ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
CREATING RULES

To create HFS 118, relating to Wisconsin's Statewide Trauma Care System.

Statute interpreted

The rules interpret s. 146.56, Stats.

Statutory authority

The Department's authority to create these rules is found in s. 146.56 (2), Stats.

Explanation of agency authority

Section 146.56 (2), Stats., authorizes the Department to develop and promulgate rules necessary to implement the trauma care system. The rules must include a method by which to classify all hospitals as to their respective emergency care capabilities. The classification rule must be based on standards developed by the American College of Surgeons.

Related statutes or rules

Several sections of chapter 146, Stats., relate to these rules. Section 146.50, relating to emergency medical services personnel, licensing and training, s. 146.53, relating to a state emergency medical services plan, s. 146.55, relating to emergency medical services programs, and s. 146.58, relating to the emergency medical services board, all relate to a trauma care system insofar as emergency medical services are the focal point of responding to traumatic events.

In addition, the Department has promulgated several chapters of administrative rules pertaining to emergency medical services. These rules correspond to the differing levels of competencies among emergency medical service personnel. Chapters HFS 110, 111 and 112 pertain to the licensing of different levels of emergency medical technicians. Chapter HFS 113 concerns the certification of first responders.

Plain language analysis

The Department proposes to create ch. HFS 118, rules governing the development and operation of Wisconsin's Statewide Trauma Care System. The system's objective is to reduce death and disability resulting from traumatic injury by:

- Decreasing the incidence of trauma;
- Providing optimal care of trauma victims and their families; and
- Collecting and assessing trauma-related data.

Trauma is a sudden physical injury caused by the application of an external force or violence, such as a motor vehicle crash, a fall or a blow from a blunt or penetrating instrument. Trauma is the leading cause of death in Wisconsin among people under age 35 and is the fourth leading cause of death among the general Wisconsin population. Traumatic injury and its resultant care may, directly or indirectly, affect all Wisconsin residents and visitors. Section 146.56, Stats., directs the Department of Health and Family Services to develop and implement a statewide trauma care system. Through a statewide trauma system, health care and public safety participants will best be

able to respond to and address the needs of trauma victims and their families. The Statewide Trauma Advisory Council, established under s. 15.197 (25), Stats., and appointed by the Secretary of the Department of Health and Family Services, has been collaborating with the Department for the past four years towards the development and implementation of Wisconsin's Statewide Trauma Care System. Wisconsin's Statewide Trauma Care System, when fully implemented, will enhance community health through an organized system of injury prevention, acute care and rehabilitation that is fully integrated with the public health care system in a community.

The Department is proposing the following through its creation of chapter HFS 118:

- A method by which to classify the emergency care capabilities of all Wisconsin hospitals;
- Use of the American College of Surgeons publication, *Resources for Optimal Care of the Injured Patient: 1999*, to evaluate the adequacy of hospitals' trauma care capabilities;
- Policies guiding the development and use of Regional Trauma Advisory Councils for the purpose of developing, implementing and monitoring the trauma care system; and
- Policies governing the establishment and operation of a statewide trauma registry; triage and transfer protocols among trauma care providers; and the promotion of improved trauma care provider performance.

Data collected from the state trauma registry on injury incidence, patient care and outcomes, specified in section HFS 118.09, will help identify problems and evaluate the performance of the existing trauma care system. Through this information, communities will be able to assess the nature of traumatic injuries in Wisconsin and establish appropriate injury prevention programs to reduce the occurrence of injuries, expedite patients' recovery and minimize the lasting effects of injuries.

Summary of, and comparison with, existing or proposed federal regulation

There are no federal regulations that pertain to trauma care at this time. Federal grant money exists for the development of state trauma systems, however, these monies are optional at this time.

Comparison with rules in adjacent states

- Iowa

Iowa enacted state legislation establishing a state trauma care system in 1995 and administrative rules in 1997. The system became fully operational in 2001. All 117 hospitals in the state participate in the trauma system. Iowa's enabling statute created a trauma system advisory council that has 20 members. Iowa's law also established a system evaluation and quality improvement committee as well as a trauma registry. Hospitals self-define their level of commitment. Once the hospital chooses the level at which it wants to be verified, the state health department verifies that the hospital meet the requirements for verification of that level of trauma capability. Hospitals that are not verified do not receive trauma patients by ambulance. The state health department does an onsite verification of Level 1, 2 and 3 (but not for Level 4) trauma facilities. Administrative rules for trauma care are contained in chapters 134 to 138 of the Department of Public Health's code. Those rules:

- Authorize the state health department to:
  - deny authorization for a hospital to be a trauma care facility;
  - issue a citation and warning;
  - place a trauma care facility on probation; and

- suspend or revoke existing trauma care verification authorization.
- Direct the department of health to investigate complaints.
- Direct the department to categorize hospitals as a particular level trauma care facility after conducting a site survey of every hospital.
- Allow the department to accept ACS verification as a substitute for department verification.
- Establish mandatory reporting of trauma care data for the department's use in compiling and maintaining a trauma care registry.
- Specify required health care professional trauma education and training by level of trauma care facility.
- Establish a statewide trauma system evaluation quality improvement committee to analyze trauma data and recommend improvements in the state's trauma system.

- Illinois

Illinois promulgated administrative rules for trauma care in 1995, and has revised them several times since then. The rules are in Subchapter H (515.2000 to 515.2200) of Part 515, of Title 77 of the Illinois Adm. Code. With the following exceptions, the topics addressed in the rule are comparable to those proposed by the Department of Health and Family Services in ch. HFS 118. The Illinois rules:

- Mandate the existence of at least one Level 1 (highest level) trauma care facility in each EMS region in the state.
- Require the state health department to conduct a site visit to each hospital that applies to be designated as a Level 1 or 2 trauma center.
- Authorize the state health department to immediately revoke a trauma center's designation.
- Direct the department to issue a violation notice and require the trauma center to submit a plan of correction to the department within 10 days if violation of the rules does not present substantial probability that death or serious physical harm will result.
- Are much more prescriptive regarding the specific criteria for trauma center Level 1 and 2 designation and ongoing operation. (HFS 118 places the onus for approval of Level 1 and 2 designation on the hospital's being verified as a Level 1 or 2 trauma facility by ACS; and DHFS relies on a hospital's operation in accordance with the ACS document insofar as trauma care facilities will be expected to conform in accordance with applicable sections of the ACS document.)
- List each specific type of information hospitals are to report for trauma registry. (HFS 118 simply states that the data items required to be reported will be contained in a DHFS data submission manual.)
- Specify trauma registry data confidentiality guidelines, along with persons who have access to the registry data.
- Prohibit the department of health from requiring hospitals to provide information on cases that are dated more than two years before the department's request for further information.
- Contain guidelines for patient evaluation and transfer.
- Authorize the department to delegate the designation of trauma centers to a local health department in an area where there are a lot of trauma centers (i.e., large cities).
- Require local health departments to submit to the department of health copies of all complaints within two working days after receipt and copies of all final investigation reports within 10 working days after the completion of the investigation.
- Require local health departments to submit to the department of health copies of quarterly trauma center focused outcome analyses.

- Assure the confidentiality of trauma center medical audit data, and grants immunity from civil liability to the same extent hospitals are given under section 10.2 of the state's hospital licensing act.
- Direct the state health department to annually distribute funds to all trauma centers in the state.

- Michigan and Minnesota

Michigan and Minnesota are two of only about six states that do not have an organized trauma network. However, both states are progressing towards the establishment of a statewide trauma care system. In Minnesota, following a couple of years during which support was organized, legislation either has already been or is likely to soon be introduced to authorize the state's organization for and establishment of a trauma care system. In Michigan, a group of surgeons and lawmakers has launched an effort to create a statewide trauma system. That effort came two years after a government-commissioned report found a number of problems with trauma care in Michigan, including a lack of trauma centers in the northern part of the state and the absence of a system to collect data about traumatic injuries. Michigan received a $38,000 federal grant to develop a plan for creating a statewide trauma care system.

Summary of factual data and analytical methodologies

The Department based its development of ch. HFS 118 on the Wisconsin Statewide Trauma Care System Report, completed in January 2001. The Report was a joint effort of the Department and the Statewide Trauma Advisory Committee. The Committee and its subcommittees were composed of statewide representatives of hospitals, emergency physicians, trauma nurses, fire departments, emergency medical service providers, and surgeons. The Trauma Care System Report and these proposed rules recognize the need for a continuum of care that provides a comprehensive approach to the triage, treatment, transport, and ultimate care of major trauma victims. The Advisory Committee and the Department have heavily relied on the document "*Resources for the Optimal Care of the Injured Patient: 1999*" written by the American College of Surgeons Committee on Trauma, in developing these rules.

Analysis and supporting documents used to determine effect on small business

This chapter will primarily affect Wisconsin hospitals, rural medical centers and ambulance service providers. Based on fiscal year 2002 data, three hospitals had annual revenues under $5 million. There are currently 456 ambulance service providers in Wisconsin. The Department does not have annual revenue data for ambulance service providers. However, the Department presumes that most, if not all, ambulance service providers have annual revenues under $5 million.

