Article 13. Trauma Center Designation

R9-25-1301. Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

The following definitions apply in this Article, unless otherwise specified:

- 1. "ACS" means the American College of Surgeons Committee on Trauma.
- 2. "ACS site visit" means an on-site inspection of a trauma facility conducted by ACS for the purpose of determining compliance with ACS trauma facilities criteria, or ACS trauma facilities criteria and state standards, at the Level of designation sought.
- 3. "Administrative completeness time period" means the number of days from the Department's receipt of an application until the Department determines that the application contains all of the items of information required by rule to be submitted with an application.
- 4. "ATLS" means the ACS Advanced Trauma Life Support Course.
- 5. "Available" means accessible for use.
- 6. "Chief administrative officer" means an individual assigned to control and manage the day-to-day operations of a health care institution on behalf of the owner or the body designated by the owner to govern and manage the health care institution.
- 7. "CME" means continuing medical education courses for physicians.
- 8. "Comply with" means to satisfy the requirements of a stated provision.
- 9. "CT" means computed tomography.
- 10. "Current" means up-to-date and extending to the present time.
- 11. "CVP" means central venous pressure.
- 12. "Department" means the Arizona Department of Health Services.
- 13. "Designation" means a formal determination by the Department that a health care institution has the resources and capabilities necessary to provide trauma services at a particular Level and is a trauma center.
- 14. "EMS" means emergency medical services.
- 15. "Health care institution" has the same meaning as in A.R.S. § 36-401.
- 16. "Hospital" has the same meaning as in A.A.C. R9-10-201.
- 17. "ICU" means intensive care unit.
- 18. "In compliance with" means satisfying the requirements of a stated provision.
- 19. "In-house" means on the premises at the health care institution.
- 20. "ISS" means injury severity score, the sum of the squares of the abbreviated injury scale scores of the three most severely injured body regions.

- 21. "Major resuscitation" means a patient:
 - a. If an adult, with a confirmed blood pressure < 90 at any time or, if a child, with confirmed age-specific hypotension;
 - b. With respiratory compromise, respiratory obstruction, or intubation, if the patient is not transferred from another health care institution;
 - c. Who is transferred from another hospital and is receiving blood to maintain vital signs;
 - d. Who has a gunshot wound to the abdomen, neck, or chest;
 - e. Who has a Glasgow Coma Scale score < 8 with a mechanism attributed to trauma; or
 - f. Who is determined by an emergency physician to be a major resuscitation.
- 22. "Meet the ACS standards," "meeting the ACS standards," or "meets the ACS standards" means be operated, being operated, or is operated in compliance with each applicable criterion for verification as required by ACS for verification.
- 23. "Meet the state standards," "meeting the state standards," or "meets the state standards" means be operated, being operated, or is operated in compliance with each applicable criterion listed in Exhibit I at least as frequently or consistently as required by the minimum threshold stated for the criterion in Exhibit I or at least 95% of the time, whichever is less.
- 24. "On-call" means assigned to respond and, if necessary, come to a health care institution when called by health care institution personnel.
- 25. "Owner" means one of the following:
 - a. For a health care institution licensed under 9 A.A.C. 10, the licensee;
 - b. For a health care institution operated under federal or tribal laws, the administrative unit of the U.S. government or sovereign tribal nation operating the health care institution.
- 26. "Person" means:
 - a. An individual;
 - b. A business organization such as an association, cooperative, corporation, limited liability company, or partnership; or
 - c. An administrative unit of the U.S. government, state government, or a political subdivision of the state.
- 27. "Personnel" means an individual providing medical services, nursing services, or health-related services to a patient.
- 28. "PGY" means postgraduate year, a classification for residents in postgraduate training indicating the year that they are in during their post-medical-school residency program.
- 29. "Self-designated Level I trauma facility" means a health care institution that as of July 1, 2004, met the definition of a Level I trauma center under A.A.C. R9-22-2101(F)(1).
- 30. "SICU" means surgical intensive care unit.
- 31. "Signature" means:
 - a. A handwritten or stamped representation of an individual's name or a symbol intended to represent an individual's name, or
 - b. An "electronic signature" as defined in A.R.S. § 44-7002.

- 32. "Substantive review time period" means the number of days after completion of the administrative completeness time period during which the Department determines whether an application and owner comply with all substantive criteria required by rule for issuance of an approval.
- 33. "Transfer agreement" means a written contract between the owners of two health care institutions in which one owner agrees to have its health care institution receive a patient from the other owner's health care institution if the patient falls within specified criteria related to diagnosis, acuity, or treatment needs.
- 34. "Trauma center" has the same meaning as in A.R.S. § 36-2225.
- 35. "Valid" means that a license, certification, or other form of authorization is in full force and effect and not suspended or otherwise restricted.
- 36. "Verification" means formal confirmation by ACS that a health care institution has the resources and capabilities necessary to provide trauma services as a Level I, Level II, Level III, or Level IV trauma facility.
- 37. "Working day" means the period between 8:00 a.m. and 5:00 p.m. on a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.

R9-25-1302. Eligibility for Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. To be eligible to obtain designation for a health care institution, an owner shall:
 - 1. If applying for designation as a Level I trauma center:
 - a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level I trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level I trauma center;
 - 2. If applying for designation as a Level II trauma center:
 - a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level II trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level II trauma center;
 - 3. If applying for designation as a Level III trauma center:

- a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
- b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level III trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level III trauma center; and
- 4. If applying for designation as a Level IV trauma center:
 - a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate, issued by the Department under 9 A.A.C. 10; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution under federal or tribal law; and
 - b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level IV trauma facility; or
 - ii. Demonstrate, during an on-site survey of the health care institution conducted by the Department as described in R9-25-1310, that the health care institution meets the state standards for a Level IV trauma center.
- B. To be eligible to retain designation for a health care institution, an owner shall:
 - 1. Maintain a current and valid regular license for the health care institution to operate, if applicable; and
 - 2. Comply with the trauma center responsibilities in R9-25-1313.

R9-25-1303. Expired

R9-25-1304. Initial Application and Designation Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. An owner applying for initial designation shall submit to the Department an application including:
 - 1. An application form provided by the Department containing:
 - a. The name, address, and main telephone number of the health care institution for which the owner seeks designation;
 - b. The owner's name, address, and telephone number and, if available, fax number and e-mail address:
 - c. The name and telephone number and, if available, fax number and e-mail address of the chief administrative officer for the health care institution for which the owner seeks designation;
 - d. The designation Level for which the owner is applying;
 - e. If the owner holds verification for the health care institution for which designation is sought, the Level of verification held and the effective and expiration dates of the verification;
 - f. The asserted basis for designation:
 - i. The owner holds verification for the health care institution,
 - ii. The owner's health care institution meets the state standards, or
 - iii. The owner is eligible for the grace period under R9-25-1303;

- g. Unless the owner is an administrative unit of the U.S. government or a sovereign tribal nation, the hospital or health care institution license number for the health care institution for which designation is sought;
- h. If applying for designation as a Level I, Level II, or Level III trauma center, the name and telephone number and, if available, fax number and e-mail address of the health care institution's trauma medical director;
- i. The name, title, address, and telephone number of the owner's statutory agent or the individual designated by the owner to accept service of process and subpoenas;
- j. Attestation that the owner knows all applicable requirements in A.R.S. Title 36, Chapter 21.1 and this Article;
- k. Attestation that the information provided in the application, including the information in the documents attached to the application form, is accurate and complete; and
- 1. The dated signature of:
 - i. If the owner is an individual, the individual;
 - ii. If the owner is a corporation, an officer of the corporation;
 - iii. If the owner is a partnership, one of the partners;
 - iv. If the owner is a limited liability company, a manager or, if the limited liability company does not have a manager, a member of the limited liability company;
 - v. If the owner is an association or cooperative, a member of the governing board of the association or cooperative;
 - vi. If the owner is a joint venture, one of the individuals signing the joint venture agreement;
 - vii. If the owner is a governmental agency, the individual in the senior leadership position with the agency or an individual designated in writing by that individual; and
 - viii. If the owner is a business organization type other than those described in subsections (A)(1)(l)(ii) through (vi), an individual who is a member of the business organization;
- 2. Unless the owner is an administrative unit of the U.S. government or a sovereign tribal nation, a copy of the current regular hospital or health care institution license issued by the Department for the health care institution for which designation is sought;
- 3. If applying for designation based on verification, documentation issued by ACS establishing that the owner holds current verification for the health care institution at the Level of designation sought and showing the effective and expiration dates of the verification; and
- 4. If applying for designation as a Level I, Level II, or Level III trauma center based on meeting the state standards, current documentation issued by ACS establishing that the owner's health care institution meets the state standards listed in Exhibit I for the Level of designation sought.
- B. The Department shall process an application as provided in R9-25-1315.
- C. The Department shall approve designation if the Department determines that an owner is eligible for designation as described in R9-25-1302.

