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64J-2.002 Prehospital Requirements for Trauma Care.

(1) Each EMS provider shall ensure that upon arrival at the location of an incident, an EMT or paramedic shall assess the condition of each adult trauma patient using the adult trauma scorecard methodology to determine the transport destination, as provided in Rule 64J-2.004, F.A.C., and the transport destination of each pediatric patient by using the pediatric trauma scorecard methodology included in Rule 64J-2.005, F.A.C.

(2) Each EMS provider shall transport, or cause to be transported, every trauma alert patient to a trauma center nearest to the location of the incident, unless the distance is not relevant to the length of time for transport due to the use of an air ambulance. Pediatric trauma alert patients shall be transported to the nearest trauma center with pediatric services even if a trauma center without pediatric services is nearer to the location of the incident, except as provided in department-approved TTPs. If a trauma center further from the location of the incident has a special resource(s) that the nearest trauma center does not have, such as burn center or hyper baric chamber, which is needed for the immediate condition of the trauma alert patient, the EMS provider may transport to the trauma center having that special resource(s) even if the trauma center is not nearest to the incident. These exceptions to transporting to the nearest trauma center, or other exceptions the EMS provider wishes to request, shall be addressed in the EMS provider's TTPs which shall be submitted to the department for approval, in accordance with Section 395.4045, F.S., and Rule 64J-2.003, F.A.C.

(3) A trauma alert patient may be transported to a hospital other than a trauma center only if the hospital is closer to the scene of the incident, and the patient's immediate condition is such that the patient's life will be endangered if care is delayed by proceeding directly to the trauma center. If an EMS provider intends to transport trauma alert patients to hospitals other than a trauma centers under any other circumstances, those circumstances must be described in and authorized by the EMS provider's department-approved TTPs, as required in this section.

(a) An EMS provider must transport a trauma alert patient to a trauma center, except as may be provided in the EMS provider's department-approved TTPs. For situations for which the EMS provider intends to transport a trauma alert patient to a hospital other than trauma center, as indicated in the provider's or trauma agency's department-approved TTPs, the EMS provider or trauma agency shall ensure beforehand that the hospital meets the following criteria:

1. Is staffed 24-hours-per-day with a physician and other personnel who are qualified in emergency airway management, ventilatory support, and control of life threatening circulatory problems which shall include but not be limited to placement of endotracheal tubes; establishment of central intravenous lines; and insertion of chest tubes;
2. Has equipment and staff in-hospital and available to conduct chest and cervical spine x-rays;
3. Has laboratory facilities, equipment and staff in-hospital and available to analyze and report laboratory results;
4. Has equipment and staff on call and available to initiate definitive care required by a trauma alert patient within 30 minutes of the patient's arrival at the hospital, or can initiate procedures within 30 minutes of the patient's arrival to transfer the trauma alert patient to a trauma center; and

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5. Has a written transfer agreement with at least one trauma center. The transfer agreement shall provide specific procedures to ensure the timely transfer of the trauma alert patient to the trauma center.

(b) Any exceptions to this requirement shall be included in the EMS provider's TTPs and be approved by the department.

(c) Prior to submitting an application for an ALS, BLS or air ambulance license, or to renew such a license, each EMS provider shall request in writing, from the chief executive officer of each hospital (excluding trauma centers) to which the EMS provider intends to transport trauma alert patient's, written documentation that verifies that the hospital meets the requirements provided in paragraph (3)(a) of this section. When submitting TTPs for department approval, EMS providers shall include copies of each letter sent to the chief executive officer of such hospital as well as the response, if any, from the chief executive officer indicating whether the hospital complies with paragraph (3)(a) of this section.

(d) A trauma agency that has developed uniform TTPs may request written documentation from the hospitals in lieu of each EMS provider, in accordance with the requirements of this section.

(e) If an EMS provider does not receive a response from a hospital, or if the hospital indicates that it is not in compliance with the criteria in paragraph (3)(a) of this section, the EMS provider shall not deliver a trauma alert patient to that hospital. Any exception must also be included in the EMS provider's department-approved TTPs.

(f) If a hospital's compliance with the criteria in paragraph (3)(a) of this section changes during the EMS provider's biennial licensure period, the EMS provider shall submit, within 30 days of becoming cognizant of the change, revised TTPs to the department for approval, in accordance with Rule 64J-2.003, F.A.C.

(g) If a hospital to which an EMS provider transports trauma alert patients, as provided in the EMS provider's or trauma agency department-approved TTPs, becomes a trauma center, including those granted provisional status by the department, the EMS provider shall begin immediately transporting trauma alert patients to that trauma center. The EMS provider or trauma agency shall revise and submit TTPs to the department for approval within 30 days of the hospital becoming a trauma center. Within 30 days of an EMS provider or a trauma agency receiving notification that a trauma center intends to discontinue as a trauma center, the EMS provider or trauma agency shall submit revised TTPs to the department for approval, in accordance with Rule 64J-2.003, F.A.C.

(4) ALS non-transporting vehicle personnel shall provide to the transporting vehicle personnel complete information about the patient's identity, the initial patient assessment and care provided prior to arrival of the transporting vehicle personnel, at the time that responsibility for the patient is transferred.

(5) The EMS provider responsible for the patient shall ensure that a prehospital trauma alert is issued upon determining that a trauma patient meets the requirements of Rules 64J-2.004 and 64J-2.005, F.A.C. The words "trauma alert" shall be used when notifying the trauma center, or hospital that EMS is en route with a trauma alert patient. The medical director of the EMS provider issuing the trauma alert, or the physician at the receiving trauma center, or hospital, are the only people authorized to change the trauma alert status. The EMS provider issuing the trauma alert shall also provide the trauma center or hospital with information required under subsection 64J-1.014(5), F.A.C., and the information listed below at the time the patient is transferred to the personnel of the receiving trauma center or hospital:

(a) Time of injury if different from the time of the call;

(b) Date of injury if different from day of call;

(c) County of injury;

(d) County of residence of patient;

(e) Cause of injury;

(f) Injury site/type;

(g) Trauma alert criteria if met as defined in Rule 64J-2.004 or 64J-2.005, F.A.C., and

(h) Protective devices if motor vehicle crash, bicycle or marine crash.

The information listed above shall be documented on the patient care record of the transporting unit that delivered the patient in accordance with the requirements of Rule 64J-1.014, F.A.C.

(6) Each EMS provider or trauma agency shall submit to the department TTPs for approval as required by the Trauma Transport Protocols Manual, December 2004, which is incorporated by reference and available from the department.

Specific Authority 395.4045, 395.405, 401.35 FS. Law Implemented 395.401-.403, 395.404-.405, 395.4045, 401.30, 401.35 FS. History—New 8-3-88, Amended 12-10-92, 11-30-93, Formerly 10D-66.100, Amended 8-4-98, 7-14-99, 2-20-00, 11-3-02, 11-24-02, 6-9-05, Formerly 64E-2.015.

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64J-2.003 Trauma Transport Protocols Approval and Denial Process.

TTPs shall be approved by the EMS provider's or trauma agency's medical director prior to submission to the department for approval and in accordance with the Trauma Transport Protocols Manual, December 2004, which is incorporated in Rule 64J-2.002, F.A.C.

Specific Authority 395.405, 401.35 FS. Law Implemented 395.4045, 395.405, 401.30, 401.35 FS. History—New 8-3-88, Amended 12-10-92, Formerly 10D-66.101, Amended 11-24-02, 6-9-05, Formerly 64E-2.016.

64J-2.004 Adult Trauma Scorecard Methodology.

(1) Each EMS provider shall ensure that upon arrival at the location of an incident, an EMT or paramedic shall:

(a) Assess the condition of each adult trauma patient using the adult trauma scorecard methodology, as provided in this section, to determine whether the patient should be a trauma alert.

(b) In assessing the condition of each adult trauma patient, the EMT or paramedic shall evaluate the patient's status for each of the following components: airway, circulation, best motor response (a component of the Glasgow Coma Scale which is defined and incorporated by reference in subsection 64J-1.001(10), F.A.C.), cutaneous, longbone fracture, patient's age, and mechanism of injury. The patient's age and mechanism of injury shall only be assessment factors when used in conjunction with assessment criteria included in subsection (3) of this section.

(2) The EMT or paramedic shall assess all adult trauma patients using the following criteria in the order presented and if any one of the following conditions are identified, the patient shall be considered a trauma alert patient:

(a) Airway: The patient receives active airway assistance beyond the administration of oxygen.

(b) Circulation: The patient lacks a radial pulse with a sustained heart rate greater than 120 beats per minute or has a blood pressure of less than 90 mmHg.