Under these proposed HFS 118 rules, the Department would require all ambulance service providers to affiliate and participate with a Regional Trauma Advisory Council (RTAC). The purpose of such affiliation is to participate in their region's trauma care system. The proposed rules require ambulance service providers to state their RTAC affiliation choice in the ambulance service provider's operational plan. Under chapter HFS 110, ambulance service providers already must submit operational plans to the Department. The Department collects operational plans to ensure the appropriate operation of ambulance services. There will be no additional cost to fulfill this obligation.

Under section HFS 118.09 of these proposed rules, the Department also intends to develop and publish a data submission manual that specifies what information ambulance service providers will need to collect and submit to the Department for the purpose of analyzing trauma injury and care. The purpose of the analysis is to reduce trauma care injuries and improve the performance of the

trauma care system. Such data collection is essential to evaluating and improving health status and system performance.

Section 227.114 (2) of the statutes lists a variety of methods for reducing the effect rules have on small businesses. These methods are:

- Establishing less stringent compliance or reporting requirements for small businesses;
- Establishing less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- Consolidating or simplifying compliance or reporting requirements for small businesses;
- Establishing performance standards for small businesses to replace design or operational standards required in the rule; and
- Exempting small businesses from any or all requirements of the rule.

The Department has chosen not to reflect any of the preceding methods in its requirements to collect and submit trauma care data because it believes that exempting or modifying individual entities from data collection and reporting responsibilities would compromise the quality and usefulness of information needed to protect and improve the public's health.

Anticipated costs incurred by private sector

The Department believes that these proposed rules will not impose appreciable costs on the private sector that entities do not already incur in the provision of trauma care.

Trauma facilities are state-classified as Level I, II, III or IV or "unclassified," depending on the comprehensiveness of the trauma care provided. As required under s. 146.56 of the statutes, this rule requires hospitals to report their level of emergency care capability to the Department. The rule does not, however, assign a level to any hospital, nor does the rule require any hospital to attain a certain level of trauma care facility. Each hospital determines the level of trauma facility care it provides and qualifies for against published national standards. Classification as a Level I or II trauma facility includes verification of that status by the American College of Surgeons (ACS). The initial cost for a trauma center verification visit from ACS is approximately $3,000 plus the expenses and honoraria for two trauma surgeons responsible for performing the ACS inspection. Any costs that hospitals incur in becoming a Level I or II trauma care facility would be the result of the verification process, not the reporting requirement of the rule. There will, therefore, be no cost to hospitals as the result of this requirement. The ACS re-verification cost would include the ACS administration fee of $2,200 plus the two surgeon's expenses and honoraria. Any hospital that chooses to be a state-classified Level III or IV trauma care facility must complete the Department's self-assessment checklist and application form. All hospitals that choose a Level I, II, III or IV state classification shall be responsible for expenses associated with the classification process. The Department cannot determine the cost to become state classified as a Level III or IV because that cost will be based on what existing trauma care capabilities the hospital already has. The expenses are the same across the board for Level I, II, III or IV to become ACS-verified.

The rule requires emergency medical services providers to become affiliated with an RTAC. There will be no cost to providers for this affiliation.

The rule also establishes policies governing the operation of a statewide trauma registry and the promotion of improved trauma provider performance. When the registry is operational, hospitals and EMS providers will be required to submit trauma data on a quarterly basis to the registry. The Department will use this data to improve trauma care. It is likely that most agencies will collect trauma data for their own purposes. Hospitals with Level I and Level II trauma centers, for

example, are required to collect trauma data as a condition of their verification. The requirements of this rule are not expected to result in significant additional cost for agencies that are already collecting this data. To the extent that hospitals and EMS providers will be required to gather data that has not previously been collected, this requirement may result in some costs to these agencies. It is not possible to estimate these costs, but they are not expected to be significant.

Effect on small business

These proposed rules will require ambulance services to complete reports pertaining to their trauma care activities.

Agency contact person

Marianne Peck; 608-266-0601; peckme@dhfs.state.wi.us

Place where comments are to be submitted and deadline for submission

The Department opened the public comment period on the proposed rules on June 14, 2004 and closed it on August 6, 2004. During that period, persons had the opportunity to submit oral or written comments on the rules in person, via email and postal mail, and via the Internet at the Department's administrative rules website.

Rule text

SECTION 1. HFS 118 is created to read:

Chapter HFS 118

TRAUMA CARE

Subchapter I – General Provisions

HFS 118.01 Authority and purpose.
HFS 118.02 Applicability.
HFS 118.03 Definitions.

Subchapter II - Statewide Organization for Trauma Care

HFS 118.04 Lead agency.
HFS 118.05 Statewide trauma advisory council.
HFS 118.06 Regional trauma advisory councils.
HFS 118.07 EMS services.
HFS 118.08 Hospitals.

Subchapter III - Trauma Care Improvement

HFS 118.09 Trauma registry.
HFS 118.10 Performance improvement.

Subchapter I – General Provisions

HFS 118.01 Authority and purpose. This chapter is promulgated under the authority of s. 146.56 (2), Stats., to develop and implement a statewide trauma care system. The purpose of the statewide trauma care system is to reduce death and disability resulting from traumatic injury by decreasing the incidence of trauma, providing optimal care of trauma victims and their families, and collecting and analyzing trauma-related data.

HFS 118.02 Applicability. This chapter applies to all of the following:

(1) The department.

(2) All persons who are any of the following:

(a) An EMT – basic or EMT – basic IV.

(b) An EMT – intermediate.

(c) An EMT – paramedic.

(d) A medical director.

(e) A first responder.

(3) A hospital approved under subch. II of ch. 50, Stats., and ch. HFS 124, excluding hospitals whose principal purpose is to treat persons with a mental illness.

(4) An ambulance service provider licensed under s. 146.50, Stats., and chs. HFS 110, 111 and 112.

(5) A regional trauma advisory council developed by the department pursuant to s. 146.56 (1), Stats.

(6) Any health care provider involved in the detection, prevention or care of an injured person and is a member of a Wisconsin RTAC.

(7) A Wisconsin law enforcement agency that is a member of a Wisconsin RTAC.

HFS 118.03 Definitions. In this chapter:

(1) “Ambulance service provider” has the meaning specified in s. 146.50 (1) (c), Stats., namely, a person engaged in the business of transporting sick, disabled or injured individuals by ambulance to or from facilities or institutions providing health services.

(2) “ACS” means the American college of surgeons.

(3) “Assessment and classification criteria” means the required trauma care services and capabilities for a hospital to be classified as a Level III or IV trauma care facility.

(4) “Audit” means a close examination of a situation or event in a multidisciplinary peer review.

(5) “Bypass” means to forego delivery of a patient to the nearest hospital for a hospital whose resources are more appropriate for the patient’s injury pursuant to direction given to a pre-hospital emergency medical service by on-line medical direction or predetermined triage criteria.

(6) "Classification" means the process whereby a hospital identifies its service level as a trauma care facility and the department reviews and approves the hospital as a provider of a level of trauma care services to meet the needs of the severely injured patient.

(7) “Coordinating facility” means an ACS verified level I or II hospital that has a collaborative relationship with the regional trauma advisory council and the department as specified under s. HFS 118.06 (3) (c).

(8) “Definitive care” means comprehensive care for the full spectrum of injuries beyond the initial assessment and resuscitation phase.

(9) “Department” means the department of health and family services.

(10) “Dispatch” means identifying and coordinating the emergency resources needed to respond to a specific traumatic injury or illness.

(11) “Emergency medical technician” or “EMT” means an individual licensed by the department under ch. HFS 110, 111 or 112 as an EMT-basic, EMT-basic IV, EMT-intermediate or EMT-paramedic.

(12) “Executive council” means the RTAC leadership body, which is composed of professionals from each region who reflect trauma care expertise, leadership and diversity within each trauma care region.

(13) “First responder” means a person who is certified under ch. HFS 113 and who provides emergency care to a sick, disabled or injured individual prior to the arrival of an ambulance as a condition of employment or as a member of a first responder service.

(14) “First responder service" means a group of persons licensed by the department as a first responder group under s. 146.50 (8), Stats., who are employed or organized to provide emergency care to sick, disabled, or injured individuals as a response for aid requested through a public service access point in conjunction with the dispatch of an ambulance, but who do not provide ambulance transportation of a patient.

(15) “Fiscal agent” means the person or organization responsible for transactions of RTAC funds.

(16) “Health care provider” means a medical professional who or organization that is involved in either the detection, prevention or care of an injured person and includes all of the following:

(a) A nurse licensed under ch. 441, Stats.

(b) A dentist licensed under ch. 447, Stats.

(c) A physician or physician assistant licensed under subch. II of ch. 448, Stats.

(d) A rural medical center, as defined in s. 50.50 (11), Stats.

(e) A hospital.

(f) An ambulance service provider.

(g) An emergency medical technician.

(h) A first responder.

(i) A doctor of podiatric medicine and surgery licensed under subch. IV of chapter 448, Stats.

(17) “Hospital” means entities approved under subch. II of ch. 50, Stats., and ch. HFS 124, including critical access hospitals, that routinely provide trauma care, excluding hospitals whose principal purpose is to treat persons with a mental illness.

(18) “Indicator review” means the RTAC’s assessment of trauma system performance based on desired trauma system measurements and used by the RTAC in the performance improvement process.