R9-25-1305. Eligibility for Provisional Designation; Provisional Designation Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

A. The owner of a health care institution may apply for one 18-month provisional designation as a Level I, Level II, or Level III trauma center if:

- 1. When the owner applies for provisional designation, the owner's health care institution has not produced at least 12 consecutive months of data related to trauma services provided at the health care institution; and
- 2. The owner cannot comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b).
- B. To be eligible to obtain provisional designation for a health care institution, an owner shall:
 - 1. Comply with one of the following:
 - a. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - b. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - 2. Make the attestations described in subsection (C)(2).
- C. An owner applying for provisional designation shall submit to the Department an application including:
 - 1. An application form that contains the information and items listed in R9-25-1304(A)(1)(a) through (A)(1)(d), (A)(1)(g) through (A)(1)(l), and (A)(2); and
 - 2. Attestation that:
 - a. The owner's health care institution has the resources and capabilities necessary to meet the state standards for the Level of designation sought and will meet the state standards for the Level of designation sought during the term of the provisional designation; and
 - b. During the term of the provisional designation, the owner will:
 - i. Ensure that the trauma center meets the state standards;
 - ii. Apply for verification for the trauma center; and
 - iii. Provide to the Department, within 30 days after applying for verification, documentation issued by ACS establishing that the owner has applied for verification.
- D. The Department shall process an application submitted under this Section as provided in R9-25-1315.
- E. The Department shall approve provisional designation if the Department determines that an owner is eligible for provisional designation as described in subsection (B).
- F. To be eligible to retain provisional designation for a health care institution, an owner shall:
 - 1. Comply with subsection (B)(1)(a) or (b);
 - 2. Comply with the trauma center responsibilities in R9-25-1313;
 - 3. Apply for verification for the trauma center; and
 - 4. Provide to the Department, within 30 days after applying for verification, documentation issued by ACS establishing that the owner has applied for verification.
- G. An owner who holds provisional designation and who desires to retain designation shall, before the expiration date of the provisional designation:
 - 1. If the owner can comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for initial designation under R9-25-1304; or

- 2. If the owner cannot comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for an extension of the provisional designation under subsection (H).
- H. An owner who holds provisional designation and who will not be able to comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b) on the expiration date of the provisional designation may apply to the Department, on a form provided by the Department, for one 180-day extension of the provisional designation and shall include with the application documentation issued by ACS showing the owner's progress in obtaining an ACS site visit.
- I. The Department shall grant an extension if an owner provides documentation issued by ACS:
 - 1. Establishing that the owner has applied for verification; and
 - 2. Showing the owner's progress in obtaining an ACS site visit.
- J. The Department may:
 - 1. Investigate, as provided under R9-25-1311, a trauma center that is the subject of a provisional designation; and
 - 2. Revoke, as provided under R9-25-1312, a provisional designation.

R9-25-1306. Designation Renewal Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. At least 60 days before the expiration date of a current designation, an owner who desires to obtain renewal of designation shall submit to the Department an application including:
 - 1. An application form that contains the information listed in R9-25-1304(A)(1);
 - 2. If applying for renewal of designation as a Level I, Level II, or Level III trauma center based on meeting the state standards, one of the following:
 - a. Documentation issued by ACS no more than 60 days before the date of application establishing that the owner's trauma center meets the state standards listed in Exhibit I for the Level of designation sought; or
 - b. Documentation issued by ACS establishing that the owner has applied for verification for the trauma center, at the Level corresponding to the Level of designation sought, for the three-year period directly following the expiration of the owner's current designation; and
 - 3. If applying for renewal of designation based on verification, documentation issued by ACS establishing that the owner:
 - a. Holds verification for the trauma center, at the Level corresponding to the Level of designation sought, for the three-year period directly following the expiration of the owner's current verification and designation; or
 - b. Has applied for verification for the trauma center, at the Level corresponding to the Level of designation sought, for the three-year period directly following the expiration of the owner's current verification and designation.
- B. The Department shall process an application as provided in R9-25-1315.
- C. The Department shall renew designation if the Department determines that the owner is eligible to retain designation as described in R9-25-1302(B).

D. The Department shall not renew designation based on verification or ACS's determination that a trauma center meets the state standards until the Department receives documentation that complies with subsection (A)(2)(a) or (A)(3)(a).

R9-25-1307. Term of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. The Department shall issue initial designation or renewal of designation:
 - 1. When based on verification, with a term beginning on the date of issuance and ending on the expiration date of the verification upon which designation is based; and
 - 2. When based on meeting the state standards or eligibility under R9-25-1303, with a term beginning on the date of issuance and ending three years later.
- B. The Department shall issue a provisional designation with a term beginning on the date of issuance and ending 18 months later and an extension of provisional designation with a term beginning on the expiration date of the provisional designation and ending 180 days later.
- C. The Department shall issue a modified designation with a term beginning on the date of issuance and ending on the expiration date of the designation issued before the application for modification of designation under R9-25-1309.
- D. If an owner submits an application for renewal of designation as described in R9-25-1306 before the expiration date of the current designation, or submits an application for extension of provisional designation as described in R9-25-1305 before the expiration date of the provisional designation, the current designation does not expire until the Department has made a final determination on the application for renewal of designation or extension of provisional designation.

R9-25-1308. Changes Affecting Designation Status (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. At least 30 days before the date of a change in a trauma center's name, the owner of the trauma center shall send the Department written notice of the name change.
- B. At least 90 days before a trauma center ceases to offer trauma services, the owner of the trauma center shall send the Department written notice of the intention to cease offering trauma services and the desire to relinquish designation.
- C. Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:
 - 1. For a notice described in subsection (A), issue an amended designation that incorporates the name change but retains the expiration date of the current designation; or
 - 2. For a notice described in subsection (B), send the owner written confirmation of the voluntary relinquishment of designation, with an effective date consistent with the written notice.
- D. An owner of a trauma center shall notify the Department in writing within three working days after:
 - 1. The trauma center's hospital or health care institution license expires or is suspended, revoked, or changed to a provisional license;
 - 2. A change in the trauma center's verification status; or

- 3. A change in the trauma center's ability to meet the state standards or, if designation is based on verification, to meet the ACS standards, that is expected to last for more than one week.
- E. An owner of a trauma center who obtains verification for the trauma center during a term of designation based on meeting the state standards may obtain a new initial designation based on verification, with a designation term based on the dates of the verification, by submitting an initial application as provided in R9-25-1304.

R9-25-1309. Modification of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. An owner of a trauma center who desires to obtain a designation that requires fewer resources and capabilities than the trauma center's current designation shall, at least 30 days before ceasing to provide trauma services consistent with the current designation, send the Department an application for modification of the trauma center's designation, including:
 - 1. The name, address, and main telephone number of the trauma center for which the owner seeks modification of designation;
 - 2. The owner's name, address, and telephone number and, if available, fax number and e-mail address;
 - 3. A list of the applicable ACS or state criteria for the current designation with which the owner no longer intends to comply;
 - 4. An explanation of the changes being made in the trauma center's resources or operations related to each criterion listed under subsection (A)(3);
 - 5. The state Level of designation requested;
 - 6. Attestation that the owner knows the state standards for the Level of designation requested and will ensure that the trauma center meets the state standards if modified designation is issued;
 - 7. Attestation that the information provided in the application is accurate and complete; and
 - 8. The dated signature of the owner, as prescribed in R9-25-1304(A)(1)(1).
- B. The Department shall process an application as provided in R9-25-1315.
- C. The Department shall issue a modified designation if the Department determines that, with the changes being made in the trauma center's resources and operations, the trauma center will meet the state standards for the Level of designation requested.
- D. An owner who obtains modified designation shall, during the term of the modified designation, ensure that the owner's trauma center meets the state standards that were the subject of the owner's attestation described in subsection (A)(6).

