(6))

<u>R9-25-1311.</u> Renumbered

<u>R9-25-1312.</u> Renumbered

TITILE 9. HEALTH SERVICES CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

ARTICLE 13. TRAUMA CENTER DESIGNATION CENTERS

R9-25-1301.	Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))			
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R9 25 1308.R	2-25-1304. Changes Affecting Designation Status (A.R.S. §§ 36-2202(A)(4), 36-			
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R9 25 1312.R	Denial or Revocation of Designation and Dedesignation (A.R.S. §§ 36-			
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	36-2209(A)(2), <u>36-2221</u> , and 36-2225(A)(4), (5), and (6))			
R9-25-1309.	Trauma Registry Data (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))			
R9 25 1406.R	2-25-1310. 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			

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R9-25-	-1313	Renumbered

- R9-25-1315. Application Processing Time Periods (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4)) Repealed
- Table 1. Application Processing Time Periods (in days) (A.R.S. \$\$ 36 2202(A)(4), 36 2209(A)(2), and 36 2225(A)(4)) Repealed
- Exhibit I. Table 13.1. Arizona Trauma Center Standards (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4)) Becomes Table 13.1. Depending on how much the Table is changed, it may be easier to just repeal the Exhibit and create a new Table 13.1.]

ARTICLE 14. TRAUMA REGISTRY; TRAUMA SYSTEM QUALITY ASSURANCE REPEALED

Section	
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	2221, and 36 2225(A)(5) and (6)) Repealed
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	36 2209(A)(2), 36 2221, and 36 2225(A)(5) and (6)) Repealed
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	2209(A)(2), 36-2221, and 36-2225(A)(5) and (6)) Repealed
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	2225(A)(5) and (6)) Repealed
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) Repealed
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)) Renumbered

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)) In addition to the definitions in A.R.S. § 36-2201 and R9-25-101, the 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.
- 1. "Business day" means a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.
- 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.
- 13.2. "Designation" means a formal determination by the Department that a health care institution has the resources and capabilities necessary to provide trauma services at complies with requirements in A.R.S. § 36-2225 and this Article for providing a particular Level and is a of trauma center service.
- 3. "Emergency department" means a designated area of a hospital that provides emergency services, as defined in A.A.C. R9-10-201, as an organized service, 24 hours per day, seven days per week, to individuals who present for immediate medical attention.
- 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.
- 4. "ICD-code" means an International Classification of Diseases code, a set of numbers or letters or a combination of letters and numbers that specify a disease, condition, or injury; the location of the disease, condition, or injury; or the circumstances under which a patient may have incurred the disease, condition or injury, which is used by a health care institution for billing purposes.
- 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;
 - With respiratory compromise, respiratory obstruction, or intubation, if the patient
 is not transferred from another health care institution;
 - e. 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.
- 5. "Medical services" means the services pertaining to the "practice of medicine," as defined in A.R.S. § 32-1401, or "medicine," as defined in A.R.A. § 32-1800, performed at the direction of a physician.
- 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.

- 6. "National verification organization" has the same meaning as in A.R.S. § 36-2225.
- 7. "Nursing services" means services that pertain to the curative, restorative, and preventive aspects of "registered nursing," as defined in A.R.S. § 32-1601, performed:
 - a. At the direction of a physician; and
 - <u>b.</u> By or under the supervision of a registered nurse licensed:
 - i. According to Title 32, Chapter 15; or
 - <u>ii.</u> When performed in a health care institution operating under federal or tribal law as an administrative unit of the U.S. government or a sovereign tribal nation, by a similar licensing board in another state.
- $\underline{24-8}$. "On-call" means assigned to respond and, if necessary, come to a health care institution when called by \underline{a} health care institution personnel \underline{member} .
- 25.9. "Owner" means one of the following:
 - a. For a health care institution licensed under 9 A.A.C. 10, the licensee;
 - 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;
- A business organization such as an association, cooperative, corporation, limited liability company, or partnership; or
- e. An administrative unit of the U.S. government, state government, or a political subdivision of the state.
- 27.10. "Personnel member" means an individual providing medical services, nursing services, or health-related services, as defined in A.R.S. § 36-401, 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.
- 11. "Physician" means an individual licensed:
 - a. According to A.R.S. Title 32, Chapter 13 or 17; or
 - When working in a health care institution operating under federal or tribal law as
 an administrative unit of the U.S. government or a sovereign tribal nation, by a
 similar licensing board in another state.
- 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.

- 31.12. "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.
- 13. "Substantial compliance" has the same meaning as in A.R.S. § 36-401.
- 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.
- 14. "Transport" means the conveyance of a patient by ground ambulance or air ambulance from one location to another location.
- 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.
- 15. "Trauma care" means medical services and nursing services provided to a patient suffering from a sudden physical injury.
- 34.16. "Trauma center" has the same meaning as in A.R.S. § 36-2225.
- 17. "Trauma critical care course" means a multidisciplinary class or series of classes consisting of interactive tutorials, skills teaching, and simulated patient management scenarios of trauma care, consistent with training recognized by the American College of Surgeons.
- 18. "Trauma facility" means a health care institution that provides trauma care to a patient as an organized trauma service.
- 19. "Trauma service" means designated personnel members, equipment, and area within a health care institution and the associated policies and procedures for the personnel members to follow when providing trauma care to a patient.
- 20. "Trauma team" means a group of personnel members with defined roles and responsibilities in providing trauma care to a patient.
- 21. "Trauma team activation" means a notification to respond that is sent to trauma team personnel members in reaction to triage information received concerning a patient with injury or suspected injury.
- 35. "Valid" means that a license, certification, or other form of authorization is in full force and effect and not suspended or otherwise restricted.

- 36.22. "Verification" means formal confirmation by ACS a national verification organization that a health care institution has the resources and capabilities necessary to provide meets the national verification organization's standards for providing trauma services as care at a Level II, Level III, or Level IV specific Level of trauma facility service.
- 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:
 - 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;
 - b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level IV trauma facility; or
 - 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.
- A. A health care institution is eligible for designation as a Level I, Level II, or Level III trauma center if the health care institution:

- 1. Is either:
 - <u>a.</u> <u>Licensed by the Department under 9 A.A.C. 10 to operate as a hospital; or </u>
 - <u>b.</u> Operating as a hospital under federal or tribal law as an administrative unit of the
 U.S. government or a sovereign tribal nation; and
- 2. For designation as a:
 - <u>a.</u> <u>Level I trauma center:</u>
 - i. <u>Holds verification, issued within the six months before the date of designation, as a Level I trauma facility; or</u>
 - ii. Has documentation issued by a national verification organization or the

 Department, within the six months before the date of designation, stating
 that the health care institution meets the standards specified in R9-25
 1308 and Table 13.1 for a Level I trauma center;
 - b. Level II trauma center:
 - i. <u>Holds verification, issued within the six months before the date of</u> designation, as a Level II trauma facility; or
 - ii. Has documentation issued by a national verification organization or the

 Department, within the six months before the date of designation, stating
 that the health care institution meets the standards specified in R9-251308 and Table 13.1 for a Level II trauma center; or
 - c. Level III trauma center:
 - <u>i.</u> <u>Holds verification, issued within the six months before the date of designation, as a Level III trauma facility; or </u>
 - ii. Has documentation issued by a national verification organization or the

 Department, within the six months before the date of designation, stating
 that the health care institution meets the standards specified in R9-251308 and Table 13.1 for a Level III trauma center.
- **B.** A health care institution is eligible for designation as a Level IV trauma center if the health care institution:
 - 1. <u>Is either:</u>
 - <u>a.</u> <u>Licensed by the Department under 9 A.A.C. 10 to operate as:</u>
 - i. A hospital; or
 - ii. An outpatient treatment center authorized to provide emergency room services, as defined in A.A.C. R9-10-1001, according to A.A.C. R9-10-1019; or

- <u>b.</u> Operating as a hospital or an outpatient treatment center providing emergency services under federal or tribal law as an administrative unit of the U.S. government or a sovereign tribal nation; and
- <u>Analysis</u> Analysis of the date of designation or ganization or the Department, within the six months before the date of designation, stating that the health care institution meets the standards specified in R9-25-1308 and Table 13.1 for a Level IV trauma center.
- C. A health care institution is eligible to retain designation as a specific Level of trauma center if the health care institution complies with the requirements in this Article for the specific Level of trauma center.

R9-25-1304.R9-25-1303. Initial Application and Designation Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4)) Since the application requirements were the same, both initial applications and applications for renewal are now in this Section.

- 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;
 - 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 II, 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)(1)(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 II, Level III, 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. [Requirements in R9-25-1315 are moved below or to new R9-25-1307]
- C. The Department shall approve designation if the Department determines that an owner is eligible for designation as described in R9 25 1302.
- An owner applying for initial designation or to renew designation for a health care institution shall submit to the Department an application including:
 - 1. The following information, in a Department-provided format:
 - a. The name, address, and telephone number of the health care institution for which the owner is requesting designation;
 - <u>b.</u> <u>The owner's name, address, e-mail address, telephone number, and, if available, fax number;</u>
 - c. The name, e-mail address, telephone number, and, if available, fax number of the chief administrative officer, as defined in A.A.C. R9-10-101, for the health care institution for which the owner is requesting designation;
 - d. The designation Level for which the owner is applying;
 - Whether the owner is requesting designation for the health care institution basedon:
 - i. Verification, or
 - <u>ii.</u> Meeting the applicable standards specified in R9-25-1308 and Table 13.1;
 - <u>f.</u> <u>If the owner is requesting designation for the health care institution based on verification:</u>
 - <u>i.</u> The name of the national verification organization;
 - ii. The name, telephone number, and e-mail address for a representative of the national verification organization;
 - iii. The Level of verification held;
 - iv. The effective date of the verification, and

- v. The expiration date of the verification;
- g. If the owner is requesting designation for the health care institution based on the health care institution meeting the applicable standards specified in R9-25-1308 and T able 13.1:
 - i. Whether:
 - (1) A national verification organization has assessed the health care institution, or
 - (2) The Department will be assessing the health care institution;
 - ii. If a national verification organization has assessed the health care institution:
 - (1) The name of the national verification organization;
 - (2) The name, telephone number, and e-mail address for a representative of the national verification organization; and
 - (3) The date the national verification organization will be assessing the health care institution; and
 - iii. If the Department will be assessing the health care institution, the date
 the health care institution will be ready for the Department to assess the
 health care institution;
- h. Unless the owner is an administrative unit of the U.S. government or a sovereign tribal nation, the license number, issued by the Department, for the health care institution for which designation is being requested;
- i. The name, e-mail address, telephone number, and, if available, fax number of the health care institution's trauma program manager;
- j. If applying for designation as a Level II, Level III, or Level III trauma center, the name, e-mail address, telephone number, and, if available, fax number of the health care institution's trauma medical director;
- <u>k.</u> 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;
- <u>1.</u> <u>Attestation that:</u>
 - i. The owner will comply with all applicable requirements in A.R.S. Title

 36, Chapter 21.1 and this Article; and
 - ii. The information and documents provided as part of the application are accurate and complete; and

- n. The dated signature of the applicable individual according to R9-25-102;
- 2. If applicable, documentation demonstrating that the health care institution is operating as a hospital or an outpatient treatment center providing emergency services under federal or tribal law as an administrative unit of the U.S. government or a sovereign tribal nation; and
- 3. <u>If applying for designation based on:</u>
 - a. Verification, documentation issued by the national verification organization, specified according to subsection (A)(1)(f)(i), establishing that the owner holds verification for the health care institution at the Level of designation being requested and showing the effective date and expiration date of the verification;
 - b. The national verification organization, specified according to subsection
 (A)(1)(g)(ii)(1), assessing the health care institution's meeting the applicable
 standards specified in R9-25-1308 and Table 13.1, documentation from the
 national verification organization that demonstrates that the health care
 institution meets the applicable standards; and
 - c. The Department assessing the health care institution's meeting the applicable standards specified in R9-25-1308 and Table 13.1:

[After reviewing the new R9-25-1308 and Table 13.1 this subsection will be revised to describe what needs to be submitted.]

