ADDENDUM

157.125 Requirements For Trauma Facility Designation
Trauma Systems Committee Draft 2
November 17, 2003

Legend for ADDENDUM:
Violet = Staff recommendation (including TDH Office of General Counsel recommendations; incorporation of “intent” of existing Trauma System Policies, Rule Clarifications, and/or Issue Papers)
Green = staff comment

157.125 (a) The Bureau of Emergency Management (bureau) shall recommend to the commissioner of health (commissioner) the designation of trauma facilities by levels of care capability (reflects verbiage in original Rule 157.125, effective February 17, 1992 and inadvertently removed from current Rule 157.125, effective September 1, 2000), not necessarily the level requested by the applicant, (in accord with intent of verbiage in original Rule 157.125, effective February 17, 1992 and inadvertently removed from current Rule 157.125, effective September 1, 2000) When the bureau receives an application for designation or re-designation from a hospital, it will review the applicant facility’s resources and propose the appropriate level for pursuit of designation in the following fashion:
• Level I or Level II: if the facility has full-time general surgery, neuro surgery, and orthopedic surgery capabilities
• Level III: if the facility has full-time general surgery and orthopedic capabilities
• Level IV: no full-time surgical capabilities

In general, the physician services capabilities described above must be in place 24/7. In determining whether capability is present, TDH may use the concept of substantial compliance that is defined as having capability at least 90% of the time.

If a facility disagrees with the designation level proposed to be appropriate by TDH, it may appeal to the bureau in writing within 60 days. The written appeal must include a signed letter of support from the hospital’s Board of Directors with an explanation as to why designation at the level proposed in the application would be in the best interest of the citizens of the affected trauma service area (TSA) or the citizens of the state of Texas.

The written appeal may include a signed letter(s) of support from Executive Board of the trauma regional advisory council (RAC) or individual hospitals and/or EMS providers within the affected trauma service area with an explanation as to why designation at the level proposed in the application would be in the best interest of the citizens of the affected trauma service area (TSA) or the citizens of the state of Texas.

If the bureau denies the appeal and the facility disagrees, the case shall be referred to the Associate Commissioner for Consumer Health Protection for final decision. In all cases, TDH retains the statutory authority to determine the appropriate level of designation for a hospital. (in accord with Trauma Policy Systems Policy # TS-04-B:”Trauma Facility Designation: Appropriate Level Of Designation”, reviewed by GETAC Trauma Systems Committee at its August 2003 meeting)

157.125 (a) (1), (2), (3), and (4): “…if the hospital meets or exceeds…” essential criteria. (superfluous; TDH Office of General Counsel recommendation to remove)
157.125 (a)   EMS\Trauma Registry data submission requirements for designation purposes are as follows:

(A) Initial Designation: six months of data prior to the initial designation survey must be uploaded. Subsequent to initial designation, data should be uploaded to the EMS\Trauma Registry on at least a quarterly basis (with monthly submissions recommended) as indicated in 25 TAC 103.19 Electronic Reporting.

(B) Re-designation: the facility’s trauma registry should be current with at least quarterly uploads of data (monthly submissions recommended) as indicated in 25 TAC 103.19 Electronic Reporting. (in accord with Trauma Systems Policy #TS-02-A “EMS\Trauma Registry Participation Standards”, reviewed by GETAC Trauma System Committee at its January 2001 meeting)

157.125 (o) A designated trauma facility shall:

(1) notify the bureau and its RAC plus other affected RACs when appropriate, and the hospitals to which it customarily transfers trauma patients or from which it customarily receives trauma transfers within 5 days if temporarily unable to comply with designation standards

(2) notify the bureau and its RAC plus other affected RACs when appropriate, and the hospitals to which it customarily transfers trauma patients or from which it customarily receives trauma transfers within 5 days if it is requesting an exception to essential criteria. If the hospital disagrees with the bureau’s corrective action plan for it to come in to compliance, it may request a secondary review by a designation review committee as outlined in section (i)(3)(B) of this rule. If the DRC disagrees with the bureau’s corrective action plan for the hospital to come into compliance with essential criteria, the case shall be referred to the Associate Commissioner for Consumer Health Protection for recommendation to the Commissioner of Health. At the end of the final phases of the review process, opportunity for an appeal in accordance with the Administrative Procedure Act, Government Code, Chapter 2001 shall be offered if the hospital disagrees with the bureau’s recommendations.

