Significant Legislative Rule Analysis

WAC 246-976-580
A Rule Concerning Trauma Designation Process - Criteria for minimum and maximum distribution of trauma services

Washington State Department of HEALTH

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Section 1

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed.

The proposed rule is intended to formalize a process and set of criteria to be met by health care facilities applying for level I or II trauma service designations in order to meet the trauma needs of the state and to ensure access and equity. Since the beginning of the trauma system's inception in 1991, there has not been a formalized process or set of criteria by which the trauma care regions and the department make minimum and maximum number (min/max) decisions on the number of trauma level I and II hospitals.

RCW 70.168.060(4) directs the Department of Health (department) to establish the minimum and maximum number of hospitals that may provide designated trauma care services across the state of Washington. These designations are based upon approved regional emergency medical services and trauma care plans which require designations to be consistent with state standards determined by availability of resources and the distribution of trauma within the region. Furthermore, the originating statutes and subsequent rules do not specify the process or criteria that trauma facilities must meet in order to change trauma level designation.

As the trauma system continues to mature, trauma designated facilities have expressed interest in applying for new level I or II designations. However, there is currently no formalized process or set of criteria that enables the objective evaluation of the need for additional higher level I and level II trauma service designation and the potential impact on the state trauma system.

The proposed changes to WAC 246-976-580 establish criteria to determine the need for new level I and II trauma services which will help ensure that Washingtonians have optimal access to trauma care services while maintaining a robust system that balances access, quality, equity, and the needs of the existing trauma services. Developing such criteria aligns with the recommendations from the American College of Surgeons 2019 state trauma system assessment conducted on behalf of the department and included in the Washington State EMS & Trauma Care System final report.[1] The report recommended that a more uniform and objective process be developed to aid in decision making related to the minimum and maximum number of designated trauma services. The criteria included in the proposed rule will objectively allow the department to identify areas in the state which would benefit from higher designated level I or II trauma services while mitigating any negative impact on the system. The proposed rule will impact any facility seeking designation as a level I or II trauma service.

[1] American College of Surgeons Committee on Trauma. Trauma System Consultation Report. April 2019: https://doh.wa.gov/sites/default/files/legacy/Documents/2900/346-NonDOH-ACS-WA-TSC.pdf?uid=638fd8848923c

Section 2

Significant Analysis Requirement

Yes, as defined in RCW 34.05.328, portions of the proposed rule require a significant analysis (SA). The department determined the proposed amendments include some significant legislative rule amendments that are subject to the requirements of RCW 34.05.328(5). The following SA Table 1 identifies portions of the rule section that the department has determined exempt from significant analysis based on the exemptions provided in RCW 34.05.328(5) (b) and (c). Not included in SA Table 1 are technical changes made to the numbering of former subsections (3) through (13) as the result of new subsections being added.

SA Table 1. Summary of rule sections not requiring analysis

WAC Section and Title	Description of Proposed Changes	Rationale for Exemption Determination
246-976-580(2) Trauma Designation Process	Proposed rule change directs the reader to new subparagraphs and clarifies the process for new and existing trauma services.	This section of rule is exempt from analysis under RCW 34.05.328 (5)(b)(iv). The proposed change clarifies language in the rule without changing its effect.
246-976-580(8) formerly 246-976-580(3) Trauma Designation Process	Proposed rule change deletes the language "within a region" and adds "by the department", to reflect current processes.	This section of rule is exempt from analysis under RCW 34.05.328 (5)(b)(iv). The proposed change clarifies language in the rule without changing its effect.

Section 3

Goals and objectives of the statute that the rule implements.

Authority for the adoption and revision of Trauma Designation Process rules is established in RCW 70.168.060: Department Duties - Timelines. RCW 70.168.060(4) directs the department to "establish the minimum and maximum number of hospitals and health care facilities in the state and within each emergency medical services and trauma care planning and service region that may provide designated trauma care services based upon approved regional emergency medical services and trauma care plans." The proposed rule meets this intent by accomplishing the following:

1. Establishes the process and set of criteria by which new level I and II designations may be granted.

2. Supports the overarching goal of RCW 70.168.010(4) by "providing optimal care for the trauma victim" and "containing costs of trauma care" by developing criteria for new level I and II designations that balances concerns for access and quality while minimizing duplication of trauma related services.