E. The Department may:

- 1. Investigate, as provided under R9-25-1311, a trauma center that is the subject of a modified designation; and
- 2. Revoke, as provided under R9-25-1312, a modified designation.
- F. An owner who holds modified designation shall, before the expiration date of the modified designation:

- 1. If the owner desires to retain designation based on the trauma center's meeting the state standards at the Level of the modified designation, apply for renewal of designation under R9-25-1306; or
- 2. If the owner desires to obtain designation based on verification or based on the trauma center's meeting the state standards at a Level other than the Level of the modified designation, apply for initial designation under R9-25-1304.

R9-25-1310. On-Site Survey for Designation as a Level IV Trauma Center Based on Meeting the State Standards (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. Before issuing initial or renewal designation to an owner applying for designation as a Level IV trauma center based on meeting the state standards, the Department shall complete an announced on-site survey of the owner's health care institution that includes:
 - 1. Reviewing equipment and the physical plant;
 - 2. Interviewing personnel; and
 - 3. Reviewing:
 - a. Medical records;
 - b. Patient discharge summaries;
 - c. Patient care logs;
 - d. Personnel rosters and schedules;
 - e. Performance-improvement-related documents other than peer review documents privileged under A.R.S. §§ 36-445.01 and 36-2403, including reports prepared as required under R9-10-204(B)(2) and the supporting documentation for the reports; and
 - f. Other documents relevant to the provision of trauma services as a Level IV trauma center and that are not privileged under federal or state law.
- B. A Department surveyor shall make a verbal report of findings to an owner upon completion of an on-site survey.
- C. Within 30 days after completing an on-site survey, the Department shall send to an owner a written report of the Department's findings, including a list of any deficiencies identified during the on-site survey and a request for a written corrective action plan.
- D. Within 10 days after receiving a request for a written corrective action plan, an owner shall submit to the Department a written corrective action plan that includes for each identified deficiency:
 - 1. A description of how the deficiency will be corrected, and
 - 2. A date of correction for the deficiency.
- E. The Department shall accept a written corrective action plan if it:
 - 1. Describes how each identified deficiency will be corrected, and
 - 2. Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.

R9-25-1311. Investigations (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4) and (5))

- A. If the Department determines based upon Trauma Registry data collected by the Department or receives a complaint alleging that a trauma center is not meeting the state standards or, if designation is based on verification, is not meeting the ACS standards, the Department shall conduct an investigation of the trauma center.
 - 1. The Department may conduct an announced or unannounced onsite survey as part of an investigation.
 - 2. Within 30 days after completing an investigation, the Department shall send to the owner of the trauma center investigated a written report of the Department's findings, including a list of any deficiencies identified during the investigation and a request for a written corrective action plan.
- B. Within 10 days after receiving a request for a written corrective action plan, an owner shall submit to the Department a written corrective action plan that includes for each identified deficiency:
 - 1. A description of how the deficiency will be corrected, and
 - 2. A date of correction for the deficiency.
- C. The Department shall accept a written corrective action plan if it:
 - 1. Describes how each identified deficiency will be corrected, and
 - 2. Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.

R9-25-1312. Denial or Revocation of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. The Department may deny or revoke designation if an owner:
 - 1. Has provided false or misleading information to the Department;
 - 2. Is not eligible for designation under R9-25-1302(A) or (B) or, if applicable, R9-25-1305(B) or (F);
 - 3. Fails to submit to the Department all of the information requested in a written request for additional information within the time prescribed in R9-25-1315 and Table 1;
 - 4. Fails to submit a written corrective action plan as requested and required under R9-25-1310 or R9-25-1311;
 - 5. Fails to comply with a written corrective action plan accepted by the Department under R9-25-1310 or R9-25-1311;
 - 6. Fails to allow the Department to enter the premises of the owner's health care institution, to interview personnel, or to review documents that are not documents privileged under federal or state law; or
 - 7. Fails to comply with any applicable provision in A.R.S. Title 36, Chapter 21.1 or this Article.
- B. In determining whether to deny or revoke designation, the Department shall consider:

- 1. The severity of each violation relative to public health and safety;
- 2. The number of violations;
- 3. The nature and circumstances of each violation;
- 4. Whether each violation was corrected, the manner of correction, and the duration of the violation; and
- 5. Whether the violations indicate a lack of commitment to having the trauma center meet the state standards or, if applicable, the ACS standards.
- C. If the Department denies or revokes designation, the Department shall send to the owner a written notice setting forth the information required under A.R.S. § 41-1092.03.
 - 1. An owner may file a written notice of appeal with the Department within 30 days after receiving a notice of denial or revocation, as provided in A.R.S. § 41-1092.03.
 - 2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

R9-25-1313. Trauma Center Responsibilities (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4), (5), and (6))

The owner of a trauma center shall ensure that:

- 1. The trauma center meets the state standards or, if designation is based on verification, meets the ACS standards;
- 2. Data related to the trauma services provided at the trauma center are submitted to the Department's Trauma Registry as required by the Department;
- 3. The owner and the trauma center staff comply with the applicable provisions of A.R.S. Title 36, Chapter 21.1 and this Article; and
- 4. The owner and the trauma center staff comply with all applicable federal and state laws relating to confidentiality of information.

R9-25-1314. Confidentiality of Information (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4) and (6))

The Department shall comply with all applicable federal and state laws relating to confidentiality of information.

R9-25-1315. Application Processing Time Periods (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. The application processing time periods for each type of approval granted by the Department under this Article are listed in Table 1 and may be extended through a written agreement between an owner and the Department.
- B. The Department shall, within the administrative completeness time period specified in Table 1, review each application submitted for administrative completeness.

- 1. If an application is incomplete, the Department shall send to the owner a written notice listing each deficiency and the information or items needed to complete the application.
- 2. If an owner fails to submit to the Department all of the information or items listed in a notice of deficiencies within the time period specified in Table 1, the Department shall consider the application withdrawn.
- C. After determining that an application is administratively complete, the Department shall review the application for substantive compliance with the requirements for approval.
 - 1. The Department shall complete its substantive review of each application, and send an owner written notice of approval or denial, within the substantive review time period specified in Table 1.
 - 2. As part of the substantive review for an application for initial designation or renewal of designation as a Level IV trauma center based on meeting the state standards, the Department shall conduct an announced onsite survey of the health care institution or trauma center as described in R9-25-1310.
 - 3. An owner applying for renewal of designation who submits documentation of the owner's having applied for verification as permitted under R9-25-1306(A)(2)(b) or (A)(3)(b) shall submit to the Department during the substantive review time period documentation that complies with R9-25-1306(A)(2)(a) or (A)(3)(a).
 - 4. During the substantive review time period, the Department may make one written request for additional information, listing the information or items needed to determine whether to approve the application, including, for an owner applying for renewal described in subsection (C)(3), a request for documentation that complies with R9-25-1306(A)(2)(a) or (A)(3)(a).
 - 5. For an application for initial designation or renewal of designation as a Level IV trauma center based on meeting the state standards, a written request for additional information may include a request for a corrective action plan to correct any deficiencies identified during an onsite survey of the health care institution or trauma center.
 - 6. If an owner fails to submit to the Department all of the information or items listed in a written request for additional information, including, if applicable, a corrective action plan, within the time period specified in Table 1, the Department shall deny the application.