- B. An owner applying to renew designation for a health care institution shall submit the application in subsection (A) to the Department at least 60 calendar days and no more than 90 calendar days before the expiration of the current designation.
- C. Within 30 calendar days after receiving an application submitted according to subsection (A), the Department shall review the application submitted for completeness, and, if the application is:
 - 1. Incomplete, send to the owner a written notice listing each deficiency and the information or items needed to complete the application;
 - 2. Based on verification and is complete, comply with R9-25-1307(A)(1);
 - 3. Based on a national verification organization assessing the health care institution's meeting the applicable standards specified in R9-25-1308 and Table 13.1 and is complete, comply with R9-25-1307(A)(2); and
 - 4. Based on the Department assessing the health care institution's meeting the applicable standards specified in R9-25-1308 and Table 13.1 and is complete, begin a review to assess compliance with applicable requirements in A.R.S. Title 36, Chapter 21.1 and this Article, according to R9-25-1307(A)(3).

- <u>D.</u> The Department shall consider an application withdrawn if an owner: [from R9-25-1315]
 - 1. Fails to submit to the Department all of the information or items listed in a notice of deficiencies within 60 calendar days after the date on the notice of deficiencies, unless the Department and the owner agree to an extension of this time; or
 - 2. Submits a written request withdrawing the application.
- E If an owner submits an application for renewal of designation for a health care institution according to subsection (A) before the expiration date of the current designation, the designation of the health care institution remains in effect until the: [from R9-25-1307(D)]
 - 1. Department has determined whether or not to issue a renewal of the designation, or
 - 2. Application is withdrawn.
- **F.** The Department shall issue a designation to a health care institution:
 - 1. If the Department determines that the application in subsection (A) is complete and the health care institution:
 - a. Complies with applicable requirements in this Article, or
 - <u>b.</u> Is in substantial compliance with applicable requirements in this Article and the owner of the health care institution submits to the Department a written corrective action plan according to R9-25-1306(E); and
 - With a term beginning on the date of issuance of the designation and ending: [from R9-25-1307]
 - a. When based on verification, on the expiration date of the verification upon which designation is based; and
 - b. When based on meeting the applicable standards specified in R9-25-1308 and Table 13.1:
 - i. Three years later, if the health care institution complies with the applicable standards specified in in R9-25-1308 and Table 13.1; and
 - One year later, if the health care institution is in substantial compliance
 based on the applicable standards specified in R9-25-1308 and Table

 13.1 and the owner of the health care institution submits to the

 Department a written corrective action plan according to R9-25-1306(E).
- **G.** The Department shall:
 - 1. Not issue a designation to a health care institution if the health care institution is:
 - a. Not in substantial compliance based on the applicable standards specified in R9-25-1308 and Table 13.1, or
 - b. <u>In substantial compliance based on the applicable standards specified in R9-25-</u>

- 1308 and Table 13.1, but does not submit to the Department a written corrective action plan according to R9-25-1306(E); and
- 2. If the Department declines to issue a designation to a health care institution, send to the owner a written notice setting forth the information required under A.R.S. § 41-1092.03(A).
- <u>H.</u> An owner may file a written notice of appeal with the Department within 30 calendar days after receiving the notice in subsection (G)(2), according to A.R.S. § 41-1092.03(B).
- 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)) [Now included as a regular designation, likely with a 1-year term.]
- 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:
 - 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)(1), 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.
- It 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:
 - 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)) [Since the application requirements were the same, both initial applications and applications for renewal are now in R9-25-1303.]
- 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 II, 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)) [Now included in the revised R9-25-1303.]
- 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.
- Dr 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.R9-25-1304. 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.
- Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:
 - 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.
- 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.
- 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.
- A. The owner of a trauma center shall:
 - 1. Notify the Department, in writing or in a Department-provided format, no later than 60 calendar days after the date of a change in the health care institution's:
 - a. Name,
 - b. Trauma program manager, or
 - c. If applicable, trauma medical director; and
 - 2. Provide the effective date of the change and, as applicable, the:
 - a. Current and new name of the health care institution, or
 - b. Name of the new trauma program manager or trauma medical director.
- B. An owner of a trauma center shall notify the Department in writing within three business days after:
 - 1. The trauma center's health care institution license expires or is suspended, revoked, or changed to a provisional license;
 - 2. The trauma center no longer holds verification; or
 - 3. A change, which is expected to last for more than seven consecutive calendar days, in the trauma center's ability to meet:
 - a. The applicable standards specified in R9-25-1308 and Table 13.1, or
 - b. <u>If designation is based on verification, the national verification organization's</u> standards for verification.
- C. At least 90 calendar days before a trauma center ceases to provide a trauma service, the owner of the trauma center shall notify the Department, in writing or in a Department-provided format, of the owner's intention to cease providing a trauma service and to relinquish designation, including the effective date.
- <u>**D.**</u> The Department shall, upon receiving a notice described in:
 - 1. Subsection (A), issue an amended designation that incorporates the name change but retains the expiration date of the current designation;

- Subsection (B)(1) that the health care institution license has expired or was suspended or revoked, send the owner a written notice stating that the health care institution no longer meets the definition of a trauma center and has been dedesignated;
- 3. Subsection (B)(1) that the health care institution license has been changed to a provisional license, evaluate the restrictions on the provisional license to determine if the trauma service was affected and may send the owner a written notice of the Department's intention to:
 - a. Dedesignate the health care institution, according to R9-25-1307(B);
 - b. Require a modification of the health care institution's designation, according to R9-25-1305; or
 - <u>c.</u> Require a corrective action plan to address issues of compliance with the
 applicable standards specified in R9-25-1308 and Table 13.1, according to R9

 25-1306(E);
- 4. Subsection (B)(2), send the owner written notice that the owner is required, within 15 calendar days after the date of the notice, to submit to the Department:
 - a. An initial application for designation at a specific Level of trauma center,

 according to R9-25-1303, based on meeting the applicable standards specified in

 R9-25-1308 and Table 13.1;
 - b. Written notification of the owner's intention to relinquish designation;
- 5. Subsection (B)(3), send the owner written notice that the owner is required, within 15 calendar days after the date of the notice, to submit to the Department:
 - a. An application for modification of the health care institution's designation,
 according to R9-25-1305;
 - A corrective action plan to address issues of compliance with the applicable standards specified in R9-25-1308 and Table 13.1, according to R9-25-1306(E); or
 - c. Written notification of the owner's intention to relinquish designation; and
- 6. Subsection (C), (D)(4)(b), or (D)(5)(c), send the owner written confirmation of the voluntary relinquishment of designation, with an effective date consistent with the written notice.
- An owner of a trauma center, who obtains verification for the trauma center during a term of

 designation that was based on the trauma center meeting the applicable standards specified in R9
 25-1308 and Table 13.1, 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

according to R9-25-1303.

$\frac{\text{R9-25-1309.R9-25-1305.}}{\text{and 36-2225(A)(4)}} \\ \text{Modification of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2),} \\ \text{and 36-2225(A)(4))} \\$

- 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;
 - 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;
 - 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.
- P. 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 (Λ)(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:

- 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
- 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.
- At least 30 calendar days before ceasing to provide a trauma service consistent with a trauma center's current designation, an owner of a trauma center may request to obtain a designation that requires fewer resources and capabilities than the trauma center's current designation by submitting to the Department an application for modification of the trauma center's designation, in a Department-provided format, that includes:
 - 1. The name and address of the trauma center for which the owner is requesting modification of designation;
 - A list of the criteria for the current designation with which the owner no longer intends to comply;
 - 3. An explanation of the changes being made in the trauma center's resources or operations, related to each criterion specified according to subsection (A)(3), to ensure the health and safety of a patient;
 - The state Level of designation requested;
 - 5. Attestation that:
 - a. The owner will comply with all applicable requirements in A.R.S. Title 36,
 Chapter 21.1 and this Article for the Level of designation requested if modified designation is issued; and
 - b. The information provided in the application is accurate and complete; and
 - 6. The dated signature of the applicable individual according to R9-25-102.
- B. The Department shall issue a modified designation for a term of one year beginning on the date of issuance of the modified designation, according to R9-25-1307(A)(3), and may require a written corrective action plan according to R9-25-1306(E), if the Department determines that, with the changes being made in the trauma center's resources and operations, the trauma center will be in substantial compliance based the applicable standards specified in R9-25-1308 and Table 13.1 for the Level of designation requested.
- <u>C.</u> To retain trauma center designation for a health care institution, an owner who holds modified designation shall, before the expiration date of the modified designation:

- 1. Apply for renewal of designation according to R9-25-1303, based on the health care institution's meeting the applicable standards specified in R9-25-1308 and Table 13.1 for the Level of the modified designation; or
- 2. Apply for initial designation according to R9-25-1303, based on the health care institution meeting the applicable standards specified in R9-25-1308 and Table 13.1 for a Level other than the Level of the modified designation.

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))

[Now included in the new R9-25-1306]

- 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
 - Reviewing:
 - a. Medical records;
 - b. Patient discharge summaries;
 - e. 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.
- 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.
- 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
 - 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)) [Now included in the new R9-25-1306]

- 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.
- 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
 - 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
 - Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.