(19) “Lead agency” means an organization or agency that serves as the focal point for program development on the local, regional and state level. In this chapter, the department serves as the lead agency.

(20) “Level I” means a class of trauma care facility that is characterized by the hospital’s capability of providing leadership and total care for every aspect of traumatic injury from prevention through rehabilitation, including research.

(21) “Level II” means a class of trauma care facility that is characterized by the hospital’s ability to provide initial definitive trauma care regardless of the severity of injury, but may not be able to provide the same comprehensive care as a level I trauma center.

(22) "Level III" means a class of trauma care facility that is characterized by the hospital’s ability to:

a. Provide assessment, resuscitation and stabilization.

b. Provide emergency surgery and arrange, when necessary, transfer to a level I or II trauma facility for definitive surgical and intensive trauma care.

(23) "Level IV" means a class of trauma care facility that is characterized by the hospital’s ability to stabilize and provide advanced trauma life support prior to patient transfer.

(24) “Loop-closure” means the process whereby an RTAC has identified a quality improvement problem, completed an evaluation, developed an action plan and notified appropriate health care providers of the results.

(25) "Medical director" means the physician who is designated in an EMT operational plan to be responsible for all of the following off-line medical direction activities:

(a) Controlling, directing and supervising all phases of the emergency medical services program operated under the plan and the EMT's performing under the plan.

(b) Establishing standard operating protocols for EMTs performing under the plan.

(c) Coordinating and supervising evaluation activities carried out under the plan.

(d) Designating on-line medical control physicians, if the physicians are to be used in implementing the emergency medical services program.

(26) “Needs assessment” means a written report prepared by an RTAC identifying and documenting trauma care and injury prevention resources and deficiencies within a defined area of the trauma system and which serves as the basis for developing a regional trauma plan.

(27) “Nurse anesthetist” means a professional nurse licensed under ch. 441, Stats., who has obtained, through additional education and successful completion of a national examination, a certification as an anesthesia nursing specialist.

(28) "Off-line medical direction" means medical direction that does not involve voice communication provided to EMTs and first responders providing direct patient care.

(29) “On-line medical direction” means medical direction of the activities of an EMT that involves voice communication provided to the EMTs by the medical director or by a physician designated by the medical director.

(30) “On-line medical control physician” means a physician who is designated by the medical director to provide voice communicated medical direction to emergency medical technician and first responder personnel and to assume responsibility for the care provided by emergency medical technician and first responder personnel in response to that direction.

(31) “Out-of-hospital” means care provided to sick or injured persons before or during transportation to a medical facility, including any necessary stabilization of the sick or injured person.

(32) "Pediatric trauma center" means a hospital that is dedicated to providing for the trauma needs of a pediatric patient population and meets the resource requirements outlined by the ACS in chapter 10 of the publication *Resources for Optimal Care of the Injured Patient: 1999”* for verification as a pediatric trauma center. The trauma center may be freestanding or a separate administrative unit in a larger hospital.

Note: The publication, *Resources for Optimal Care of the Injured Patient: 1999*, Committee on Trauma, American College of Surgeons (1998), is on file in the Department’s Division of Public Health, the Revisor of Statutes Bureau and the Secretary of State’s Office, and is available for purchase from the American College of Surgery, 633 W. Saint Clair St., Chicago, Illinois 60611-3211. Chapter 10 is titled “*Pediatric Trauma Care*.”

(33) “Performance improvement” means a method of evaluating and improving processes of trauma patient care that emphasizes a multidisciplinary approach to problem solving.

(34) "Physician" means a person licensed under ch. 448, Stats., to practice medicine and surgery.

(35) "Protocol" means a written statement approved by the department and signed and dated by the medical director that lists and describes the steps any out-of-hospital care provider is to follow in assessing and treating a patient.

(36) “Regional trauma advisory council” or “RTAC” means an organized group of healthcare entities and other concerned individuals who have an interest in organizing and improving trauma care within a specified geographic region approved by the department.

(37) “Regional trauma plan” means a written report prepared by an RTAC that meets all of the following criteria:

(a) Identifies the region’s current trauma care development strengths and weaknesses.

(b) Describes specific goals for future growth and activities in the region.

(c) Is based on the RTAC’s needs assessment.

(38) “Resource hospital” means a hospital in Wisconsin or a bordering state that makes a written commitment to assist the level III coordinating facility of an RTAC to meet the needs required for the development, implementation, maintenance and evaluation of the regional trauma system.

(39) “Rural” means outside a metropolitan statistical area specified under 42 CFR 412.62 (ii) (A) or in a city, village or town with a population of less than 14,000.

(40) “Statewide trauma advisory council” or “STAC” means the entity established by the department to advise the department on a variety of issues pertaining to the establishment and operation of the statewide trauma care system.

(41) “Trauma care system” means a comprehensive and organized approach to facilitating and coordinating a multidisciplinary system response to traumatically injured patients and includes the continuum of care from initial injury detection through definitive care, rehabilitation and injury control.

(42) “Trauma care facility” means a hospital that the department has approved as having the services and capabilities of a level I, II, III or IV trauma care facility.

(43) “Traumatic injury” means major or severe injuries to more than one system of a person’s body or major injury to a single system of the body that has the potential of causing death or major disability.

(44) “Trauma registry” means a system for collecting data from hospitals for which the department manages and analyzes the data and disseminates the results.

(45) “Triage” means classifying patients according to the severity of their medical conditions at the scene of an injury or onset of illness and subsequently providing care first to those patients with the greatest medical needs and who are likely to benefit from that care.

(46) "Unclassified hospital" means a hospital that either has chosen not to be a part of Wisconsin's trauma care system, or a hospital that the department has not approved as a level I, II, III or IV trauma care facility.

(47) “Urban” means an area within a metropolitan statistical area specified under 42 CFR 412.62 (ii) (A) or in a city, village or town with a population of 14,000 or more.

(48) “Verification” means the process specified by the ACS whereby a hospital desiring recognition as a level I, II, III or IV trauma care facility is designated as that level by the ACS.

Subchapter II - Statewide Organization for Trauma Care

HFS 118.04 Lead agency. (1) DESIGNATION. The department shall be the lead agency for the development, implementation and monitoring of the statewide trauma care system.

(2) LEAD AGENCY DUTIES. The lead agency shall do all of the following:

(a) *General duties*. Develop and revise guidelines and administrative rules for the statewide trauma care system.

(b) *Organize and structure RTACs*. 1. Approve the designation of all trauma care geographic regions based on consideration of what represents the best care of the trauma patient.

Note: Wisconsin is divided into 9 trauma care geographic regions. Each region has an RTAC. A trauma care region is defined by the location of the health care providers that have selected a particular RTAC for primary membership and in which the majority of each provider’s trauma care and prevention occurs.

2. Review the geographic distribution and organization of regional trauma advisory councils and ensure executive councils that promote the optimal operation of the statewide trauma care system.

3. Approve regional trauma advisory councils under sub. (6) (c).

4. Approve coordinating facilities, fiscal agents, executive councils and resource hospitals under sub. (6) (c).

(c) *Classify trauma care facilities*. 1. Establish and revise the assessment and classification criteria for characterizing a hospital as a trauma facility.

2. Review and approve hospital applications to be a trauma care facility in accordance with standards and guidance given by the American college of surgeons in the publication *Resources for Optimal Care of the Injured Patient: 1999* and the criteria in appendix 1 and according to the process under sub. (6) (a).

Notes: 1. The publication, *Resources for Optimal Care of the Injured Patient: 1999*, Committee on Trauma, American College of Surgeons (1998), is on file in the Department’s Division of Public Health, the Revisor of Statutes Bureau and the Secretary of State’s Office, and is available for purchase from the American College of Surgery, 633 W. Saint Clair St., Chicago, Illinois 60611-3211.

2. Hospitals are verified by the American College of Surgeons as level I or II trauma care facilities based on conformance with the standards and guidelines contained in the publication, *Resources for Optimal Care of the Injured Patient: 1999*. The Department bases its classification of hospitals as level III or IV trauma care facilities on Appendix 1 of this chapter.

3. Review and approve a hospital's selection of an RTAC with which the hospital will participate under s. HFS 118.08 (1).

(d) *Guide RTAC plan development*. 1. With the advice of the STAC, establish the guidelines for RTAC needs assessments and trauma plans developed pursuant to s. HFS 118.06 (3) (L) and triage and transport protocols developed pursuant to s. HFS 118.06 (3) (o).

2. Review and approve regional trauma needs assessments, triage and transport protocols and plans under sub. (6) (c).

(e) *Develop and operate state trauma registry*. 1. Develop, implement and maintain the state trauma registry under s. HFS 118.09.

2. Develop and prepare standard reports on Wisconsin's trauma system using the state trauma registry as described in s. HFS 118.09 (4).

(f) *Guide improvement of regional trauma care performance*. 1. Provide all of the following reports to RTACs:

a. Quarterly standard reports of trauma registry results for the region.

b. Other reports as requested by RTACs.

2. Develop guidelines for a regional performance improvement program under s. HFS 118.10 that includes all of the following:

a. The purpose and principles of the program.

b. How to establish and maintain the program.

c. The requirements for membership of the regional performance improvement committee.

d. The authority and responsibilities of the performance improvement committee.