(c) Best Motor Response (BMR): The patient exhibits a score of four or less on the motor assessment component of the Glasgow Coma Scale, or exhibits the presence of paralysis or there is the suspicion of a spinal cord injury or the loss of sensation.

(d) Cutaneous: The patient has 2nd or 3rd degree burns to 15 percent or more of the total body surface area, or amputation proximal to the wrist or ankle, or any penetrating injury to the head, neck, or torso (excluding superficial wounds where the depth of the wound can be determined).

(e) Fracture: The patient reveals signs or symptoms of two or more long bone fracture sites (humerus, (radius, ulna), femure, (tibia or fibula)).

(3) Should the patient not be identified as a trauma alert using the criteria listed in subsection (2) of this section, the trauma patient shall be further assessed using the criteria in subsection (3) of this section and shall be considered a trauma alert patient when a condition is identified from any two of the seven components included in this section.

(a) Airway: The patient has a respiratory rate of 30 or greater.

(b) Circulation: The patient has a sustained heart rate of 120 beats per minute or greater.

(c) BMR: The patient has a BMR of 5 on the motor component of the Glasgow Coma Scale.

(d) Cutaneous: The patient has a soft tissue loss from either a major degloving injury, or a major flap avulsion greater than 5 inches, or has sustained a gun shot wound to the extremities of the body.

(e) Longbone Fracture: The patient reveals signs or symptoms of a single longbone fracture resulting from a motor vehicle collision or a fall from an elevation of 10 feet or greater.

(f) Age: The patient is 55 years of age or older.

(g) Mechanism of Injury: The patient has been ejected from a motor vehicle (excluding any motorcycle, moped, all terrain vehicle, bicycle or the open body of a pick-up truck), or the driver of the motor vehicle has impacted with the steering wheel causing steering wheel deformity.

(4) If the patient is not identified as a trauma alert patient after evaluating the patient using the criteria in subsections (2) and (3) of this section, the trauma patient will be evaluated using all elements of the Glasgow Coma Scale. If the patient's score is 12 or less, the patient shall be considered a trauma alert patient (excluding patients whose normal Glasgow Coma Scale Score is 12 or less, as established by the patient's medical history or preexisting medical condition when known).

(5) Where additional local trauma alert criteria has been approved by the medical director of the EMS service and presented as part of the state TTP approval process, the use of local trauma alert criteria as the basis for calling a trauma alert shall be documented in the patient care record in accordance with the requirements of in Rule 64J-1.014, F.A.C. Local trauma assessment

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criteria can only be applied after the patient has been assessed as provided in subsections (2), (3), and (4) of this section.

(6) In the event that none of the conditions are identified using the criteria in subsections (2), (3), (4), or (5) of this section in the assessment of the adult trauma patient, the EMT or paramedic can call a trauma alert if, in his or her judgment, the patient's condition warrants such action. Where EMT or paramedic judgment is used as the basis for calling a trauma alert, it shall be documented in the patient care record in accordance with the requirements of Rule 64J-1.014, F.A.C.

(7) The results of the patient assessment shall be recorded and reported in the patient care record in accordance with the requirements of Rule 64J-1.014, F.A.C.

Specific Authority 395.4045, 395.405, 401.35 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.4045, 395.405, 401.30, 401.35 FS. History—New 8-3-88, Amended 12-10-92, 11-30-93, Formerly 10D-66.102, Amended 11-4-99, 2-20-00, Formerly 64E-2.017.

64J-2.005 Pediatric Trauma Scorecard Methodology.

(1) Each EMS provider shall ensure that upon arrival at the location of an incident, the EMT or paramedic shall assess the pediatric trauma patient by evaluating the patient's status for each of the following components: Airway, Consciousness, Circulation, Fracture, Cutaneous and the pediatric patient's size when used in conjunction with the other components in subsection (3) of this section. The assessment of the pediatric patient using the weight and length parameter and the other components of this section shall be referred to as the Pediatric Trauma Scorecard Methodology. In assessing the pediatric patient, the criteria for each of the components in subsections (2) and (3) of this section shall be used to determine the transport destination for pediatric trauma patients.

(2) The EMT or paramedic shall assess all pediatric trauma patients using the following criteria and if any of the following conditions are identified, the patient shall be considered a pediatric trauma alert patient:

(a) Airway: In order to maintain optimal ventilation, the patient is intubated, or the patient's breathing is maintained through such measures as manual jaw thrust, continuous suctioning or through the use of other adjuncts to assist ventilatory efforts.

(b) Consciousness: The patient exhibits an altered mental status that includes: drowsiness, lethargy, the inability to follow commands, unresponsiveness to voice, totally unresponsive, or is in a coma or there is the presence of paralysis; or the suspicion of a spinal cord injury; or loss of sensation.

(c) Circulation: The patient has a faint or nonpalpable carotid or femoral pulse or the patient has a systolic blood pressure of less than 50 mmHg.

(d) Fracture: There is evidence of an open long bone (humerus, (radius, ulna), femur, (tibia or fibula)) fracture or there are multiple fracture sites or multiple dislocations (except for isolated wrist or ankle fractures or dislocations).

(e) Cutaneous: The patient has a major soft tissue disruption, including major degloving injury, or major flap avulsions or 2nd or 3rd degree burns to 10 percent or more of the total body surface area, or amputation at or above the wrist or ankle, or any penetrating injury to the head, neck or torso (excluding superficial wounds where the depth of the wound can be determined).

(3) In addition to the criteria listed in subsection (2) of this section, a trauma alert shall be called when a condition is identified from any two of the components included in subsection (3) of this section.

(a) Consciousness: The patient exhibits symptoms of amnesia, or there is loss of consciousness.

(b) Circulation: The carotid or femoral pulse is palpable, but the radial or pedal pulses are not palpable or the systolic blood pressure is less than 90 mmHg.

(c) Fracture: The patient reveals signs or symptoms of a single closed long bone fracture. Long bone fractures do not include isolated wrist or ankle fractures.

(d) Size: Pediatric trauma patients weighing 11 kilograms or less, or the body length is equivalent to this weight on a pediatric length and weight emergency tape (the equivalent of 33 inches in measurement or less).

(4) In the event that none of the criteria in subsections (2) or (3) of this section are identified in the assessment of the pediatric patient, the EMT or paramedic can call a "Trauma Alert" if, in his or her judgment, the trauma patient's condition warrants such action. Where EMT or paramedic judgment is used as the basis for calling a trauma alert, it shall be documented in the patient care record in accordance with Rule 64J-1.014, F.A.C.

Specific Authority 395.405, 395.4045, 401.35 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.4045, 395.405, 401.30, 401.35 FS. History—New 8-4-98, Amended 2-20-00, 9-3-00, Formerly 64E-2.0175.

64J-2.006 Trauma Registry.

Instructions for completing and submitting data are defined in the Florida Trauma Registry Manual, February 2008, which is

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incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C.

Specific Authority 395.405 FS. Law Implemented 395.3025(4)(f), 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, 395.405, 401.30, 401.35 FS. History—New 8-3-88, Amended 12-10-92, 11-30-93, Formerly 10D-66.103, Amended 7-14-99, 11-19-01, 6-3-02, 6-9-05, 4-25-06, 7-8-08, Formerly 64E-2.018.

64J-2.007 Trauma Agency Formation, Continuation, and Plan Requirements.

(1) To form a trauma agency, a county or counties (if regional), or an entity with which the county or counties contract for the purpose of trauma service administration shall:

(a) Obtain formal authority to create the agency from the county commission of each of the counties in which the agency plans to operate.

(b) Establish interlocal agreements between county governments if the proposed agency shall provide service to more than one county.

(2) For the formation and for continuation of a trauma agency, a county or counties, or an entity with which the county or counties contract for the purpose of trauma agency service administration, shall submit a trauma agency plan initially and an update at five-year intervals thereafter to the department for approval. Prior to the submission of the trauma agency plan or five-year plan update to the department, the county or counties, an entity with which the county or counties contract or the existing trauma agency shall:

(a) Hold a public hearing at least 60 days prior to the submission of the plan to the department, and give adequate notice of the hearing to the public in the defined geographic area to be served by the trauma agency. Adequate notice shall consist of publishing the notice, at least 30 days prior to the public hearing, in at least one newspaper of general circulation in each affected county. If a newspaper is not published in a county in which the trauma agency shall operate, adequate notice may be given by publishing the notice in at least one newspaper of general circulation in adjoining affected counties.

(b) Develop and submit an electronic copy of the trauma agency plan or five-year plan update to the department for review and approval.

(3) The trauma agency initial plan or five-year plan update shall contain the following information in the following order:

(a) Table of Contents;

(b) Population and Geographic Area to be Served.

