RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 19-086

Ch. DHS 118

Basis and Purpose of Proposed Rule

Wisconsin Statute §256.25(2) directs the Department of Health Services to promulgate rules to develop and implement a statewide trauma care system.Wisconsin Statute §256.25(2) further directs that these rules shall include a method by which to classify all hospitals as to their respective emergency care capabilities and that these rules shall be based on the standards developed by the American College of Surgeons.

The purposed rule updates the standards used to classify hospitals as to their emergency care capabilities and updates the standards to be based on the most recent standards developed by the American College of Surgeons.

Department Response to Legislative Council Rules Clearinghouse Recommendations

The Department accepted all of the recommendations from the Legislative Council Rules Clearinghouse.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s).

Not applicable

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives.

Not applicable

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule.

Not applicable

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule.

Not applicable

The reason for including or not including in the proposed rule any of the following methods for reducing the rule's impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule's impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

Not applicable

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

None

Fiscal Estimate/Economic Impact Analysis

None

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and through the Department's Administrative Rules Website on September 19th, 2019. A public hearing was held on October 11th, 2019, in Madison, Wisconsin. Public comments on the proposed rule were accepted until close of business on October 11th, 2019.

List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.

Registrant	**Position Taken** (Support or Opposed)
Ben Eithun, UW Health	Support
Dr. David Gourlay, Children's Hospital of Wisconsin	Support
Cinda Werner, Children's Hospital of Wisconsin	Support
Ann Zenk, WHA	Not indicated
Marshall Beckman	Not indicated
Kelly Jung	Not indicated
Thomas Ellison, UW Health	Not indicated
Amanda Daniels	Not indicated
Tabitha Uitenbroek	Not indicated

Summary of Public Comments to the Proposed Rule and the Agency's response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.

Rule Provision	Public Comment	Department Response
DHS 118, Appendix A	This comment was from an individual who is unhappy with the American College of Surgeon.	DHS does not have a response to this comment as it was not related to the content of the rule text.
DHS 118 Appendix A, multiple provisions	This comments contains several concerns relating to different provisions of DHS 118, Appendix A: • Transfer Agreements: Some WHA members believe that mandating transfer agreements could allow some hospitals to dictate standards that are not required (and possibly were rejected) by DHS. If the hospitals that would be party to an agreement are unable to agree, a community's access to the trauma care system could be limited. WHA asks DHS to remove the required transfer agreements and, instead, rely on the TCFs to work collaboratively as a trauma care system as recognized in one of the criterion. • TCF "capability": The proposed rule includes a number of standards for Level III TCFs that apply to Level IV TCFs only if the Level IV TCF has the "capability" and other standards that apply to TCFs generally only if the TCF has the capability. Without additional clarify, WHA is concerned that some TCFs might trigger higher level trauma standards by offering needed, but limited, services to their communities. We ask DHS to revise the rule to recognize that some TCFs will offer limited services that should not trigger the higher-level trauma care standards. • Orthopedic coverage: The proposed rule would require Level III TCFs to have an orthopedic surgeon on call and promptly available 24 hours a day. The proposal also states that Level III TCFs and Level IV TCFs with orthopedic surgery capability, when an orthopedic surgeon is not dedicated to a single facility or is unavailable while on call, must have a published back-up schedule. WHA's understanding has been that Level IV TCFs would not be required to have orthopedic surgeon on call at all times, which is not clear in this criterion. Also, Level III TCFs might be unable to maintain continuous call coverage. WHA asks DHS to clarify that	• Transfer Agreements: DHS has removed the criteria that require TCFs to have transfer agreements. • TCF "capability": DHS has replaced the term "capability" with language that adds additional clarification as to what "capability" means and further clarifies that these standards are only related to the care of trauma patients. For example, one criterion was changed from "III if the TCF has neurosurgery capability" to "III If the TCF provides neurosurgery for trauma patients." • Orthopedic coverage: DHS has added clarifying language to the criterion regarding the need for a back-up schedule for orthopedic surgeons at Level IV TCFs: "For Level IV TCFs that provide orthopedic surgery for trauma patients, an orthopedic surgeon is not required to be on call and promptly available 24 hours a day. However, when the Level IV TCF does have an orthopedic surgeon on call, the TCF must have a published back-up schedule." DHS has not made changes to the criterion that Level III TCFs must have an orthopedic surgeon on call and promptly available 24 hours a day. In a survey conducted by DHS in 2016 of the Level III and IV TCFs in the state, the question was asked "For Level III hospitals, does your facility have 24/7 orthopedic surgeon coverage? How difficult will this requirement be for your hospital?" 69% of the Level III TCFs that responded to this question responded that this would not be difficult to meet and that it would not impact their Level III classification. Continuous surgical and orthopedic coverage is a defining difference between Level III and IV TCFs. It is important for EMS, other TCFs, other medical partners and the general public to know what services they can expect to be provided at the various levels of TCFs throughout the state.