Section 4

Explanation of why the rule is needed to achieve the goals and objectives of the statute, including alternatives to rulemaking and consequences of not adopting the proposed rule.

The department has determined that the rule is necessary to implement the general goals and specific objectives of RCW 70.168.060 which requires establishing the minimum and maximum number of health care facilities that may provide designated trauma care services across the state and within each emergency medical services and trauma care planning and service region. Formalizing this process in rule ensures that the needs of the state trauma system are being met and that trauma patients have timely access to care at level I and II trauma services.

The department and trauma system interested parties agree that it is important to develop a clear, equitable, and enforceable process to evaluate the need for additional level I and II trauma services in the state, and that the department is best positioned to administer this process through rules. In 2019, a state trauma system assessment was conducted by the American College of Surgeons Committee on Trauma (ACS-COT) which determined in their findings that an objective and standardized process be developed to better determine the minimum and maximum number of trauma services in the state.[2] In October 2021, the ACS-COT published a position statement titled, *Revised Statement on Trauma Center Designation Based upon System Need and the Economic Drivers Impacting Trauma Systems*, which supports state trauma systems developing criteria to determine the need for additional trauma services through a process guided by community needs, regional planning, and the potential impact on existing designated facilities.[3] The ACS-COT statement encourages government officials responsible for trauma service designation to develop metrics to determine the need for additional trauma care prior to adding or upgrading new trauma services in a region.

In 2020, the department convened the Min/Max Workgroup to develop a methodology for determining the minimum and maximum number of level I and II trauma services needed for the state. The workgroup made suggestions by which the determinations could be made. These suggestions included a set of criteria to consider and conducting an assessment to determine need or geographic gaps in trauma care. The workgroup and the department agreed that rulemaking was necessary to: 1) ensure interested party input on establishing a set of criteria, and 2) be able to enforce the set of criteria that must be met for trauma service designation.

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[2] American College of Surgeons Committee on Trauma. Trauma System Consultation Report. April 2019: https://doh.wa.gov/sites/default/files/legacy/Documents/2900/346-NonDOH-ACS-WA-TSC.pdf?uid=638fd8848923c

[3] American College of Surgeons Committee on Trauma. Revised Statement on Trauma Center Designation Based upon System Need and the Economic Drivers Impacting Trauma Systems. October 2021. https://bulletin.facs.org/2021/10/revised-statement-on-trauma-center-designation-based-upon-system-need-and-the-economic-drivers-impacting-trauma-systems/#printpreview

Alternatives to rule making included the request to incorporate the analysis and decision-making for new level I and II trauma services into the existing department Certificate of Need program or develop a similar program within the Trauma Designation program. The recommendation did not receive support from interested parties or the department. Another alternative to rule making included developing a methodology to determine the need for new level I and II trauma services outside of rules. There were concerns regarding the ability to develop such a process given there is no national consensus or reference material on what methodology and criteria should be used. There were also concerns about the ability to enforce such a process outside of rule.

Section 5

Analysis of the probable costs and benefits (both qualitative and quantitative) of the proposed rule being implemented, including the determination that the probable benefits are greater than the probable costs.

Background

Trauma is a longstanding public health epidemic and according to the Centers for Disease Control and Prevention, in 2019, traumatic injury was the leading cause of death for people 0-46 years of age.[4] In Washington, the volume of trauma patients has steadily increased since the system was established in 1995 with relatively no change in the state trauma services designation levels or locations. In 1995, the annual trauma patient volume was approximately 6,000 patients. In 2019, that number had grown to well over 40,000 patients (Figure 1). Major trauma is commonly defined using an injury severity score (ISS) threshold of 15. While the total volume of injured patients in the state has grown significantly over the years, the number of severely injured patients with an ISS greater than 15, has been relatively constant.