1. Describe the population and defined geographic area to be served by the trauma agency;

2. Include a map showing the defined geographic area of the trauma agency, each major geographical barrier, all medical facilities, all prehospital ground and air facilities, and all other significant factors that affect the determination of the geographic area boundaries; and

3. Describe the historical patient flow, patient referral, and transfer patterns used to define the geographic areas of the trauma agency.

(c) Organizational Structure:

1. Provide a detailed description of the managerial and administrative structure of the proposed agency;

2. Include a table of organization, the names of the board of directors and each member's affiliation, and identify the individuals who will administer or operate the trauma agency, if known;

3. Provide the names, job descriptions and responsibilities of officials who shall be directly responsible for trauma agency personnel, and the names, job descriptions and responsibilities of individuals who shall be responsible for managing and operating the trauma agency on a daily basis; and

4. Describe in detail the specific authority that trauma agency personnel shall have in directing the operation of prehospital and hospital entities within the purview of the trauma agency, if approved, be it a single or multi-county trauma agency.

(d) Trauma System Structure:

1. Describe the operational functions of the system; the components of the system; the integration of the components and operational functions; and the coordination and integration of the activities and responsibilities of trauma centers, hospitals, and prehospital EMS providers; and

2. Include a list of all participating and non-participating trauma care resources within the defined geographical area of the trauma agency and documentation showing that these entities have been given the opportunity to participate in the system. Trauma care resources shall include, but are not limited to, hospitals, trauma centers, EMS providers, training centers, emergency medical

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dispatch, and planning entities; and

3. Include the trauma agency's recommendation and justification for the number and location of trauma centers required to serve its defined geographical area.

(e) Objectives, Proposed Actions, and Implementation Schedule. Provide a description of the objectives of the plan, a detailed list of the proposed actions necessary to accomplish each objective, and a timetable for the implementation of the objectives and action.

(f) Describe the source of income and anticipated expenses by category for the trauma agency;

(g) Describe the trauma agency's fiscal impact on the trauma system which includes a description of any increased costs related to providing trauma care.

(h) Transportation System Design:

1. Describe the EMS ground, water, and air transportation system design of the trauma system; and

2. Include trauma patient flow patterns, emergency inter-hospital transfer agreements and procedures, and the number, type, and level of service of the EMS providers within the trauma system.

(i) TTPs:

1. Provide confirmation that existing department-approved TTPs for each EMS provider, within the defined geographical area of the trauma agency, are accurate and shall be adopted by the trauma agency, pending department approval of the plan;

2. A trauma agency may develop uniform TTPs for department approval that shall be adhered to by all EMS providers that serve the geographical area of the trauma agency. If uniform TTPs are submitted to the department for approval, the TTPs shall include the name of each EMS provider that shall operate according to the uniform TTPs, and proof of consultation with each EMS provider's medical director. TTPs developed and submitted by a trauma agency shall be processed in accordance with Rule 64J-2.003, F.A.C.; and

3. The trauma agency shall provide a copy of any county ordinance governing the transport of trauma patients within the defined geographic area of the trauma agency.

(j) Medical Control and Accountability. Identify and describe the qualifications, responsibilities and authority of individuals and institutions providing off-line (system) medical direction and on-line (direct) medical control of all hospitals and EMS providers operating under the purview of the trauma agency.

(k) Emergency Medical Communications:

1. Describe the EMS communication system within the trauma agency's trauma service area; and

2. Verify that the existing communications within the trauma agency's trauma service area meet all the requirements for compliance with the Florida Emergency Medical Services Communications Plan, Volume I – March 2004 and Volume II – July 2008, to include all hospitals with emergency departments. The Florida Emergency Medical Services Communications Plan (Volumes I and II) is incorporated by reference and a copy of the document can be obtained by mail from the Department of Management Services, Division of Telecommunications, 4030 Esplanade Way, Suite 180, Tallahassee, Florida 32399; or electronically through the following web link: http://dms.myflorida.com/suncom/public_safety/radio_communications/radio_communication_plans.

(l) Data Collection. Describe the trauma data management system developed for the purpose of documenting and evaluating the trauma systems operation.

(m) Trauma System Evaluation. Describe the methodology by which the trauma agency shall evaluate the trauma system.

(n) Mass Casualty and Disaster Plan Coordination. Describe the trauma agency's role with local and/or regional emergency management entities in the coordination of the prehospital and hospital component's mass casualty and disaster plan for the defined geographic area it represents.

(o) Public Information and Education. Describe the trauma agency's programs designed to increase public awareness of the trauma system and public education programs designed to prevent, reduce the incidence of, and care for traumatic injuries within the defined geographic area it represents.

(p) Attachments. Include the following:

1. A sample of each type of contract and agreement entered into by the trauma agency for the benefit and operation of the trauma system. A description of these agreements may be substituted.

2. Documentation showing that the county commission of the county or counties in the geographic area to be served by the trauma agency have endorsed the initial plan or five-year plan update, pending department approval of the same; and

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3. A copy of the public hearing notice and minutes of the hearing for the initial plan or five-year plan update.

Specific Authority 395.401, 395.405, 401.35 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.405, 401.35 FS. History—New 8-3-88, Amended 12-10-92, Formerly 10D-66.104, Amended 11-24-02, 6-9-05, Formerly 64E-2.019, Amended 3-25-09.

64J-2.008 Trauma Agency Plan Approval and Denial Process.

(1) The department shall, within 30 days of receipt of the initial trauma agency plan or the five-year plan update, review the trauma agency's trauma system plan and notify the trauma agency that the plan is complete, or that there are omissions. If there are omissions, the department shall request the required additional information to be submitted by the trauma agency.

(2) The trauma agency shall submit the requested additional information to the department within 30 days of receipt of the notice of omissions.

(3) The department shall deem the plan complete upon receipt of the additional information or the expiration of the 30-day time period, whichever occurs first.

(4) The department shall review the plan to determine compliance with Chapters 395 and 401, F.S., and Chapters 59A-3 and 64J-2, F.A.C., within 60 days of receipt of the additional information or of the plan being deemed complete.

(5) The department shall issue a letter of approval to the trauma agency upon determination that the plan is in compliance with Chapters 395 and 401, F.S., and Chapters 59A-3 and 64J-2, F.A.C.

(6) The department shall issue a letter of denial to the trauma agency upon determination that the plan is not in compliance with Chapters 395 and 401, F.S., and Chapters 59A-3 and 64J-2, F.A.C. The letter shall specify the deficiencies in the plan and include notification of any right to a hearing pursuant to Section 120.57, F.S.

Specific Authority 395.401, 395.405, 401.35 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.405, 401.35 FS. History—New 8-3-88, Amended 12-10-92, Formerly 10D-66.106, Amended 11-24-02, Formerly 64E-2.020, Amended 3-25-09.

64J-2.009 Trauma Agency Implementation and Operation Requirements.

(1) To implement a trauma system, a department-approved trauma agency shall:

(a) Implement the trauma system in accordance with its department-approved planned timetable for implementation.

(b) Submit proposed changes to the department-approved plan to the department for approval, as provided in Rule 64J-2.008, F.A.C. The trauma agency may, at its own risk, institute proposed changes to the plan and submit a request for department approval within 30 days after a change is instituted if a delay in approval would have an adverse impact on the current level of care. The trauma agency's request shall explain how the delay in approval would have adversely affected the current level of care. Each request shall document that affected trauma care resources within the defined geographical area of the agency concur with these proposed changes.

(2) Each trauma agency shall operate the trauma system in accordance with the department-approved plan, and shall:

(a) Conduct reviews of trauma center applications from any hospital within the defined geographic area of the trauma agency. Submission of a trauma center's application to the trauma agency by a hospital seeking approval shall be in accordance with the time frames described in paragraph 64J-2.012(1)(c), F.A.C. The department will coordinate the prospective trauma center's application development and review process with the relevant trauma agency to facilitate sufficient time to increase familiarity with the application and conduct the final review. Results of the trauma agency's review shall be submitted to the department no later than April 7 of each year, in order to be considered by the department.

(b) Conduct annual performance evaluations and submit annual reports on the status of the trauma agency's trauma system to the department to be included in the department's Florida Trauma System annual reports. The trauma agency annual report shall be submitted by May 1 following the end of the previous calendar year. This evaluation shall include at least the following:

1. Description of any funding sources and any other related issues, such as: the fiscal impact on the trauma agency's system, including increased costs related to providing trauma care, the reduction or increase in budget or human resources, specialty physician coverage, etc.

2. Documentation that all trauma centers in the geographic area of the trauma agency participate in the trauma agency's quality assurance and improvement activities.