	a Level IV TCF with orthopedic capability can satisfy the criterion by having guidelines for transfer applicable generally, and not only when an on call orthopedic surgeon is unavailable. Further, WHA asks DHS to clarify that Level III TCFs can satisfy the call coverage through guidelines for transfer when there is a break in the on call schedule. • Trauma Registry: The proposed rule criteria states that "TCFs that admit 500 or more trauma patients annually must dedicate one full-time FTE equivalent employee to process the data capturing for the trauma registry. The proposed rule also provides that the TCF's trauma registrar must have previously attended two specific courses within 12 months of being hired. WHA asks DHS to remove the staffing and education requirements and, instead, work with TCFs to ensure that adequate training is accessible and cost effective. • ICU Staffing Ratio: The proposed rule includes the criterion "For trauma patients, the patient-to-nurse ratio in the ICU must not exceed two to one." WHA objects to mandated staffing ratios. • Implementation of New Requirements: WHA comments that there is a significant cost to the estimated annual implementation and compliance costs of the revised rule and that it is unclear where the proposed rule indicates that the new standards would not apply to a hospital until the hospital's next review date. WHA asks DHS to delay the implementation for all hospitals, but to clarify that hospitals will not be expected to meet the new standards until their review dates. • Economic Impact: WHA comments that the revenue available to trauma hospitals will not increase based on the increased regulatory burden of the proposed standards and that the amount actually billed by Level III and IV TCFs for trauma activations in 2018 was about $13 million, significantly less than DHS' estimate.	• Trauma Registry: DHS has removed the specific staffing requirements for the trauma registry. The criterion now reads "The TCF must demonstrate that appropriate staff resources are dedicated to the trauma registry." The criterion for the trauma registrar education requirement states that the trauma registrar must have previously attended or must attend within 12 months of being hired two educational courses. DHS has changed this criterion to state that "At least one staff trauma registrar must either have previously attended the following two courses or attend the following two courses within 12 months of being hired…" DHS has also changed this criterion to state that "This requirement will take effect on January 1, 2022." These educational requirements are important to ensure that quality data is entered in to the registry. Quality data is a vital part of a TCFs' trauma program and the regional and statewide trauma program as it is a key component of performance improvement, it supports timely review of trauma care across the continuum and helps to identify weaknesses in the trauma system. DHS appreciates that there is a cost associated with these courses and is exploring options to mitigate some of those costs during the first few years of implementation. • ICU Staffing Ratio: DHS has removed the mandated staffing ratio and has changed the criterion to read "For trauma patients in the ICU, the TCF must have adequate numbers of licensed registered nurses, licensed practical nurses and other personnel to provide nursing care to all trauma patients in the ICU." • Implementation of New Requirements: DHS has edited the effective date and has added additional language to clarify that hospitals will not be expected to meet the new standards until their review dates. The effective date has been updated to January 1, 2021. • Economic Impact: DHS notes that there is a lack of awareness about the ability to bill for trauma activations among TCFs in the state. Accordingly, while there is potentially a significant cost to TCFs to implement these new standards there is also potentially a significant amount of revenue that is being missed. Informing TCFs of the ability to charge for trauma activations