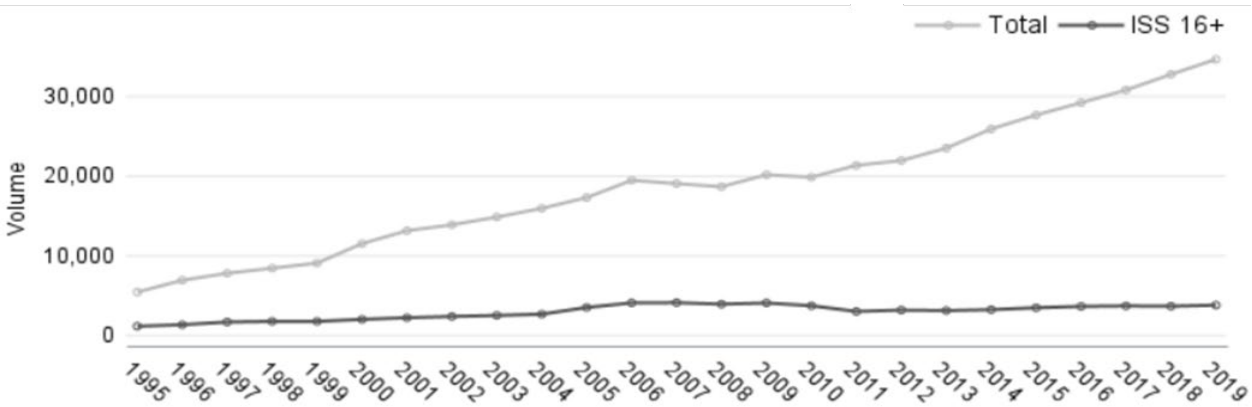

Figure 1. Number of trauma patients entered into the Washington state Trauma Registry.

The value of the state trauma system is evident, with decreased morbidity and mortality noted in states with established trauma systems when compared to those without.[5] The Washington state trauma system follows an inclusive model in which providers, public health representatives, and other interested parties of trauma care in a geographical region collaborate to plan, provide, and manage the treatment of major trauma patients. The American College of Surgeons Committee on Trauma (ACS-COT), in 2014, convened a group of experts for a trauma systems evaluation and planning committee. This committee published a

[4] Heron M. Deaths: Leading causes for 2019. National Vital Statistics Reports; vol 70 no 9. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: https://dx.doi.org/10.15620/cdc:107021.

[5] Nathens, Avery B. MD, PhD; Jurkovich, Gregory J. MD; Rivara, Frederick P. MD, MPH; Maier, Ronald V. MD. Effectiveness of State Trauma Systems in Reducing Injury-Related Mortality: A National Evaluation. The Journal of Trauma: Injury, Infection, and Critical Care: January 2000 - Volume 48 - Issue 1 - p 25

position statement indicating the recommendation for state trauma systems to designate facilities based on patient need. The ACS-COT added to this statement in 2021 acknowledging the changing healthcare landscape with the growth of hospital networks and network-driven insurance and its potential negative impact on trauma systems of care.[6] This addendum from the ACS-COT executive committee gave two recommendations to state trauma systems:

1. State and regional authorities should conduct a detailed analysis of access to care and model the impact of the new center on the volumes of existing trauma centers.
2. State and regional authorities should develop objective metrics to determine the need for additional trauma centers in their region.

Having a sufficient number of trauma services to support community needs is vital but the proliferation of those services in close proximity can have negative impacts on the existing trauma services and patient outcomes.[7] While there may be an economic advantage for new trauma service development, it could undermine the current system by creating scenarios where trauma services, and their availability, may change as local and state economies fluctuate. Proliferation of trauma services may also lead to programs not being able to maintain case volumes, which can impact patient outcomes, the availability of specialty services, and physician training programs. There is also a potential impact to the financial health of any existing facilities.[8]

WAC 246-976-580 Trauma Designation Process.

Description: The proposed changes take into consideration the need to support equitable access to trauma care with considerations to preventing the over proliferation of trauma services which could negatively impact quality. The proposed changes:

- Establish a requirement for the department to conduct a trauma system assessment, including geospatial analysis conducted by the department, that will be used to evaluate access to care at level I and level II trauma services and identify areas where trauma services are needed. An optimal trauma system is one where level I and level II trauma services are not overburdened or under-utilized and are able to provide effective patient care to best support the trauma system.
- For facilities applying for a level I trauma designation, the health care facility must:

[6] American College of Surgeons Committee on Trauma. Revised Statement on Trauma Center Designation Based upon System Need and the Economic Drivers Impacting Trauma Systems. October 2021. https://bulletin.facs.org/2021/10/revised-statement-on-trauma-center-designation-based-upon-system-need-and-the-economic-drivers-impacting-trauma-systems/#printpreview