3. Description of public and healthcare education, injury prevention activities, and outreach programs, conducted in the trauma agency's geographical area, which are designed to prevent, reduce the incidence of and improve the care for traumatic injuries within the defined geographic area.

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4. Documentation of data, including the nature of injuries and trends identified in the trauma agency's defined geographic area.

5. Documentation of monitoring the effectiveness of the adult and pediatric trauma alert criteria with regard to determination of appropriate destinations.

(3) Each trauma agency shall have personnel or arrange for management service personnel with clear authority and responsibility to operate the trauma agency. The administrative function of the trauma agency shall not be carried out or performed under the direct supervision of any individual who administers or operates any health care entity in the trauma system, whether a single or multi-county system.

Specific Authority 395.405, 401.35 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.405, 401.35 FS. History--New 12-10-92, Formerly 10D-66.1065, Amended 8-4-98, 11-19-01, 11-24-02, 6-9-05, Formerly 64E-2.021, Amended 3-25-09.

64J-2.010 Apportionment of Trauma Centers within a Trauma Service Area (TSA).

(1) The number and composition of TSAs shall be in accordance with Section 395.402, F.S.

(2) The number of trauma centers in each TSA shall be in accordance with the maximum number set forth in the table below. Each trauma service area shall have at least one Level I or Level II trauma center position.

(3) The number of trauma center positions for each TSA is as follows:

TSA	Counties	Trauma Centers
1	Escambia; Okaloosa; Santa Rosa; Walton	2
2	Bay; Gulf; Holmes; Washington	1
3	Calhoun; Franklin; Gadsden; Jackson; Jefferson; Leon; Liberty; Madison; Taylor; Wakulla	1
4	Alachua; Bradford; Columbia; Dixie; Gilchrist; Hamilton; Lafayette; Levy; Putnam; Suwannee; Union	2
5	Baker; Clay; Duval; Nassau; St. Johns	2
6	Citrus; Hernando; Marion	1
7	Flagler; Volusia	2
8	Lake; Orange; Osceola; Seminole; Sumter	3
9	Pasco; Pinellas	3
10	Hillsborough	2
11	Hardee; Highlands; Polk	3
12	Brevard; Indian River	2
13	DeSoto; Manatee; Sarasota	3
14	Martin; Okeechobee; St. Lucie	1
15	Charlotte; Glades; Hendry; Lee	2
16	Palm Beach	2
17	Collier	1
18	Broward	3
19	Dade; Monroe	6
	TOTAL	42

(4) The trauma center will be assigned by the department according to Section 395.402(4), F.S.

Specific Authority 395.405 FS. Law Implemented 395.401, 395.4015, 395.402, 395.405 FS. History--New 12-10-92, Formerly 10D-66.1075, Amended 6-9-05, 12-18-06, Formerly 64E-2.022.

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64J-2.011 Trauma Center Requirements.

(1) The standards for Level I, Level II and Pediatric trauma centers are published in DH Pamphlet (DHP) 150-9, January 2008, which is incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C. Trauma centers must be in full compliance with these standards by January 1, 2009.

(2) To be a Level I trauma center, a hospital shall be a state licensed general hospital and shall:

(a) Meet and maintain after receiving provisional status and during the 7 year approval period the standards for a Level I trauma center as provided in DHP 150-9, January 2008;

(b) Meet the site visit requirements described in Rule 64J-2.016, F.A.C.;

(c) Meet and maintain after receiving provisional status and during the 7 year approval period the requirements provided in Rule 64J-2.006, F.A.C., regarding the collecting and reporting of trauma registry data; and

(d) Maintain and update at least annually an in-hospital copy of the application that was approved by the department as described in Rule 64J-2.012, F.A.C., so that the application reflects current and accurate information. Documentation used by the trauma center to update the application, but maintained elsewhere between annual application updates shall be immediately available for department review at any time. The application shall be maintained and updated after receiving provisional status and during the 7 year approval period, and organized in the same manner as was required at the time of application.

(3) To be a Level II trauma center, a hospital shall:

(a) Meet and maintain after receiving provisional status and during the 7 year approval period the standards for a Level II trauma center, as provided in DHP 150-9, January 2008;

(b) Meet the site visit requirements described in Rule 64J-2.016, F.A.C.;

(c) Meet and maintain after receiving provisional status and during the 7 year approval period the requirements provided in Rule 64J-2.006, F.A.C., regarding the collecting and reporting of trauma registry data; and

(d) Maintain and update at least annually an in-hospital copy of the application that was approved by the department as described in Rule 64J-2.012, F.A.C., so that the application reflects current and accurate information. The application shall be maintained and updated after receiving provisional status and during the 7 year approval period, and organized in the same manner as was required at the time of application.

(4) To be a pediatric trauma center, a hospital shall:

(a) Meet and maintain after receiving provisional status and during the 7 year approval period the standards for a pediatric trauma center, as provided in DHP 150-9, January 2008;

(b) Meet the site visit requirements described in Rule 64J-2.016, F.A.C.;

(c) Meet and maintain after receiving provisional status and during the 7 year approval period the requirements provided in Rule 64J-2.006, F.A.C., regarding the collecting and reporting of trauma registry data; and

(d) Maintain and update at least annually an in-hospital copy of the application that was approved by the department as described in Rule 64J-2.012, F.A.C., so that the application reflects current and accurate information. Documentation used by the trauma center to update the application, but maintained elsewhere between annual application updates shall be immediately available for department review at any time. The application shall be maintained and updated after receiving provisional status and during the 7 year approval period, and organized in the same manner as was required at the time of application.

(5) The standards published in DHP 150-9, January 2008, are subject to revision at any time through rule promulgation. Any hospital that has been granted Provisional trauma center status or has been granted a 7 year Certificate of Approval as a trauma center shall comply with all revisions to the standards published in DHP 150-9, beginning on the date the amended rule becomes effective.

Specific Authority 395.405 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, 395.405 FS. History—New 8-3-88, Amended 12-10-92, 12-10-95, Formerly 10D-66.108, Amended 8-4-98, 2-20-00, 6-3-02, 6-9-05, 3-5-08, Formerly 64E-2.023.

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64J-2.012 Process for the Approval of Trauma Centers.

(1) Beginning September 1, 1990, and annually thereafter, the department shall approve trauma centers in accordance with the schedule shown in Table I; (Unless stated otherwise all dates given by calendar month and day refer to that date each year.)

Table I

Reference Section 64E-2.012, F.A.C.

PROCESS FOR APPROVAL OF TRAUMA CENTERS

Task	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
	E	C	O	E	A	E	A	P	A	U	U	U	E	C	O	E	A	E	A	P	A	U	U
	P	T	V	C	N	B	R	R	Y	N	L	G	P	T	V	C	N	B	R	R	Y	N	L
Hospitals Submit Letters of Intent																							
DH Sends Applications to Hospitals																							
Hospitals Complete Applications																							
Hospitals Submit Applications																							
Preliminary Review of Applications by DH																							
Hospitals Respond to Deficiencies																							
Hospitals Informed of Provisional Status																							
In-Depth Review of Applications by DH																							
Revised Applications Submitted by Provisional Trauma Centers																							
DH Final Review of Applications																							
Provisional Trauma Centers Notified of In-Depth Review Findings																							
DH Conducts Site Visit Quality of Care Assessments																							
DH Approves Trauma Centers																							
DH Notifies Hospitals of Approval as Trauma Centers																							

(a) The department shall accept a letter of intent, DH Form 1840, January 2008, "Trauma Center Letter of Intent", which is incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C., postmarked no earlier than September 1 and no later than midnight, October 1, from any acute care general or pediatric hospital. The letter of intent is non-binding, but preserves the hospital's right to submit an application by the required due date if an available position, as provided in Rule 64J-2.010, F.A.C., exists in the hospital's TSA. If the hospital does not submit an application by April 1 of the following year,

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the hospital's letter of intent is void;

(b) By October 15, the department shall send to those hospitals submitting a letter of intent an application package which will include, as a minimum, instructions for submitting information to the department for selection as a trauma center, DHP 150-9, January 2008, Trauma Center Standards, which is incorporated by reference in Rule 64J-2.011, F.A.C., and available from the department, as defined by subsection 64J-1.001(8), F.A.C., and the requested application(s);

(c) No later than April 1 of the calendar year following the submission of a letter of intent, a hospital seeking approval as a trauma center shall submit to the department an original and 3 copies of the respective application as indicated below. Each hospital in a TSA with a department-approved local or regional trauma agency shall, at the time a trauma center application is submitted to the department, submit a duplicate of the application to the trauma agency for review. Recommendations from the trauma agency shall be submitted to the department no later than April 7, as provided in Rule 64J-2.009, F.A.C.