(g) *Maintain statewide trauma care system*. 1. Resolve conflicts concerning trauma care and prevention issues between the RTAC and trauma care providers and any other entity within the RTAC's geographic region according to the process specified under sub. (3).

2. Maintain awareness of national trends in trauma care and periodically report on those trends to RTACs and trauma care system participants.

3. Encourage public and private support of the statewide trauma care system.

4. Assist the RTACs with developing injury prevention, training and education programs.

5. Seek the advice of the statewide trauma advisory council in developing and implementing the statewide trauma care system.

(h) *Enforce chapter requirements*. 1. Regulate and monitor trauma care facilities.

2. Investigate complaints and alleged violations of this chapter.

3. Enforce the requirements of this chapter.

(3) COMPLAINT AND DISPUTE RESOLUTION. (a) 1. Upon receipt of a complaint about the trauma system, the department shall either investigate the complaint or request one or more RTACs to initially investigate and respond to the complaint. The department shall monitor how the RTAC or RTACs are addressing and responding to the complaint. When the RTAC has completed its investigation and has prepared its response, the RTAC shall communicate its response to the department.

2. Regardless of whether the department has requested one or more RTACs to investigate and respond to the complaint, the department may initiate an investigation of and response to a complaint within 2 business days following the department's receipt of the complaint.

Note: The time within which the Department resolves a complaint depends on the nature of the complaint and the resources required to investigate and resolve the complaint.

(b) 1. The department shall maintain a record of every complaint and how each complaint was addressed and resolved.

2. Within the constraints imposed by laws protecting patient confidentiality, the department shall make available its complaint record under subd. 1. to any person requesting to review it.

Note: To request review of the Department's complaint record, contact the Statewide Trauma Care Coordinator by calling 608-266-0601 or by writing to Statewide Trauma Care System Coordinator, Bureau of Local Health Support and Emergency Medical Services, Room 118, 1 West Wilson St., Madison, WI 53701, or by sending a fax to 608-261-6392.

(4) INVESTIGATIONS. (a) An authorized employee or agent of the department, upon presentation of identification, shall be permitted to examine equipment or vehicles or enter the offices of an RTAC, a hospital seeking or having department recognition as a trauma care facility or an ambulance service provider during business hours with 24 hour advance notice or at any other reasonable prearranged time. The authorized employee or agent of the department shall be permitted to inspect and review all equipment and vehicles and inspect, review and reproduce records of the trauma care facility, ambulance service provider or RTAC pertinent to the nature of the complaint, including, but not limited to, administrative records, personnel records, training records and vehicle records. The right to inspect, review and reproduce records applies regardless of whether the records are maintained in written, electronic or other form.

(b) If, based on the department's investigation, the department determines that corrective action by the trauma care facility is necessary, the trauma care facility shall make the corrective actions. The department may subsequently conduct a final investigation following corrective action and notify the trauma facility of the results.

(5) WAIVERS. The department may waive any nonstatutory requirement under this chapter, upon written request, if the department finds that strict enforcement of the requirement will create an unreasonable hardship for the provider in meeting the emergency medical service needs of an area and that waiver of the requirement will not adversely affect the health, safety or welfare of patients or the general public. The department's denial of a request for a waiver shall constitute the final decision of the department and is not subject to a hearing under sub. (7).

Note: To request a waiver from a nonstatutory requirement under this chapter, contact the statewide trauma care coordinator by calling 608-266-0601 or by writing to Statewide Trauma Care System Coordinator, Bureau of Local Health Support and Emergency Medical Services, Room 118, 1 West Wilson St., Madison, WI 53701, or by sending a fax to 608-261-6392.

(6) DEPARTMENT REVIEW PROCESS. (a) *Department review of and decision on hospital trauma care facility applications*. 1. A hospital requesting department approval to act or advertise as a trauma care facility shall submit an application to the department on a form provided by the department.

Note: For a copy of the Department's assessment and classification criteria application form for approval as a trauma care facility, write to the Wisconsin Trauma Care System Coordinator, Division of Public Health, P.O. Box 2659, Madison WI 53701–2659 or download the form from the DHFS website at: www.dhfs.state.wi.us/DPH_EMSIP/index.htm.

2. The department shall review each hospital application submitted pursuant to s. HFS 118.08 (2).

3. The department may require a hospital to document the basis for the hospital's professed level of trauma care facility.

4. The department may perform a site visit of a level III or IV trauma facility to determine compliance with the trauma facility assessment and classification criteria in accordance with all of the following conditions:

a. The department shall select the site visit team.

Note: The Department recommends that a trauma surgeon, emergency room physician and a trauma coordinator, all from a Level I or II verified trauma care facility, minimally comprise the site visit team.

b. The department's site visit shall be to determine whether the facility meets the assessment and classification criteria in appendix 1.

c. The site visit team shall submit their findings to the department within 30 calendar days of completing the site visit.

5. a. Except as provided under subd. par. b., within 60 business days of receiving a complete application for department approval to be a trauma care facility, the department shall either approve or deny the application and notify the applicant hospital in writing. In this subdivision paragraph, "complete application" means a completed application form and the documentation necessary to establish that the hospital is a level I, II, III or IV trauma care facility.

b. If the department determines a need to conduct a site visit of the applicant hospital, the department shall notify the applicant hospital of its level of trauma care within 10 business days following the department's receipt of the site visit findings under subdivision 4. c.

c. If the department does not approve the applicant hospital's application, the department shall give the applicant reasons, in writing, for the denial and shall inform the applicant of the right to appeal the department's decision under sub. (7).

d. In the absence of other evidence of receipt, receipt of the department's notice under this subdivision is presumed on the 5th day following the date the department mails the notice.

6. If the department determines the applicant hospital's trauma care capabilities do not warrant the hospital being approved as a trauma care facility, the department shall consider the hospital to be an unclassified hospital.

(b) *Department review of and decision on a hospital's selection of an RTAC for primary membership*. 1. The department shall review each hospital selection of an RTAC for primary membership pursuant to s. HFS 118.08 (1) (a) 2.

2. If the department does not notify the hospital of its approval or disapproval within 30 calendar days of receiving a hospital RTAC selection for department approval, the hospital may consider their selection approved by the department.

3. If the department does not approve the hospital's selection of an RTAC, the department shall give the applicant reasons, in writing, for the denial and shall inform the applicant of the right to appeal the department's decision under sub. (7).

4. In the absence of other evidence of receipt, receipt of the department's notice under this subdivision is presumed on the 5th day following the date the department mails the notice.

(c) *Department review of and decision on RTAC applications, selections, needs assessments, triage and transport protocols and plans*. 1. An RTAC requesting department approval of any of the following shall submit it to the department:

a. An application under s. HFS 118.06 (3) (a).

b. A selection of an executive council, coordinating facility, fiscal agent and resource hospital under s. HFS 118.06 (3) (c), (d), (e) and (f).

c. A needs assessment of its trauma region under s. HFS 118.06 (3) (L), and a triage and transport protocol or plan under s. HFS 118.06 (3) (o).

2. The department shall review each RTAC submission made under subd. 1.

3. a. Within 90 business days of receiving an RTAC submission under subd. par. 1., the department shall either approve or deny the RTAC submission and notify the RTAC in writing.

b. If the department does not approve an RTAC's submission, the department shall give the RTAC reasons, in writing, for the denial. The department shall also inform the applicant of the right to appeal the department's decision under sub. (7).

c. In the absence of other evidence of receipt, receipt of the department's notice under this subdivision is presumed on the 5th day following the date the department mails the notice.

4. In response to the department's non-approval under subd. 3., the RTAC may modify its submission and submit the revision to the department for subsequent department review or appeal the department's decision pursuant to sub. (7).

(d) *Department withdrawal of RTAC approval*. 1. The department may withdraw its approval of an RTAC's operations if the department makes a finding of any of the following:

a. The RTAC does not meet the eligibility requirements established in s. 146.50, Stats., and this chapter.

b. The department approval was obtained through error or fraud.

c. The RTAC violated any provision or timeline of s. 146.50, Stats., or this chapter.

2. The department shall send written notice of the department's proposed action and of the right to request a hearing under sub. (7) to the RTAC within 48 hours after the withdrawal takes place. In the absence of other evidence of receipt, receipt of the department's notice is presumed on the 5th day following the date the department mails the notice.

(7) APPEALS OF DEPARTMENT DECISIONS. (a) If under sub. (6), the department does not approve a hospital's application under sub. (6) (a) or selection under sub. (6) (b), or an RTAC's submission under sub. (6) (c) or the department withdraws its approval of an RTAC under sub. (6) (d), the hospital or RTAC may request a hearing under s. 227.42, Stats. The request for a hearing shall be submitted in writing to and received by the department of administration's division of hearings and appeals within 30 days after the date of the notice required under sub. (6). A request is considered filed when received by the division of hearings and appeals.

(b) The division of hearings and appeals shall hold the hearing no later than 30 days after receiving the request for the hearing unless both parties agree to a later date and shall provide at least 10 days prior notification of the date, time and place for the hearing.

(c) The hearing examiner shall issue a proposed or final decision within 30 days after the hearing. The department decision shall remain in effect until a final decision is rendered.

Note: A hearing request should be addressed to the Division of Hearings and Appeals, P.O. Box 7875, Madison, WI 53707. Hearing requests may be delivered in person to that office at 5005 University Ave., Room 201, Madison, WI or submitted by facsimile to 608-264-9885.