D. In applying this Section, the Department shall:

- 1. In calculating an owner's time to respond, begin on the postmark date of a notice of deficiencies or written request for additional information and end on the date that the Department receives all of the information or documents requested in the notice of deficiencies or written request for additional information; and
- 2. In calculating the Department's time periods, not include any time during which the Department is waiting for an owner to submit information or documents to the Department as requested by the Department in a notice of deficiencies or written request for additional information.
- E. If the Department denies an application, the Department shall send to the owner a written notice of denial setting forth the information required under A.R.S. § 41-1092.03.
 - 1. An owner may file a written notice of appeal with the Department within 30 days after receiving the notice of denial, as provided in A.R.S. § 41-1092.03.

2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

Table 1. Application Processing Time Periods (in days) (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

Type of Approval	Department's Administrative Completeness Time Period	Owner's Time to Respond to Notice of Deficiencies	Department's Substantive Review Time Period	Owner's Time to Respond to Written Request for Additional Information
Initial Designation (R9-25-1304)	30	30	90	60
Provisional Designation (R9-25-1305)	30	30	90	60
Extension of Provisional Designation (R9-25-1305)	15	30	15	30
Renewal of Designation (R9-25-1306)	30	30	90	120
Modification of Designation (R9-25-1309)	30	30	90	60

Exhibit I. Arizona Trauma Center Standards (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

E = Essential and required

		Levels				
Trauma Facilities Criteria	I	II	III	IV		
A. Institutional Organization						
1. Trauma program	Е	E	E	-		
2. Trauma service	Е	E	E	-		
3. Trauma team	E	E	E	E		
4. Trauma program medical director1	E	E	E	-		
5. Trauma multidisciplinary committee	E	Е	E	-		
6. Trauma coordinator/trauma program manager2	Е	Е	E	E		
B. Hospital Departments/Divisions/Sections						
1. Surgery	E	E	E	-		
2. Neurological surgery	Е	Е	-	-		
a. Neurosurgical trauma liaison	Е	Е	i -	-		
3. Orthopaedic surgery	E	Е	Е	-		
a. Orthopaedic trauma liaison	E	E	E	-		
4. Emergency medicine	E	E	E	-		
a. Emergency medicine liaison3	E	E	E	-		
5. Anesthesia	E	E	E	-		
C. Clinical Capabilities						
1. Published on-call schedule for each listed specialty required in (C)(2) and (3)	E	E	E	_		
2. Specialty immediately available 24 hours/day						
a. General surgery4	E	Е	Е	-		
i. Published back-up schedule	E	E	-	-		
ii. Dedicated to single hospital when on-call	E	Е	-	-		
b. Anesthesia5	E	Е	Е	-		
c. Emergency medicine6	E	Е	Е	-		
3. On-call and promptly available 24 hours/day7						
a. Cardiac surgery8	E	-	-	-		
b. Hand surgery	E	Е	ll	-		
c. Microvascular/replant surgery	E_					
d. Neurologic surgery	E_	Е	-	_		
i. Dedicated to one hospital or back-up call	E	E		-		
e. Obstetrics/gynecologic surgery	Е	-	-	-		
f. Ophthalmic surgery	Е	Е	-	-		
g. Oral/maxillofacial surgery9	Е	Е	-	-		

	Lev	els		
Trauma Facilities Criteria	I	II	III	IV
h. Orthopaedic surgery	Е	Е	Е	-
i. Dedicated to one hospital or back-up call	E	Е	-	-
i. Plastic surgery	E	E	-	-
j. Critical care medicine	E	Е	-	-
k. Radiology	E	E	E	-
1. Thoracic surgery	E	Е		
D. Clinical Qualifications				
1. General/Trauma Surgeon				
a. Board certification10	Е	Е	Е	-
b. 16 hours CME/year11	Е	Е	-	-
c. ATLS certification12	Е	Е	Е	Е
d. Multidisciplinary peer review committee attendance > 50%13	Е	Е	Е	-
2. Emergency Medicine3				
a. Board certification10	Е	Е	-	-
b. Trauma education - 16 hours CME/year11	E	Е		-
c. ATLS certification12	E	Е	E	E
d. Multidisciplinary peer review committee attendance > 50%13	E	Е	E	-
3. Neurosurgery				
a. Board certification	Е	Е	-	-
b. 16 hours CME/year11	Е	E	-	-
c. Multidisciplinary peer review committee attendance > 50%13	Е	Е	Е	-
4. Orthopaedic Surgery				
a. Board certification	Е	Е	-	-
b. 16 hours CME/year in skeletal trauma11	Е	Е	-	-
c. Multidisciplinary peer review committee attendance > 50%13	Е	Е	Е	-
E. Facilities/Resources/Capabilities				
1. Volume Performance14	E			
2. Presence of surgeon at resuscitation (immediately available)15	E	E	<u> </u>	
3. Presence of surgeon at resuscitation (promptly available)16	_	-	Е	-
4. Presence of surgeon at operative procedures	E	Е	Е	Е
5. Emergency Department				
a. Personnel				
i. Designated physician director	Е	Е	Е	-
b. Resuscitation Equipment for Patients of All Ages				
i. Airway control and ventilation equipment	Е	Е	Е	Е
ii. Pulse oximetry	Е	E	E	Е
iii. Suction devices	Е	Е	Е	E

uma Facilities Criteria			Levels			
unia i acintics Criteria	I	II	III			
iv. Electrocardiograph-oscilloscope-defibrillator	E	Е	E			
v. Internal paddles	E	Е	E	Ī		
vi. CVP monitoring equipment	E	E	E	-		
vii. Standard intravenous fluids and administration sets	E	E	E	-		
viii. Large-bore intravenous catheters	E	E	E	_		
ix. Sterile Surgical Sets for						
(1) Airway control/cricothyrotomy	Е	Е	E			
(2) Thoracostomy	Е	Е	Е			
(3) Venous cutdown	E	Е	Е			
(4) Central line insertion	E	Е	Е			
(5) Thoracotomy	Е	Е	Е			
(6) Peritoneal lavage	Е	Е	Е	-		
x. Arterial catheters	E	Е	-	-		
xi. Drugs necessary for emergency care	E	Е	Е	_		
xii. X-ray availability 24 hours/day	E	Е	Е	_		
xiii. Broselow tape	E_	Е	E	_		
xiv. Thermal Control Equipment				_		
(1) For patient	Е	Е	Е			
(2) For fluids and blood	E	Е	E			
xv. Rapid infuser system	E	Е	Е			
xvi. Qualitative end-tidal CO2 determination	Е	Е	Е	_		
c. Communication with EMS vehicles	Е	Е	Е	-		
d. Capability to resuscitate, stabilize, and transport pediatric patients17	E	Е	Е	=		
6. Operating Room				=		
a. Immediately available 24 hours/day	E	Е	-	_		
b. Personnel				-		
i. In-house 24 hours/day18	E			_		
ii. Available 24 hours/day19		E	E			
c. Age-Specific Equipment				_		
i. Cardiopulmonary bypass	E	-	-			
ii. Operating microscope	E	-	_			
d. Thermal Control Equipment						
i. For patient	E	Е	Е			
ii. For fluids and blood	E	E	E			
e. X-ray capability including C-arm image intensifier		E	E			
f. Endoscopes, bronchoscope	E	E	E	_		
g. Craniotomy instruments	E	E				