1. To apply for approval as a Level I Trauma Center, applicants must submit all forms contained in the Level I Trauma Center Application Manual, January 2008. The manual and the forms contained therein are incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C. The manual contains the following forms: DH Form 2032, January 2008, General Information for Level I Trauma Center Application; DH Form 2032-A, January 2008, Level I Trauma Center Approval Standards Summary Chart; DH Form 2032-B, January 2008, Application for Level I Trauma Center Approval Letter of Certification; DH Form 2032-C, January 2008, Level I Trauma Center Surgical Specialties Certifications; DH Form 2032-D, January 2008, Level I Trauma Center Non-Surgical Specialties Certifications; DH Form 2032-E, January 2008, Level I Trauma Center General Surgeons Commitment Statement; DH Form 2032-F, January 2008, Level I Trauma Center General Surgeons Available for Trauma Surgical Call; DH Form 2032-G, January 2008, Level I Trauma Center Neurosurgeons Available for Trauma Surgical Call; DH Form 2032-H, January 2008, Level I Trauma Center Neurological, Pediatric Trauma and Neurological, and Neuroradiology Statements; DH Form 2032-I, January 2008, Level I Trauma Center Surgical Specialists On Call and Promptly Available; DH Form 2032-J, January 2008, Level I Trauma Center Emergency Department Physicians; DH Form 2032-K, January 2008, Level I Trauma Center Anesthesiologists Available for Trauma Call; DH Form 2032-L, January 2008, Level I Trauma Center C.R.N.A.s Available for Trauma Call; and DH Form 2032-M, January 2008, Level I Trauma Center Non-Surgical Specialists On Call and Promptly Available.

2. To apply for approval as a Level II Trauma Center, applicants must submit all forms contained in the Level II Trauma Center Application Manual, January 2008. The manual and the forms contained therein are incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C. The manual contains the following forms: DH Form 2043, January 2008, General Information for Level II Trauma Center Application; DH Form 2043-A, January 2008, Level II Trauma Center Approval Standards Summary Chart; DH Form 2043-B, January 2008, Application for Level II Trauma Center Approval Letter of Certification; DH Form 2043-C, January 2008, Level II Trauma Center Surgical Specialties Certifications; DH Form 2043-D, January 2008, Level II Trauma Center Non-Surgical Specialties Certifications; DH Form 2043-E, January 2008, Level II Trauma Center General Surgeons Commitment Statement; DH Form 2043-F, January 2008, Level II Trauma Center General Surgeons Available for Trauma Surgical Call; DH Form 2043-G, January 2008, Level II Trauma Center Neurosurgeons Available for Trauma Surgical Call; DH Form 2043-H, January 2008, Level II Trauma Center Neurological, Pediatric Trauma and Neurological, and Neuroradiology Statements; DH Form 2043-I, January 2008, Level II Trauma Center Surgical Specialists On Call and Promptly Available; DH Form 2043-J, January 2008, Level II Trauma Center Emergency Department Physicians; DH Form 2043-K, January 2008, Level II Trauma Center Anesthesiologists Available for Trauma Call; DH Form 2043-L, January 2008, Level II Trauma Center C.R.N.A.s Available for Trauma Call; and DH Form 2043-M, January 2008, Level II Trauma Center Non-Surgical Specialists On Call and Promptly Available.

3. To apply for approval as a Pediatric Trauma Center, applicants must submit all forms contained in the Pediatric Trauma Center Application Manual, January 2008. The manual and the forms contained therein are incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C. The manual contains the following forms: DH Form 1721, January 2008, General Information for Pediatric Trauma Center Application; DH Form 1721-A, January 2008, Pediatric Trauma Center Approval Standards Summary Chart; DH Form 1721-B, January 2008, Application for Pediatric Trauma Center Letter of Certification; DH Form 1721-C, January 2008, Pediatric Trauma Center Surgical Specialties Certifications; DH Form 1721-D, January 2008, Pediatric Trauma Center Non-Surgical Specialties Certifications; DH Form 1721-E, January 2008, Pediatric Center General Surgeons Commitment Statement; DH Form 1721-F, January 2008, Pediatric Trauma Center General Surgeons Available for Trauma Surgical Call; DH Form 1721-G, January 2008, Pediatric Trauma Center Neurosurgeons Available for Trauma Surgical

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Call; DH Form 1721-H, January 2008, Pediatric Trauma Center Neurological, Pediatric Trauma and Neurological, and Neuroradiology Statements; DH Form 1721-I, January 2008, Pediatric Trauma Center Surgical Specialists On Call and Promptly Available; DH Form 1721-J, January 2008, Pediatric Trauma Center Emergency Department Physicians; DH Form 1721-K, January 2008, Pediatric Trauma Center Anesthesiologists Available for Trauma Call; DH Form 1721-L, January 2008, Pediatric Trauma Center C.R.N.A.s Available for Trauma Call; and DH Form 1721-M, January 2008, Pediatric Trauma Center Non-Surgical Specialists On Call and Promptly Available.

(d) After considering the results of the local or regional trauma agency's recommendations, the department shall, by April 15, conduct a provisional review to determine completeness of the application and the hospital's compliance with the standards of critical elements for provisional status. The standards of critical elements for provisional review for Level I and Level II trauma center applications are specified in DHP 150-9, January 2008, as follows:

Level I

STANDARD

- I. Administrative: A, E, and F;
- II. Trauma Service: A, B.1, 5, 6, and 9, C, and D;
- III. Surgical Services: A, B, C, and D;
- IV. Non-Surgical Services: A, B, and C;
- V. Emergency Department: A, B, C.1, D, and E.4,
- VI. Operating Room and Post-Anesthesia Recovery Area: A.1, 2, and 3 and B.1 and 2;
- VII. Intensive Care Unit and Pediatric Intensive Care Unit: B, C, D, and E;
- VIII. Training and Continuing Education Programs: A, B, and C;
- IX. Equipment: A, B, C, D, and E;
- X. Laboratory Services: A and B;
- XII. Radiological Services: A, B, and C;
- XIII. Organized Burn Care: A;
- XIV. Acute Spinal Cord and Brain Injury Management Capability: A;
- XV. Acute Rehabilitative Services: B;
- XVI. Psychosocial Support Services: A;
- XVII. Outreach Programs: B, C, and E;
- XVIII. Quality Management: A through H;
- XIX. Trauma Research: B;
- XX. Disaster Planning and Management.

Level II

STANDARD

- I. Administrative: A, E, and F;
- II. Trauma Service: A, B.1, 5, and 6, C, and D;
- III. Surgical Services: A, B, C, and D;
- IV. Non-Surgical Services: A, B, and C;
- V. Emergency Department: A, B, C.1, D, and E.4;
- VI. Operating Room and Post-Anesthesia Recovery Area: A.1, 2, and 3 and B.1 and 2;
- VII. Intensive Care Unit: A, B, C, and D;
- VIII. Training and Continuing Education Programs: A, B, and C;
- IX. Equipment: A, B, C, D, and E;
- X. Laboratory Services: A and B;
- XII. Radiological Services: A, B, and C;
- XIII. Organized Burn Care: A;
- XIV. Acute Spinal Cord and Brain Injury Management Capability: A;
- XV. Acute Rehabilitative Services: B;
- XVI. Psychosocial Support Services: A;
- XVII. Outreach Programs: B, C, and E;

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XVIII. Quality Management: A through H;

XIX. Disaster Planning and Management.

Pediatric

STANDARD

I. Administrative: A, E, and F;

II. Trauma Service: A, B.1, 5, 6, and 9, C, and D;

III. Surgical Services: A, B, C, and D;

IV. Non-Surgical Services: A, B, and C;

V. Emergency Department: A, B, C.1, D, and E.4;

VI. Operating Room and Post-Anesthesia Recovery Area: A.1, 2, and 3 and B.1 and 2;

VII. Pediatric Intensive Care Unit: A, B, C, and D;

VIII. Training and Continuing Education Programs: A, B, and C;

IX. Equipment: A, B, C, D, and E;

X. Laboratory Services: A and B;

XII. Radiological Services: A, B, and C;

XIII. Organized Burn Care: A;

XIV. Acute Spinal Cord and Brain Injury Management Capability: A;

XV. Acute Rehabilitative Services: B;

XVI. Psychosocial Support Services: A;

XVII. Outreach Programs: B, C, and E;

XVIII. Quality Management: A through H;

XIX. Trauma Research B;

XX. Disaster Planning and Management.

(e) No later than April 15, each hospital whose application the department finds to be unacceptable or deficient during the department's provisional review, will be notified in writing of deficiencies and given the opportunity to submit additional clarifying or corrective information.