HFS 118.05 Statewide trauma advisory council. The statewide trauma advisory council shall be responsible for all of the following:

(1) Advising the department on issues related to the development, implementation and evaluation of the statewide trauma care system.

(2) Reviewing and approving the department's proposed format and content of RTAC trauma plans.

(3) Reviewing and recommending components of the department's trauma data submission manual under s. HFS 118.09 (2) (a) and the use of trauma registry data under s. HFS 118.09 (4) (a).

HFS 118.06 Regional trauma advisory councils. (1) PURPOSE. The purpose of a regional trauma advisory council is to develop, implement, monitor and improve the regional trauma system.

(2) PARTICIPATION IN RTAC ACTIVITIES. A regional trauma advisory council may include facilities or organizations located in a neighboring state that provide trauma care to Wisconsin residents.

(3) REGIONAL TRAUMA ADVISORY COUNCIL RESPONSIBILITIES. A regional trauma advisory council shall do all of the following:

(a) Submit an application to the department for approval as an RTAC pursuant to s. HFS 118.04 (2) (b) 3.

Note: To obtain an application, contact the statewide trauma care coordinator by calling 608-266-0601 or by writing to Statewide Trauma Care System Coordinator, Bureau of Local Health Support and Emergency Medical Services, Room 118, 1 West Wilson St., Madison, WI 53701, or by sending a fax to 608-261-6392.

(b) 1. Establish an executive council that has all of the following characteristics:

a. Reflects professional representation from out-of-hospital trauma care providers, trauma care facilities, education and injury prevention.

Note: Out-of-hospital trauma care providers include EMTs, first responders or air medical personnel.

b. May have representation of an out-of-state hospital or ambulance service provider if the hospital or ambulance service provider regularly provides care for persons injured in Wisconsin.

c. Includes representation from both urban and rural areas.

d. Does not have more than 50 percent of its representation from any single organization. In this subdivision paragraph, "organization" means corporate affiliation, entity or ownership.

e. Is responsive to the input of its primary membership and participants.

f. Has officers who either live or work in Wisconsin.

g. Has representatives who serve only on that single executive council.

Note: The Department believes that limiting primary service to the executive council of one RTAC will promote a representative's focus on and allegiance to that RTAC. Any person, however, may participate in the activities of more than one RTAC.

2. Submit the names and affiliations of council members to the department for review and approval pursuant to s. HFS 118.04 (2) (b) 4.

(c) 1. Select a coordinating facility. The coordinating facility shall be or do all of the following:

a. Work in collaboration with the department and the regional trauma advisory council to meet the needs required for the development, implementation, maintenance and evaluation of the regional trauma system.

b. Except as provided in subd. pars. c. and d., be a Wisconsin-based ACS-verified level I or II trauma facility.

c. If a regional trauma advisory council area contains no ACS-verified level I or II trauma facility, the coordinating facility may be an entity that provides written commitment to the department that the entity will become an ACS-verified level I or II trauma facility within 3 years of that assurance.

d. If a regional trauma advisory council area contains no ACS-verified level I or II trauma facility, and no entity can provide the department the assurance under subd. par. c., the coordinating facility may be an entity that assures the department in writing that the entity will obtain the department's recognition as a level III trauma facility within the time frame specified in the RTAC application.

e. Have an ACS-verified level I or II hospital, or an equivalent hospital from an adjoining state, serving as its resource hospital if a level III hospital is serving as the coordinating facility.

f. If 2 facilities agree to serve as co-coordinating facilities, one of the facilities shall be an ACS-verified level I or II trauma facility.

2. Submit the name of the facility selected under subd. 1. to the department for review and approval pursuant to s. HFS 118.04 (2) (b) 4.

3. Notify the department and the RTAC executive council at least 30 days before relinquishing the title of coordinating facility if the coordinating facility is unable to fulfill the duties required by the regional trauma advisory council.

(d) 1. Select a Wisconsin fiscal agent and submit the name of the fiscal agent to the department for review and approval pursuant to s. HFS 118.04 (2) (b) 4.

2. Ensure that the fiscal agent holds and distributes funds only for the purpose of RTAC activities by not commingling RTAC funds with other funds or using RTAC funds for personal purposes.

3. Ensure that the fiscal agent notifies the department and the executive council at least 30 days before relinquishing the title of fiscal agent if the fiscal agent is unable to fulfill the duties required by the regional trauma advisory council.

(e) Select a resource hospital and submit the name of the hospital to the department for review and approval pursuant to s. HFS 118.04 (2) (b) 4.

(f) Transmit all pertinent materials to all regional trauma advisory council members in a timely manner.

(g) Develop a format for meetings, agendas and minutes, and provide the department with all RTAC meeting times, agendas and minutes.

(h) Designate a liaison with the department.

(i) Analyze local and regional trauma registry data collected under s. HFS 118.09.

(j) Create a local and regional performance improvement process that is consistent with that specified in s. HFS 118.10.

(k) Develop and implement injury prevention and education strategies based on performance improvement findings.

(L) 1. Develop and submit to the department by June 1, 2006, a regional trauma plan based on a needs assessment and with the structure specified by the department.

2. Update the regional trauma plan specified under subd. 1. and submit the plan to the department every 2 years beginning June 1, 2008 following the submittal of the of the initial plan on June 1, 2006.

3. Beginning June 1, 2005, submit a yearly progress report to the department, in the format specified by the department, that contains a description of the progress being made towards achieving the actions specified under the most recent regional trauma plan.

(m) Resolve conflicts concerning trauma care and injury prevention within the region through a process having the following characteristics:

1. Conflicts needing resolution by the RTAC shall be addressed by the executive council.

2. If the executive council is unable to resolve a contested issue, the executive council chair shall submit the issue to the department for resolution.

(n) Notify the department within 30 days of any changes in leadership, bylaw revisions or other substantive revisions to the RTAC policies or operations.

(o) Develop regional triage and transport protocols.

HFS 118.07 EMS services. (1) RESPONSIBILITY TO AFFILIATE WITH ONE RTAC. (a) All ambulance service providers and first responder services shall select one regional trauma advisory council for primary membership by July 30, 2005.

(b) Nothwithstanding par. (a), an EMT, first responder or ambulance service provider may participate in any regional trauma advisory council.

(c) An ambulance service provider or first responder service shall notify the department if the service changes membership in an RTAC.

(2) EFFECT OF NON-PARTICIPATION. The department and the pertinent RTAC may not recognize as a trauma system participant an ambulance service provider that does not participate in the activities of its chosen RTAC pursuant to sub. (1) (a), or submit data to the department under s. HFS 118.09 (3).

Note: Pursuant to s. HFS 110.08 (2) (v), an ambulance service provider must specify in its operational plan the name of the regional trauma advisory council that it has chosen for its primary membership.

HFS 118.08 Hospitals. (1) HOSPITAL RESPONSIBILITY TO AFFILIATE WITH AN RTAC. (a) 1. All hospitals shall select one regional trauma advisory council for primary membership by July 30, 2005.

2. Pursuant to s. HFS 118.04 (2) (c) 3., the hospital shall submit its selection under subd. 1. to the department for approval.

(b) Notwithstanding par. (a), a hospital may participate in the activities of any regional trauma advisory council.

(c) A hospital shall notify the department if the hospital changes membership in an RTAC.

(2) CLASSIFICATION OF HOSPITALS. (a) *Initial hospital selection of trauma care level*. 1. 'All hospitals.' a. All hospitals shall declare their current trauma care capabilities to the department within 180 days of the effective date of this section [revisor inserts date] according to the criteria specified in this section.

b. A hospital desiring level I or II classification and verification shall be responsible for expenses associated with the verification process under s. HFS 118.04 (2) (c) 2. and (6) (a).

c. A hospital desiring level III or IV classification may be responsible for expenses associated with the classification process under s. HFS 118.04 (2) (c) 2. and (6) (a).

2. 'Level I and II trauma care facilities.' a. A hospital declaring itself as a level I or II trauma care facility shall have been verified at that level by the American college of surgeons in accordance with the publication *Resources for Optimal Care of the Injured Patient*.

Note: The publication, *Resources for Optimal Care of the Injured Patient: 1999*, Committee on Trauma, American College of Surgeons (1998), is on file in the Department's Division of Public Health, the Revisor of Statutes Bureau and the Secretary of State's Office, and is available for purchase from the American College of Surgery, 633 W. Saint Clair St., Chicago, Illinois 60611-3211.

b. A hospital desiring department approval as a level I or II trauma care facility, but which has not received ACS verification at that level, may only be approved as a level III or IV trauma care facility.

3. 'Level III and IV trauma care facilities.' a. A hospital desiring department approval as a level III or IV trauma care facility shall either submit documentation to the department that it has received ACS verification at level III or IV or complete the department's assessment and classification criteria application form.

Note: For a copy of the Department's assessment and classification criteria application form for approval as a trauma care facility, please write to the Wisconsin Trauma Care System Coordinator, Division of Public Health, P.O. Box 2659, Madison WI 53701–2659 or download the form from the DHFS website at www.dhfs.state.wi.us/DPH_EMSIP/index.htm.

b. The department shall review the information in the hospital's application and base its approval or disapproval of the application on the conformance of the facility with the criteria in appendix 1.