uma Facilities Criteria	Lev			
ma racinues entena	I	II	III	
h. Equipment for long bone and pelvic fixation	E	Е	E	٦
i. Rapid infuser system	E	E	E	Ī
7. Postanesthetic Recovery Room (SICU is acceptable)				
a. Registered nurses available 24 hours/day	E	E	E	
b. Equipment for monitoring and resuscitation	E	E_	E	_
c. Intracranial pressure monitoring equipment	E	E	<u> </u>	_
i. Pulse oximetry	Е	E	E	
ii. Thermal control	Е	Е	Е	
8. Intensive or Critical Care Unit for Injured Patients				
a. Registered nurses with trauma training	Е	Е	Е	
b. Designated surgical director or surgical co-director	E	Е	E	Ī
c. Surgical ICU service physician in-house 24 hours/day20	Е	-	-	_
d. Surgically directed and staffed ICU service20	E	E	-	-
e. Equipment for monitoring and resuscitation	E	E	E	_
f. Intracranial pressure monitoring equipment	E	E	 	_
g. Pulmonary artery monitoring equipment	E	E	E	_
9. Respiratory Therapy Services				_
a. Available in-house 24 hours/day	Е	Е	-	
b. On-call 24 hours/day	_	-	E	
10. Radiological Services (Available 24 hours/day)				=
a. In-house radiology technologist	E	Е	-	
b. Angiography	Е	Е	-	
c. Sonography	E	Е	Е	_
d. Computed tomography	E	E	E	-
i. In-house CT technician	E	E	-	_
e. Magnetic resonance imaging	E	 	-	_
11. Clinical Laboratory Service (Available 24 hours/day)				_
a. Standard analyses of blood, urine, and other body fluids, including	T.		-	_
microsampling when appropriate	E	E	E	
b. Blood typing and cross-matching	E	E	E	
c. Coagulation studies	Е	E	E	
d. Comprehensive blood bank or access to a community central blood bank and adequate storage facilities	E	E	E	
e. Blood gases and pH determinations	Е	Е	Е	=
f. Microbiology	E	Е	Е	
12. Acute Hemodialysis				_
a. In-house	Е	-	-	
b. Transfer agreement		E	E	_

Гrauma Facilities Criteria	Lev	els		
Trauma Facilities Citteria	I	II	III	Γ
13. Burn CareOrganized				
a. In-house or transfer agreement with burn center	Е	E	E	E
14. Acute Spinal Cord Management				
 a. In-house or transfer agreement with regional acute spinal cord injury rehabilitation center 	Е	Е	Е	E
F. Rehabilitation Services				
1. Transfer agreement to an approved rehabilitation facility	E	Е	Е	F
2. Physical therapy	E	E	E	-
3. Occupational therapy	E	E	-	-
4. Speech therapy	E	E	-	-
5. Social Services	E	Е	Е	-
G. Performance Improvement				
1. Performance improvement programs	Е	Е	E	I
2. Trauma Registry				Ī
a. In-house	Е	Е	Е	1
b. Participation in state, local, or regional registry	E	Е	Е]
3. Audit of all trauma deaths	E_	E	E]
4. Morbidity and mortality review	E	E	E]
5. Trauma conference - multidisciplinary	E	E	E	ļ.
6. Medical nursing audit	E	Е	Е	I
7. Review of prehospital trauma care	E	E	E	-
8. Review of times and reasons for trauma-related bypass	Е	Е	-	-
9. Review of times and reasons for transfer of injured patients	E	Е	Е	I
10. Performance improvement personnel dedicated to care of injured patients	Е	Е	-	-
I. Continuing Education/Outreach				
1. Outreach activities21	Е	E	-	F
2. Residency program22	E	-	-	ŀ
3. ATLS provide/participate23	 E	<u> </u>	<u> </u>	╬-
4. Programs provided by hospital for:				
a. Staff/community physicians (CME)	E	Е	E24	
b. Nurses	_ E_	E	E	-
c. Allied health personnel	E	E	E	-
d. Prehospital personnel provision/participation	E	Е	Е	-
. Prevention				
1. Prevention program25	E	E	-	Ī.
2. Collaboration with existing national, regional, state, and community programs26	E	E	E	
J. Research		-11	-11	L

Trauma Facilities Criteria		Levels				
Trauma Facilities Criteria	I	II	III	IV		
1. Research program27	Е	-	-	-		
2. Trauma registry performance improvement activities	E	Е	Е	-		
3. Identifiable Institutional Review Board process	E	-	-	-		
4. Extramural education presentations	E28	-	_	-		
K. Additional Requirements for Trauma Centers Represented as Caring for Pediatric						
Trauma Patients29						
1. Trauma surgeons credentialed for pediatric trauma care	E	E	_	-		
2. Pediatric emergency department area	E	E		-		
3. Pediatric resuscitation equipment in all patient care areas	E	E		-		
4. Microsampling	Е	E	E	-		
5. Pediatric-specific performance improvement program	Е	Е	Е	Е		
6. Pediatric intensive care unit	E30	E31	-	-		

- 1. An individual may not serve as trauma medical director for more than one trauma center at the same time.
- 2. For a Level I trauma center, this shall be a full-time position.
- 3. This does not apply if emergency medicine physicians do not participate in the care of a hospital's trauma patients.
- 4. For this criterion, "immediately available" means that:
 - 1. For a Level I trauma center, a PGY 4 or 5 surgery resident or a trauma surgeon is on the hospital premises at all times; and
 - 2. For all major resuscitations in a Level I, II, or III trauma center:
 - a. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
 - b. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department:
 - i. For a Level I or II trauma center, no later than 15 minutes after patient arrival; or
 - ii. For a Level III trauma center, no later than 30 minutes after patient arrival.

The minimum threshold for compliance with #2 is 80%.

A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

- 5. For this criterion, "immediately available" means that:
 - 1. For a Level I trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is on the hospital premises at all times;
 - 2. For a Level II trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department no later than 15 minutes after patient arrival;

- 3. For a Level III trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department no later than 30 minutes after patient arrival; and
- 4. For a Level I, II, or III trauma center, an anesthesiologist is present for all surgeries.
- 6. For this criterion, "immediately available" means that an emergency medicine physician is physically present in the emergency department at all times. However, if emergency medicine physicians do not participate in the care of a hospital's trauma patients, an emergency medicine physician is not required to be immediately available 24 hours per day.
- 7. For the criteria in (C)(3)(a)-(1), "promptly available" means that:
 - 1. A physician specialist is present in the emergency department no later than 45 minutes after notification, based on patient need; or
 - 2. For hand surgery and microvascular/replant surgery, the owner has transfer agreements to ensure that a patient in need of hand surgery or microvascular/replant surgery can be expeditiously transferred to a health care institution that has a hand surgeon or microvascular/replant surgeon on the premises.
- 8. This criterion is satisfied by a physician authorized by the hospital to perform cardiothoracic surgery.
- 9. This criterion is satisfied by a dentist or physician authorized by the hospital to perform oral and maxillofacial surgery. If a physician, the individual shall be a plastic surgeon or an otolaryngologist.
- 10. In a Level I or II trauma center, a non-board-certified physician may be included in the trauma service if the physician:
 - 1. If a surgeon, is in the examination process by the American Board of Surgery;
 - 2. If the trauma medical director, is a Fellow of ACS;
 - 3. Unless the trauma medical director, complies with the following:
 - a. Has a letter written by the trauma medical director demonstrating that the health care institution's trauma program has a critical need for the physician because of the physician's individual experience or the limited physician resources available in the physician's specialty;
 - b. Has successfully completed an accredited residency training program in the physician's specialty, as certified by a letter from the director of the residency training program;
 - c. Has current ATLS certification as a provider or instructor, as established by documentation;
 - d. Has completed 48 hours of trauma CME within the past three years, as established by documentation;
 - e. Has attended at least 50% of the trauma quality assurance and educational meetings, as established by documentation;
 - f. Has been a member or attended local, regional, and national trauma organization meetings within the past three years, as established by documentation;
 - g. Has a list of patients treated over the past year with accompanying ISS and outcome for each;
 - h. Has a quality assurance assessment by the trauma medical director showing that the morbidity and mortality results for the physician's patients compare favorably with the morbidity and mortality results for comparable patients treated by other members of the trauma service; and
 - i. Has full and unrestricted privileges in the physician's specialty and in the department with which the physician is affiliated; or

- 4. Complies with the following:
 - a. Has provided exceptional care of trauma patients, as established by documentation such as a quality assurance assessment by the trauma medical director;
 - b. Has numerous publications, including publication of excellent research;
 - c. Has made numerous presentations; and
 - d. Has provided excellent teaching, as established by documentation.

In a Level III trauma center, only the trauma medical director is required to be board-certified.