(f) The hospital shall submit the requested information to the department by close of business 5 working days after April 15. Failure to provide the requested information, or failure to successfully address the deficiencies identified by the department, shall result in the denial of the hospital's application.

(g) The department shall send written notification to each applicant on or before May 1:

1. The department shall notify each hospital whose application it has found acceptable upon completion of the provisional review that the hospital shall operate as a Provisional trauma center beginning May 1;

2. The department shall inform each hospital whose provisional application it has denied of the remaining deficiencies in the application and shall inform the hospital that it may submit a letter of intent at the beginning of the next approval cycle.

(h) The department shall, between May 1 and June 30, complete an in-depth review of all sections of the Provisional trauma center's application. The department shall notify the hospital of any omissions, deficiencies, or problems and request additional information to be submitted by the hospital.

(i) To have additional information considered during the department's in-depth review of the application, the Provisional trauma center shall submit the requested additional information to the department no later than September 1.

(j) By September 30, the department shall determine whether the omissions, deficiencies, or problems have been corrected. The department shall notify each Provisional trauma center on or before October 1 of any omissions, deficiencies, or problems that were not resolved by submission of the requested additional information.

(k) Provisional trauma centers are subject to a site visit from October 1 to May 30. Any Provisional trauma center that was notified by the department on or before October 1 at the conclusion of the in-depth review that omissions, deficiencies, or problems were not resolved shall be given 30 calendar days from the department's notification following the completion of the site visit to provide additional information, as discussed in Rule 64J-2.016, F.A.C.

(l) The department shall deny the application of any Provisional trauma center that has not corrected the omissions, deficiencies, or problems noted from the in-depth review within 30 calendar days from the department's notification following the completion of the site visit, as provided in Rule 64J-2.016, F.A.C., regardless of the findings of the out-of-state review team regarding the quality

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of trauma patient care and trauma patient management provided by the Provisional trauma center.

(m) By July 1, the department shall approve or deny trauma centers based upon the recommendations of the out-of-state review team, the result of the in-depth review and, if necessary, upon application of the additional criteria in subsection 64J-2.016(10), F.A.C.:

1. The department shall issue the certificate to the hospital upon approval as a trauma center.
2. The department shall issue a letter of denial to each hospital not approved as a trauma center, specifying the basis for denial and informing the hospital of the next available approval cycle, and the hospital's right to an administrative hearing pursuant to Sections 120.57 and 395.4025, F.S.

(2) Each hospital denied provisional status or not approved as a trauma center may, within 30 days of receipt of the denial notice, request a hearing in which to contest the findings of the department.

(3) The department shall deny, suspend, or revoke the approval of any Provisional trauma center which misrepresents a material fact in its application for trauma center approval, including the site survey process.

(4) In the event a trauma center intends to terminate its trauma services, it shall give advance notice of its intent to terminate to the department via a letter signed by its CEO or designee. The letter shall be addressed to the Division Director, Division of Emergency Medical Operations, and shall reference and comply with Section 395.4025(8), F.S. The letter shall include an explanation of the specific reason or reasons why the trauma center wants to terminate its trauma services. The termination will be effective 6 months from receipt of the letter by the department unless a longer time is specified in the letter. Upon termination, the hospital shall cease operating or holding itself out as a trauma center.

Specific Authority 395.405 FS. Law Implemented 395.1031, 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, 395.405 FS. History--New 8-3-88, Amended 12-10-92, 12-10-95, Formerly 10D-66.109, Amended 8-4-98, 2-20-00, 6-3-02, 6-9-05, 3-5-08, Formerly 64E-2.024.

64J-2.013 Extension of Application Period.

(1) Any hospital may request that the department grant up to 18 months additional time to complete its application to become a trauma center if the hospital determines prior to submitting an application that the hospital cannot meet all of the standards of critical elements as provided in paragraph 64J-2.012(1)(d), F.A.C. The standards of critical elements provided in paragraph 64J-2.012(1)(d), F.A.C., are the only standards for which an extension shall be considered. The request for extension must also comply with the requirements provided in this section.

(2) To be considered for an extension, a hospital must submit an application in accordance with the requirements in Rule 64J-2.012, F.A.C., together with a request for extension. The request for extension must contain the following:

- (a) The specific date the hospital desires to have the department begin the provisional review of the hospital's application;
- (b) A reference to each standard, or specific part of a standard, in DHP 150-9, January 2008, Trauma Center Standards, which is incorporated by reference in Rule 64J-2.011, F.A.C., and available from the department, as defined by subsection 64J-1.001(8), F.A.C., that the hospital is unable to meet;
- (c) For each standard, or specific part of a standard, that the hospital is unable to meet, a detailed and separate explanation as to why the standard, or specific part of a standard, cannot be met; and
- (d) An action plan that describes the major activities planned to meet each standard, or specific part of a standard, and the completion date for each activity.

(3) The department shall, by April 15, conduct a review of the hospital's extension request for completeness and to determine any deficiencies.

(4) No later than April 15, hospitals with extension requests found to be incomplete or deficient will be notified in writing of the deficiencies or incomplete sections, and shall be given the opportunity to submit additional clarifying or corrective information.

(5) The hospital shall submit the requested information to the department no later than 5 working days after receipt of the department's notification. Failure to provide the requested information or failure to address the deficiencies or incomplete information identified by the department shall result in the denial of the hospital's extension request.

(6) The department shall notify the hospital on or before May 1 of the approval or denial of the hospital's extension request. If the extension is granted, the department shall provide written notification to the hospital of the beginning and ending dates of the extension.

(7) The department shall make a final determination on whether to approve or deny a hospital's extension request only after the provisional review of all other trauma center applications in the hospital's TSA are completed, and it has been determined that the

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number of trauma centers and Provisional trauma centers, in the hospital's TSA is less than the allocated number of positions available for that TSA.

(8) If the hospital's request for extension is denied, the hospital may, within 30 days of receipt of the notification of denial, request a hearing to contest the decision of the department, in accordance with Chapter 120.57, F.S.

(9) The hospital may modify any date for completion of a major activity in the department-approved action plan discussed in paragraph (d) of this rule without prior department approval. When any date for completion of a major activity is modified by the hospital, the hospital must provide an updated action plan to the department. The hospital must complete all major activities within the extension period granted by the department. The department will not begin the provisional review of the hospital's application for approval as a trauma center at the end of the extension period, or earlier at the request of the hospital, unless the hospital can substantiate completion of all major activities in the action plan. The department may conduct a site visit to determine the hospital's compliance with the approved action plan.

(10) The department shall begin a provisional review of the hospital's trauma center application on the date the hospital specified in the extension request, as approved by the department. The hospital may request that the department begin the provisional review earlier than the date specified in the extension request if the hospital completes all action steps before the expiration of the approved extension period. The department's provisional review of the hospital's application shall be conducted in accordance with the timeframes for processing the application provided in Rule 64J-2.012, F.A.C., but will not coincide with the dates provided in that section.

(11) The hospital shall ensure that the trauma center's application provided at the time the hospital submitted the extension request is current on the date the department begins the provisional review.

(12) A hospital receiving an extension greater than 12 months shall have its extension terminated if the number of trauma centers or provisional trauma centers in the hospital's TSA equals the number of available positions allocated to the TSA, resulting in the denial of its application and the department will inform the applicant of its right to a Section 120.57, F.S., hearing regarding this denial.

(13) The department shall complete an in-depth review of the application of each hospital that received an extension and became a Provisional trauma center within 90 days of the hospital receiving provisional status according to the following schedule:

(a) The department shall review the application and inform the Provisional trauma center of any omissions, deficiencies, or problems within 30 days of the date the department begins the in-depth review;

(b) The Provisional trauma center may provide additional information in response to the department's notice of omissions, deficiencies, or problems within 30 days of receipt of the department's notification. If the Provisional trauma center does not provide additional information within 30 days, the department shall inform the Provisional trauma center of any omissions, deficiencies, or problems that were not corrected at the conclusion of the in-depth review.

(c) If the Provisional trauma center submits additional information, the department shall review the additional information and inform the Provisional trauma center of any remaining omissions, deficiencies, or problems that were not corrected at the conclusion of the in-depth review.

(14) A hospital approved by the department as a Provisional trauma center following an approved extension period, shall receive a site visit during the next scheduled site visit phase. The hospital shall operate as a Provisional trauma center no less than 6 consecutive months prior to the site visit.

Specific Authority 395.405 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, 395.405 FS. History--New 12-10-92, Amended 12-10-95, Formerly 10D-66.1095, Amended 8-4-98, 2-20-00, 6-3-02, 6-9-05, 3-5-08, Formerly 64E-2.025.

64J-2.014 Certificate of Approval.