R9-25-1306. <u>Inspections</u> (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4)) Combines requirements currently in R9-25-1310 and R9-25-1311

A. Before issuing initial, renewal, or modified designation to an owner applying for designation of a health care institution as a trauma center based on meeting the applicable standards in R9-25-1308 and Table 13.1, the Department may complete an announced inspection of the owner's

health care institution that may include:

- 1. Reviewing equipment and the physical plant;
- Interviewing personnel members; and
- Reviewing:
 - a. Medical records;
 - b. Patient discharge summaries;
 - c. Patient care logs;
 - <u>d.</u> Rosters and schedules of personnel members;
 - e. Performance-improvement-related documents, other than peer review documents
 privileged under A.R.S. § 36-445.01, including reports prepared as required
 under R9-10-204(B)(2) and the supporting documentation for the reports; and
 - <u>f.</u> Other documents relevant to the provision of a trauma service.
- **B.** The Department may conduct an announced inspection of a trauma center that may include the actions described in subsections (A)(1) through (3):
 - 1. If the owner of the trauma center has submitted to the Department a corrective action plan under subsection (E), or
 - 2. The health care institution is randomly selected to receive an inspection.
- C. If the Department has reason to believe that a trauma center is not complying with applicable requirements in A.R.S. Title 36, Chapter 21.1 and this Article, the Department may conduct an announced or unannounced inspection of the trauma center that includes the actions described in subsections (A)(1) through (3).
- Within 30 calendar days after completing an inspection, the Department shall send to an owner a written report of the Department's findings, including, if applicable, a list of any deficiencies identified during the inspection and a request for a written corrective action plan.
- <u>E</u> Within 10 calendar 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.
- F. The Department shall accept a written corrective action plan if it:
 - 1. Describes how each identified deficiency will be corrected, and
 - Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.

R9-25-1312.R9-25-1307. Denial or Revocation of Designation and Dedesignation (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.
- A. The Department shall issue designation to a health care institution according to R9-25-1303(F) or send to the owner a written notice that the Department is declining to issue a designation to the health care institution according to R9-26-1303(G)(2):
 - 1. If the designation is based on verification, within 45 calendar days after receiving a

- complete application according to R9-25-1303(A), which may include an inspection of the health care institution according to R9-25-1306(A);
- If the designation is based on a national verification organization assessing the health
 care institution's meeting the applicable standards specified in R9-25-1308 and Table
 13.1:
 - a. After the Department has reviewed the national verification organization's assessment that the health care institution meets the applicable standards specified in R9-25-1308 and Table 13.1, which may include an inspection of the health care institution according to R9-25-1306(A); and
 - b. Within 60 calendar days after receiving a complete application according to R9-25-1303(A); and
- 3. If the designation is based on the Department assessing the health care institution's meeting the applicable standards specified in in R9-25-1308 and Table 13.1:
 - a. After the Department has conducted an inspection of the health care institution according to R9-25-1306(A); and
 - <u>b.</u> Within 90 calendar days after receiving a complete application according to R9-25-1303(A) or R9-25-1305(A).
- **B.** The Department may dedesignate a health care institution as a trauma center if an owner:
 - 1. Has provided false or misleading information to the Department;
 - 2. <u>Is not eligible for designation under R9-25-1302(A) or (B); or</u>
 - 3. Fails to comply with an applicable requirement in A.R.S. Title 36, Chapter 21.1 or this Article
- C. In determining whether to dedesignate a health care institution as a trauma center, the Department shall consider:
 - 1. The severity of each instance relative to public health and safety;
 - 2. The number of instances;
 - 3. The nature and circumstances of each instance;
 - 4. Whether each instance was corrected, the manner of correction, and the duration of the instance; and
 - 5. Whether the instances indicate a lack of commitment to having the trauma center meet the verification standards of a national verification organization or, if applicable, the standards specified in R9-25-1308 and Table 13.1.
- <u>D.</u> If the Department dedesignates a health care institution, the Department shall send to the owner a written notice setting forth the information required under A.R.S. § 41-1092.03(A).

<u>An owner may file a written notice of appeal with the Department within 30 calendar days after</u> receiving the notice in subsection (D), according to A.R.S. § 41-1092.03(B).

 $\frac{\text{R9-25-1313.R9-25-1308.}}{2208(\text{A})}, 36\text{-}2209(\text{A})(2), \underbrace{36\text{-}2221}_{\text{A}}, \text{and } 36\text{-}2225(\text{A})(4), (5), \text{and } (6))}$

[Now includes information that had been in the Exhibit/footnotes or in R9-25-1402.]

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;
- 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
- The owner and the trauma center staff comply with all applicable federal and state laws
 relating to confidentiality of information.

A. The owner of a trauma center shall ensure that:

- 1. If designation is based on:
 - a. <u>Verification, the trauma center meets the applicable standards of the verifying national verification organization; and</u>
 - Meeting the applicable standards specified in this Section and Table 13.1, the
 trauma center meets the applicable standards for the Level of trauma center for
 which designation has been issued;
- 2. The trauma center complies with a written corrective action plan accepted by the Department according to R9-25-1306(F); and
- 3. The Department has access to the trauma center, to personnel members present in the trauma center, and to documents that are requested by the Department and not confidential under A.R.S. Title 36, Chapter 4, Article 4 or 5, within two hours after the Department's request.

B. The owner of a trauma center shall:

- 1. Ensure that a trauma service is established within the health care institution;
- Ensure that policies and procedures for the trauma service are established, documented, and implemented that include:
 - a. The composition of the trauma team;
 - b. The qualifications, skills, and knowledge required of each personnel member of

the trauma team;

- <u>c.</u> <u>Continuing education or continuing medical education requirements for each personnel member of the trauma team;</u>
- d. The roles and responsibilities of each personnel member of the trauma team;
- e. Under what circumstances the trauma team is activated; and
- f. How the trauma team is activated;
- 3. Ensure that the personnel members on the trauma team are selected according to policies and procedures;
- 4. If the trauma center is required according to Table 13.1 to have a trauma medical director, appoint a board-certified surgeon as trauma medical director;
- 5. Prohibit a physician from serving as trauma medical director for the trauma center if the physician is serving as trauma medical director for another health care institution;
- <u>6.</u> Ensure that the trauma medical director completes:
 - a. If the trauma center's designation is for a three-year period, at least 48 hours of trauma-related continuing medical education during the term of the designation; and
 - b. If the trauma center's designation is for a one-year period, at least 16 hours of trauma-related continuing medical education during the term of the designation;
- 7. Authorize an individual to act as trauma program manager to coordinate trauma service activities;
- 8. Authorize an individual to act as trauma registrar to coordinate trauma registry activities according to subsection (C)(5) and, if more than 750 patients are added to the trauma center's trauma registry per year, an additional individual to assist with trauma registry activities for each additional group of 750 patients or less;
- 9. Ensure that each surgeon on the trauma team designated according to subsection (B)(3) attends at least 50% of the meetings of the multidisciplinary peer review committee in subsection (C)(3);
- 10. If the trauma center is designated as a Level I or Level II trauma center, ensure that the following personnel members on the trauma team are board-certified, each:
 - <u>a.</u> <u>General surgeon,</u>
 - b. Emergency medicine physician,
 - c. Neurosurgeon, and
 - d. Orthopedic surgeon; and
- 11. Ensure that the following personnel members on the trauma team:

- a. Hold current certification in a trauma critical care course:
 - i. Trauma medical director, if applicable;
 - ii. Each emergency medicine physician who is not board-certified; and
 - iii. Each physician assistant or registered nurse practitioner who is
 responsible for patients in an emergency department in the absence of an
 emergency physician; or
- <u>b.</u> <u>Have held certification in a trauma critical care course:</u>
 - i. Each general surgeon other than the trauma medical director, and
 - <u>ii.</u> Each emergency medicine physician who is board-certified.
- <u>C.</u> The owner of a trauma center shall ensure that the trauma center:
 - 1. Except as provided in subsection (I), establishes a trauma registry of patients receiving trauma care who meet the criteria specified in subsection (H)(1) that contains the information required in Table 13.2, as applicable for the specific Level of the trauma center;
 - Establishes a performance improvement program for the trauma service to develop and implement processes to improve trauma care parameters;
 - 3. If required according to Table 13.1, establishes as part of the performance improvement program, established according to subsection (C)(2), a multidisciplinary peer review committee to review trauma registry parameters and suggest methods to improve performance;
 - <u>4.</u> Establishes, documents, and implements policies and procedures for patient transfer, consistent with A.A.C. R9-10-211, that include:
 - a. The criteria for transferring a patient,
 - <u>b.</u> The health care institution to which a patient meeting specific criteria will be transferred.
 - <u>c.</u> The personnel members who are responsible for coordinating the transfer of a patient, and
 - d. The process for transferring a patient;
 - 5. Establishes, documents, and implements policies and procedures for the trauma registry established according to subsection (C)(1) that include:
 - Ensuring that individuals responsible for collecting, entering, or reviewing information in the trauma registry have received training in gaining access to, and retrieving information from, the trauma registry;
 - <u>b.</u> <u>Collection of the information required in Table 13.2 about the patients specified</u>

- in subsection (H)(1) receiving trauma care;
- <u>c.</u> <u>Submission to the Department of the information required in subsection (H)(2);</u>
- d. Review of information in the trauma center's trauma registry; and
- e. Performance improvement activities required in R9-25-1310;
- 6. Establishes, documents, and implements policies and procedures for the performance improvement program established according to subsection (C)(2), including:
 - a. A list of personnel members who have defined roles in the performance improvement program, required in subsection (C)(2), and, if applicable, a list of personnel members whose positions are dedicated to performance improvement activities for patients receiving trauma care from the trauma center;
 - <u>b.</u> <u>The qualifications, skills, and knowledge of the personnel members specified according to subsection (C)(6)(a);</u>
 - <u>c.</u> The role each personnel member specified according to subsection (C)(6)(a) plays in the performance improvement program;
 - d. The trauma care parameters to be reviewed as part of the performance improvement program;
 - e. The frequency of review of trauma care parameters;
 - <u>f.</u> <u>If applicable, the composition, duties, and responsibilities of the multidisciplinary peer review committee established according to subsection (C)(3);</u>
 - g. <u>If applicable, how the multidisciplinary peer review committee collaborates with</u> the trauma center's quality management program; and
 - <u>h.</u> <u>How changes proposed by the performance improvement program are reviewed and criteria for the implementation of changes:</u>
- 7. Participates in state, local, or regional trauma-related activities such as:
 - a. The State Trauma Advisory Board, established by A.R.S. § 36-2222;
 - <u>A regional emergency medical services coordinating council described in A.R.S.</u>
 § 36-2222(A)(3);
 - <u>c.</u> <u>Trauma Registry Users Group, established by the Department;</u>
 - d. Trauma Managers Workgroup, established by the Department; or
 - e. <u>Injury Prevention Council;</u>
- 8. If the trauma center holds a designation as a Level II, Level III, or Level III trauma center, conducts continuing education activities related to trauma care for physicians, trauma center personnel members, and EMCT s;
- 9. Participates in existing injury prevention programs at the national, regional, state, or local

levels;

- 10. If the trauma center holds a designation as a Level I or Level II trauma center, establishes and maintains an injury prevention program:
 - a. <u>Independently or in collaboration with other health care institutions, health</u> advocacy groups, or the Department; and
 - b. That includes:
 - <u>Designating a prevention coordinator who serves as the trauma center's</u>
 <u>representative for injury prevention and injury control activities.</u>
 - ii. Conducting injury control studies,
 - iii. Monitoring the progress and effect of the injury prevention program, and
 - <u>iv.</u> Providing injury prevention and injury control information resources for the public;
- 11. If the trauma center holds a designation as a Level I or Level II trauma center, establishes and maintains an educational outreach program:
 - a. <u>Independently or in collaboration with other health care institutions, health</u>
 advocacy groups, or the Department:
 - <u>b.</u> <u>That includes providing education to physicians, trauma center personnel</u> members, EMCTs, and the general public; and
 - <u>c.</u> That may include education about:
 - <u>i.</u> <u>Injury prevention,</u>
 - ii. Trauma care,
 - iii. Criteria for assessing a patient who may require trauma care,
 - iv. Criteria for the transfer of a patient requiring trauma care,

[anything else?]