(A) No changes
(B) No changes

(3) notify the bureau its RAC plus other affected RACs when appropriate, and the hospitals to which it customarily transfers trauma patients or from which it customarily receives trauma transfers if it chooses to no longer provide trauma services commensurate with its designation level, as follows:

(C) If a trauma facility permanently loses or adds capabilities beyond those that define its existing designation level, it shall notify BEM within 30 days of the change(s). It shall also be necessary to repeat the designation process as described in subsections (b) – (c) of this section. There shall then be a paper review by the bureau to determine if andor when a full survey shall be required. (in accord with BEM Issue Paper Draft February 2001 “Trauma Designation Upgrade”)
Level III

ESSENTIAL CRITERIA

Orthopedic Surgery: Remains “E” (essential criterion) as per existing draft rule for Level IIIs in urban counties; change to “D” (desired criterion) for rural counties as defined by population < 50,000) *(BEM response to GETAC Trauma Systems Committee request for modification of existing draft rule verbiage)*

All Surgical Specialties: add “E” (essential criterion): When the specialty surgeon is not activated initially and it has been determined by the attending trauma surgeon or the emergency physician that a specialty surgical consult is necessary, maximum response time of the specialty surgeon should be 60 minutes from notification. This system will be continuously monitored by the performance improvement program. *(comparable to existing standard for general trauma surgeons)*

All Surgical Specialties: add “E” (essential criterion): There shall be a documented system for obtaining specialty surgery care for situations when the specialty surgeon on call is unavailable. This system will be continuously monitored by the performance improvement program. *(comparable to existing standard for general trauma surgeons)*

STANDARDS

Telemedicine: add The use of telemedicine shall not be used in lieu of the physical presence of physicians to care for major and severe trauma patients, including all trauma team activations. *(in accord with Trauma Systems Policy TS-01-B, reviewed by GETAC Trauma Systems Committee at its May 2001 meeting)*

Physician Assistants and Nurse Practitioners: add The physical presence of physician assistants and/or nurse practitioners shall not be used in lieu of the physical presence of physicians to care for major and severe trauma patients, including all trauma team activations. *(in accord with Trauma Systems Policy TS-02-B “Physician Assistants and Nurse Practitioners in Trauma Facilities”, reviewed by GETAC Trauma Systems Committee at its November 2002 meeting)*

Pre-Transfer Diagnostics: add A Level III trauma facility and all lower-level designated trauma facilities from which it receives transfers of major/severe trauma patients should prospectively discuss the issue of pre-transfer diagnostic laboratory and radiological studies so that each is cognizant of each other’s performance expectations. *(in accord with the final draft of Trauma Systems Policy “Trauma Facilities: Pre-Transfer Diagnostics at Texas Basic [Level IV] Trauma Facilities”, reviewed by GETAC Trauma Systems Committee at its November 2003 meeting)*

Regional Advisory Council: add A Level III trauma facility shall participate in the performance improvement program of the regional advisory council (RAC) in the trauma service area (TSA) where it is located, and shall also participate in the performance improvement program as requested by executive boards of RACs in TSAs to which the facility has transferred a patient. *(in accord with Trauma Systems Policy TS-01-A “Regional Trauma Treatment Protocols, reviewed by GETAC Trauma Systems Committee at its May 2001 meeting)*