Each hospital approved as a trauma center shall be issued a DH Form 2032-Z, January 2008, Level I Trauma Center Certificate of Approval, DH Form 2043-Z, January 2008, Level II Trauma Center Certificate of Approval, or DH Form 1721-Z, January 2008, Pediatric Trauma Center Certificate of Approval, which are incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C. The certificates shall include:

- (1) The date effective and the date of termination;
- (2) The hospital's name; and
- (3) The approved trauma center level.

Specific Authority 395.4025, 395.405 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, 395.405 FS. History--New

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8-3-88, Amended 12-10-92, Formerly 10D-66.110, Amended 2-20-00, 4-15-01, 6-9-05, 3-5-08, Formerly 64E-2.026.

64J-2.015 Process for Renewal of Trauma Centers.

(1) At least 14 months prior to the expiration of the trauma center's certification, the department shall send, to each trauma center that is eligible to renew, a blank DH Form 2032R, January 2008, Trauma Center Application to Renew, which is incorporated by reference and available from the department, as defined by subsection 64J-1.001(8), F.A.C., in accordance with the provisions of this section. Within 15 calendar days after receipt, the trauma center choosing to renew its certification shall submit to the department the completed DH Form 2032R, January 2008.

(2) All renewing trauma centers shall receive an on-site survey after the department's receipt of the completed DH Form 2032R, January 2008. The department shall notify each trauma center of the results of the site survey within 30 working days from completion of the site survey. If the trauma center desires to provide additional information regarding the results of the site survey to the department to be considered, the information must be provided in writing and be received by the department within 30 calendar days of the hospital's receipt of the department's notice. If the trauma center elects not to respond to the department's notice within 30 calendar days, the department shall make the final determination of approval or denial based solely on information collected during the applicant's site survey.

(3) At least 45 days prior to the expiration of the certification, the department shall simultaneously notify each facility in writing of their approval or denial to renew. If approved, this renewal certification shall be for a period of 7 years beginning the day after the current certification expires.

(4) A trauma center which does not desire to be re-approved shall follow the notification provisions of Section 395.4025(8), F.S. *Specific Authority 395.4025, 395.405 FS. Law Implemented 395.401, 395.402, 395.4025, 395.404, 395.4045, 395.405 FS. History—New 8-3-88, Amended 12-10-92, 1-23-96, Formerly 10D-66.111, Amended 3-15-98, 2-20-00, 6-9-05, 3-5-08, Formerly 64E-2.027.*

64J-2.016 Site Visits and Approval.

(1) Each Provisional trauma center shall receive an on-site evaluation to determine whether the hospital is in substantial compliance with standards published in DHP 150-9, January 2008, Trauma Center Standards, which is incorporated by reference in Rule 64J-2.011, F.A.C., and available from the department, as defined by subsection 64J-1.001(8), F.A.C., and to determine the quality of trauma care provided by the hospital.

(2) The on-site evaluation shall be conducted by a review team of out-of-state reviewers with knowledge of trauma patient management as evidenced by experience in trauma care at a trauma center approved by the governing body of the state in which they are licensed

(3) All Provisional trauma center shall receive a site visit between October 1 of each year and June 1 of the following year.

(4) The reviewers shall assess each applicant hospital's compliance with the standards published in DHP 150-9, January 2008, by means of direct observation, review of call schedules, and review of patient charts. Reviewers also shall assess the quality of trauma patient care and trauma patient management by reviewing facility trauma mortality data, by reviewing patient charts and by reviewing trauma case summaries and minutes of trauma quality management committee meetings pursuant to Standard XVIII of DHP 150-9, January 2008.

(5) Evaluation of the Quality of Trauma Patient Care and Trauma Patient Management:

(a) The reviewers shall judge the quality of trauma patient care and the quality of trauma patient management in each Provisional trauma center by analyzing each facility's trauma patient care and trauma patient outcomes, by reviewing trauma patient charts and by evaluating the effectiveness of the trauma quality management program through reviews of trauma case summaries and minutes of trauma quality management committee meetings.

(b) Evaluations of trauma patient care and trauma patient management will also be conducted using trauma patient data collected from the hospital trauma registry and the Florida Trauma Registry from the time the hospital received provisional trauma center status through the date of the on-site review. Trauma patient data may also be collected from the emergency department patient log, audit filter log, or quality management committee minutes. The patient population for review shall be selected on the basis of Injury Severity Scores (ISS). The ISS shall be determined using Abbreviated Injury Scaling (AIS-90). If the Provisional trauma center has an in-hospital trauma registry which computes the ISS using the International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM), the computer program shall contain AIS-90 as a component of the program.

(c) Patient charts to be reviewed shall be selected by the department from cases meeting the criteria listed in Standard XVIII B.2., published in DHP 150-9, January 2008. A minimum of 75 cases shall be selected for review in each facility. If the cases total

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less than 75, then all cases are subject to review.

(d) Patient charts shall be reviewed to identify factors related to negative patient outcome or compromised patient care. When such factors are identified, trauma case reviews by the medical director of the trauma service or the trauma nurse coordinator, as well as minutes of trauma quality management committee meetings, shall be reviewed to determine if corrective action was taken by the trauma service and appropriate peer review committees within the facility.

(e) Reviewers shall study the trauma case reviews and trauma quality management committee meeting minutes to evaluate the overall effectiveness of the quality management program.

(6) The reviewers shall rate a Provisional trauma center which they have reviewed as either acceptable, acceptable with corrections, or unacceptable. The rating shall be based on each facility's substantial compliance with the standards published in DHP 150-9, January 2008, and upon the performance of each Provisional trauma center in providing acceptable trauma patient care and trauma patient management which resulted in acceptable patient outcomes.

(7) The department shall evaluate the results of the site visit review and the in-depth application review of each Provisional trauma center between June 1 and July 1. All applicant hospitals shall be notified simultaneously of their approval or denial to become a trauma center on or before July 1. The department's selection will be based on the results of the site visit and the in-depth application review. In those situations in which there are more trauma centers or Provisional trauma centers than available positions in the TSA, the criteria in subsection (11) of this section shall be applied for final selection.

(8) The department shall notify each Provisional trauma center of the results of the site visit within 30 working days from completion of the site visit. The department shall include in the notice any problems that the Provisional trauma center was informed of at the conclusion of the department's in-depth application review. If the Provisional trauma center desires to provide additional information regarding the results of the site visit or in-depth application review to the department to be considered during the final evaluation between June 1 and July 1, the information must be provided in writing and be received by the department within 30 calendar days of the hospital's receipt of the department's notice. If the Provisional trauma center elects not to respond to the department's notice within 30 calendar days, the department shall make the final determination of approval or denial based solely on information collected during the applicant's site visit and in-depth application review.

(9) Site Visits may be conducted at any reasonable time at the discretion of the department at any Provisional trauma center or trauma center by the department staff or reviewers to:

(a) Verify information provided pursuant to subsection (8); and

(b) Ensure each trauma center maintains substantial compliance with trauma center standards, quality of trauma patient care, and quality of trauma patient management.

(10) Section 395.4025(12), F.S., makes confidential and exempt from the provisions of Section 119.07(1), F.S., not only patient care, transport or treatment records and patient care quality assurance proceedings, but also records or reports made or obtained pursuant to Sections 119.07(3)(v), 395.3025(4)(f), 395.401, 395.4015, 395.402, 395.4025, 395.403, 395.404, 395.4045, and 395.405, F.S. The department identifies the confidential and exempt records included within the authority of these laws to be the following:

(a) Patient care, transport or treatment records;

(b) Patient care quality assurance proceedings, records, or reports;

(c) Any site survey instrument of the department, its agents, or surveyors in any form;

(d) Any site survey findings of the department; and

(e) A hospital's response to the department's site survey findings.

(11) If the number of Provisional trauma centers found eligible for selection by the department in a given TSA exceeds the number permitted, as provided in subsection 64J-2.010(3), F.A.C., the following criteria shall be applied independently and consecutively to all Provisional trauma centers in the TSA until application of the criteria results in the number of trauma centers authorized in subsection 64J-2.010(3), F.A.C., for that TSA. When that occurs, the remaining criteria shall not be considered. The criteria to be applied are as follows:

(a) A hospital recommended to be a trauma center in the department-approved local or regional trauma agency plan pursuant to subparagraph 64J-2.007(2)(d)3., F.A.C., shall be given approval preference over any hospital which was not recommended.