; and

- 12. If the trauma center holds a designation as a Level I trauma center:
 - <u>a.</u> Establishes and maintains, either independently or in collaboration with other
 <u>hospitals</u>, a residency program that provides advanced medical training in
 emergency medicine, general surgery, orthopedic surgery, or neurosurgery;
 - b. Participates in the provision of a trauma critical care course; [ATLS or equivalent]
 - c. Conducts or participates in research related to trauma and trauma care; and
 - Maintains an Institutional Review Board, according to 45 CFR Part 46, to review
 biomedical and behavioral research related to trauma and trauma care involving

<u>human subjects</u>, conducted, funded, or sponsored by the trauma center, in order to protect the rights of the human subjects of such research.

- <u>As part of the performance improvement program, the owner of a trauma center shall ensure that the trauma program manager and, if applicable, trauma medical director periodically, according to policies and procedures:</u>
 - 1. Review the information in the trauma center's trauma registry; and
 - 2. Monitor at least the following trauma care parameters, as applicable, for patients in the trauma registry:

[This should list all the required audits. Anything that should be removed? Anything else?]

- a. EMS received by a patient;
- b. Length of stay longer than two hours in the emergency department;
- c. <u>Instances of trauma team activation;</u>
- d. Time from notification of a surgeon on the trauma team that a patient described in subsection (E)(6)(a) is in the emergency department to when the surgeon arrives in the emergency department;
- e. <u>Documentation of the nursing services provided to a patient;</u>
- <u>f.</u> <u>Instances and reasons for transfer of a patient;</u>
- g. <u>Instances and reasons for transfer to a hospital not designated as a trauma center;</u>
- h. For a hospital designated as a Level I or Level II trauma center, instances and reasons for trauma-related bypass;
- <u>i.</u> <u>Circumstances related to the death of a patient;</u>
- j. Other patient outcomes; and
- k. The completeness and timeliness of trauma data submission.
- **E.** The owner of a trauma center shall:
 - 1. Ensure the presence of a surgeon at all operative procedures;
 - <u>If the trauma center provides emergency medicine, neurosurgery, or orthopedic surgery as an organized service, ensure that:</u>
 - a. A physician from the service is designated to act as a liaison between the service and the trauma center's trauma service;
 - <u>b.</u> The physician in subsection (E)(2)(a) completes:
 - i. If the trauma center's designation is for a three-year period, at least 48
 hours of trauma-related continuing medical education during the term of the designation; and

- ii. If the trauma center's designation is for a one-year period, at least 16
 hours of trauma-related continuing medical education during the term of the designation; and
- c. The physician in subsection (E)(2)(a) attends at least 50% of the meetings of the multidisciplinary peer review committee in subsection (C)(3); and
- 3. Ensure that, when a physician is on-call for general surgery, neurosurgery, or orthopedic surgery, the physician is not on-call or on a back-up call list at another health care institution;
- 4. Ensure that policies and procedures are established, documented, and implemented for:
 - a. If the trauma center is designated as a Level I, Level II, or Level III trauma center, the formulation of blood products to be available during an event requiring multiple blood transfusions for a patient or patients; and
 - b. If the trauma center is designated as a Level IV trauma center, the expedited release of blood products during an event requiring multiple blood transfusions for a patient or patients; and
- 5. Ensure that the trauma center complies with the policies and procedures required in subsection (C)(4) for transferring a patient needing:
 - a. Burn care as an organized service, acute hemodialysis, acute spinal cord management, or pediatric trauma care to a hospital providing the required service if the trauma center is designated as a:
 - <u>i.</u> <u>Level III or Level IV trauma center; or </u>
 - ii. Level II trauma center and does not provide, as applicable, burn care as
 an organized service, acute hemodialysis, acute spinal cord management,
 or pediatric trauma care; or
 - <u>b.</u> Hand surgery or microvascular/replant surgery to a hospital providing the required service if the trauma center is designated as a Level III or Level IV trauma center;
- 6. If the trauma center holds a designation as a Level I trauma center, require that a surgeon on the trauma team or a surgery resident in the fourth or fifth year of residency training is on the hospital premises at all times;
- 7. If the trauma center holds a designation as a Level II, Level II, or Level III trauma center, require that a surgeon on the trauma team is present in the emergency department, according to policies and procedures required in subsection (B)(2)(e):
 - <u>a.</u> For a patient:

- i. If an adult, with a systolic blood pressure less than 90 mm Hg or, if a child, with confirmed age-specific hypotension;
- ii. With respiratory compromise, respiratory obstruction, or intubation;
- iii. Who is transferred from another hospital and is receiving blood to maintain vital signs;
- iv. Who has a gunshot wound to the abdomen, neck, or chest;
- v. Who has a Glasgow Coma Scale score less than 8 associated with an injury attributed to trauma; or
- vi. Who is determined by an emergency department physician to have an injury that has the potential to cause prolonged disability or death; and
- b. No later than the following times:
 - i. For a Level I or Level II trauma center, within 15 minutes after
 notification or at the time the patient arrives in the emergency
 department, whichever is later; or
 - ii. For a Level III trauma center, within 30 minutes after notification or at the time the patient arrives in the emergency department, whichever is later;
- 8. If the trauma center holds a designation as a Level II, Level III, or Level III trauma center, require that an emergency medicine physician is present in the emergency department at all times; and
- 9. If the trauma center holds a designation as a Level II, Level II, or Level III trauma center, require that one of the following anesthesia personnel members is available for an operative procedure on a patient at the indicated time point:
 - a. For a Level I trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is on the hospital premises at all times;
 - <u>b.</u> For a Level II trauma center, an anesthesiologist, anesthesiology chief resident,
 <u>or certified registered nurse anesthetist is present in the emergency department or in an operatory suite awaiting the patient no later than 15 minutes after patient
 <u>arrival in the emergency department; and</u>
 </u>
 - c. For a Level III trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department or in an operatory suite awaiting the patient no later than 30 minutes after patient arrival in the emergency department.
- F. The Department shall consider a trauma center to be in compliance with subsection (E)(7), (8), or

- (9), as applicable, if the trauma center has documentation showing that the individual required to be present at the indicated location and within the indicated time period was present 80% or more of the time.
- G. The requirement in subsection (E)(7) applies whether or not the owner of a trauma center allows a surgery resident in the fourth or fifth year of residency training to begin treating a patient described in subsection (E)(7)(a) while awaiting the arrival of the surgeon on the trauma team, as required in subsection (E)(7)(b)(i) or (ii).
- **H.** The owner of a trauma center shall ensure that:
 - 1. The trauma registry, established according to subsection (C)(1), includes the information required in R9-25-1309 for each patient with whom the trauma center had contact who meets one or more of the following criteria:
 - a. A patient with injury or suspected injury who is:
 - i. Transported from a scene to a trauma center or hospital emergency department based on the responding emergency medical services provider's or ambulance service's triage protocol required in R9-25-201(E)(2)(b), or
 - <u>ii.</u> Transferred from one health care institution to another by an emergency medical services provider or ambulance service;
 - b. A patient with injury or suspected injury for whom a trauma team activation occurs; or
 - c. A patient with injury, who is admitted as a result of the injury or who dies as a result of the injury, and whose medical record includes one or more of specific ICD-codes indicating that:
 - i. The patient had:
 - (1) An injury or injuries to specific body parts initial encounter,
 - (2) Unspecified multiple injuries,
 - (3) Injury of an unspecified body region,
 - (4) A burn or burns to specific body parts initial encounter,
 - (5) Burns assessed through Total Body Surface Area percentages, or
 - (6) Traumatic Compartment Syndrome initial encounter; and
 - ii. The patient's injuries or burns were not only:
 - (1) An isolated distal extremity fracture from a same-level fall,
 - (2) An isolated femoral neck fracture from a same-level fall,

- (3) Effects resulting from an injury or burn that developed after the initial encounter,
- (4) A superficial injury or contusion, or
- (5) A foreign body entering through an orifice;
- <u>2.</u> The following information is submitted to the Department, in a Department-provided format, on a quarterly basis:
 - a. The name and physical address of the trauma center;
 - <u>b.</u> <u>The date the trauma registry information is being submitted to the Department;</u>
 - c. The total number of patients whose trauma registry information is being submitted:
 - <u>d.</u> The quarter and year for which the trauma registry information is being submitted;
 - e. The range of emergency department or hospital arrival dates for the patients for whom trauma registry information is being submitted;
 - <u>f.</u> The name, title, phone number, fax number, and e-mail address of the trauma center's point of contact for the trauma registry information;
 - g. Any special instructions or comments to the Department from the trauma center's point of contact;
 - <u>h.</u> The information from the trauma registry for patients identified during the quarter specified according to subsection (H)(2)(c); and
 - <u>i.</u> <u>Updated information for any patients identified during the previous quarter,</u> <u>including the patient's name, medical record number, and admission date; and</u>
- The information required in subsection (H)(2) is submitted as follows:
 - a. For patients identified between January 1 and March 31, so that the information in subsections (H)(2)(a) through (h) is received by the Department by July 1 of the same calendar year;
 - b. For patients identified between April 1 and June 30, so that the information in subsections (H)(2)(a) through (h) is received by the Department by October 1 of the same calendar year;
 - c. For patients identified between July 1 and September 30, so that the information in subsections (H)(2)(a) through (h) is received by the Department by January 2 of the following calendar year; and

- <u>d.</u> For patients identified between October 1 and December 31, so that the information in subsections (H)(2)(a) through (h) is received by the Department by April 1 of the following calendar year.
- <u>I.</u> Trauma centers under the same governing authority may establish a single, centralized trauma registry and submit to the Department consolidated information from the trauma registry, according to subsections (H)(2) and (3), if:
 - 1. The information submitted to the Department specifies for each patient in the trauma registry the trauma center that had contact with the patient, and
 - 2. Each trauma center contributing information to the centralized trauma registry is able to:
 - a. Access, edit, and update the information contributed by the trauma center to the centralized trauma registry; and
 - <u>b.</u> <u>Use the information contributed by the trauma center to the centralized trauma registry when complying with performance improvement program requirements in this Section.</u>
- J. An ALS base hospital certificate holder that chooses to submit trauma registry information to the Department, as allowed by A.R.S. § 36-2221(A), shall:
 - 1. Include in the ALS base hospital's trauma registry at least the information required in

 Table 13.2 for each patient who meets one or more of the criteria in subsections (H)(1)(a) through (c), and
 - 2. Comply with the submission requirements in subsections (H)(2) and (3).

