

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS:

64J-2.001 Definitions.

*Amendments and additions to this section will be identified through rule development workshops and public comment.*

~~(1) Abbreviated Injury Score (AIS 90) — means a consensus derived, anatomically based system that classifies individual injuries by body region on a 6 point ordinal severity scale ranging from 1 to 6. The methodology for determining AIS 90 Code is found in the “Abbreviated Injury Scale 1990 — Update 98,” which is incorporated by reference and is available from the Association for the Advancement of Automotive Medicine, P. O. Box 4176, Barrington, IL 60011-4176.~~

(2) through (6) renumbered (1) through (5) No change.

~~(7) ICD 9 CM — means the “International Classification of Disease, 9th Revision, Clinical Modification,” March, 1989, U.S. Department of Health and Human Services Publication No. (PHS) 89-1260; an internationally applied method by which diseases or groups of medical conditions or injuries are coded for the purpose of statistical analyses. This book is incorporated by reference and available for purchase from the American Hospital Association, Central Office on ICD 9 DM, 1(800)242-2626, AHA, Post Office Box 92683, Chicago, IL 60675-2683.~~

(8) through (17) renumbered (6) through (15) No change.

64J-2.009 Trauma Agency Implementation and Operation Requirements.

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

(2) Each trauma agency must:

~~(a) Conduct reviews of trauma center applications from any hospital within the defined geographic area of the trauma agency. 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.~~

~~(a)(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.~~

~~(b) Submit t~~The trauma agency annual report ~~shall be submitted~~ by May 1 following the end of the previous calendar year, ~~and~~ ~~This evaluation shall~~ include at least the following:

1. through 5. No change.

~~(c)(2) Trauma agencies shall every five years Ssubmit to the department every five years for approval an updated plan in accordance with Section 395.401(1)(n), F.S.~~

*Rulemaking Authority 395.401, 395.405, 401.35 FS. Law Implemented 395.401, 395.4025 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, 9-5-16, mm-dd-yy.*

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 ~~will shall~~ send, by electronic mail to the email address of record of each trauma center that is eligible to renew, a blank DH Form 2032R, January 2010, Trauma Center Application to Renew, which is incorporated by reference and available from the department, as defined by subsection 64J-2.001(4), 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 T~~the completed DH Form 2032R must be returned to the department within 15 days of receipt to apply to renew the certification.

(2) All renewing trauma centers ~~will shall~~ receive an on-site survey after the department’s receipt of the completed DH Form 2032R. The department ~~will shall~~ notify each trauma center of the results of the site survey within ~~4530 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 ~~4530 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 ~~4530 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~~ 10 days prior to the expiration of the certification, the department ~~will~~ 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.~~

*Rulemaking 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, Amended 11-5-09, 4-20-10, \_\_\_\_.*

#### 64J-2.016 Site Visits and Approval.

(1) Each ~~Provisional~~ trauma center ~~will~~ shall receive an on-site evaluation to determine whether the hospital is in substantial compliance with standards published in DHP 150-9, 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-2.001(4), F.A.C., and to determine the quality of trauma care provided by the hospital.

(2) The on-site evaluation ~~will~~ 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 centers ~~will~~ shall receive a site visit no later than one year following the submission of a renewal application or beginning operations as a trauma center. Trauma centers that submit a completed Trauma Center Application to Renew, DH Form 2032R, more than 14 months before expiration of the current certification, will receive an on-site survey not less than 60 days from the date the current certification expires between October 1 of each year and June 1 of the following year.