(b) A hospital shall be given selection preference based on the level of service they intend to provide according to the following sequence:

1. A Provisional Level I trauma center will be given preference over a Provisional Level II trauma center with pediatrics, a

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Provisional Level II trauma center, and a Provisional pediatric trauma center;

2. A Provisional Level II trauma center with pediatrics will be given preference over a Provisional Level II trauma center and a Provisional pediatric trauma center; and

3. A Provisional Level II trauma center will be given preference over a Provisional pediatric trauma center in TSA having only one allocated trauma center position, and in a TSA with more than one allocated trauma center position if there already exists an approved Level I trauma center, Level II trauma center with pediatrics, or a pediatric trauma center, or if in the instant selection process a Level I trauma center, Level II trauma center with pediatrics, or pediatric trauma center is to be selected.

(c) An applicant hospital in a geographic location that is most conducive to access by the greatest number of people to be served within a TSA shall be given preference for selection.

(d) A hospital representing the best geographic distribution with respect to terrain, population served and projected service population in a given TSA shall be given preference for selection.

(e) A hospital which, according to the most recent complete year of Agency for Health Care Administration data, shows a higher level of commitment of care to the service area, as evidenced by the ratio of non-paying to paying patients, shall be given preference for approval.

(12) The department shall inform in writing each Provisional trauma center denied approval as a trauma center of its opportunity to request a hearing in which to contest the denial in accordance with Section 120.57, F.S.

Specific Authority 395.4025, 395.405 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, 395.405 FS. History—New 8-3-88, Amended 12-10-92, 10-2-94, 12-10-95, Formerly 10D-66.112, Amended 8-4-98, 2-20-00, 6-3-02, 6-9-05, 3-5-08, Formerly 64E-2.028.

64J-2.017 Application by Hospital Denied Approval.

Any hospital that was not approved as a trauma center based on the application of criteria in Rule 64J-2.016, F.A.C., may submit a completed Letter of Intent DH Form 1840, January 2008, which is available from the department, as defined by subsection 64J-1.001(8), F.A.C., postmarked no earlier than September 1 and no later than midnight October 1 of the following year.

Specific Authority 395.4025, 395.405 FS. Law Implemented 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, 395.405 FS. History—New 8-3-88, Amended 12-10-92, 12-10-95, Formerly 10D-66.113, Amended 2-20-00, 6-9-05, 3-5-08, Formerly 64E-2.029.

64J-2.018 Do Not Resuscitate Order (DNRO) Form and Patient Identification Device.

(1) An emergency medical technician or paramedic shall withhold or withdraw cardiopulmonary resuscitation:

(a) Upon the presentation of an original or a completed copy of DH Form 1896, Florida Do Not Resuscitate Order Form, December 2004, which is incorporated by reference and available from the department at no cost, or, any previous edition of DH Form 1896; or

(b) Upon the presentation or observation, on the patient, of a Do Not Resuscitate Order patient identification device.

(2) The Do Not Resuscitate Order:

(a) Form shall be printed on yellow paper and have the words “DO NOT RESUSCITATE ORDER” printed in black and displayed across the top of the form. DH Form 1896 may be duplicated, provided that the content of the form is unaltered, the reproduction is of good quality, and it is duplicated on yellow paper. The shade of yellow does not have to be an exact duplicate;

(b) Patient identification device is a miniature version of DH Form 1896 and is incorporated by reference as part of the DNRO form. Use of the patient identification device is voluntary and is intended to provide a convenient and portable DNRO which travels with the patient. The device is perforated so that it can be separated from the DNRO form. It can also be hole-punched, attached to a chain in some fashion and visibly displayed on the patient. In order to protect this device from hazardous conditions, it shall be laminated after completing it. Failure to laminate the device shall not be grounds for not honoring a patient’s DNRO order, if the device is otherwise properly completed.

(3) The DNRO form and patient identification device must be signed by the patient’s physician. In addition, the patient, or, if the patient is incapable of providing informed consent, the patient’s health care surrogate or proxy as defined in Section 765.101, F.S., or court appointed guardian or person acting pursuant to a durable power of attorney established pursuant to Section 709.08, F.S., must sign the form and the patient identification device in order for them to be valid.

(4) An emergency medical technician or paramedic shall verify the identity of the patient who is the subject of the DNRO form or patient identification device. Verification shall be obtained from the patient’s driver license, other photo identification, or from a witness in the presence of the patient.

(5) During each transport, the EMS provider shall ensure that a copy of the DNRO form or the patient identification device

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accompanies the live patient. The EMS provider shall provide comforting, pain-relieving and any other medically indicated care, short of respiratory or cardiac resuscitation.

(6) A DNRO may be revoked at any time by the patient, if signed by the patient, or the patient's health care surrogate, or proxy or court appointed guardian or person acting pursuant to a durable power of attorney established pursuant to Section 709.08, F.S. Pursuant to Section 765.104, F.S., the revocation may be in writing, by physical destruction, by failure to present it, or by orally expressing a contrary intent.

Specific Authority 381.0011, 401.45(3) FS. Law Implemented 381.0205, 401.45, 765.401 FS. History—New 11-30-93, Amended 3-19-95, 1-26-97, Formerly 10D-66.325, Amended 2-20-00, 11-3-02, 6-9-05, Formerly 64E-2.031.

64J-2.019 Funding for Verified Trauma Centers.

(1) For purposes of Sections 318.14 and 395.4036, F.S., and this rule, in addition to those terms defined in the Florida Trauma Registry Manual, December 2005, (see Rule 64J-2.006, F.A.C.) and elsewhere in these rules, the following definitions also apply:

(a) "Attestation" – means a letter on hospital letterhead, signed under oath consistent with Section 92.50, F.S., by the person with direct or delegated authority to make such a statement, stating that the proceeds received by the hospital under Section 395.4036, F.S., were used in compliance with law.

(b) "Certified trauma center", "verified trauma center" and "trauma center" – all mean a Level I, Level II or Pediatric Trauma Center.

(c) "Caseload volume", "trauma caseload volume", and "volume of trauma cases" – all mean the number of verified trauma patients served by a trauma center during a calendar year, after 2004, on whom data timely supplied by the trauma center to the trauma registry satisfies the Florida Trauma Registry Manual, December 2005, reporting requirements for determining trauma caseload volume (see page 5 of the manual).

(d) "International Classification Injury Severity Score" (ICISS) means a mathematical system of risk stratification based on anatomic diagnosis of trauma patients as initially defined and validated in the following reference: "Osler T, Rutledge R, Deis J, Bedrick E., ICISS: an international classification of disease-9 based injury severity score, Journal of Trauma. 1996 Sep;41(3):380-6; discussion 386-8."

(e) "Severe Injury Patient" – Through December 31, 2007, means a verified trauma patient with a computed ICISS Ps<.90 and, after December 31, 2007, means a verified trauma patient with computed ICISS Ps<.85.

(f) "Verified Trauma Patient" means a patient treated at a state certified trauma center with at least one ICD-9-CM discharge diagnosis between 800 and 959.9 with a Survival Risk Ratio (SRR)<1 whose data is used by the trauma registry to determine caseload volume. SRRs for each diagnosis code will be determined from analysis of data in the trauma registry by the Department consistent with ICISS and shall be published by the Department.

(g) "Year" – means the most recent complete calendar year for which caseload volume is available from the trauma registry.

(2) Funds collected under Sections 318.14(5) and 318.18(15), F.S., and deposited into the department's administrative trust fund shall be distributed quarterly to the certified trauma centers.

(a) All distribution shall be consistent with subsection (2) or upon resolution of all relevant administrative and judicial challenges, whichever is later.

(b) Funds collected under Section 318.14(5), F.S., and deposited into the department's administrative trust fund shall be distributed to the trauma center as follows: $[(.5 \times \text{funds}) / \text{Current total number of trauma centers}] + [(.5 \times \text{funds}) \times (\text{Caseload volume for the trauma center for the year} / \text{The sum of caseload volume for all trauma centers during the year})]$.

(c) Funds collected under Section 318.18(15), F.S., and deposited into the department's administrative trust fund under Section 395.4095(1), F.S., shall be distributed as follows:

1. To each trauma center in a region receiving a local funding contribution as of December 31 of the previous year: $(.2 \times \text{funds}) \times (\text{Caseload volume for the trauma center for the year} / \text{The sum of caseload volume for the year for all trauma centers receiving funding under subparagraph (2)(c)1. of this rule})$.

2. To each trauma center: $(.4 \times \text{funds}) \times (\text{Caseload volume of the trauma center during the year} / \text{The sum of caseload volume for all trauma centers during the year})$.

3. To each trauma center: $(.4 \times \text{funds}) \times (\text{The total number of severe injury patients served by the trauma center for the year} / \text{The total number of all severe injury patients served by all trauma centers for the year})$.

Specific Authority 395.4036 FS. Law Implemented 395.4036 FS. History—New 4-25-06, Amended 1-9-07, Formerly 64E-2.040.

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