R9-25-1315. Application Processing Time Periods (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and $\frac{36-2225(A)(4)}{A}$ Repealed

- 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.
 - 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.
 - 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
- 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)) Repealed

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

E = Essential and required FTE = Full time equivalent ICU = Intensive care unit

In-house = On the premises of the health care institution

ISS = Injury severity score, the sum of the squares of the abbreviated injury scale scores of the three

most severely injured body regions

[Columns for the following could be added into the Table, with appropriate requirements noted.]

I(P) = Level I, specializing in patients under 18 years of age II(P) = Level II, specializing in patients under 18 years of age

Tra	Trauma Facilities Criteria		Levels				
			I	П	Ш	IV	
A.	Ins	titutional Organization					
	1.	Trauma program	E	E	E	-	
	2.	Trauma service	Е	Е	E	-	
	3.	Trauma team	E	E	E	E	
	4.	Trauma program medical director	Е	Е	Е	-	
	5.	Trauma multidisciplinary committee	Е	Е	Е	-	
	6.	T rauma coordinator/trauma program manager	E (1 FTE)	E (1 FTE)	E (0.5 FTE)	E (0.25 FTE)	
	7.	Trauma registrar	E E	E	<u>(0.3 F1E)</u>	<u>(0.23 F1E)</u>	
B.		spital Departments/Divisions/Sections					
		Surgery	Е	Е	Е	_	
	2.		Е	Е	-	-	
		a. Neurosurgical trauma liaison	E	E		-	
	3.	Orthopaedie Orthopedic surgery	Е	Е	Е	-	
		a. Orthopaedie trauma liaison	E	E	E	-	
	4.	Emergency medicine	Е	Е	Е	_	
		a. Emergency medicine liaison*	E	E	E	-	
	5.	Anesthesia	Е	Е	Е	-	
C.	Cli	nical Capabilities					
	1.	Published on-call schedule for trauma care, including as applicable for each tisted specialty required in (C)(2) and (3) (C)(2) through (4)	Е	Е	Е	<u>E</u> -	

Commented [RS1]: Can add FTE requirements for trauma registrars here, consistent with R9-25-1308(B)(8).

 $\begin{tabular}{ll} \textbf{Commented [RS2]:} A new row for "Pediatric emergency department area" could be added here (as currently in (K)) for Levels I(P) and II(P) \\ \end{tabular}$

2.	Specialty Physician specialist immediately available 24	İ	1	ĺ	
	hours/day				
	a. General surgery	Е	Е	Е	_
	i. Published back-up schedule	Е	Е	-	-
	ii. Dedicated to single hospital when on-call	Е	Е	-	-
	b. Anesthesia*	E	E	E	-
	c. Emergency medicine	Е	Е	Е	-
[3.	On-call Physician specialist on-call and promptly available within 45 minutes after notification 24 hours/day ^a				
	a. Cardiac surgery	Е	-	-	-
	b. Hand surgery	Е	Е	-	-
	c. Microvascular/replant surgery	Е	-	-	-
	d. Neurologie surgery Neurosurgery	Е	Е	-	-
	i- Dedicated to one hospital or back up call	E	E	7	-
	e. Obstetrics/gynecologic surgery	Е	-	-	-
	f. Ophthalmic surgery	Е	Е	-	-
	g. Oral/maxillofacial surgery."	<u>E</u>	E.	-	-
	h. Orthopaedic Orthopedic surgery	Е	Е	Е	1
	i. Dedicated to one hospital or back-up call	E	E	-	-
	i. Plastic surgery	Е	Е	-	-
	j. Critical care medicine	Е	Е	-	-
	k. Radiology	Е	Е	Е	-
	l. Thoracic surgery	Е	Е	-	-
<u>4</u> .	Qualified personnel member on-call and available within 45 minutes after notification 24 hours/day				
	a. Anesthesia (physician or certified nurse anesthetist)	E	E	<u>E</u>	_
	b. Oral/maxillofacial surgery (plastic surgeon,	E	E	- <u> </u>	<u>-</u> <u>-</u>
	otolaryngologist, or oral/maxillofacial surgeon)		_	_	_
` /	nical Qualifications				
1.	General/Trauma Surgeon				
	a. Board certification th	E	E	E	-
	b. 16 hours CME/year 11	E	E	-	-

Commented [RS3]: A new row for "Surgeons credentialed for pediatric trauma care" could be added under here (as currently in (K)) for Levels I(P) and II(P)

Commented [RS4]: Moved to the new (C)(4)

Commented [RS5]: Subcategories would be easier to read if ordered by number of levels to which the requirement applied

Commented [RS6]: Takes into account the info that had been in footnotes 5 and 9

Commented [RS7]: Now in R9-25-1308

1		ATT O CONTROL 4	I 	l 	l -	l
		e. ATLS certification 14	E	E	E	E
		d. Multidisciplinary peer review committee attendance > 50% 12	E	E	E	-
	2.	Emergency Medicine*				
		a. Board certification "	<mark>E</mark>	E	-	-
		b. Trauma education—16 hours CME/year "	E	E	-	-
		e. ATLS certification ¹²	<mark>E</mark>	E	<mark>E</mark>	E
		d. Multidisciplinary peer review committee attendance > 50% ¹³	E	E	E	-
	3.	Neurosurgery				
		a. Board certification	E	E	-	-
		b. 16 hours CME/year⁺⁺	E	E	-	-
		e. Multidisciplinary peer review committee attendance > 50% 13	E	E	E	-
	4.	Orthopaedic Surgery				
		a. Board certification	E	E	-	-
		b. 16 hours CME/year in skeletal trauma ¹¹	E	E	-	-
		c. Multidisciplinary peer review committee attendance > 50% 13	E	E	E	-
E.	Fac	cilities/Resources/Capabilities				
	1.	Volume Performance 11	<mark>E</mark>	_	_	_
	2.	Presence of surgeon at resuscitation (immediately available) 45	<u>E</u>	<u>E</u>	_	_
	3.	Presence of surgeon at resuscitation (promptly available) 16	-	-	E	-
	4.	Presence of surgeon at operative procedures	E	E	E	E
	5.	Emergency Department				
		a. Personnel				
		i. Designated physician director	Е	Е	Е	-
		b. Resuscitation Equipment for Patients of All Ages Sizes				
		i. Airway control and ventilation equipment	Е	Е	Е	Е
		ii. Pulse oximetry	Е	Е	Е	Е
		iii. Suction devices	Е	Е	Е	Е
		iv. Electrocardiograph-oscilloscope-defibrillator	Е	Е	Е	Е
					1	L

Commented [RS8]: Discuss

Commented [RS9]: These three requirements now in R9-25-1308

Commented [RS10]: Discuss whether sonography equipment should be required in ED

vi. CVP Central venous pressure monitoring equipment	_			1
	E	Е	Е	-
vii. Standard intravenous fluids and administration sets	Е	Е	Е	Е
viii.Large-bore intravenous catheters	Е	Е	Е	Е
ix. Sterile Surgical Sets for:				
(1) Airway control/cricothyrotomy	Е	Е	Е	Е
(2) Thoracostomy	Е	Е	Е	Е
(3) Venous cutdown	E	E	E	E
(4) Central line insertion	Е	Е	Е	-
(5) Thoracotomy	Е	Е	Е	-
(6) Peritoneal lavage	E	E	E	-
x. Arterial catheters	Е	Е	-	-
xi. Drugs necessary for emergency care	E	E	E	E
xii. X-ray availability 24 hours/day	Е	Е	Е	-
xiii. Broselow tape Color-coded, length-based, tape measure to assist with medication dosing and equipment selection for children	Е	Е	Е	Е
xiv.Thermal Control Equipment				
(1) For patient	Е	Е	Е	Е
(2) For fluids and blood	Е	Е	Е	Е
xv. Rapid infuser system	Е	Е	Е	Е
xvi. Qualitative end-tidal CO_2 determination monitoring	Е	Е	Е	Е
c. Communication with EMS vehicles Capability of communicating with EMS providers	Е	Е	Е	Е
 d. Capability to resuscitate, stabilize, and transport transfer pediatric patients¹² 	Е	Е	Е	Е
6. Operating Room				
a. Immediately available 24 hours/day	Е	Е	-	-
b. Personnel Dedicated personnel				
i. In-house 24 hours/day	Е	-	-	-
ii. Available within 45 minutes after notification 24 hours/day	-	Е	Е	-
c. A ge Specific <u>Size-Specific</u> Equipment				

Commented [RS11]: Discuss

i. Cardiopulmonary bypass	E	-	-	-
ii. Operating microscope	Е	-	-	-
d. Thermal Control Equipment				
i. For patient	Е	Е	Е	Е
ii. For fluids and blood	Е	Е	Е	Е
e. X-ray capability including C-arm image intensifier	Е	Е	Е	-
f. Endoscopes, bronchoscope	Е	Е	Е	-
g. Craniotomy instruments	Е	Е	-	-
h. Equipment for long bone and pelvic fixation	Е	Е	Е	-
i. Rapid infuser system infusion system/capability	Е	Е	Е	Е
7. Postanesthetic Postanesthesia Recovery Room (SICU is acceptable) or Surgical ICU				
a. Registered nurses available 24 hours/day	Е	Е	Е	θ
b. Equipment for monitoring and resuscitation	Е	Е	Е	Е
c. Intracranial pressure monitoring equipment	Е	Е	-	-
<mark>i-d.</mark> Pulse oximetry	E	Е	Е	Е
<mark>ii.e.</mark> [Γhermal control]	Е	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	Е	Е	Е	-
c. Surgical ICU service physician in-house 24 hours/day 24	Е	-	-	-
d. Surgically directed and staffed ICU service	Е	Е	-	-
e. Equipment for monitoring and resuscitation	Е	Е	Е	-
f. Intracranial pressure monitoring equipment	Е	Е	-	-
g. Pulmonary artery monitoring equipment	Е	Е	Е	-
9. Respiratory Therapy Services				
a. Available in-house 24 hours/day	Е	Е	-	-
b. On-call <u>and available within 45 minutes after notification</u> 24 hours/day	-	-	Е	-
10. Radiological Services (Available 24 hours/day)				
a. In-house radiology technologist	Е	Е	<u>-E</u>	-

