NOTICE OF FINAL EXPEDITED RULEMAKING TITLE 9. HEALTH SERVICES

2023 SEP 18 PM 4: 31

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

FILED

PREAMBLE

<u>1.</u>	Article, Part or Sections Affected (as applicable)	Rulemaking Action
	R9-25-1301	Amend
	R9-25-1304	Amend
	R9-25-1306	Amend
	R9-25-1307	Amend
	R9-25-1308	Amend
	Table 13.1	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 36-132(A)(1), 36-136(G), 36-2202(A)(4)

Implementing statutes: A.R.S. §§ 36-2221, 36-2225

<u>3.</u> The effective date of the rules:

The rule is effective the day the Notice of Final Expedited Rulemaking is filed with the Office of the Secretary of State.

Citations to all related notices published in the Register as specified in R1-1-409(A) that 4. pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 29 A.A.R. 620, February 24, 2023

Notice of Proposed Expedited Rulemaking: 29 A.A.R. 1445, June 30, 2023

The agency's contact person who can answer questions about the rulemaking: <u>5.</u>

Name:

Rachel Garcia, Bureau Chief

Address:

Arizona Department of Health Services

Division of Public Health Services

Bureau of Emergency Medical Services and Trauma System

150 N. 18th Avenue, Suite 540

Phoenix, AZ 85007

Telephone:

(602) 364-3150

Fax:

(602) 364-3568

E-mail:

Rachel.Garcia@azdhs.gov

or

Name:

Stacie Gravito, Office Chief

Address:

Arizona Department of Health Services

Office of Administrative Counsel and Rules

150 N. 18th Ave., Suite 200

Phoenix, AZ 85007

Telephone:

(602) 542-1020

Fax:

(602) 364-1150

E-mail:

Stacie.Gravito@azdhs.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Arizona Revised Statutes (A.R.S.) § 36-2225 requires the Arizona Department of Health Services (Department) to develop and administer a statewide emergency medical services and trauma system to implement the Arizona emergency medical services and trauma system plan, required under A.R.S. § 36-2208. A.R.S. § 36-2225 further requires the Department to adopt rules for the designation of trauma centers and to require trauma centers to submit data to the trauma registry established by the Department under A.R.S. § 36-2208. The Department has implemented these statutes in Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Article 13. As part of a recent five-year-review, the Department identified several issues with the current rules and proposed making changes to the rules. After receiving an exception according to A.R.S. § 41-1039(A), the Department plans to clarify the rules through expedited rulemaking, under A.R.S. § 41-1027, consistent with the five-year review report, to reduce the regulatory burden.

7. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

Under A.R.S. § 41-1055(D)(2), the Department is not required to provide an economic, small

business, and consumer impact statement.

10. A description of any changes between the proposed expedited rulemaking, including supplemental notices, and the final expedited rulemaking:

Between the proposed expedited rulemaking and the final expedited rulemaking, no changes were made to the rulemaking.

11. Agency's summary of the public or stakeholder comments or objections made about the rulemaking and the agency response to the comments:

The Department did not receive public or stakeholder comments about the rulemaking.

- 12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:
 - Whether the rule requires a permit, whether a general permit is used and if not, the
 reasons why a general permit is not used:

The rules do not require a permit, but allow for designation. A health care institution may provide the same services with or without designation.

Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No business competitiveness analysis was received by the Department.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Not applicable

14. Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

The rule was not previously made as an emergency rule.

15. The full text of the rules follows:

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

ARTICLE 13. TRAUMA CENTERS AND TRAUMA REGISTRIES

Section	
R9-25-1301.	Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1304.	Changes Affecting Designation Status (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-
	2225(A)(4)
R9-25-1306.	Inspections (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1307.	Designation and Dedesignation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-
	2225(A)(4))
R9-25-1308.	Trauma Center Responsibilities (A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2),
	36-2221, and 36-2225(A)(4), (5), and (6))
Table 13.1.	Arizona Trauma Center Standards (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-
	2225(A)(4))

ARTICLE 13. TRAUMA CENTERS AND TRAUMA REGISTRIES

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 following definitions apply in this Article, unless otherwise specified:

- 1. "Admitted" means when a patient is either:
 - a. Held for observation of a trauma-related injury; or
 - b. Considered an inpatient, as defined in A.A.C. R9-10-201.
- 2. "Business day" means a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.
- 3. "Designation" means a formal determination by the Department that a health care institution complies with requirements in A.R.S. § 36-2225 and this Article for providing a particular Level of trauma service.
- 4. "Emergency department" means a designated area of a hospital that provides emergency services, as defined in A.A.C. R9-10-201 R9-10-101, as an organized service, 24 hours per day, seven days per week, to individuals who present for immediate medical services.
- 5. "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.
- 6. "Level I Pediatric trauma center" means a Level I trauma center that has a trauma service specifically intended to meet the needs of children requiring trauma care.
- 7. "Level II Pediatric trauma center" means a Level II trauma center that has a trauma service specifically intended to meet the needs of children requiring trauma care.
- 8. "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.S. § 32-1800, performed at the direction of a physician.
- 9. "National verification organization" has the same meaning as in A.R.S. § 36-2225.
- 10. "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
 - b. By or under the supervision of a registered nurse licensed:
 - i. According to Title 32, Chapter 15; or

- ii. 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.
- 11. "On-call" means assigned to respond and, if necessary, come to a health care institution when notified by a personnel member of the health care institution.
- 12. "Organized service" has the same meaning as in A.A.C. R9-10-201.
- 13. "Owner" means one of the following:
 - a. For a health care institution licensed under 9 A.A.C. 10, the licensee;
 - b. For a health care institution operated under federal or tribal laws, the administrative unit of the U.S. government or sovereign tribal nation operating the health care institution.
- 14. "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.
- 15. "Physician" means an individual licensed:
 - a. According to A.R.S. Title 32, Chapter 13 or 17; or
 - b. 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.
- 16. "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.
- 17. "Substantial compliance" has the same meaning as in A.R.S. § 36-401.
- 18. "Transport" means the conveyance of a patient by ground ambulance or air ambulance from one location to another location.
- 19. "Trauma care" means medical services and nursing services provided to a patient suffering from a sudden physical injury.
- 20. "Trauma center" has the same meaning as in A.R.S. § 36-2225.
- 21. "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.
- 22. "Trauma facility" means a health care institution that provides trauma care to a patient as an organized trauma service.

- 23. "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.
- 24. "Trauma team" means a group of personnel members with defined roles and responsibilities in providing trauma care to a patient.
- 25. "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.
- 26. "Verification" means formal confirmation by a national verification organization that a health care institution meets the national verification organization's standards for providing trauma care at a specific Level of trauma service.

R9-25-1304. Changes Affecting Designation Status (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. An 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 or revoked;
 - 2. The trauma center's health care institution license is changed to a provisional license under A.R.S. § 36-425;
 - 3. The trauma center no longer holds verification; or
 - 4. 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. If designation is based on verification, the national verification organization's 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 the trauma service and to relinquish designation, including the effective date.

- **D.** 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;
 - 2. Subsection (B)(1), send the owner a written notice stating that the health care institution no longer meets the definition of a trauma center and that the Department intends to dedesignate the health care institution, according to R9-25-1307(J)(2);
 - 3. Subsection (B)(2), 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(J) through (M);
 - b. Require a modification of the health care institution's designation within 15 calendar days after the date of the notice, according to R9-25-1305; or
 - c. 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)(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:
 - An 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; or
 - b. Written notification of the owner's intention to relinquish designation;
 - 5. Subsection (B)(4), 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;
 - b. 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; or
 - 6. Subsection (C), (D)(4)(b), or (D)(5)(c), send the owner written confirmation of the voluntary relinquishment of designation.

E. 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 application according to R9-25-1303.

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

- A. When the Department inspects a health care institution applying for a trauma center designation or a health care institution designated as a trauma center to determine compliance with the applicable requirements in this Article, the Department:
 - 1. Shall use criteria for assessing compliance developed using recommendations from the State Trauma Advisory Board, according to A.R.S. § 36-2222(E)(1); and
 - 2. May:
 - a. Evaluate the health care institution's equipment and physical plant;
 - b. Interview the health care institution's personnel members, including any individuals providing trauma care; and
 - c. Review any of the following:
 - i. Medical records;
 - ii. Patient discharge summaries;
 - iii. Patient care logs;
 - Rosters and schedules of personnel members and individuals who
 provide trauma care as part of the trauma service;
 - v. Performance-improvement-related documents, including quality management program documents required in A.A.C. R9-10-204 or R9-10-1004 as applicable; and
 - vi. Other documents relevant to the provision of trauma care as part of the trauma service.
- B. The Department shall determine whether there is a need for an inspection of a health care institution and which components in subsection (A)(2) to include in an inspection, based on the health care institution's application; previous inspections, if applicable; and the operating history of the health care institution and may conduct an announced inspection of the identified components:
 - 1. Before issuing an initial, renewal, or modified designation to an owner applying for designation of a health care institution as a trauma center;
 - 2. If an owner of a health care institution designated as a trauma center has submitted a