4. 'Pediatric trauma center.' A hospital may not refer to itself as a pediatric trauma center unless it has received ACS verification as a pediatric trauma center.

5. 'Unclassified hospital.' A hospital that chooses not to participate in the Wisconsin trauma care system or that has not been approved by the department as a level I, II, III or IV trauma care facility shall be considered an unclassified hospital.

Note: To obtain a form for selection of trauma care level and application for Department approval of the chosen level, contact the Statewide Trauma Care Coordinator by phone at 608-266-0601 or by writing to the Statewide Trauma Care System Coordinator, Department of Health and Family Services, Bureau of Local Health Support and Emergency Medical Services, Room 118, 1 West Wilson, Madison, WI 53701 or by sending a fax to 608-261-6392.

(b) *Trauma care facility change in capability*. 1. 'Level I or II trauma care facility.' If a hospital loses its ACS verification as a level I or II trauma care facility, the following shall occur:

a. The hospital shall notify the department of that change within 30 calendar days.

b. The department may no longer recognize the hospital as having the level of trauma care that the ACS previously verified the hospital as having.

c. The hospital may complete and submit to the department a new application form under par. (a) or choose to be an unclassified hospital.

2. 'Level III or IV trauma care facility.' a. A level III or IV trauma care facility shall notify the department of the facility's intent to change its level of trauma care. If the trauma care facility meets the department's trauma care assessment and classification criteria under sub. (1), or has been verified by the ACS as being another level trauma care facility, the department shall recognize the facility at the level desired.

b. The department may revoke its approval of a level III or IV trauma care facility if the department determines the facility does not meet the criteria associated with the facility's existing classification.

c. The department may perform a site visit of a level III or IV trauma facility to determine compliance with the evaluation criteria in accordance with s. HFS 118.04 (6) (a) 4.

d. If a level III or IV trauma care facility is unable to continue functioning at its current level of trauma care, the facility shall notify the department no more than 30 calendar days after the facility no longer continues to function as a level III or IV trauma care facility.

(c) *Renewal of a hospital's level III or IV classification*. 1. At least once every 3 years after initial classification, the department shall provide all level III and IV trauma care facilities an assessment and classification criteria form.

2. The trauma care facility shall declare to the department the facility's level of trauma care capability on the assessment and classification form.

3. The trauma care facility shall submit the assessment and classification criteria form to the department at least 6 months before the expiration of the department's approval of facility's existing level of trauma care capability.

4. A level III or IV trauma care facility's existing classification shall continue until the department makes a final decision on the renewal request, unless the department determines a compromise in patient care exists, at which time the department may immediately revoke the facility's classification.

5. A level III or IV trauma facility that does not renew its classification within the time specified under this paragraph shall automatically lose its department approval as its existing level of trauma care facility and shall be considered an unclassified hospital.

(d) *Restricted use of term "trauma care facility" or "trauma facility."* 1. A hospital may not advertise in any manner or otherwise represent itself as either a trauma care facility or trauma facility unless the hospital has been classified as a level I, II, III or IV trauma care facility by the department in accordance with this chapter.

2. A hospital's advertisement or public representation of its classification as a trauma care facility shall include its level.

(3) COMPLAINTS. (a) A trauma care facility may submit a complaint to the department regarding a department action.

(b) The department shall respond to the complaint pursuant to s. HFS 118.04 (3).

Subchapter III - Trauma Care Improvement

HFS 118.09 Trauma Registry. (1) PURPOSE. The purpose of the trauma registry is to collect and analyze trauma system data to evaluate the delivery of adult and pediatric trauma care, develop injury prevention strategies for all ages, and provide resources for research and education.

(2) DEPARTMENT COORDINATION OF DATA COLLECTED BY TRAUMA CARE FACILITIES, AMBULANCE SERVICE PROVIDERS AND FIRST RESPONDER SERVICES. The department shall do all of the following:

(a) Develop and publish a data submission manual that specifies all of the following:

1. Data elements and definitions.

2. Definitions of what constitutes a reportable trauma case.

3. Method of submitting data to the department.

4. Timetables for data submission.

5. Electronic record format.

6. Protections for individual record confidentiality.

(b) Notify trauma care facilities, ambulance service providers and first responder services of the required registry data sets and update the facilities and providers, as necessary, when the registry data set changes.

(c) Specify both the process and timelines for hospital and ambulance service provider submission of data to the department.

(3) SUBMISSION OF DATA. All hospitals, ambulance service providers and first responder services shall submit to the department on a quarterly basis trauma data determined by the

department to be required for the department's operation of the state trauma registry. The department shall prescribe all of the following:

(a) Standard application and report forms to be used by all applicants and trauma care facilities.

(b) The form and content of records to be kept and the information to be reported to the department.

(4) REGISTRY USE. (a) The department and RTACs shall use the trauma registry data to identify and evaluate patient care and to prepare standard quarterly and annual reports and other reports and analyses as requested by RTACs.

(b) The department shall use injury data collected under s. 146.56 (2), Stats., for confidential review relating to performance improvement in the trauma care system. The department may use the confidential injury data for no other purpose.

HFS 118.10 Performance improvement. (1) PURPOSE. Each RTAC shall use the trauma registry data collected under s. HFS 118.09 to improve trauma care, reduce death and disability and correct local and regional injury problems.

Note: The RTAC should include in its performance improvement activities for all patient ages a surgeon involved in trauma care, an emergency department physician, an EMS representative, an EMS medical director, a person who coordinates the trauma program or the performance improvement process in a trauma facility, and other trauma care and prevention professionals the RTAC determines appropriate.

(2) DATA CONFIDENTIALITY. Each RTAC shall observe the confidentiality provisions of the Health Insurance Portability and Accountability Act under 45 CFR 164.

(3) PROCESS. The performance improvement process shall include all of the following for both pediatrics and adults:

(a) Data collection and analysis.

(b) Adult and pediatric-specific quality indicators for evaluating the trauma system and its components.

(c) A system for case referral.

(d) A process for indicator review and audit.

(e) A mechanism for loop-closure.

(f) A mechanism for feedback to executive council.

(g) An evaluation of system performance.

(h) A procedure for ensuring that all parties having access to information associated with individuals and entities with respect to a trauma care system problem or issue keep the information confidential throughout the performance improvement process.

SECTION 2. HFS 110.03 (47m) is created to read:

HFS 110.03 (47m) "Regional trauma advisory council" means an organized group of healthcare entities and other concerned individuals who have an interest in organizing and improving trauma care within a specified geographic region approved by the department.

SECTION 3. HFS 110.08 (2) (v) is created to read:

HFS 110.08 (2) (v) The regional trauma advisory council that the ambulance service provider has chosen for its primary membership.

SECTION 4. HFS 111.03 (36m) is created to read:

HFS 111.03 (36m) "Regional trauma advisory council" means an organized group of healthcare entities and other concerned individuals who have an interest in organizing and improving trauma care within a specified geographic region approved by the department.

SECTION 5. HFS 111.07 (2) (v) is created to read:

HFS 111.07 (2) (v) The regional trauma advisory council that the ambulance service provider has chosen for its primary membership.

SECTION 6. HFS 112.03 (35m) is created to read:

HFS 112.03 (35m) "Regional trauma advisory council" means an organized group of healthcare entities and other concerned individuals who have an interest in organizing and improving trauma care within a specified geographic region approved by the department.

SECTION 7. HFS 112.07 (2) (v) is created to read:

HFS 112.07 (2) (v) The regional trauma advisory council that the ambulance service provider has chosen for its primary membership.

Effective date

This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2) (intro.), Stats.

Wisconsin Department of Health
and Family Services

Dated: October 20, 2004

By: _____
Helene Nelson
Secretary

SEAL:

Appendix 1

Key: E = Essential
D = Desirable

Level III & IV Hospital Assessment and Classification Criteria

	III	IV	YES	NO	COMMENTS
GENERAL STANDARDS					
1. Trauma Care Facility (TCF) Commitment	E[1]	E[1]			
2. Acceptance of Patients	E[2]	E[2]			
3. Membership and participation in Regional Trauma Advisory Council(s)	E	E			
A. HOSPITAL OR EMERGENCY CARE FACILITY ORGANIZATION					
1. Trauma Service	E[3,5,6]	D[4,5] or E[6]			
2. Trauma Service Director	E[7]	E[8]			
3. Trauma Multidisciplinary Committee	E	D[9]			
4. Hospital Departments, Divisions or Sections					
a. General Surgery	E	----			
b. Orthopedic Surgery	D	----			
c. Emergency	E	E			
d. Anesthesia	E	----			

	III	IV	YES	NO	COMMENTS
B. CLINICAL CAPABILITIES – Specialty Availability					
1. On Call & Promptly Available[10]					
a. General Surgery	E[11]	----			
b. Orthopedic Surgery	D[12]	----			
c. Emergency Medicine	E[13]	E[13]			
d. Anesthesiology	E[14]	----			
e. Internal Medicine	D	----			
f. Obstetric or Gynecologic Surgery	D	----			
g. Pediatrics	D	----			
h. Radiology	D[16]				
i. Neurosurgery	----	----			
C. FACILITIES OR RESOURCES OR CAPABILITIES					
1. Emergency Department					
a. Personnel					
1. Designated Physician Director	E[17]	D[17]			
2. Physician capable of initial resuscitation who is on call & promptly available to the ED upon arrival of the trauma patient.	E[13]	E[13]			