Commented [RS12]: Discuss

Commented [RS13]: Discuss whether this should be the same as (6)(d) above

	<u>#.</u>	Radiology technologist on-call and available within 45	-	-	-	E
		minutes after notification 24 hours/day				
	b.	Angiography	Е	E	-	-
	c.	Sonography	Е	Е	Е	-
	d.	Computed tomography (CT)	Е	Е	Е	-
		i. In-house CT technician	Е	Е	-	-
		ii. CT technician on-call and available within 45 minutes after notification 24 hours/day	-	-	E	-
	ę.	Magnetic resonance imaging	Е	-	-	-
	11. Cli	nical Laboratory Service (Available 24 hours/day)				
	a.	Standard analyses of blood, urine, and other body fluids, including microsampling when appropriate	Е	Е	Е	Е
	b.	Blood typing and cross-matching	Е	Е	Е	-
	c.	Coagulation studies	Е	Е	Е	Е
	d.	Comprehensive blood bank or access to a community central blood bank and adequate storage facilities	Е	Е	Е	-
	e.	Blood gases and pH determinations	Е	Е	Е	Е
	f.	Microbiology	Е	Е	Е	-
	12. Ac	cute Hemodialysis				
	a.	In-house	Е	-	-	-
	b.	Transfer agreement	-	Е	Е	Е
	13. Bu	rn Care—Organized	E			
	a.	In-house or transfer agreement with burn center	E	E	E	E
	14. Ac	cute Spinal Cord Management	E			
	a.	In house or transfer agreement with regional acute spinal cord injury rehabilitation center	E	E	E	E
F. 1	Rehal	pilitation Services				
	I. Tr	ansfer agreement to an approved rehabilitation facility	E	E	E	E
2	2. Ph	ysical therapy	Е	Е	Е	-
3	3. Oc	ccupational therapy	Е	Е	-	-
2	4. Sp	eech therapy	Е	Е	-	-
:	5. So	cial Services	Е	Е	Е	-
G .)	Perfo	rmance Improvement				

Commented [RS15]: Discuss

Commented [RS16]: Discuss

Commented [RS17]: Discuss

Commented [RS18]: All but #s 5 and 10 moved into R9-25-1308

1. I	Performance improvement programs	E	E	E	E
2. 1	Frauma Registry				
a	. In house	<mark>E</mark>	<mark>E</mark>	E	E
b	Participation in state, local, or regional registry	E	E	E	E
3 . 4	Audit of all trauma deaths	E	E	E	E
4 . 1	Morbidity and mortality review	E	E	E	E
5. Т	Γrauma conference – multidisciplinary	E	Е	Е	-
6. 1	Medical nursing audit	<mark>E</mark>	<mark>E</mark>	E	E
	Review of prehospital trauma care	<mark>₽</mark>	E	E	-
	Review of times and reasons for trauma related bypass	E	E	-	-
	Review of times and reasons for transfer of injured patients	E	<mark>E</mark>	<mark>E</mark>	E
10. F	Performance improvement personnel dedicated to care of njured patients	E	E	-	-
H. Con	tinuing Education/Outreach				
1. (Dutreach activities**	E	E		-
2. F	Residency program ²²	E	-	-	-
3. 4	ATLS provide/participate **	<mark>⊑</mark>	-	-	-
4 . F	Programs provided by hospital for:				
a	a. Staff/community physicians (CME)	E	E	E ²⁴	-
b	s. Nurses	<mark>E</mark>	<mark>E</mark>	E	-
	Allied health personnel	<mark>E</mark>	<mark>E</mark>	E	-
e	l. Prehospital personnel provision/participation	E	E	E	•
I. Prev	rention				
	Prevention program	E	E	•	•
	Collaboration with existing national, regional, state, and community programs ²⁴	E	E	E.	E
J. Rese					
	Research program ***	E	-	-	-
	Frauma registry performance improvement activities	<mark>E</mark>	<mark>E</mark>	E	=
	dentifiable Institutional Review Board process	E	-	-	-
4 . I	Extramural education presentations	E ²⁸	-		_

Commented [RS19]: Now in R9-25-1308

Commented [RS20]: Now in R9-25-1308

Commented [RS21]: Now in R9-25-1308

K. Additional Requirements for Trauma Centers Represented as Caring for Pediatric Trauma Patients ²⁰				
1. Trauma surgeons credentialed for pediatric trauma care	E	E	-	-
2. Pediatric emergency department area	E	<mark>E</mark>	-	-
3. Pediatric resuscitation equipment in all patient care areas	E	<mark>E</mark>	-	-
4. Microsampling	E	E	E	-
5. Pediatric specific performance improvement program	E	E	E	E
6. Pediatric intensive care unit	E ³⁰	E31	-	-

⁴ An individual may not serve as trauma medical director for more than one trauma center at the same time.

- 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
 - 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:

- 4- For a Level Itrauma 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.

- 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.

Commented [RS22]: Could be put elsewhere in the Table

² For a Level I trauma center, this shall be a full time position.

²-This does not apply ifemergency medicine physicians do not participate in the care of a hospital's trauma patients.

⁴ For this criterion, "immediately available" means that:

L. For a Level Itrauma center, a PGY 4 or 5 surgery resident or a trauma surgeon is on the hospital premises at all times; and

⁶For 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.

² For the criteria in (C)(3)(a)-(1), "promptly available" means that:

⁸ This criterion is satisfied by a physician authorized by the hospital to perform cardiothoracic surgery.

^aThis criterion is satisfied by a dentist or physician authorized by the hospital to performoral 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;
 - 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;
 - e. 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
- 4. Complies with the following:
 - 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 orthopædic trauma liaison. This criterion is satisfied by an average of 16 hours annually, or 48 hours over three years, o 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 orthopædic trauma liaison.

4 Except for Level) 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

Commented [RS23]: Discuss

for the trauma surgeon.

16 For this criterian "promptly available" means that for all major resuscitations in a Level III traum center:

- 4. 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.
- A Level I trauma center shall have a complete operating roomteam 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 roomteam shall be assigned to the operating roomas their primary function; they cannot also be dedicated to other functions within the institution.
- A Level II trauma center shall have a complete operating roomteam available when needed. The need to have an in-house operating roomteam depends on a number of things, including the patient population served, the ability to share responsibility for operating roomcoverage with other hospital stall, prehospital communication, and the size of the community served by the trauma center. If an out-of house operating roomteam 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 performeritical care procedures.
- This requirement is met through having an independent outreach programor 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
 - e. A collaborative residency programthat 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 programor 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,
 - ${\bf 3.} \quad {\bf Providing\ in\ formation\ resources\ for\ the\ public, and}$
 - 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 programorganized at the national, regional, state, or local community level.

²². This requirement is met through having an independent research programor 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 programactivities if they have a stated focused hypothesis or research question:

²⁸ The trauma programshall provide at least 12 educational presentations every three years outside the academically affiliated institutions of the trauma center.

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.

 $^{\rm 31}$ This requirement may be satisfied by a transfer agreement.

Commented [RS24]: Discuss

Art 14, 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)) Table 1 in Article 14 will be made as a new Section (not Table) in Article 13 and the Table struck. For ease of discussion, updates to the Table are shown below and are included in the new R9-25-1309.]

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.

E = 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 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	X
City of Residence	X	X
County of Residence	X	X
State of Residence	X	X
Country of Residence	X	
Alternate Home Residence	X	X

Commented [RS25]: Per the definition of trauma center, a HCI can't be a TC without designation

Co-Morbid Conditions (Pre-Existing)	X	
INJURY DATA ELEMENTS		
Injury Date	X	X
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	X
State of Injury	X	X
Primary ICD-9-CM E-code Injury Descriptor	X	X
Additional ICD-9-CM E-code Injury Descriptor	X	
Trauma Type	X	X
Work-Related	X	
Patient Occupational Industry	X	
Patient Occupation	X	
Patient Position in Vehicle	X	
Protective Devices	X	X
Child Specific Restraint	X	X
Airbag Deployment	X	X
Safety Equipment Issues	X	
PREHOSPITAL TRANSPORT DATA ELEMEN	NTS	
EMS Provider Type	X	
Transport Mode (Into Reporting Facility)	X	X
Other Transport Modes	X	
[Transport] Agency	X	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	

Commented [RS26]: Will describe using the defined term "ICD-codes"

Commented [RS27]: Country of Injury is currently being collected and will be added to the full data set.

Commented [RS28]: The activity that the patient was engaged in at the tile of the injury is also currently being collected and will be added to the full data set.

Commented [RS29]: The type of vehicle is also currently being collected and will be added to the full data set.

Commented [RS30]: Also add "Incident Number"

Commented [RS31]: If this field applies in non-EMS situations, it should be reworded

Time of EMS Patient Contact	X	
Date EMS Provider Departed Scene	X	
Time EMS Provider Departed Scene	X	
Date of Arrival at Destination	X	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	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 HOSPITAL DATA EL	LEMENTS	
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	
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/IRAUMA 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	X
ED Discharge Disposition	X	X
ED Discharge Destination Hospital	X	X
Discharge Transport Agency	X	X
Transfer Reason	X	X
ED/Hospital Initial Pulse Rate	X	X
ED/Hospital Initial Respiratory Rate	X	X
ED/Hospital Initial Respiratory Assistance	X	X
ED/Hospital Initial Oxygen Saturation	X	X
ED/Hospital Initial Supplemental Oxygen	X	X
ED/Hospital Intubation Status	X	X
ED/Hospital Paralytic Agent in Effect	X	X
ED/Hospital Initial Systolic Blood Pressure	X	X
ED/Hospital Initial GCS – Eye Opening	X	X
ED/Hospital Initial GCS – Verbal Response	X	X
ED/Hospital Initial GCS – Motor Response	X	X
ED/Hospital Initial GCS – Total	X	X
ED/Hospital Initial GCS Assessment Qualifiers	X	
ED/Hospital Initial Temperature	X	X
ED/Hospital Initial Units of Temperature	X	X
ED/Hospital Initial Temperature Route	X	X

Commented [RS32]: Add "Another factor that could affect GCS"

Г		
ED/Hospital Initial Revised Trauma Score	X	X
Alcohol Use Indicator	X	X
Blood Alcohol Content (mg/dl)	X	X
Drug Use Indicator	X	X
Toxicology Substances Found	X	X
DISCHARGEDATA 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	X
Transfer Reason	X	X
Autopsy Identification Number	X	
[Injury] Diagnoses – ICD 9 CM N codes	X	X
AIS Six-Digit Injury Identifier	X*	
AIS Severity Code	X	
AIS Body Region of Injury	X	
Injury Severity Score	X	X
Probability of Survival	X	
ED/Hospital Procedure Location	X	
ED/Hospital Procedure Start Date	X	
ED/Hospital Procedure Start Time	X	
ED/Hospital CD-9-CM-Procedure Codes	X	
Hospital Complications	X	
Primary Method of Payment	X	X
Secondary Method of Payment	X	X
Total Hamital Charges	X	X
Total Hospital Charges	71	71

Commented [RS33]: Will describe using the defined term "ICD-codes"

Commented [RS34]: Calculated based on AIS identifiers that are not being required

Commented [RS35]: Will describe using the defined term "ICD-codes"

Commented [RS36]: Adding fields for: Suspected abuse Investigation of suspected abuse Child released to other caregiver

R9-25-1309. Trauma Registry Data (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2208(A), 36-2209(A)(2), 36-2221, and 36-2225(A)(5) and (6)) [Table 1 in Article 14 is made as a New Section in Article 13.]