(4) The reviewers ~~will~~ shall assess each applicant hospital's compliance with the standards published in DHP 150-9, Trauma Center Standards, and the quality of trauma patient care and patient management by means of direct observation, review of call schedules, and review of patient charts, hospital. ~~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.~~

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

(a) The reviewers ~~will assess~~ 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 began operations as a received provisional trauma center status through the date of the onsite review. Trauma patient data may also be collected from the emergency department patient log, audit filter log, or quality management committee minutes, as the reviewer requires to complete the assessment. ~~The patient population for review shall be selected on the basis of Injury Severity Scores (ISS). The ISS shall be determined using Abbreviated Injury Scoring (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 ~~will~~ shall be selected by the department from cases meeting the criteria listed in Standard XVIII B.2., published in DHP 150-9, Trauma Center Standards. A minimum of 75 cases ~~will~~ shall be selected for review in each facility. If the cases total less than 75, then all cases are subject to review.

(d) Patient charts ~~will~~ 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, ~~will~~ shall be reviewed to determine if corrective action was taken by the trauma service and appropriate peer review committees

within the facility.

(e) Reviewers ~~will 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 ~~will shall~~ rate a ~~Provisional~~ trauma center which they have reviewed as either acceptable, acceptable with corrections, or unacceptable. The rating ~~will shall~~ be based on each facility's substantial compliance with the standards published in DHP 150-9, Trauma Center Standards, 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 rule, shall be applied for final selection.~~

~~(7)(8) The department will shall~~ notify each hospital or 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 hospital or 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.~~

~~(8)(9) Site visits will 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 ~~(7)(8)~~; and,
- (b) No change.

~~(9)(10) Section 395.4025(123), 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) through (e) No change.

~~(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 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.~~

~~(10)(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. Rulemaking 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, Amended 11-5-09, 4-20-10, mm-dd-yy.~~

#### 64J-2.019 Funding for Verified Trauma Centers.

(1)(a) through (b) No change.

(c) “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.”~~ an International Classification of Diseases (ICD)-based multiplicative prediction model that calculates the likelihood of survival of an injured patient based on the assumption that all injuries contribute to the overall severity. The department will calculate the ICISS score for each injured patient in the most recent complete year of the Agency for Health Care Administration’s Hospital Discharge Data Set based upon the multiplicative product all of the Survival Risk Ratios (SRR) associated with each ICD code listed in the patient’s record.

(d) No change.

(e) “Year” – means the most recent complete calendar year for which trauma caseload volume is available from the Agency for Health Care Administration trauma registry.

(f) For purpose of this section only “trauma caseload volume” means all patients treated at trauma centers that are identified as “trauma” in the “Priority of Admission” field in the Agency for Health Care Administration’s Hospital Inpatient Data File.

(2) Funds governed under this rule ~~will shall~~ be distributed to verified trauma centers in the quarter following deposit into the Department’s trust funds.

(a) All distribution ~~will 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., governed under this rule ~~will shall~~ be distributed to the verified trauma centers as follows:

$$[(.5 \times \text{funds}) / \text{Current total number of verified trauma centers}] + [(.5 \times \text{funds}) \times (\text{Trauma caseload volume for the verified trauma center for the year} / \text{The sum of trauma caseload volume for all verified trauma centers during the year})]$$

(c) Funds collected under Sections 318.18(15), 316.0083(1)(b)3.a. and 316.0083(1)(b)3.b., F.S., governed under this rule and deposited in accordance with Section 395.4036(1), F.S., ~~will shall~~ be distributed as follows:

1. through 3. No change.

(d) Funds collected under Sections 318.18(5)(c) and (20), F.S., governed under this rule ~~will shall~~ be distributed as follows.

1. through 3. No change.

(3) Hospitals that are not subject to audit pursuant to Section 215.97 F.S. and operate a verified trauma center that receives proceeds under Section 395.4036, F.S., must annually submit to the department an attestation stating the proceeds received by the hospital were used in compliance with Section 395.4036(3)(a), F.S.

*Rulemaking Authority 395.4036 FS. Law Implemented 395.4036 FS. History—New 4-25-06, Amended 1-9-07, Formerly 64E-2.040, Amended 10-22-09, 12-22-10, 12-21-15, \_\_\_\_\_.*