	III	IV	YES	NO	COMMENTS
3. Nursing personnel assigned to the ED with special capability in trauma care who provide continual monitoring of the trauma patient from hospital arrival to disposition in ICU, OR, patient care unit, or until transfer.	E[18]	D			
4. Nursing personnel in-house 24 hours a day responsible for and capable of responding to the ED and initiating the assessment or care of the trauma patient prior to the arrival of the physician in the ED and who can provide continual monitoring of the trauma patient from hospital arrival until transfer.	----	E[18]			
b. Equipment for resuscitation of patients of ***all*** ages shall include but not be limited to:					
1. Airway control & ventilation equipment, including laryngoscopes and endotracheal tubes of all sizes, bag-mask resuscitator, pocket masks, and oxygen.	E	E			
2. Pulse oximetry	E	E			
3. End Tidal $C0_2$ determination	E	E			
4. Suction devices	E	E			
5. ECG monitor or defibrillator	E	E			
6. CVP monitoring apparatus	E	D			
7. Standard intravenous fluids & large bore administration devices & catheters	E	E			
8. Sterile surgical sets for:					

	III	IV	YES	NO	COMMENTS
a. Airway or Cricothyrotomy	E	E			
b. Thoracostomy	E	D			
c. Vascular access	E	E			
d. Chest decompression	E	E			
9. Gastric decompression	E	E			
10. Drugs necessary for emergency care	E	E			
11. 24 hour x-ray availability	E[19]	D[19]			
12. Two-way radio communication with ambulance or rescue	E[20]	E[20]			
13. Skeletal & cervical immobilization devices	E	E			
14. Arterial catheters	E	D			
15. Thermal Control Equipment					
a. For patient	E	E			
b. For blood & fluids	E	E			
16. Capability for rapid infusion of fluids	E	E			
2. Operating Suite					
a. Personnel & Operating Room					
1. Immediately available to patient on arrival in the OR or when requested by the surgeon	E[21]	----			

	III	IV	YES	NO	COMMENTS
b. Equipment for ***all*** ages shall include but not be limited to:					
1. Thermal Control Equipment					
a. For patient	E	----			
b. For blood & fluids	E	----			
2. X-Ray capability available 24 hours per day	E	----			
a. C-arm intensifier	D	----			
3. Endoscopes or Bronchoscope	D	----			
4. Equipment appropriate for fixation of long-bone and pelvic fractures	D	----			
5. Rapid infusion or rapid fluid recovery capability	E	----			
3. Post-Anesthetic Recovery Room (Surgical ICU Acceptable)					
a. RNs and other essential personnel in-house or on call promptly available when patient arrives in recovery or ICU	E	----			
b. Equipment for the continuous monitoring of temperature, hemodynamics and gas exchange.	E	----			
c. Pulse oximetry	E	----			
d. End-Tidal $C0_2$ monitoring	E	----			
e. Thermal control	E	----			
4. Intensive Care Unit (ICU) for Trauma Patients					
a. Personnel					

	III	IV	YES	NO	COMMENTS
1. Designated Physician Director for Trauma Patients	D[22]	----			
2. Physician with TCF privileges in critical care and approved by the trauma director, on call and immediately available to the hospital.	D	----			
b. Appropriate monitoring or resuscitation equipment	E	----			
c. Support Services					
1. Immediate access to clinical diagnostic services	E[23]	----			
5. Acute Hemodialysis Capability or Transfer Agreement	E	----			
6. Organized Burn Care	E	E			
a. Physician-directed burn center staffed and equipped to care for extensively burned patients **OR**	--	--			
b. Facilitate Transfer	E	E			
7. Acute Spinal Cord or Head Injury Management	E	E			
a. If a designated spinal cord rehabilitation center exists in region, early transfer should be considered.	E	E			
b. If a head injury center exists in the region, early transfer should be considered.	E	E			
8. Radiological Capabilities available 24 hours per day	E[19]	D[19]			
a. Angiography	D or E[15]	----			
b. Sonography	D or E[15]	----			
c. Nuclear Scanning	D or E[15]	----			

	III	IV	YES	NO	COMMENTS
d. Computed Tomography	D or E[15]	----			
9. Rehabilitation					
a. Rehabilitation service staffed by personnel trained in rehabilitation care and properly equipped for the acute care of the critically injured patient **OR**	D	----			
b. Facilitate Transfer	E	E			
10. Clinical Laboratory Service	E[24]	E[24]			
a. Blood Typing & Cross Matching	E	D			
b. Coagulation Studies	E	D			
c. Comprehensive blood bank or access to a community central blood bank and adequate storage facilities	E[25]	D			
d. Blood gas & pH determination capability	E	D			
e. Microbiology capability	E	D			
f. Alcohol screening capability	E	D			
g. Drug screening capability	D	D			
D. QUALITY IMPROVEMENT					
1. Quality Improvement Programs	E[26]	E[26]			
2. Trauma Registry	E[27]	E[27]			
3. Special audit for ***all*** trauma deaths	E[28]	E[28]			

	III	IV	YES	NO	COMMENTS
4. Morbidity & Mortality Review	E[28]	E[28]			
5. Trauma review, multidisciplinary	E	D[29]			
6. Medical Nursing Audit, Utilization Review, Tissue Review	E[28]	E[28]			
7. Review of Out-of-Hospital Trauma Care	E[28]	E[28]			
8. Published on-call schedule shall be maintained for surgeons, anesthesiology, and other major specialists.	E	----			
9. Quality Improvement personnel specifically responsible for the trauma program.	E[26 or 33]	E[26 or 33]			
10. Times of and reasons for trauma-related bypass documented and reviewed by the QI Program	E	E			
E. OUTREACH PROGRAM					
1. Availability of telephone, computer network, or on-site consultations with physicians of higher level TCF	E	E			
F. PREVENTION					
1. Epidemiology research					
a. Conduct studies in injury control	----	----			
b. Collaborate with other institutions in research	D[30]	D[30]			
c. Consult with qualified researchers on evaluation measures	D[30]	D[30]			
2. Surveillance					
a. Special ED and field collection projects	----	----			
b. Expanded Trauma Registry data	D	----			
c. Minimal Trauma Registry data	E[27]	E[27]			

	III	IV	YES	NO	COMMENTS
3. Prevention					
a. Designated prevention coordinator	D	D			
b. Outreach activities and program development	D	D			
c. Information resource	D	D			
d. Collaboration with existing national, regional (Midwest) and state programs	E	E			
G. CONTINUING EDUCATION					
1. Formal Programs in continuing education provided by the hospital for:					
a. Staff physicians	E[31]	E[31]			
b. Nurses	E[31]	E[31]			
c. Allied health personnel	E[31]	E[31]			
d. Community physicians	E[31]	----			
e. Out-of-hospital personnel	D[31]	----			
H. TRAUMA SERVICE SUPPORT PERSONNEL					
1. Trauma coordinator	E[32]	E[33]			
I. ORGAN PROCUREMENT ACTIVITIES					
1. Organ procurement activities	E	E			
J. TRANSFER AGREEMENTS					
1. As transferring facility	E	E			

	III	IV	YES	NO	COMMENTS
2. As receiving facility	E[34]	----			

Footnotes

[1]A Trauma Care Facility (TCF), specifically its board of directors, administration, medical staff, and nursing staff, shall make a commitment to providing trauma care commensurate to the level at which they are classified. Written documentation of such by each of these groups shall include but not be limited to appropriate dedicated financial, physical, and human resources and organizational structure necessary to provide optimal trauma care with outcome evaluation through a quality assessment and quality improvement process.

[2]A TCF shall agree to accept all patients who present to their facility requiring trauma stabilization or care appropriate to their classified level regardless of race, sex, disability, creed, or ability to pay.

[3]Trauma patients admitted to a Level III TCF are not required to be admitted to a separate trauma service but may be admitted to the service of the physician caring for the patient. However, the TCF shall have policies, protocols, and an organizational chart that 1) defines how trauma care is managed at the TCF, and 2) identifies trauma team members and their respective responsibilities in the care of the trauma patient.

[4]The Level IV TCF is not required to have the same type of trauma service and team as the upper level facilities. However, the administration, physicians, nurses and support personnel, with aid of guidelines, protocols, and transfer agreements, make a commitment to assess, stabilize, and transfer patients to the appropriate level TCF. Any inpatients admitted to a Level IV TCF shall not have injuries requiring major surgical or surgical specialty care.

[5]Level III and Level IV TCF physicians involved in the care of trauma patients shall take the Advanced Trauma Life Support (ATLS) Course and the refresher course every four years to meet CME requirements. If a physician currently is Emergency Medicine Board Certified, ATLS course only needs to be completed once.

[6]Level III and Level IV TCFs shall have a Trauma Team Activation Protocol or Policy that 1) defines response requirements for all team members when a trauma patient is enroute or has arrived at the TCF, 2) establishes or identifies the criteria, based on patient severity of injury, for activation of the trauma team, and 3) identifies the person(s) authorized to activate the trauma team. The Trauma Protocol or Policy can be facility specific but team member roles should be clearly documented.

