Overview and Legal and Fiscal Impact

These regulations update standards for the designation of neurotrauma centers to reflect current standards for the care of traumatic brain injured and spinal cord injured patients.

The regulations present no legal issue of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Maryland Institute for Emergency Medical Services Systems:
Designation of Trauma and Specialty Referral Centers: Neurotrauma Center Standards: COMAR 30.08.10.01 through .13

Legal Analysis

Background

The Maryland Institute of Emergency Medical Services Systems (MIEMSS) establishes standards for the 48 hospital emergency departments in the State. For patients who need a higher level of emergency care, MIEMSS has designated nine trauma centers and specialty referral centers, including ones for burns, cardiac, spinal cord injuries, pediatrics, eye, hand/upper extremity, hyperbaric, neurotrauma, perinatal, and stroke (primary and comprehensive) centers across the State.

There is currently one designated neurotrauma center in the State, the neurotrauma center at the R Adams Cowley Shock Trauma Center of the University of Maryland Medical System in Baltimore City.

Summary of Regulations

The regulations update standards for the designation of neurotrauma centers that relate to the care of patients who have traumatic brain or spinal cord injuries. Specific and noteworthy provisions are summarized below.
Hospital Organization

Under the regulations, to be a designated neurotrauma center, a hospital must maintain a specialized unit dedicated to traumatic brain injury and spinal cord injury and meet other organizational standards specified under current regulations.

Patient Volume and Prehospital Care

A neurotrauma center must receive a minimum annual volume of 100 traumatic brain injured patients, spinal cord injured patients, or patients with both conditions. A neurotrauma center must also demonstrate participation and involvement in local, regional, State, and trauma emergency medical services (EMS) systems.

Neurotrauma Center Director

The regulations require a neurotrauma center to have a director who provides oversight to all care for neurotrauma patients admitted to the center. Among other responsibilities, the director must provide direction of the center administrative functions in collaboration with Level 1/Primary Adult Resource Center (PARC) leadership.

Medical Staff

A neurotrauma center must have specified team members. Among other team members, a center must have a board-certified or board-eligible in-house neurosurgery attending physician or a post-graduate year two or higher physician, dedicated 24 hours a day to trauma care with a neurosurgery attending physician on-call who must be at the patient bedside within 30 minutes after emergent consultation has been requested by the trauma team leader for injured patients based on institution-specific criteria. A center also must have a board-certified orthopedic or neurosurgery resident with an attending on-call within a 30-minute response to the patient bedside.

Requirements for Neurotrauma Surgeons and Nursing Personnel

Under the regulations, all neurosurgeons, among other requirements, must be board-certified or board-eligible in neurosurgery. A qualified neurosurgeon must be regularly involved in the care of patients with neurologic injuries, must be credentialed by the hospital with general neurological privileges, and complete a certain amount of neurotrauma related continuing education each year.

In addition to current requirements, a neurotrauma center nursing department must have a continuing education (CE) – after completion of certain mandatory introductory education – that is current and meets certain requirements. The regulation specifies that a department must have eight hours of neuro/trauma-related CE every year for emergency and neurotrauma critical care or intermediate care nurses caring primarily for neurotrauma patients or four hours of neuro/trauma CE every year for nurses caring for trauma patients who are from other clinical areas.
Facility and Equipment Requirements

A neurotrauma center must have immediate access to a Computed Tomography (CT) scanner for emergency resuscitation. In addition, the Post Anesthesia Care Unit (PACU) must have the necessary equipment and medications to manage the traumatic brain or spinal cord injured patient resuscitation and monitoring. A center must also have advanced neuro-monitoring equipment in the intensive care unit and radiological specialty capabilities, including CT scan availability and magnetic resonance imagery (MRI) capability 24 hours a day.

Neurotrauma Rehabilitation

The regulations require a neurotrauma center to have transfer agreements to specified rehabilitation hospitals, a full in-house or transfer process in place to a rehabilitation service for acute care or sub-acute care, and ongoing continuity of care for patients with traumatic brain and spinal cord injuries provided in affiliated rehabilitation acute or sub-acute facilities.

Research

Under the regulations, a neurotrauma center must meet certain requirements relating to research, including an organized neurotrauma research program and a documented research plan, evidence of productivity through peer-reviewed publications, proposals reviewed by an institutional review board, and clinical research trials designed to enhance the trauma system’s ability to resuscitate, stabilize, and treat neurotrauma patients in the most cost-effective manner.

Other Changes

The regulations also include other updates to provisions relating to quality management program and education requirements and policies, protocols, and agreements.

Legal Issues

The regulations present no legal issue of concern.

Statutory Authority and Legislative Intent

The institute cites § 13-509 of the Education Article as authority for the regulations. Section 13-502 requires the State Emergency Medical Services (EMS) Board to develop and adopt an EMS plan to ensure effective coordination and evaluation of emergency medical services delivered in the State. Section 13-509(b) requires the plan to include, among other things, criteria for the designation of trauma and specialty referral facilities. This provision also requires the EMS Board to adopt regulations to implement the plan.

This authority is correct and complete. The regulations comply with the legislative intent of the law.
Technical Corrections and Special Notes

In Regulation .08(B) of the proposed regulations relating to a requirement for a neurotrauma center to have an inpatient acute care rehabilitation program, a clause is struck that requires a center to “[r]equire physical and occupational therapists, and speech and language pathologists to be appropriately licensed or registered in their specific disciplines.” New language is then added requiring a center to “[m]eet rehabilitation requirements as follows[.]” In what follows, two item numbers are listed and followed by a parenthetical reference that the text is “unchanged”. As written, however, it is unclear what regulatory text is intended to be unchanged under the proposal since the sole existing provision in Regulation .08(B) is being struck and the draft proposal contemplates a restructuring of the regulation with two itemized clauses.

The institute has been notified of the issue above and has responded with a clarification. According to the institute, the proposed regulation is intended to require a center to have: (1) rehabilitation services staffed by personnel trained in rehabilitative care and properly equipped for acute care of the traumatic brain injured or spinal cord injured patient and (2) rehabilitation consultation services, provided by personnel appropriately licensed and/or registered in their specific disciplines (i.e., occupational therapy, speech therapy, physical therapy, and social services available in the critical care phase, as needed). The institute indicates that the proposed regulations will be amended to address the issue and resubmitted for publication.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations update standards for the voluntary designation of a hospital as a neurotrauma center. MIEMSS advises that the regulations have no impact on State or local governments. The Department of Legislative Services concurs.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

As hospitals are not small business, MIEMSS advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.
Additional Comments

The Department of Legislative Services notes that, although the regulations do not have a fiscal impact on small businesses in the State, hospitals that seek designation as a neurotrauma center may incur additional expenses. MIEMSS advises that start-up and ongoing costs for equipment and personnel will be required, but the Department of Legislative Services notes that increased revenue from related services will likely offset these expenditures.

Contact Information

Legal Analysis: Patrick D. Carlson – (410) 946/(301) 970-5350
Fiscal Analysis: Amberly Holcomb – (410) 946/(301) 970-5510