[7] Tepas, Joseph J. III MD; Kerwin, Andrew J. MD; Ra, Jin Hee MD. Unregulated proliferation of trauma centers undermines cost efficiency of population-based injury control. Journal of Trauma and Acute Care Surgery: March 2014 - Volume 76 - Issue 3 - p 576-581 doi: 10.1097/TA.0000000000000125

[8] Nathens, A. B., Jurkovich, G. J., Maier, R. V., Grossman, D. C., MacKenzie, E. J., Moore, M., & Rivara, F. P. (2001). Relationship between trauma center volume and outcomes. JAMA, 285(9), 1164–1171. https://doi.org/10.1001/jama.285.9.1164

    - Be located in a geographic area where access to a level I trauma service is limited because an existing designated facility cannot be reached within 60 minutes average ground transport time from point of injury, **OR**
    - If the health care facility is not located within the geographic area, then the facility must:
        - Be farther than 30 minutes average ground transport time from an existing level I service; and
        - In accordance with its transfer-in and transfer-out guidelines required under WAC 246-976-700(8) and (9), have a minimum of 240 annual trauma patient admissions with an Injury Severity Score of more than 15 or admit at least 1,200 trauma patients annually; and
        - Meet all level I designation standards and be fully designated and substantially in compliance as a level II trauma service for at least one full three-year designation period immediately prior to applying for a new level I designation.
- For facilities applying for a level II trauma designation, the health care facility must:
    - Be located in a geographic area where access to a level II trauma service is limited and cannot be reached within 60 minutes average ground transport time from the point of injury, **OR**
    - If the health care facility is not located within the geographic area, then the facility must be farther than 30 minutes average ground transport time from an existing level I or II service; and the facility must meet all level II designation standards and be fully designated and substantially in compliance as a level III trauma service for at least one full three-year designation period immediately prior to applying for a new level II designation.

Cost(s): The department does not anticipate any additional costs to any facility applying for a new level I or level II service.

- The department will conduct the trauma system assessment and assume all associated costs with existing department staff and resources.
- For those health care facilities applying for level I designation and that are not in the defined geographic area, the department has an established process to conduct trauma designations which evaluates a facility's ability to meet the standards in WAC 246-976-700. This process has not changed.
- For those health care facilities applying for level II designation and that are not in the defined geographic area, the department has an established process to conduct trauma designations which evaluates a facility's ability to meet the standards in WAC 246-976-700. This process has not changed.

Benefit(s): The proposed rules provide the following benefits:

A trauma system assessment will evaluate access to care at level I and II trauma services. It will also evaluate the distribution and locations of these services to ensure the needs of the state trauma system are being met and injured patients have timely access to care at level I and II trauma services. The assessment will include a geospatial analysis which is consistent with research publications which use this method to evaluate state trauma systems and facility locations.[9] The assessment will be conducted by the department using existing trauma registry and healthcare related databases. The assessment may reveal areas within the state where higher level designated trauma services are needed which would improve access to care and potentially reduce trauma related morbidity and mortality.

Establishing criteria for services located within an average ground transport time from the point of injury within a geographic area help determine areas in the state where access to level I or level II trauma services are limited, but may be needed. It also identifies the best locations for level I and level II trauma services. This information may help support further expansion of the state's trauma care system. The 60-minute average transport time has been used in several related journal publications in the past.[10]

For those facilities where access to a level I or II trauma service can be reached in 60 minutes, establishing a criterion of 30 minutes average ground transport time between designated facilities helps determine the best locations of level I and level II trauma services and helps to maintain sufficient volume to ensure quality.

For applicants applying for level I designation and located within the described geographic area of another level I facility, requiring compliance with transfer out guidelines aligns with the American College of Surgeons-Committee on Trauma (ACS-COT) verification standards which has the same patient volume requirements.[11] This is a nationally recognized standard. It ensures level I trauma services have sufficient volume of more severely injured patients to support ACGME resident training programs and subspecialty needs.

Requiring a full year of designation at the immediate lower level of designation that the applicant is applying for provides assurance that the facility is able to meet all the designation requirements at the lower level prior to applying for more rigorous requirements and commitments at the higher level. This helps ensure only the best qualified and capable facilities are designated as a level I or II trauma service.

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[9] Winchell, R. J., Xu, P., Mount, L. E., & Huegerich, R. (2019). Development of a geospatial approach for the quantitative analysis of trauma center access. The journal of trauma and acute care surgery, 86(3), 397–405. https://doi.org/10.1097/TA.0000000000002156

[10] Id.