		has been a focus of the site review team members as they are on site during site reviews. Additionally, many TCFs throughout the state have already been increasing their capabilities and may be able to meet these new standards without significant or any additional cost. Without knowing specifically where TCFs currently stand in regards to the new standards, it is difficult to estimate what the cost will be to the TCFs throughout the state.
DHS 118, Appendix A, Provision 10(a)	This comment provides support from the Wisconsin Emergency Medical Services for Children program for TCFs having transfer agreements with at least one facility with pediatric ICU capability. The Emergency Nurses Association and the Society of Trauma Nurses support the use of transfer agreements and guidelines to facilitate rapid and safe transport of all patients. The National Emergency Medical Services for Children program also recognizes the importance of transfer agreements and has established a national performance measure to address this. Finally, this comment cites two national publications in support of transfer agreements.	Factoring in all of the comments and information received regarding transfer agreements, DHS has removed the requirements for formal transfer agreements. However, the criterion still remains that "A TCF that stabilizes pediatric trauma patients in the emergency department must have guidelines to assure appropriate and safe care of children." There are also several additional criteria relating to pediatric trauma care. These criteria aim to improve pediatric trauma care in Wisconsin while also providing the flexibility for TCFs to develop guidelines appropriate for their facility.
DHS 118, Appendix A, Provision 7(e)(7)	This comment states that a criterion requires registered nurses to take ATLS when registered nurses do not take this course and that provision 16(g) has a reference to a surgeon in the emergency medicine section.	DHS did not find any criterion that requires ATLS for registered nurses; this was corrected from a prior version. There is no provision 16(g), however DHS did find this issue in provision 7(e)(7) and the surgeon reference in the emergency medicine section was corrected.
DHS 118, Appendix A, Provision 14(h)	This comment was a question about what is meant by admitting; specifically if admitting excludes activations discharged from the ER and patients transferred out.	Based on other public comments, the language in this criterion requiring one registrar FTE per 500 admitted patients has been removed. This criterion no longer contains the use of the word "admitting."
DHS 118, Appendix A, Provision 5(d) and 7(e)(7)	This comment states that in provision 5(d) the criterion states that the TMD must staff the emergency department. This comment notes that if the TMD is a surgeon he/she would not be responsible for staffing the emergency department. This comment also notes that in provision 7(e)(7) there is reference to a surgeon in the emergency medicine section.	DHS has updated provision 5(d) to reflect the fact that a surgeon would not be responsible for staffing the emergency department. DHS has also corrected the language in provision 7(e)(7).
DHS 118, Appendix A, Provision 10(a)	This comment requests that provision 10(a) be changed to "A TCF that stabilizes pediatric trauma patients in the emergency department must have guidelines to assure appropriate and safe care of children" and notes that the guidelines listed are part of the stabilization process.	DHS has updated provision 10(a) to reflect these requested changes.
DHS 118, Appendix A, Provisions 2(m) and 7(j)	This comment requests that provisions 2(m) and 7(j) be changed to require physicians licensed to practice medicine who treat trauma patients in the emergency department be current in ATLS.	DHS has updated provisions 2(m) and 7(j) to reflect these requested changes.

DHS 118, Appendix A, Provisions 2(m) and 7(j)	This comment requests that provisions 2(m) and 7(j) be changed to require physicians licensed to practice medicine who treat trauma patients in the emergency department be current in ATLS.	DHS has updated provisions 2(m) and 7(j) to reflect these requested changes.
DHS 118, Appendix A, Provisions 2(m) and 7(j)	This comment requests that provisions 2(m) and 7(j) be changed to require physicians licensed to practice medicine who treat trauma patients in the emergency department be current in ATLS.	DHS has updated provisions 2(m) and 7(j) to reflect these requested changes.
DHS 118, Appendix A	This comment supports the proposed order as it is the foundation to provide optimal trauma care across our state trauma system to all patients, both adult and pediatric. Level III and IV TCFs play an integral role for our mostly rural state and the state trauma system should support them to be able to provide optimal care, given available resources.	DHS appreciates the time and effort spent to provide this comment. No changes have been made to the rule as a result of this comment.
DHS 118, Appendix A	This comment states that "all the new requirements will stress our current Level III independent trauma center financially and personnel."	DHS is committed to working with partners to meet the new criteria and will provide as much support as possible to this program.
DHS 118, Appendix A, pediatric provisions	This comment was a written comment as well as a spoken comment at the public hearing. This comment is in support of the pediatric guidelines, specifically those relating to child abuse.	DHS appreciates the time and effort spent to provide this comment. No changes have been made to the rule as a result of this comment.
DHS 118, Appendix A, pediatric provisions and provision 5(l)(1)	This comment was a written comment as well as a spoken comment at the public hearing. This comment appreciates and supports DHS' recognition that the needs of Wisconsin's kids as well as adults are important and are addressed in the proposed update to DHS 118. Additionally, this comment specifically requests that provision 5(l)(1) use the language "delineated by age range" rather than the language that is currently in the criterion because there is a range among the pediatric population and in an emergent situation calculating the number is not necessary.	DHS has updated provision 5(l)(1) to reflect the requested change.
DHS 118, Appendix A	This comment was a spoken comment from the public hearing in support of the new standards, particularly the fact that if a facility is going to offer specialty services that it needs to be done at a certain level and that the registry needs to be robust, accurate and timely.	DHS appreciates the time and effort spent to provide this comment. No changes have been made to the rule as a result of this comment.
DHS 118, Appendix A	This comment was a spoken comment from the public hearing in support of having continuous coverage in specialty services (orthopedics, neurosurgery, etc.) as having a lack of continuous coverage can cause delays in treatment and confusion for EMS providers. This commenter also supports the registry standards as well because the registry is vital to continuously improve trauma outcomes in Wisconsin.	DHS appreciates the time and effort spent to provide this comment. No changes have been made to the rule as a result of this comment.
DHS 118, Proposed Rule Order,	This comment was a spoken comment from the public hearing and noted that there was a typo	DHS has corrected the typo in this section to reflect that the Iowa Department of Public Health verifies Level III and IV TCFs.