- At trauma registry established according to R9-25-1308(C)(1) includes the following in the record of a patient's episode of care, as defined in A.A.C. R9-11-101, for each patient meeting the criteria in R9-25-1308(H)(1):
 - 1. An identification code specific to the health care institution that had contact with the patient during the episode of care;
 - 2. <u>Demographic information about the patient:</u>
 - a. The unique number assigned by the health care institution to the patient;
 - b. A code indicating whether the patient's record will be submitted to the Department as required in R9-25-1308(H)(2);
 - c. The unique number assigned by the health care institution for the episode of care;
 - d. The date the patient was admitted to the health care institution for the episode of care;
 - e. For the episode of care, a code indicating whether the patient:
 - i. Was directly admitted to the health care institution,
 - ii. Was admitted to the health care institution through the emergency department,
 - <u>Was seen in the emergency department then transferred to another health</u>
 <u>care institution by an ambulance service or emergency medical services</u>
 provider,
 - iv. Was seen in the emergency department and discharged, or
 - v. Died in the emergency department or was dead on arrival;
 - <u>f.</u> The patient's first name, middle initial, and last name;
 - g. The patient's Social Security Number;
 - h. The patient's date of birth and age;
 - i. Codes indicating the patient's gender, race, and ethnicity;
 - j. The zip code of the patient's residence or, if applicable, an indication of why no zip code was reported; and
 - k. The city, state, and county of the patient's residence;
 - 3. <u>Information about the occurrence of the patient's injury:</u>
 - <u>a.</u> The date and time the injury occurred;
 - <u>b.</u> <u>The ICD-code describing the type of location where the injury occurred;</u>

- <u>c.</u> The zip code of the location where the injury occurred;
- <u>d.</u> The city, state, and county where the injury occurred;
- e. A code indicating whether the patient's injury resulted from blunt force trauma, a penetrating wound, or a burn;
- <u>f.</u> The ICD-code indicating the primary mechanism or cause of the patient's injury resulting in the episode of care and the manner or intent through which the injury occurred;
- g. A description of the cause and circumstances leading to the patient's injury;
- Mhether the patient was using a protective device or safety equipment at the time
 of the injury and, if so, the type or types of protective device or safety equipment
 being used;
- i. If the patient was subject to the requirements in A.R.S. § 28-907 at the time of the injury, whether the patient was using a child restraint system, as defined in A.R.S. § 28-907, at the time of the injury and, if so, the type of child restraint system being used; and
- j. If the patient's injury resulted from a motor vehicle crash, a code describing the status of airbag deployment;
- 4. <u>Information about the patient's arrival at the trauma center:</u>
 - a. A code identifying the mode of transportation by which the patient arrived at the trauma center; and
 - b. <u>If applicable:</u>
 - <u>i.</u> The ambulance service or emergency medical services provider that transported the patient to the trauma center,
 - ii. The unique identifier given by the ambulance service or emergency medical services provider to the incident during which the patient received EMS, and
 - <u>The date the ambulance service or emergency medical services provider</u> transported the patient to the trauma center;
- 5. <u>Information about the trauma center's assessment or treatment of the patient in the</u> emergency department:
 - a. A code indicating which of the criteria in R9-25-1308(H)(1) the patient met;
 - <u>A code indicating whether an ambulance service or emergency medical services</u>
 <u>provider transported the patient to the trauma center and, if so, the criteria used</u>
 <u>by the transporting ambulance service or emergency medical services provider</u>

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- for transporting the patient to the trauma center;
- <u>c.</u> The date and time the patient arrived at the emergency department of the trauma center for the episode of care;
- d. The date and time the patient died or left the emergency department of the trauma center for the episode of care;
- e. The length of time in hours and in minutes that the patient remained in the emergency department of the trauma center during the episode of care:
- <u>f.</u> <u>If trauma team activation occurred, the time when all trauma team personnel</u> <u>members were at their assigned locations in the trauma center;</u>
- g. Whether the patient showed signs of life when the patient arrived at the trauma center;
- <u>h.</u> The values of the following for the patient at the time of their first assessment at the trauma center:
 - i. Pulse rate;
 - ii. Respiratory rate;
 - iii. Oxygen saturation;
 - iv. Systolic blood pressure; and
 - v. <u>Temperature</u>, including the units of temperature and the route used to measure the patient's temperature;
- i. A code indicating whether the patient was receiving respiratory assistance at the time the patient's respiratory rate was assessed;
- A code indicating whether the patient was receiving supplemental oxygen at the time the patient's oxygen saturation was assessed;
- k. Codes indicating the Glasgow Coma Score for:
 - i. Eye opening,
 - ii. Verbal response to stimulus, and
 - iii. Motor response to stimulus;
- 1. The patient's total Glasgow Coma Score;
- m. Whether the patient was intubated at the time of the patient's assessments in subsections (A)(5)(h)(ii) and (l);
- n. A code indicating whether a paralytic agent or sedative had been administered to the patient at the time the patient's Glasgow Coma Score was measured;
- o. A code indicating another factor that may have affected the patient's Glasgow

 Coma Score;

- <u>A revised trauma score for the patient, auto-calculated based on the patient's</u>
 systolic blood pressure, respiratory rate, and Glasgow Coma Score;
- q. A code indicating the status of alcohol use by the patient and, if applicable, the
 blood alcohol concentration in the patient's blood;
- A code indicating the status of drug use by the patient and, if applicable, the code
 for each drug class detected in the patient's blood;
- s. A code indicating the disposition of the patient at the time the patient was discharged from the emergency department; and
- <u>t.</u> <u>If the patient was transferred to another health care institution upon discharge</u> from the emergency department:
 - i. The name of the health care institution to which the patient was transferred;
 - ii. The ambulance service or emergency medical services provider providing the interfacility transport;
 - iii. A code indicating the reason for transfer; and
 - iv. If there was a delay in transferring the patient to another health care institution, a code indicating the reason for the delay;
- 6. <u>Information about the patient's discharge from the trauma center:</u>
 - a. The date and time the patient was discharged from the trauma center;
 - b. The length of time the patient remained as an inpatient, as defined in A.A.C. R9-10-201, in the trauma center;
 - c. The length of time the patient remained in the trauma center's intensive care unit;
 - d. A code indicating whether the patient was alive or dead at the time of discharge from the trauma center;
 - e. The ICD-code for each injury identified in the patient, including an indication of whether the ICD-code is for:
 - <u>i.</u> The principle diagnosis, the reason believed by the trauma center to be chiefly responsible for the patient's need for the episode of care; or
 - ii. A secondary diagnosis, another reason believed by the trauma center to have contributed to the patient's need for the episode of care;
 - <u>f.</u> The patient's Injury Severity Score;
 - g. A code indicating the disposition of the patient at the time the patient was discharged from the trauma center;
 - h. Whether a report of suspected physical abuse was reported to lawenforcement or

Commented [RS38]: 17. "Inpatient" means an individual who: a. Is admitted to a hospital as an inpatient according to policies and procedures,

b. Is admitted to a hospital with the expectation that the individual will remain and receive hospital services for 24 consecutive hours or more, or

c. Receives hospital services for 24 consecutive hours or more.

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as required by A.R.S. § 13-3620 or 46-454, if applicable, and, if so:

- <u>Whether an investigation into the suspected physical abuse was initiated</u>
 by an entity to which the suspected physical abuse was reported; and
- ii. If the patient is a child, whether the patient was discharged in the care of
 a person other than the person responsible for the care of the patient at
 the time the patient was admitted; and
- i. If the patient was transferred to a hospital upon discharge from the trauma center:
 - i. The name of the hospital to which the patient was transferred,
 - <u>ii.</u> The ambulance service or emergency medical services provider providing the interfacility transport, and
 - iii. A code indicating the reason for transfer; and
- 8. Financial information about the episode of care:
 - A code for the primary source of payment for the episode of care;
 - b. A code for a secondary source of payment for the episode of care, if applicable.
 - c. The total amount of charges for the episode of care; and
 - <u>d.</u> The total amount collected by the trauma center for the episode of care.
- B. In addition to the information required in subsection (A), a trauma registry established according to R9-25-1308(C)(1) by a Level II, Level II, or Level III trauma center includes the following in the record of a patient's episode of care, as defined in A.A.C. R9-11-101, for each patient meeting the criteria in R9-25-1308(H)(1):
 - 1. Demographic information about the patient:
 - a. The country of the patient's residence;
 - b. The country where the patient was found or from which an ambulance service or emergency medical services provider transported the patient; and
 - c. Any pre-existing medical conditions diagnosed for the patient, unrelated to the reason for the episode of care;
 - 2. <u>Information about the occurrence of the patient's injury:</u>
 - a. Whether the time specified according to subsection (A)(3)(a) is the actual time of occurrence or an estimate;
 - <u>b.</u> The street address of the location where the injury occurred or, if the location at which the injury occurred does not have a street address, another indicator of the location at which the injury occurred;
 - c. Any additional ICD-code describing the mechanism or cause of the patient's injury resulting in the episode of care and the manner or intent through which the

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injury occurred;

- <u>d.</u> <u>The ICD</u>-code indicating the activity the patient was engaged in that resulted in the patient's injury;
- e. If the patient's injury resulted from a crash involving a means of transportation, including a motor vehicle, other motorized means of transportation, watercraft, bicycle, or aircraft, a code describing the type of vehicle in use at the time of the injury and the patient's location in the vehicle;
- <u>f.</u> A description of any issues related to a protective device or safety equipment in use at the time of the patient's injury; and
- g. Whether the patient's injury occurred during the patient's paid employment and,
 if so, a code indicating:
 - i. The type of occupation associated with the patient's employment, and
 - ii. The patient's occupation;
- 3. A code indicating whether EMS was provided to the patient:
 - a. At the scene by an emergency medical services provider that did not transport the patient to the trauma center or another health care institution;

 - g. By an ambulance service or emergency medical services provider that
 transported the patient to a health care institution other than the trauma center, as
 specified according to subsection (B)(8)(a);
- 4. If the patient was transported to a rendezvous point or was seen by another health care institution for the injury resulting in the episode of care before being transported to the trauma center, information about each patient transport:
 - a. A code indicating the location from which the patient:
 - i. Came to the health care institution,
 - ii. Was transported to the rendezvous point, or
 - iii. Was transported to the health care institution;
 - <u>b.</u> <u>If the patient was transported to the health care institution from a rendezvous</u> point:
 - i. The location of the rendezvous point, and
 - <u>ii.</u> The ambulance service or emergency medical services provider that transported the patient to the rendezvous point;
 - <u>c.</u> <u>If the patient was transported to the health care institution from another health</u>