[7]Level III TCFs shall have a physician on staff whose job description defines his or her role and responsibilities for trauma patient care, trauma team formation, supervision or leadership, and trauma training or continuing education. This physician acts as the medical staff liaison for trauma care with out-of-hospital medical directors, nursing staff, administration, and higher level TCFs.

[8]Level IV TCFs shall have a physician on staff whose job description defines his or her role and responsibilities for trauma patient care, trauma team formation, supervision or leadership, and trauma training or continuing education. This physician acts as the medical staff liaison for trauma care with out-of-hospital medical directors, nursing staff, administration, and higher level TCFs.

[9]The activities of the Trauma Multidisciplinary Committee in a Level IV TCF may be handled by an appropriate standing committee of that facility that directly deals with patient care issues pertaining to quality assessment and quality improvement.

[10]Refer to each "essential" specialty footnote. Promptly shall be defined as, "without delay."

[11]For all trauma patients requiring surgical care, upon notification the surgeon shall respond to the ED. Should the surgeon be unavailable for any reason, a back-up plan for surgical coverage shall be in effect, that is, a second call surgeon available or transfer policy activated. The appropriateness and timeliness of the surgeon's response shall be evaluated in the TCF's quality assessment and quality improvement process. A 24-hour-per-day call schedule for surgeons covering trauma shall be published monthly and posted in all areas of the TCF caring for trauma patients.

[12]Having an orthopedic surgeon on staff at a Level III TCF is desirable. However, if an orthopedic surgeon is not on staff, the general surgeon and physician covering the ED for trauma shall be capable of stabilizing and immobilizing fractures prior to transfer to a higher level TCF. A transfer agreement shall be in place.

[13]Optimally, in a Level III and Level IV TCF the physician providing initial ED care for trauma patients should be in-house 24-hours-per-day. As an alternative for both Level III and Level IV TCFs, the physician may be on call and notified to meet the patient upon arrival at the TCF to assume immediate care responsibilities. The appropriateness and timeliness of the physician's response to the ED shall be evaluated in the TCF's quality assessment and quality improvement process. A 24-hour per day call schedule for the physicians providing initial ED trauma care shall be published monthly and posted in all areas of the TCF caring for trauma patients. Current Advanced Trauma Life Support (ATLS) is required of the ED physicians. The ED physicians will have three years, from the TCF's classification date or from the date of the ED physician joining the trauma team at the TCF to successfully complete this course. Physicians Board Certified in Emergency Medicine only need to complete ATLS course once.

[14]Level III TCF anesthesia requirements can be filled by an anesthesiologist or by a certified registered nurse anesthetist capable of assessing emergent situations in trauma patients and initiating preoperative and operative anesthetic care. Local criteria shall be established to allow the anesthesia provider to take call from outside the hospital, but with clear commitment that an anesthesiologist or CRNA will be immediately available for airway or operative management. Ongoing anesthesia outcome studies shall be performed by the TCF as part of the quality assessment and quality improvement process. The availability of anesthesia services and the absence of delays in airway control or operative anesthesia shall be documented by the hospital's quality assessment and quality improvement process.

[15]Essential if the institution's scope of practice includes definitive care of the organ system.

[16]Teleradiology may be an option. If utilized, this process shall be a part of the TCF's quality assessment and quality improvement process.

[17]In Level III and Level IV TCFs, one of the physicians who takes ED call, perhaps the chairperson of the ED committee (or similar committee responsible for the ED), shall be responsible for 1) physician staffing of the ED, 2) Out-of-Hospital medical direction, 3) acting as the physician liaison for other ED physicians with nursing staff and TCF administration, and 4) ensuring that physician quality assessment and quality improvement activities are in place and performed.

[18]The nursing personnel staffing the ED should be physically present in the ED prior to the arrival of the trauma patient to ensure that the room and equipment are available and ready for use. These activities shall be assessed in the TCF's quality assessment and quality improvement process. In addition, they may act as physician designees and provide communication with the out-of-hospital personnel prior to the arrival of the physician. The

nurses shall attend appropriate continuing education courses in trauma care. EXCEPTION: hospitals designated as critical access hospitals will meet nursing personnel availability standards per Medicare conditions of participation.

[19]The Level III and Level IV TCF radiology technician shall be on call and promptly available to the ED. The technician is part of the trauma team and shall be notified as part of the trauma alert activation protocol. A call schedule shall be posted in all areas of the TCF caring for trauma patients. The technician's availability and response shall be monitored as part of the TCF's quality assessment and quality improvement process.

[20]On-line medical direction (two-way communications) shall be available to all out-of-hospital services in the TCF area, with physicians or physician designees trained in receiving patient reports and giving pre-approved standing orders for patient treatment interventions or destination decisions.

[21]The operating room staff shall be on-call and promptly available when notified to respond. The OR staff is part of the trauma team and shall be notified as part of the trauma alert activation protocol. A call schedule shall be posted in all areas of the TCF caring for trauma patients. The OR staff's availability and response times shall be part of the TCF's quality assessment and quality improvement process.

[22]This function may be performed by a surgeon or the TCF's ICU, or otherwise appropriate Committee.

[23]Clinical diagnostic services such as, but not limited to, radiology, laboratory, and respiratory care shall be available to the operating room, post anesthesia recovery, intensive care unit, and all other trauma patient care areas just as they are for the ED.

[24]Level III and Level IV TCF laboratory personnel shall be on call and promptly available to the ED. They are part of the trauma team and shall be notified as part of the trauma alert activation protocol. A call schedule shall be posted in all areas of the TCF caring for trauma patients. Laboratory personnel availability and response times shall be part of the TCF's quality assessment and quality improvement process. There shall be a policy delineating the priority of a trauma patient in the collection and processing of blood and urine for evaluation.

[25]Level III TCFs shall be capable of storing blood received from out-of-hospital blood banks and providing non-crossmatched blood on patient arrival to the ED. The TCF shall have a massive transfusion protocol with the ability to perform massive transfusions.

[26]Level III and IV TCFs shall perform all quality assessment and quality improvement activities that are required of an acute care hospital as they relate to trauma. The trauma quality assessment and quality improvement process may be performed by the TCF's trauma care committee or by the TCF's standing quality assessment and quality improvement committee. This process may also be performed through agreements with higher level TCFs.

[27]Following trauma system implementation, data submission from Level III and Level IV TCFs will be phased in beginning with year two. Initial Level III and IV data submission will be either on paper or via electronic submission with data entry coordinated by the State Trauma Registrar. Level III and IV TCFs will submit data for all trauma patients meeting ***any*** of the following three criteria:

1. Persons who are admitted to the hospital or transferred to another facility for trauma care and have ICD-9 discharge diagnoses from 800.00 to 959.9, with the exception of any of the following:

    a. 905-909 (late effects of injury).
    b. 910-924 (blisters, contusions, abrasions, insect bites).

c. 930-939 (foreign bodies).
d. Drowning, unless it was a consequence of a motor vehicle crash.
e. Strangulation or asphyxiation.
f. Poisoning or a drug overdose.
g. Falls from the same level resulting in isolated closed distal extremity fracture or isolated hip fracture.

2. Persons transported to the hospital and who are dead on arrival.

3. Persons who have an injury-related death in the emergency department or after admission to the hospital.

4. Facility-specified trauma response has been activated.

[28]Level III and Level IV TCFs shall establish a procedure or process for a special audit on all trauma deaths, trauma morbidity and mortality, utilization, medical nursing audit, tissue, and out-of-hospital trauma care review as part of the TCF quality assessment and quality improvement process. This review may be performed by a TCF standing committee or through an agreement(s) with higher level TCFs.

[29]Level IV TCFs may be involved with Level I, Level II or Level III TCF multidisciplinary trauma review via, but not limited to, closed circuit TV, or computer network.

[30]Level III and Level IV TCFs shall cooperate with trauma researchers approved by the Institutional Review Board or Ethics Committee if the demands for data, time and money are not excessive.

[31]Continuing trauma education programs in Level III and Level IV TCFs may be provided by, but not limited to, the facility in-house, regular or closed circuit TV, computer networks, etc. Level III and Level IV TCFs at a minimum shall provide for educational offerings for nursing and allied health personnel. Arrangements can be made with a Level I or Level II TCF.

[32]The Trauma Care Coordinator for a Level III TCF should ideally be a RN with clinical experience in trauma care. As an alternative, other qualified allied health personnel with clinical experience in trauma care may be appropriate. A job description shall be clearly defined and available. Developing this job description should be a collaborative effort with the Level I or Level II TCF.

[33]Level IV TCFs shall have an individual who works in conjunction with the physician(s) responsible for trauma care helping to organize and coordinate the TCF's trauma care response. Ideally, this individual should be a staff or administrative RN with emergency or trauma care experience. As an alternative other allied health personnel with clinical experience in emergency or trauma care may fulfill this role. A job description shall be clearly defined and available. This position may be shared by individuals with different qualifications in clinical care, quality improvement, and data collection. These individuals shall hold the responsibility for the education of the facility trauma team in the varied aspects of trauma care within the facility. Development of this job description should be a collaborative effort with the Level I or Level II TCF.

[34]If a Level III TCF is receiving patients from a Level III or Level IV TCF, transfer protocols shall be in place.