[11] American College of Surgeons Committee on Trauma. Optimal Care for the Injured Patient 2022 Standards. March 2022.

Overall Proposed Rule Cost/Benefit

It is of note that participation in the state trauma system is voluntary; however, to participate, a health care facility must comply with established rules and laws. As proposed the rule does not impose any additional costs to health care facilities to voluntarily apply. Costs will incur for those facilities that receive designation and participate as a level I or II trauma service as they must comply with existing rules and laws established for level I and level II trauma services.

However, the department acknowledges that in some cases, the proposed rule may impact existing trauma designated facilities in the following ways:

- Potential cost impact to existing level I or II trauma designated services if a new level I or II trauma service operates in close proximity but within the geographic boundaries established in the proposed rule.
    - **Cost:** Resulting in a redistribution of patients and the potential loss or gain of volume and associated revenue.[12,13] According to literature the proliferation of existing services in close proximity can have negative impacts on the existing trauma services and patient outcomes,[14] and therefore the proposed rule was careful to follow existing literature regarding geographic area.
    - **Benefit:** Washington's trauma care statutes are focused on patient need. The need for level I or II trauma services strategically placed throughout the state is vital to the health of Washingtonians. Furthermore, it is already broadly recognized that certain parts of the state need additional higher-level trauma services.
- Potential in preventing an existing trauma facility from applying for a new level I or II trauma service designation based on the geographic boundaries and other criteria established in the proposed rule.
    - **Cost:** The loss of future revenue activities (e.g., loss of case volumes, which can impact patient outcomes).[15] Impacts timely access to acute care and specialty services.

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[12] Mabry CD, Kalkwarf KJ, Betzold RD, Spencer HJ, Robertson RD, Sutherland MJ, Maxson RT. Determining the hospital trauma financial impact in a statewide trauma system. J Am Coll Surg. 2015 Apr;220(4):446-58. doi: 10.1016/j.jamcollsurg.2014.12.039. Epub 2015 Jan 9. PMID: 25797727; PMCID: PMC4535320. doi: 10.1016/j.jamcollsurg.2014.12.039

[13] Taheri PA, Butz DA, Watts CM, Griffes LC, Greenfield LJ. Trauma services: a profit center? J Am Coll Surg. 1999 Apr;188(4):349-54. doi: 10.1016/s1072-7515(99)00021-6. PMID: 10195717.

[14] Tepas, Joseph J. III MD; Kerwin, Andrew J. MD; Ra, Jin Hee MD. Unregulated proliferation of trauma centers undermines cost efficiency of population-based injury control. Journal of Trauma and Acute Care Surgery: March 2014 - Volume 76 - Issue 3 - p 576-581 doi: 10.1097/TA.0000000000000125 DOI: 10.1016/s1072-7515(99)00021-6

[15] Nathens, A. B., Jurkovich, G. J., Maier, R. V., Grossman, D. C., MacKenzie, E. J., Moore, M., & Rivara, F. P. (2001). Relationship between trauma center volume and outcomes. JAMA, 285(9), 1164–1171. https://doi.org/10.1001/jama.285.9.1164

- **Benefit:** Create timely access to acute care and specialty services in a systematic way for Washingtonians.

Summary of all Cost(s) and Benefit(s)

The goal of the state trauma system, trauma service designation levels, and trauma service locations is a balance between improving patient access and equity, encouraging trauma system growth, and preventing facilities from being overburdened or under-utilized. The proposed rule establishes a set of criteria to support access to trauma services while limiting the impact on existing trauma designated facilities. There are probable costs associated with the implementation of this rule, which include a potential impact to the redistribution of trauma patients and the potential loss of a facility's current and future revenue activities. However, the benefits of the proposed rule include an equitable distribution of higher-level designated trauma services across the state, increased statewide access to acute care and specialty services, and a potential reduction in trauma related morbidity and mortality where access to acute trauma care services were previously limited.

Determination

Probable Benefits greater than Probable Costs

The department determined that the probable benefits of increasing access to trauma services and quality of care in the proposed rule are greater than the probable costs to existing level I or level II services.

Section 6

List of alternative versions of the rule that were considered including the reason why the proposed rule is the least burdensome alternative for those that are required to comply and that will achieve the goals and objectives of the proposed rule.