Trauma Transfers: add A Level III trauma facility with specialized trauma capabilities may not refuse a request for a trauma transfer from another hospital if it has the capacity to accept. Specialized trauma capability is any capability necessary for screening or stabilizing patients with emergency medical conditions that the transferring hospital may lack. The only two reasons a Level III trauma facility may refuse a trauma transfer request are lack of capability to handle the patient’s emergency condition or when it is at capacity. A Level III trauma facility is at capacity if it is unable to accept transfers of new patients by EMS providers, privately operated vehicles, or walk-ins. A log of all trauma transfer denials shall be maintained. *(in accord with TDH/BEM and Center for Medicare and Medicaid Services (CMS) Emergency Medical Treatment and Labor Act (EMTALA) and Trauma Diversion Technical Assistance joint document, August 2001)*

Pediatric Capabilities: add A Level III trauma facility presents its pediatric capabilities to the Regional Advisory Council (RAC) so that both EMS providers and other hospitals can determine the most appropriate facility to transport or transfer critically injured pediatric patients. *(injured pediatric patients may require special resources)*

Level III AUDIT FILTERS

Add Trauma transfer-in denials
Level IV

STANDARDS

Telemedicine: add The use of telemedicine shall not be used in lieu of the physical presence of physicians to care for major and severe trauma patients, including all trauma team activations (in accord with Trauma Systems Policy TS-01-B, reviewed by GETAC Trauma Systems at its May 2001 meeting)

Physician Assistants and Nurse Practitioners: add The physical presence of physician assistants and/or nurse practitioners shall not be used in lieu of the physical presence of physicians to care for major and severe trauma patients, including all trauma team activations. (in accord with Trauma Systems Policy TS-02-B “Physician Assistants and Nurse Practitioners in Trauma Facilities”, reviewed by GETAC Trauma Systems Committee at its November 2002 meeting)

Pre-transfer Diagnostics: add A Level IV trauma facility shall adopt guidelines that lead to early identification of patients who require transfer to a higher level of care, then transfer them as soon as possible.

Pre-transfer diagnostic laboratory and radiological studies performed at a Level IV trauma facility should in no way delay the early transfer of critical trauma patients who have been identified as requiring a higher level of care.

A Level IV trauma facility and all higher-level designated trauma facilities to which it transfers major/severe trauma patients should prospectively discuss the issue of pre-transfer diagnostic laboratory and radiological studies so that each is cognizant of each other’s performance expectations. (in accord with final draft of Trauma Systems Policy “Trauma Facilities: Pre-Transfer Diagnostics at Texas Basic [Level IV] Trauma Facilities”, reviewed by GETAC Trauma Systems Committee at its November 2003 meeting)

Regional Advisory Council: add A Level IV trauma facility shall participate in the performance program of the regional advisory council (RAC) in the trauma service area (TSA) where it is located, and shall also participate as requested by executive boards in the performance program of RACs in TSAs to which the facility has transferred a patient. (in accord with Trauma Systems Policy TS-01-A “Regional Trauma Treatment Protocols, reviewed by GETAC Trauma Systems at its May 2001 meeting)

Pediatric Transfers: add A Level IV trauma facility develops pediatric-specific policies/processes that demonstrate knowledge of the special resources potentially needed by injured pediatric patients, and is cognizant of the pediatric capabilities of the hospitals to which it customarily effectuates transfers so that it can determine the most appropriate facility. (injured pediatric patients may require special resources)

Surgeons and Surgical Capabilities: add A Level IV trauma facility with on-call general surgeon(s) shall, in careful collaboration with the highest-care designated trauma facilities in its TSA, have a policy that balances: 1) its capability to take critical trauma patients to the operating room for life/limb saving procedures to resuscitate and stabilize; with 2) the traditional “stabilize and transfer” standard for a Level IV trauma facility without surgical capabilities. The appropriateness of transferring severe or major trauma patients presenting to the ED of a Level IV trauma facility with on-call surgeon(s) shall be subject to 100% review in the hospital’s performance improvement (PI) program (in accord with TDH/REBM and Center for Medicare and Medicaid Services (CMS) Emergency Medical Treatment and Labor Act (EMTALA) and Trauma Diversions Technical Assistance joint document, August 2001)

Level IV AUDIT FILTERS

Add Severe or major trauma patients transferred when a general surgeon was on-call to the ED