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- care institution, the name of the other health care institution;
- <u>d.</u> The name of the health care institution to which the patient came or was transported;
- e. A code identifying the mode of transportation by which the patient arrived at the health care institution; and
- f. If the patient was transported by an ambulance service or emergency medical services provider to the health care institution, the ambulance service or emergency medical services provider that:
 - i. Transported the patient to the health care institution; or
 - ii. If applicable, provided EMS to the patient at the scene without transporting the patient;
- 5. If EMS was provided to the patient as described according to subsection (B)(4)(f),
 whether a prehospital incident history report was provided to the trauma center and, if so:
 - a. The date on the prehospital incident history report;
 - <u>b.</u> The identifying number on the prehospital incident history report assigned by the ambulance service or emergency medical services provider;
 - c. The date and time the ambulance service or emergency medical services provider was dispatched, as defined in R9-25-901, to the scene;
 - d. The date and time the ambulance service or emergency medical services provider responded to the dispatch;
 - <u>e.</u> <u>The date and time the ambulance service or emergency medical services provider arrived at the scene;</u>
 - <u>f.</u> The date and time the ambulance service or emergency medical services provider established contact with the patient;
 - g. The date and time the ambulance service or emergency medical services provider left the scene;
 - h. The date and time the ambulance service or emergency medical services provider arrived at the rendezvous point, trauma center, or health care institution that was the transport destination;
 - <u>i.</u> The date and time the patient's pulse, respiration, oxygen saturation, and systolic blood pressure were first measured;
 - j. At the date and time the patient's pulse, respiration, oxygen saturation, and systolic blood pressure were first measured, the patient's:
 - i. Pulse rate,

- ii. Respiratory rate,
- iii. Oxygen saturation, and
- iv. Systolic blood pressure;
- <u>Whether the patient was intubated at the date and time the patient's pulse</u>,
 respiration, and oxygen saturation were first measured;
- 1. Codes indicating the Glasgow Coma Score for:
 - i. Eye opening,
 - ii. Verbal response to stimulus, and
 - iii. Motor response to stimulus;
- m. The patient's total Glasgow Coma Score;
- <u>A code indicating whether a paralytic agent or sedative had been administered to</u>
 <u>the patient at the date and time the patient's Glasgow Coma Score was measured;</u>
- o. A revised trauma score for the patient, auto-calculated based on the patient's systolic blood pressure, respiratory rate, and Glasgow Coma Score;
- <u>p.</u> Codes indicating all airway management procedures performed on the patient by
 <u>an ambulance service or emergency medical services provider before the</u>
 <u>patient's arrival at the first health care institution; and</u>
- <u>whether the patient experienced cardiac arrest subsequent to the injury before the patient's arrival at the first health care institution;</u>
- 6. The amount of time that elapsed from the date and time the ambulance service or emergency medical services provider:
 - Was dispatched and the date and time the ambulance service or emergency
 medical services provider arrived at the scene.
 - b. Arrived at the scene and the date and time the ambulance service or emergency medical services provider left the scene,
 - c. <u>Left the scene and the date and time the ambulance service or emergency medical</u> services provider arrived at the transport destination, and
 - <u>d.</u> <u>Was dispatched and the date and time the ambulance service or emergency</u> <u>medical services provider arrived at the transport destination;</u>
- 7. Whether the patient arrived at the trauma center for treatment of the injury resulting in the episode of care through an interfacility transport;
- 8. If the patient arrived at the trauma center through an interfacility transport, information about the health care institution at which the patient was seen immediately before arriving at the trauma center:

- <u>a.</u> The name of the health care institution;
- b. The date and time the patient arrived at the health care institution in subsection (B)(8)(a);
- c. The date and time the patient left the health care institution in subsection (B)(8)(a); and
- <u>d.</u> The number of hours and the number of minutes the patient remained in the health care institution in subsection (B)(8)(a);
- 9. If the patient arrived at the health care institution in subsection (B)(8)(a) through an interfacility transport, information in subsections (B)(8)(a) through (d) about each health care institution at which the patient was seen for the injury resulting in the episode of care before arriving at the health care institution in subsection (B)(8)(a);
- 10. If the patient arrived at the trauma center through an interfacility transport, for each health care institution at which the patient was seen for the injury resulting in the episode of care before arriving at the trauma center, information for the first instance of assessing the patient's:
 - a. Respiratory rate,
 - b. Systolic blood pressure,
 - c. The patient's total Glasgow Coma Score, and
 - d. Revised trauma score; and
- 11. <u>Information about the patient's episode of care at the trauma center and the patient's</u> discharge from the trauma center:
 - a. The patient's height and weight when the patient arrived at the trauma center,
 - <u>b.</u> The number of days the patient spent on a mechanical ventilator;
 - If applicable, the identification number assigned by a medical examiner or alternate medical examiner, as defined in A.R.S. § 11-591, to the documentation of the patient's autopsy;
 - <u>d.</u> The total length of time the patient remained at the trauma center before discharge;
 - e. For each ICD-code identified according to subsection (A)(6)(e), a code that reflects the severity of the injury to which the ICD-code refers;
 - <u>f.</u> For each ICD-code identified according to subsection (A)(6)(e) that does not include an indication of the part of the patient's body that was injured, a code supplementing the ICD-code that indicates the part of the body that was injured;
 - g. For each procedure performed on the patient:

- i. The ICD-code for the procedure,
- ii. The health care institution at which the procedure was performed,
- iii. A code indicating the organized service unit within the health care institution in which the procedure was performed, and
- iv. The date and time the procedure was begun;
- <u>h.</u> <u>Any complications experienced by the patient while the patient remained at the trauma center;</u>
- <u>i.</u> The Abbreviated Injury Scale code indicating the severity of each of the patient's injuries:
- j. The Abbreviated Injury Scale code indicating the body region affected by each of the patient's injuries;
- <u>k.</u> If the trauma center is designated as a Level I trauma center, the six-digit
 <u>Abbreviated Injury Scale code and the software version used to calculate the six-digit Abbreviated Injury Scale code; and</u>
- 1. The patient's probability of survival.

R9-25-1406.R9-25-1310. [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:
 - 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.

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- 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.
- 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.
- A. To ensure the completeness and accuracy of trauma registry reporting, a health care institution submitting trauma registry information to the Department shall allow the Department to review the following, upon prior notice from the Department of at least five business days:
 - 1. The health care institution's trauma registry or other database containing trauma registry information;
 - 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 receiving trauma care.
- B. Upon prior notice from the Department of at least five business days, a health care institution submitting trauma registry information to the Department shall provide the Department with all patient medical records for a time period specified by the Department, to allow the Department to determine the accuracy and completeness of the information submitted to the trauma registry for patients receiving trauma care during the period.
- C. For purposes of subsection (B), the Department considers a health care institution to be in compliance with R9-25-1308(H)(2) if the health care institution submitted to the Department trauma registry information for 97% of the patients receiving trauma care during the period.
- D. If trauma registry information submitted to the Department by a health care institution according to R9-25-1308(H)(2) is not in compliance with requirements in R9-25-1308 or R9-25-1309, the Department shall:
 - Notify the health care institution that the trauma registry information submitted to the
 Department is not in compliance with requirements in R9-25-1308 or R9-25-1309, and

- 2. Identify the revisions that are needed to bring the data into compliance with R9-25-1308 and R9-25-1309.
- <u>A health care institution that has trauma registry information returned, as provided in subsection</u>
 (D), shall:
 - 1. Revise the trauma registry information as identified by the Department, and
 - Submit the revised data to the Department within 15 business days after the date the
 Department notified the health care institution according to subsection (D)(1) or within a longer period agreed upon between the Department and the health care institution.
- F. Within 15 business days after receiving a written request from the Department that includes a simulated patient medical record, a health care institution submitting trauma registry information to the Department shall prepare and submit to the Department the information required in R9-25-1309, applicable to the Level of health care institution, for the patient described in the simulated patient medical record.

ARTICLE 14. TRAUMA REGISTRY; TRAUMA SYSTEM QUALITY ASSURANCE REPEALED

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)) Repealed [Needed definitions moved into 1301]

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. "Seene" means a location, other than a health care institution, from which a patient is transported.
- 25. "Submitting health eare institution" means a health eare 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)) Repealed [Relevant requirements moved into the new R9-25-1308(H) and (I)]

- 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;
 - A superficial injury or contusion, as demonstrated by an ICD 9 CM N code within categories 910 through 924;
 - 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:
 - 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:
 - 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;
 - 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;
 - e. For eases 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;
- 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;
 - e. 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.
- 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)) Repealed [Moved into Article 13 as Table 13.2 R9-25-1309!]

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 FLEMENTS		
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 FLEMENTS		
Injury Date	X	X
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	
Zin Codo of Injury		
Zip Code of Injury	X	X
City of Injury	X	X
	+	
City of Injury	X	
City of Injury County of Injury State of Injury Primary ICD 9 CM E code Injury Descriptor	X X X X	
City of Injury County of Injury State of Injury	X X X	×
City of Injury County of Injury State of Injury Primary ICD 9 CM E code Injury Descriptor	X X X X	×
City of Injury County of Injury State of Injury Primary ICD 9 CM E code Injury Descriptor Additional ICD 9 CM E code Injury Descriptor	X X X X X	×
City of Injury County of Injury State of Injury Primary ICD 9 CM E code Injury Descriptor Additional ICD 9 CM E code Injury Descriptor Trauma Type	* * * * * * * * * * * * * * * * * * *	×
City of Injury County of Injury State of Injury Primary ICD 9 CM E code Injury Descriptor Additional ICD 9 CM E code Injury Descriptor Trauma Type Work Related	X X X X X X	×
City of Injury County of Injury State of Injury Primary ICD 9 CM E code Injury Descriptor Additional ICD 9 CM E code Injury Descriptor Trauma Type Work Related Patient Occupational Industry	X X X X X X X X	×

Airbag Deployment	X
PREHOSPITAL TRANSPORTDATA ELEMENTS EMS Provider Type	X
EMS Provider Type Transport Mode (Into Reporting Facility) X Other Transport Modes X Transport Agency Run Sheet Available? Run Sheet Date Transported From At Date EMS Provider Notified X Time EMS Provider Notified X Time EMS Provider Left for Scene X Time EMS Provider Left for Scene X Time EMS Provider Arrived at Scene X Time EMS Provider Arrived at Scene X Time of EMS Patient Contact Time of EMS Patient Contact Time EMS Provider Departed Scene X Time EMS Provider Departed Scene X Time of Arrival at Destination X Time of Arrival at Destination EMS Destination Total EMS Response Time (Minutes) Transport Time Scene to Destination (Minutes) X Total EMS Time (Minutes) X System Access	X
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Triage Criteria X	
3	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/IRANSFER HOSPITAL DATA E	LEMENTS	
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	
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	
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	
DISCHARGEDATA FLEMENTS		
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	<u>X*</u>	
AIS Severity Code	X	
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	

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)) Repealed

- 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.

R9-25-1405. 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), 362221, 36-2222(E)(3), 36-2225(A)(5) and (6), 36-2403(A), and 36-2404) Repealed

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

Commented [RS44]: Not needed. Just restates the statutory requirement in A.R.S. § 36-2221.

Commented [RS45]: Not needed

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. Renumbered

Commented [RS46]: This covered both TCs and non-TCs Requirements moved into Article 13 as R9-25-1310 and amended