Department staff worked closely with trauma system interested parties to develop and review a proposed set of criteria for the establishment of new level I and II trauma service designations. The department convened a Min/Max workgroup which consisted of the Trauma Medical Directors from level I and II trauma services across the state. The intent of the workgroup was to develop recommendations for methodologies for determining the need for additional level I and II trauma services. The department then held a total of seven rule workshop meetings to gather input on developing proposed rules which included a thorough review and discussion of the recommendations and concepts from the Min/Max Workgroup. The workshops were well attended, and the department received input from a wide range of interested parties. The department developed the proposed rule language and presented a comprehensive draft at the final rule workshop meeting held on January 4, 2023. This allowed for an additional opportunity for interested parties to provide input on potential impacts and concerns, as well as offer support for the proposed rules.

Many concepts and ideas were proposed, vetted, and discussed during these rules workshops. The department developed the rules based on input from all interested parties where a majority consensus was reached and where the department found statutory authority to support the proposed rule and set of criteria.

Pennsylvania adopted, in rule, a requirement for a 25 mile buffer zone around their level I and II trauma services and have had success with maintaining quality trauma care. The department considered this requirement but instead determined that a 60 minute average ground transport time from point of injury within the geographic area, and a 30 minute average ground transport time from point of injury outside the geographic area more appropriately meets the needs of Washington state. Time, as opposed to distance, was determined to be the appropriate criterion because of traffic congestion, geography, and weather conditions that frequently impact inter-facility transport times. The level I and II trauma hospitals in Washington support and advocated for this requirement or criteria to be placed in rule.

Some proposals for the rule exceeded what the department considers a national standard published by the ACS-COT. A request included criteria for trauma patient volumes at level I facilities at 1,200 trauma patients annually of which 240 must have an injury severity score (ISS) greater than 15. The ACS-COT standard includes the same volume requirements but not both (one or the other needs to be met). The draft rule language reflects the current ACS-COT requirement where a level I applicant facility must have either 1,200 trauma patient admissions annually or 240 trauma patient admissions with an ISS greater than 15.

There were proposals to use air transport times as part of the trauma system assessment and in the criteria to determine the distance between level I facilities. This alternative proposal was not considered by the department because it is not consistent with the current patient transfer process occurring in the state. Currently, over 70% of all trauma patient transports occur by ground ambulance and over 90% occur by ground ambulance from level II trauma services thus resulting in very few air transports. Using the limited data involving air transport times to assess the locations of level I trauma services would be challenging and inaccurate.

Lastly, there was a proposal to update the criteria for diversion of patients at level I applicant trauma services. The proposal allowed for no diversion time in the year prior to the designation request. The department concluded that the proposed alternative language for no diversion time did not align with existing requirements in rule and had not been thoroughly discussed by interested parties. Furthermore, the proposed alternative language was not in alignment with ACS-COT national standards which allows for 400 hours of diversion time in a three-year designation period. The proposed rules were updated to reflect the current ACS-COT standard which allows for 400 hours.

There was a proposal that any new designated level I facility could not pose any adverse material or financial impact on any existing level I facility and that the department must conduct a quality assessment prior to designating a new level I or level II facility. The department took these recommendations into consideration, but determined that: 1) the current statutes do not authorize the department to solely consider adverse material or financial impact as a threshold criterion to approve or disapprove a new level I or II facility and 2) an additional quality assessment is not needed since the proposed rules are intended to advance quality and access in addition to the established trauma designation process which is focused on advancing the quality of the system as a whole. This proposal is not included in the proposed rule; however, the department does recognize that, according to literature, the proliferation of existing services in close proximity can have negative impacts on the existing trauma services and patient outcomes.[16] Therefore, the department was careful to follow existing literature regarding geographic area in drafting the proposed rule language.

[16] Tepas, Joseph J. III MD; Kerwin, Andrew J. MD; Ra, Jin Hee MD. Unregulated proliferation of trauma centers undermines cost efficiency of population-based injury control. Journal of Trauma and Acute Care Surgery: March 2014 - Volume 76 - Issue 3 - p 576-581 doi: 10.1097/TA.0000000000000125

Section 7

Determination 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 federal laws regarding trauma designation or trauma system evaluation.

Section 8

Determination 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 department determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

Section 9

Determination 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.

Section 10

Demonstration 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.