- 11. This criterion applies only to the trauma medical director, the emergency medicine liaison, the neurosurgical trauma liaison, and the orthopaedic trauma liaison. This criterion is satisfied by an average of 16 hours annually, or 48 hours over three years, of verifiable external trauma-related CME. External CME includes programs given by visiting professors or invited speakers and teaching an ATLS course.
- 12. Among the trauma surgeons, only the trauma medical director is required to have current ATLS certification. The other trauma surgeons are required to have held ATLS certification at one time. Among the emergency medicine physicians, only non-board-certified physicians are required to have current ATLS certification. The other emergency medicine physicians are required to have held ATLS certification at one time.
- 13. Among the trauma surgeons, 50% attendance is required for each member of the trauma surgical core group. In the other specialty areas, 50% attendance is required only for the emergency medicine liaison, the neurosurgical trauma liaison, and the orthopaedic trauma liaison.
- 14. Except for Level I trauma centers that care only for pediatric patients, each Level I trauma center shall satisfy one of the following volume performance standards:
 - 1. 1200 trauma admissions per year,
 - 2. 240 admissions with ISS > 15 per year, or
 - 3. An average of 35 patients with ISS > 15 for the trauma panel surgeons per year.

Burn patients may be included in annual trauma admissions if the trauma service, not a separate burn service, is responsible for burn care in the trauma center.

- 15. For this criterion, "immediately available" means that for all major resuscitations in a Level I or II trauma center:
 - 1. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
 - 2. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department no later than 15 minutes after patient arrival.

The minimum threshold for compliance with this criterion is 80%.

A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

16. For this criterion, "promptly available" means that for all major resuscitations in a Level III trauma center:

- 1. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
- 2. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department no later than 30 minutes after patient arrival.

The minimum threshold for compliance with this criterion is 80%.

A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

- 17. A trauma center that does not admit pediatric patients shall be capable of resuscitating, stabilizing, and transporting pediatric trauma patients.
- 18. A Level I trauma center shall have a complete operating room team in the hospital at all times, so that an injured patient who requires operative care can receive it in the most expeditious manner. The members of the operating room team shall be assigned to the operating room as their primary function; they cannot also be dedicated to other functions within the institution.
- 19. A Level II trauma center shall have a complete operating room team available when needed. The need to have an in-house operating room team depends on a number of things, including the patient population served, the ability to share responsibility for operating room coverage with other hospital staff, prehospital communication, and the size of the community served by the trauma center. If an out-of-house operating room team is used, then this aspect of care shall be monitored by the performance improvement program.
- 20. This requirement may be satisfied by a physician authorized by the hospital to admit patients into the intensive care unit as the attending physician or to perform critical care procedures.
- 21. This requirement is met through having an independent outreach program or participating in a collaborative outreach program. "Collaborative outreach program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating hospitals educate the general public or current or prospective physicians, nurses, prehospital providers, or allied health professionals regarding injury prevention, trauma triage, interfacility transfer of trauma patients, or trauma care.
- 22. A Level I trauma center shall have a functional and documented teaching commitment. This requirement may be met through:
 - 1. A trauma fellowship program; or
 - 2. Active participation with one of the following types of residency programs in emergency medicine, general surgery, orthopaedic surgery, or neurosurgery:
 - a. An independent residency program;
 - b. A regional residency rotation program; or
 - c. A collaborative residency program that includes multiple hospitals, with each non-sponsor participating hospital hosting at least one rotation.
- 23. This requirement is met through participating in the provision of ATLS courses and having ATLS instructors on staff.
- 24. When a Level III trauma center is in an area that contains a Level I or Level II trauma center, this is not required.

- 25. This requirement is met through having an independent prevention program or participating in a collaborative prevention program. "Collaborative prevention program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating health care institutions promote injury prevention through primary, secondary, or tertiary prevention strategies. An independent or collaborative prevention program shall include:
 - 1. Conducting injury control studies,
 - 2. Monitoring the progress and effect of the prevention program,
 - 3. Providing information resources for the public, and
 - 4. Each participating hospital's designating a prevention coordinator who serves as the hospital's spokesperson for prevention and injury control activities.
- 26. This requirement is met through participating in a prevention program organized at the national, regional, state, or local community level.
- 27. This requirement is met through having an independent research program or participating in a collaborative research program. "Collaborative research program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating hospitals systematically investigate issues related to trauma and trauma care. Injury control studies are considered to be research program activities if they have a stated focused hypothesis or research question.
- 28. The trauma program shall provide at least 12 educational presentations every three years outside the academically affiliated institutions of the trauma center.
- 29. A trauma center is required to comply with the requirements of (K)(1) through (6), in addition to the requirements in (A) through (J), if the trauma center is represented as caring for pediatric trauma patients. "Represented as caring for pediatric trauma patients" means that a trauma center's availability or capability to care for pediatric trauma patients is advertised to the general public, health care providers, or emergency medical services providers through print media, broadcast media, the Internet, or other means such as the EMSystem, administered by the Department.
- 30. The trauma center shall have a PICU available on-site.
- 31. This requirement may be satisfied by a transfer agreement.

Article 14. Trauma Registry; Trauma System Quality Assurance

R9-25-1401. Definitions (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2221, and 36-2225(A)(5) and (6))

The following definitions apply in this Article, unless otherwise specified:

- 1. "Aggregate trauma data" means a collection of data from the trauma registry that is compiled so that it is not possible to identify a particular trauma patient, trauma patient's family, health care provider, or health care institution.
- 2. "AIS" means abbreviated injury scale, an anatomic severity scoring system established in Association for the Advancement of Automotive Medicine Committee on Injury Scaling, Abbreviated Injury Scale (AIS) 2005 (2005), incorporated by reference, including no future editions or amendments, and available from Association for the Advancement of Automotive Medicine, P.O. Box 4176, Barrington, IL 60011-4176, and www.carcrash.org.
- 3. "ALS base hospital" has the same meaning as "advanced life support base hospital" in A.R.S. 36-2201.
- 4. "Case" means a patient who meets R9-25-1402(A)(1), (2), or (3).
- 5. "Category" means a group of related codes within the ICD-9-CM, identified by the first three digits of each code number within the group, and including all code numbers that share the same first three digits.
- 6. "Data element" means a categorized piece of information.
- 7. "Data set" means a collection of data elements that includes, for each case, data that complies with Table 1.
- 8. "Department" means the Arizona Department of Health Services.
- 9. "ED" means emergency department, an organized area of a hospital that provides unscheduled emergency services, as defined in A.A.C. R9-10-201, 24 hours per day, seven days per week, to individuals who present for immediate medical attention.
- 10. "EMS" has the same meaning as "emergency medical services" in A.R.S. § 36-2201.
- 11. "EMS provider" has the same meaning as "emergency medical services provider" in A.R.S. § 36-2201.
- 12. "GCS" means Glasgow Coma Scale, a scoring system that defines eye, motor, and verbal responses in the patient with injury.
- 13. "Health care institution" has the same meaning as in A.R.S. § 36-401.
- 14. "Health care provider" means a caregiver involved in the delivery of trauma services to a patient, whether in a prehospital setting, in a hospital setting, or during rehabilitation.
- 15. "Hospital" has the same meaning as in A.A.C. R9-10-201.
- 16. "ICD-9-CM" has the same meaning as in A.A.C. R9-4-101.

- 17. "ICD-9-CM E-code" means the external cause of injury as coded according to the ICD-9-CM.
- 18. "ICD-9-CM N-code" means the nature of injury as coded according to the ICD-9-CM.
- 19. "ICD-9-CM Procedure Code" means the procedure performed on a patient as coded according to the ICD-9-CM.
- 20. "Injury" means the result of an act that damages, harms, or hurts; unintentional or intentional damage to the body resulting from acute exposure to mechanical, thermal, electrical, or chemical energy or from the absence of such essentials as heat or oxygen.
- 21. "ISS" has the same meaning as in R9-25-1301.
- 22. "Owner" has the same meaning as in R9-25-1301.
- 23. "Patient" means an individual who is sick, injured, or dead and who requires medical monitoring, medical treatment, or transport.
- 24. "Scene" means a location, other than a health care institution, from which a patient is transported.
- 25. "Submitting health care institution" means a health care institution that submits data to the trauma registry as provided in R9-25-1402.
- 26. "Trauma center" means a health care institution that meets the definition of "trauma center" in A.R.S. § 36-2201 or the definition of "trauma center" in A.R.S. § 36-2225.
- 27. "Trauma registry" has the same meaning as in A.R.S. § 36-2201.
- 28. "Trauma team" means a group of health care providers organized to provide care to trauma patients.
- 29. "Trauma team activation" means notification of trauma team members in response to triage information received concerning a patient with injury or suspected injury.
- 30. "Trauma triage protocol" means a "triage protocol," as defined in R9-25-101, specifically designed for use with patients with injury.

