. Lastly, the proposed standards would require a method for annual review of organ donation rates.

*Probable Costs*-  
No public comments were submitted and no fiscal impact has been identified. Hospitals are already meeting the strict OPO requirements of the Joint Commission, CMS and section 1138 of the Social Security Act.

*Probable Benefits*-  
A large number of organ donors die due to traumatic injury. The trauma program has a vested interest and a responsibility to identify potential organ donors and to work with OPO’s to get viable organs to patients in need. The proposed standards provide clear guidance for what is already likely being done in hospitals statewide.

**Summary**

The benefit of this proposal is it provides designated trauma centers with explicit, updated requirements that reflect current, nationally recognized standards of care that will ensure trauma centers are providing optimal care to injured Washingtonians. The benefits to the public to ensure updated standards of care outweigh the potential costs associated with the proposed
amendments. Standards in alignment with the national best practice will ensure that trauma patients receive the right level of healthcare resources, in the right amount of time, to minimize morbidity and mortality.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined 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 state 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. Nine, four-hour stakeholder meetings were conducted between March and August of 2017. These meetings were all held by phone and go-to-meeting to allow for maximum participation statewide.

Many ideas were proposed, vetted, and then accepted or rejected throughout the lengthy review process. Several proposed standards exceeded the nationally recognized ACS-COT current minimum standards. An example of a proposed revision that was considered and ultimately rejected was to require 75% attendance thresholds for providers at multidisciplinary trauma quality improvement meetings, when the ACS-COT only requires 50% attendance. After significant deliberation, it was decided to not pursue any standards that exceeded the ACS-COT. The proposed standards, as a whole, were determined to be the least costly alternative for affected hospitals and the least burdensome alternative to comply with.

SECTION 7:

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. There are no federally laws regarding trauma designation.
SECTION 8:
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. The standards are the same for all designation applications both public and private.

SECTION 9:
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 proposed amendments do not differ from any federal regulation or statute applicable to the same activity or subject matter.

SECTION 10:
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 federal, state, or local laws.