- corrective action plan under subsection (E); or
- 3. A health care institution designated as a trauma center 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 according to subsection (A).
- **D.** 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 instances of non-compliance identified during the inspection and a request for a written corrective action plan.
- E. Within 15 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 instance of non-compliance:
 - 1. A description of how the instance of non-compliance will be corrected and reoccurrence prevented, and
 - 2. A date of correction for the instance of non-compliance.
- **F.** The Department shall accept a written corrective action plan if the corrective action plan:
 - Describes how each identified instance of non-compliance will be corrected and reoccurrence prevented, and
 - 2. Includes a date for correcting each instance of non-compliance that is appropriate to the actions necessary to correct the instance of non-compliance.
- G. If the Department reviews a health care institution's facility and documentation of capabilities during a national verification organization's assessment according to R9-25-1302(C)(3) and the health care institution is not issued verification from the national verification organization at the Level of designation sought, the Department shall send to an owner of the health care institution, within 30 calendar days after the review, a written report of the Department's findings, including, if applicable, a list of any instances of non-compliance with requirements in R9-25-1308 and Table 13.1 identified during the review.
- H. A health care institution receiving a written report in subsection (G)₂ containing a list of instances of non-compliance with requirements in R9-25-1308 and Table 13.1 identified during a review of the health care institution's facility and documentation of capabilities₂ may submit to the Department a written plan to correct instances of non-compliance that includes:
 - 1. A description of how the health care institution will correct each instance of noncompliance and prevent the reoccurrence, and
 - 2. A date by which the health care institution plans to correct each instance of non-

compliance.

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

- A. For <u>initial</u> designation <u>or renewal of designation</u> of a health care institution based on verification, the Department shall, within 45 calendar days after receiving a complete application from an owner:
 - 1. If Except as provided in subsection (H)(2), if the application complies with the applicable requirements in this Article, issue a designation for the health care institution that is valid for the duration of the verification; or
 - 2. If the application does not comply with the applicable requirements in this Article, provide a written notice that complies with A.R.S. Title 41, Chapter 6, Article 10, that the Department intends to decline to issue a designation for the health care institution.
- B. Except as provided in subsection (F) specifying requirements for renewal of a one-year designation, for initial designation or renewal of designation of a health care institution based on an assessment by a national verification organization, the Department shall, within 60 calendar days after receiving a complete application from an owner, review the application and, if the Department determines that:
 - 1. The application and the health care institution comply with the applicable requirements in this Article, except as provided in subsection (H)(1), issue a designation for the health care institution that is valid for three years from the issue date;
 - 2. The application complies with the applicable requirements in this Article, the health care institution is in substantial compliance with the applicable requirements in this Article, and the Department has accepted a written corrective action plan submitted according to R9-25-1306(E), issue a designation for the health care institution that is valid for one year from the issue date; or
 - 3. The application or the health care institution does not comply with the applicable requirements in this Article, provide a written notice that complies with A.R.S. Title 41, Chapter 6, Article 10, that the Department intends to decline to issue a designation for the health care institution.
- C. Except as provided in subsection (F) <u>specifying requirements</u> for renewal of a one-year designation, for <u>initial</u> designation <u>or renewal of designation</u> of a health care institution as a Level III trauma center or a Level IV trauma center based on an assessment by the Department, an owner shall include as part of the application required in R9-25-1303(A):
 - 1. The following information in a Department-provided format:

- a. The name of the health care institution for which the owner is requesting designation;
- The services the health care institution is providing or plans to provide as part of the trauma service;
- c. The name and title of the liaison to the trauma service from each of the services listed according to subsection (C)(1)(b);
- d. If applicable, the name, e-mail address, telephone number, and, if available, fax number of the health care institution's emergency department physician director;
- e. If applicable, the name, e-mail address, telephone number, and, if available, fax number of the health care institution's surgical director or co-director;
- f. If a multidisciplinary peer review committee is required according to Table 13.1 for the Level of the trauma center, the name and title of each member of the multidisciplinary peer review committee;
- g. If the health care institution's trauma registry will be part of a centralized trauma registry, a description of the training provided to the trauma program manager to enable the trauma program manager to comply with R9-25-1308(D)(2);
- h. If applicable, for an application for initial designation, a description of the health care institution's plans for the continuing education activities related to trauma care, required in R9-25-1308(G)(4);
- i. For renewal of designation, a description of the continuing education activities conducted during the term of the designation;
- j. If applicable, the name, e-mail address, telephone number, and, if available, fax number of the health care institution's injury prevention coordinator;
- k. A description of the methods by which trauma team personnel members communicate with EMS personnel;
- 1. A description of the trauma-related training received by registered nurses in the intensive care unit;
- m. An attestation that the owner of the health care institution will prohibit:
 - The trauma medical director from serving as trauma medical director for another health care institution; and
 - A physician on-call for general surgery, neurosurgery, or orthopedic surgery to be on-call or on a back-up call list at another health care institution; and
- n. The dated signature of the applicable individual according to R9-25-102;

- 2. A copy of the policies and procedures required in R9-25-1308(B)(6) for the health care institution's trauma registry;
- 3. A copy of the policies and procedures required in R9-25-1308(B)(7) for the health care institution's performance improvement program;
- 4. A copy of the policies and procedures required in R9-25-1308(F)(2) for the health care institution's trauma service;
- 5. If applicable, a copy of the policies and procedures required in R9-25-1308(F)(9) for operating rooms;
- 6. A copy of the applicable policies and procedures required in R9-25-1308(H)(4);
- 7. A copy of the health care institution's clinical practice guidelines, describing the health care institution's capability to resuscitate, stabilize, and transfer pediatric patients;
- 8. If applicable, a copy of the bylaws of the health care institution's multidisciplinary peer review committee;
- 9. Copies of the job descriptions for the health care institution's:
 - a. Trauma program manager;
 - b. Trauma registrar; and
 - c. If applicable, injury prevention coordinator;
- 10. A list of the trauma care parameters the health care institution is or will be monitoring as part of the performance improvement program;
- 11. A list of trauma team members, including:
 - a. Name,
 - b. Title, and
 - c. Role on the trauma team;
- 12. If required for an individual listed according to subsection (C)(11), a copy of documentation of the individual's:
 - a. Board certification or board eligibility,
 - b. Most recent certification in a trauma critical care course,
 - c. Pediatric-specific credentials, and
 - d. Other trauma-related training; and
- 13. If the trauma medical director is not a member of the trauma team, the applicable documentation required in subsection (C)(12) for the trauma medical director.
- D. Except as provided in subsection (F) <u>specifying requirements</u> for renewal of a one-year designation, for <u>initial</u> designation <u>or renewal of designation</u> of a health care institution as a Level I trauma center, Level I Pediatric trauma center, Level II trauma center, or Level II Pediatric

trauma center based on an assessment by the Department under R9-25-1302(C), an owner shall include as part of the application required in R9-25-1303(A):

- 1. A copy of the documentation submitted to the national verification organization as part of an application for verification;
- 2. If not included in the documentation in subsection (D)(1):
 - a. Any information or documents required in subsection (C);
 - b. For an application for initial designation, a description of the health care institution's plans for:
 - i. Injury prevention activities, required in R9-25-1308(G)(5)(a); and
 - ii. Educational outreach activities, required in R9-25-1308(G)(5)(b); and
 - For an application for renewal of designation, a description of the injury
 prevention activities and educational outreach activities conducted during the
 term of the designation;
- 3. A copy of the national verification's organization's written report to the health care institution describing the results of the national verification organization's assessment of the health care organization;
- 4. A copy of the written report in R9-25-1306(G); and
- 5. If applicable, the written plan to correct instances of non-compliance in R9-25-1306(H).
- Except for renewal of a one-year designation as provided in subsection (G) for renewal of a one-year designation, for initial designation or renewal of designation of a health care institution based on an assessment by the Department according to subsection (C) or (D), the Department shall, within 90 calendar days after receiving a complete application from an owner, review the application, inspect the health care institution, if applicable, and, if the Department determines that:
 - 1. The application and the health care institution comply with the applicable requirements in this Article, except as provided in subsection (H)(1), issue a designation for the health care institution that is valid for three years from the issue date;
 - 2. The application complies with the applicable requirements in this Article, the health care institution is in substantial compliance with the applicable requirements in this Article, and the Department has accepted the document submitted according to R9-25-1306(E) or subsection (D)(5), issue a designation for the health care institution that is valid for one year from the issue date; or
 - 3. The application or the health care institution does not comply with the applicable requirements in this Article, provide a written notice that complies with A.R.S. Title 41,

Chapter 6, Article 10, that the Department intends to decline to issue a designation for the health care institution.