R9-25-1402. Data Submission Requirements (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2221, and 36-2225(A)(5) and (6))

- A. As required under A.R.S. § 36-2221 and R9-25-1313, an owner of a trauma center shall ensure that the data set identified in Table 1 is submitted to the Department, as prescribed in subsection (B), for each patient who meets one or more of the following criteria:
 - 1. A patient with injury or suspected injury who is triaged from a scene to a trauma center or ED based upon the responding EMS provider's trauma triage protocol;
 - 2. A patient with injury or suspected injury for whom a trauma team activation occurs; or
 - 3. A patient with injury who is admitted as a result of the injury or who dies as a result of the injury, who has an ICD-9-CM N-code within categories 800 through 959, and who does not only have:
 - a. Late effects of injury or another external cause, as demonstrated by an ICD-9-CM N-code within categories 905 through 909;

- b. A superficial injury or contusion, as demonstrated by an ICD-9-CM N-code within categories 910 through 924;
- c. Effects of a foreign body entering through an orifice, as demonstrated by an ICD-9-CM N-code within categories 930 through 939;
- d. An isolated femoral neck fracture from a same-level fall, as demonstrated by:
- i. An ICD-9-CM N-code within category 820; and
- ii. An ICD-9-CM E-code within category E885 or E886;
- e. An isolated distal extremity fracture from a same-level fall, as demonstrated by:
- i. An ICD-9-CM N-code within categories 813 through 817 or within categories 823 through 826; and
- ii. An ICD-9-CM E-code within category E885 or E886;
- f. An isolated burn, as demonstrated by an ICD-9-CM N-code within categories 940 through 949.
- B. An owner of a trauma center shall submit the data required under subsection (A) to the Department:
 - 1. On a quarterly basis according to the following schedule:
 - a. For cases identified between January 1 and March 31, so that it is received by the Department by July 1 of the same calendar year;
 - b. For cases identified between April 1 and June 30, so that it is received by the Department by October 1 of the same calendar year;
 - c. For cases identified between July 1 and September 30, so that it is received by the Department by January 2 of the following calendar year; and
 - d. For cases identified between October 1 and December 31, so that it is received by the Department by April 1 of the following calendar year;
 - 2. Through an electronic reporting system authorized by the Department;
 - 3. In a format authorized by the Department; and
 - 4. Along with the following information:
 - a. The name and physical address of the trauma center;
 - b. The date the trauma data is being submitted to the Department;
 - c. The total number of cases for whom trauma data is being submitted;
 - d. The quarter and year for which trauma data is being submitted;
 - e. The range of ED or hospital arrival dates for the cases for whom trauma data is being submitted:
 - f. The name, title, phone number, fax number, and e-mail address of the trauma center's point of contact for the trauma data; and
 - g. Any special instructions or comments to the Department from the trauma center's point of contact.
- C. An ALS base hospital certificate holder that chooses to submit trauma data to the Department, as provided in A.R.S. § 36-2221, shall comply with the data submission requirements in this Section for an owner of a trauma center.

R9-25-1403. Trauma System Data Reports; Requests for Trauma Registry Reports (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2220(A), 36-2221, and 36-2225(A)(5) and (6))

A. The Department shall produce and disseminate to each submitting health care institution a quarterly trauma system data report that includes statewide aggregate trauma data.

- B. A person may request to receive a report containing statewide aggregate trauma data for data elements not included in the quarterly trauma system data report by submitting a written public records request to the Department as provided in A.A.C. R9-1-303.
- C. The Department shall process a request for a report submitted under subsection (B) as provided in A.A.C. R9-1-303.
- D. As provided in A.R.S. § 36-2220(A)(1), Trauma Registry data from which a patient, the patient's family, or the patient's health care provider or facility might be identified is confidential and is not available to the public.

R9-25-1404. Retention of Reports and Requests for Reports (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2221, and 36-2225(A)(5) and (6))

The Department shall retain copies of each quarterly trauma system data report, request for a report submitted under R9-25-1403(B), and report generated under R9-25-1403(B) for at least 10 years after the date of the report or request for a report.

R9-25-1405. Confidentiality and Retention of Trauma System Quality Assurance Data (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2220(A), 36-2221, 36-2222(E)(3), 36-2225(A)(5) and (6), 36-2403(A), and 36-2404)

A. As provided in A.R.S. §§ 36-2220(A)(2) and 36-2403(A), all data and documents obtained by the Department or considered by the Department, the State Trauma Advisory Board, or a State Trauma Advisory Board subcommittee for purposes of trauma system quality assurance are confidential and are not available to the public.

B. The Department shall ensure that:

- 1. Each member of the State Trauma Advisory Board or member of a State Trauma Advisory Board subcommittee who will have access to the data and documents described in subsection (A) executes a written confidentiality statement before being allowed access to the data and documents;
- 2. All trauma system quality assurance activities are completed in executive session during State Trauma Advisory Board or State Trauma Advisory Board subcommittee meetings;
- 3. Except for one historical copy, all copies of data and documents described in subsection (A) and used during an executive session are collected at the end of the executive session and destroyed after the State Trauma Advisory Board or State Trauma Advisory Board subcommittee meeting; and
- 4. Executive session minutes and all copies of data and documents described in subsection (A) are maintained in a secure area and are accessible only to authorized Department employees.

R9-25-1406. Trauma Registry Data Quality Assurance (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2220(A), 36-2221, and 36-2225(A)(5) and (6))

- A. To ensure the completeness and accuracy of trauma registry reporting, a submitting health care institution shall allow the Department to review the following, upon prior notice from the Department of at least five business days:
 - 1. The submitting health care institution's database that includes data regarding cases;
 - 2. Patient medical records; and

- 3. Any record, other than those specified in subsections (A)(1) and (2), that may contain information about diagnostic evaluation or treatment provided to a patient.
- B. Upon prior notice from the Department of at least five business days, a submitting health care institution shall provide the Department with all of its patient medical records for a time period specified by the Department, to allow the Department to review the patient medical records and determine whether the submitting health care institution has submitted data to the trauma registry for the cases who received medical services within the time period.
- C. For purposes of subsection (B), the Department considers a submitting health care institution to be in compliance with R9-25-1402(A) if the submitting health care institution submitted data to the trauma registry for 97% of the cases who received medical services within the time period.
- D. The Department shall return to a submitting health care institution data not submitted in compliance with R9-25-1402 and shall identify the revisions that are needed to bring the data into compliance with R9-25-1402.
- E. A submitting health care institution that has trauma registry data returned as provided in subsection (D) shall revise the data as identified by the Department and shall submit the revised data to the Department within 15 business days after the date the Department returned the data or within a longer period agreed upon between the Department and the submitting health care institution.
- F. Within 15 business days after receiving a written request from the Department that includes a simulated patient medical record, a submitting health care institution shall prepare and submit to the Department the data set identified in Table 1 for the patient described in the simulated patient medical record.

Table 1. Trauma Registry Data Set (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2221, and 36-2225(A)(5) and (6))

KEY:

Required for TC Levels I, II, and III = An owner of a hospital designated as a Level I, Level II, or Level III trauma center under Article 13 of this Chapter shall include these data elements in the data submission required under R9-25-1402.

Required for TC Level IV, Non-Designated TC, and ALS Base Hospital = An owner of a health care institution designated as a Level IV trauma center under Article 13 of this Chapter; an owner of a trauma center, as defined in A.R.S. § 36-2201, that is not designated as a trauma center under Article 13 of this Chapter; or an ALS base hospital certificate holder that submits trauma data as provided under A.R.S. § 36-2221 shall include these data elements in the data submission required under R9-25-1402.