Comparison with rules in Adjacent States	in the Iowa section of the comparison with rules in adjacent states.	
DHS 118, Appendix A, Provisions 3(a), 3(f) and 5(i)	This comment contains several concerns, relating to different provisions of DHS 118, Appendix A: • Prehospital protocols: Because of the size, number and complexity of some community EMS systems, a number of TCFs believe it is not practical to require each TCF to participate in the training of prehospital providers and the development of prehospital protocols. The TCFs support the criterion's requirement that "The TCFs must review care and provide feedback to prehospital care providers." WHA asks DHS to limit the criterion to that goal. • Diversion: The proposed rule would require the TCF's trauma surgeon to be involved in decision each time the TCF goes on diversion for trauma related occurrences. Some TCFs made the point that diversions can be based on facility issues, which are not within a trauma surgeon's expertise. Others agreed and were concerned that interruptions to ensure trauma surgeon involvement could interfere with patient care. WHA asks DHS to remove this criterion. • Deficiencies and exclusion from trauma call: TCFs are concerned about the criterion requiring the trauma medical director, in collaboration with the trauma program manager, to have the authority and responsibility to correct deficiencies and exclude from trauma call trauma team members who do not meet specified criteria. The TCFs are concerned this requirement might conflict with other hospital approval and certification standards and a TCF's policies and procedures. The TCFs ask that the criterion, instead, require the TMD, in collaboration with the TPM, to report to the appropriate persons any deficiencies and any trauma team members who do not meet the specified call criteria. The hospital would then address deficiencies and call issues as required by the hospital's policies and procedures.	• Prehospital providers: DHS has updated provision 3(a) to remove the "EMS medical director" and has added language to help clarify what participating in the training of prehospital providers means. This training of prehospital providers is important because high-quality, consistent trauma care requires that prehospital personnel understand the trauma destination criteria, treatment protocols, transportation methods and destination facilities in their geographic region. • Diversion: DHS believes that the criterion already sufficiently specifies that the trauma surgeon must be involved with diversion decisions only for trauma related occurrences. The trauma surgeon would not be required to be involved in diversion decisions for system and/or hospital issues such as power outages or a CT scanner being down. • Deficiencies and exclusion from trauma call: DHS has updated provision 5(i) to reflect the requested change.

Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		x	
Department response to Rules Clearinghouse recommendations	x		
Final Regulatory Flexibility Analysis	x		
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis	x		
Public Hearing Summary	x		
List of Public Hearing Attendees and Commenters	x		
Summary of Public Comments and Department Responses	x		
Fiscal Estimate/Economic Impact Analysis		x	
Revised Fiscal Estimate/Economic Impact Analysis			x
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			x
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			x
DOA report under s. 227.137 (6), Stats., on rules with economic impact of $20 MM or more			x
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			x