* = Only required for hospitals designated as Level I trauma centers under Article 13 of this Chapter.

Field Name/Data Element Description	Required for TC Levels I, II, and III	Required for TC Level IV, Non-Designated TC, and ALS Base Hospital							
DEMOGRAPHIC DATA ELEMENT	DEMOGRAPHIC DATA ELEMENTS								
Reporting Facility Site ID	X	X							
Registration Number	X	X							
Medical Record Number	X	X							
Hospital Admission Date	X	X							
Admission Status	X	X							
Patient Last Name	X	X							
Patient First Name	X	X							
Patient Middle Initial	X	X							
Social Security Number	X	X							
Date of Birth	X	X							
Age	X	X							
Units of Age	X	X							
Gender	X	X							
Race	X	X							
Ethnicity	X	X							
Zip Code of Residence	X								
City of Residence	X								
County of Residence	X								
State of Residence	X	X							
Country of Residence	X								
Alternate Home Residence	X								
Co-Morbid Conditions (Pre-Existing)	X								
INJURY DATA ELEMENTS									
Injury Date	X	X							

Field Name/Data Element Description	Required for TC Levels I, II, and III	Required for TC Level IV, Non-Designated TC, and ALS Base Hospital
Injury Time	X	X
Actual versus Estimated Injury Time	X	
Injury Location ICD-9-CM E-code (E849)	X	X
Street Location of Injury	X	
Zip Code of Injury	X	X
City of Injury	X	X
County of Injury	X	
State of Injury	X	
Primary ICD-9-CM E-code Injury Descriptor	X	X
Additional ICD-9-CM E-code Injury		
Descriptor Descriptor	X	
Trauma Type	X	
Work-Related	X	
Patient Occupational Industry	X	
Patient Occupation	X	
Patient Position in Vehicle	X	
Protective Devices	X	X
Child Specific Restraint	X	
Airbag Deployment	X	
Safety Equipment Issues	X	
PREHOSPITAL TRANSPORT DATA	A ELEMENTS	
EMS Provider Type	X	
Transport Mode (Into Reporting Facility)	X	X
Other Transport Modes	X	
Transport Agency	X	
Run Sheet Available?	X	
Run Sheet Date	X	
Transported From	X	
Date EMS Provider Notified	X	
Time EMS Provider Notified	X	
Date EMS Provider Left for Scene	X	
Time EMS Provider Left for Scene	X	
Date EMS Provider Arrived at Scene	X	
Time EMS Provider Arrived at Scene	X	
Date of EMS Patient Contact	X	
Time of EMS Patient Contact	X	

Field Name/Data Element Description	Required for TC Levels I, II, and III	Required for TC Level IV, Non-Designated TC, and ALS Base Hospital
Date EMS Provider Departed Scene	X	
Time EMS Provider Departed Scene	X	
Date of Arrival at Destination	X	
Time of Arrival at Destination	X	
EMS Destination	X	
Total EMS Response Time (Minutes)	X	
Total EMS Scene Time (Minutes)	X	
Transport Time - Scene to Destination (Minutes)	X	
Total EMS Time (Minutes)	X	
System Access	X	
Triage Criteria	X	X
Date of Measurement of Vital Signs	X	
Time of Measurement of Vital Signs	X	
Initial Field Pulse Rate	X	
Initial Field Respiratory Rate	X	
Initial Field Oxygen Saturation	X	
Field Airway Management Details	X	
Field Intubation Status	X	
Field Paralytic Agent in Effect	X	
Initial Field Systolic Blood Pressure	X	
Initial Field GCS - Eye Opening	X	
Initial Field GCS - Verbal Response	X	
Initial Field GCS - Motor Response	X	
Initial Field GCS - Total	X	
Field Revised Trauma Score	X	
REFERRING/TRANSFER HOSPITA	AL DATA ELEMENTS	S
Interfacility Transfer	X	
Date of Arrival at First Referring Hospital	X	
Time of Arrival at First Referring Hospital	X	
Date of Transfer from First Referring Hospital	X	
Time of Transfer from First Referring Hospital	X	
Transferring Facility (First Referring)	X	
Length of Stay in First Referring Hospital (Hours)	X	
Destination Facility	X	

Field Name/Data Element Description	Required for TC Levels I, II, and III	Required for TC Level IV, Non-Designated TC, and ALS Base Hospital
Date of Arrival at Second Referring Hospital	X	
Time of Arrival at Second Referring Hospital	X	
Date of Transfer from Second Referring Hospital	X	
Time of Transfer from Second Referring Hospital	X	
Transferring Facility (Second Referring)	X	
Length of Stay in Second Referring Hospital (Hours)	X	
Destination Facility	X	
Vital Signs Designation (If First or Second Referring)	X	
Initial Respiratory Rate in Referring Facility	X	
Initial Systolic Blood Pressure in Referring Facility	X	
Initial GCS Total in Referring Facility	X	
Initial Revised Trauma Score in Referring Facility	X	
ED/TRAUMA DATA ELEMENTS		
ED/Hospital Arrival Date	X	X
ED/Hospital Arrival Time	X	X
ED Exit Date	X	X
ED Exit Time	X	X
Length of Stay in ED (Hours)	X	X
Complete Trauma Team Arrival Time	X	
ED Discharge Disposition	X	X
ED Discharge Destination Hospital	X	X
Discharge Transport Agency	X	
Transfer Reason	X	
ED/Hospital Initial Pulse Rate	X	
ED/Hospital Initial Respiratory Rate	X	
ED/Hospital Initial Respiratory Assistance	X	
ED/Hospital Initial Oxygen Saturation	X	
ED/Hospital Initial Supplemental Oxygen	X	
ED/Hospital Intubation Status	X	

Field Name/Data Element Description	Required for TC Levels I, II, and III	Required for TC Level IV, Non-Designated TC, and ALS Base Hospital
ED/Hospital Paralytic Agent in Effect	X	
ED/Hospital Initial Systolic Blood Pressure	X	
ED/Hospital Initial GCS - Eye Opening	X	
ED/Hospital Initial GCS - Verbal Response	X	
ED/Hospital Initial GCS - Motor Response	X	
ED/Hospital Initial GCS - Total	X	
ED/Hospital Initial GCS Assessment Qualifiers	X	
ED/Hospital Initial Temperature	X	
ED/Hospital Initial Units of Temperature	X	
ED/Hospital Initial Temperature Route	X	
ED/Hospital Initial Revised Trauma Score	X	
Alcohol Use Indicator	X	
Blood Alcohol Content (mg/dl)	X	
Drug Use Indicator	X	
Toxicology Substances Found	X	
DISCHARGE DATA ELEMENTS		
Hospital Discharge Date	X	X
Hospital Discharge Time	X	X
Hospital Admission Length of Stay (Days)	X	X
Total Length of Hospital Stay - ED plus Admission (Days)	X	
Final Outcome - Dead or Alive	X	X
Total ICU Length of Stay (Days)	X	X
Total Ventilator Days	X	
Hospital Discharge Disposition	X	X
Hospital Discharge Destination Hospital	X	X
Discharge Transport Agency	X	
Transfer Reason	X	
Autopsy Identification Number	X	
Injury Diagnoses - ICD-9-CM N-codes	X	X
AIS Six-Digit Injury Identifier	X*	
AIS Severity Code	X	

Field Name/Data Element Description	Required for TC Levels I, II, and III	Required for TC Level IV, Non-Designated TC, and ALS Base Hospital
AIS Body Region of Injury	X	
Injury Severity Score	X	
Probability of Survival	X	
ED/Hospital Procedure Location	X	
ED/Hospital Procedure Start Date	X	
ED/Hospital Procedure Start Time	X	
ED/Hospital ICD-9-CM Procedure Codes	X	
Hospital Complications	X	
Primary Method of Payment	X	
Secondary Method of Payment	X	
Total Hospital Charges	X	
Total Reimbursements	X	