- F. For renewal, at the same Level of trauma center, of a one-year designation issued according to subsection (B)(2) or (E)(2), an owner shall include, as part of the application required in R9-25-1303(A), documentation related to the completion of the plan specified in the document accepted by the Department in subsection (B)(2) or (E)(2).
- G. Except as specified in subsection (H), the The Department shall, within 60 calendar days after receiving from an owner an application submitted according to subsection (F), review the information and documentation, inspect the health care institution if applicable, and:
 - 1. Issue a designation for the health care institution that is valid for two years from the issue date if the Department determines that:
 - a. The application and the health care institution comply with the applicable requirements in this Article; and
 - b. The owner has completed the plan specified in the document accepted by the Department in subsection (B)(2) or (E)(2), as applicable; or
 - 2. Provide a written notice that complies with A.R.S. Title 41, Chapter 6, Article 10, that the Department intends to decline to issue a designation for the health care institution if the Department determines that:
 - a. The application or the health care institution do not comply with the applicable requirements in this Article; or
 - b. The owner has not completed all of the components of the plan specified in the document accepted by the Department in subsection (B)(2) or (E)(2), as applicable.
- H. The Department shall review according to R9-25-1303(C) and subsection (A), (B), or (E), as applicable, an application for renewal of designation submitted by the owner of a trauma center that:
 - 1: Had been issued a one-year designation according to subsection (B)(2) or (E)(2); and
 - 2. Has not completed all of the components of the plan specified in the document accepted by the Department in subsection (B)(2) or (E)(2), as applicable.

H. The Department may:

- 1. Issue or extend a designation to a health care institution that is longer than three years if:
 - a. The health care institution would be eligible for designation under R9-251302(A)(2)(a)(ii) or (iii), (A)(2)(b)(ii) or (iii), (A)(2)(c)(ii) or (iii), (A)(2)(d)(ii)
 or (iii), or (A)(2)(e)(ii) with assessment from a national verification organization;

- b. The national verification organization either:
 - i. Will not allow the health care institution to apply for verification within the time-frame necessary to comply with R9-25-1302(C), or
 - <u>ii.</u> Does not schedule an assessment visit to the health care institution within six months after the date of the health care institution's request;
- c. The health care institution and, if applicable, the application comply with the applicable requirements in this Article; and
- d. The health care institution provides to the Department documentation supporting subsection (H)(1)(b); or
- 2. Issue a designation based on verification to a health care institution, according to subsection (A)(1), that is shorter than the duration of the verification if the expiration of the verification is more than five years after the date of issuance.
- I. For modification of a designation according to R9-25-1305, the Department shall, within 30 calendar days after receiving a complete application for modification in R9-25-1305(A) from an owner, review the application, inspect the health care institution, if applicable, and:
 - 1. Issue a modified designation for the Level of designation requested for the health care institution that is valid for the duration of the original designation or one year from the issue date, whichever is longer, if the Department determines that:
 - a. The application and the health care institution comply with the applicable requirements in this Article for the Level of designation requested; or
 - The application complies with the applicable requirements in this Article, the
 health care institution is in substantial compliance with the applicable
 requirements in this Article for the Level of designation requested, and the
 Department has accepted a written corrective action plan submitted according to
 R9-25-1306(E);
 - 2. Issue a modified designation for a lower Level of designation than the Level of designation requested for the health care institution that is valid for the duration of the original designation or one year from the issue date, whichever is longer, if the Department determines that:
 - a. The application and the health care institution comply with the applicable requirements in this Article for the lower Level of designation and the health care institution:
 - Does not comply with the applicable requirements in this Article for the Level of designation requested; or

- ii. Is in substantial compliance with the applicable requirements in this Article for the Level of designation requested, and the Department has not accepted a written corrective action plan submitted according to R9-25-1306(E); or
- b. The application complies with the applicable requirements in this Article, the health care institution is in substantial compliance with the applicable requirements in this Article for the lower Level of designation, and the Department has accepted a written corrective action plan according to R9-25-1306(E); or
- 3. Provide a written notice that complies with A.R.S. Title 41, Chapter 6, Article 10 that the Department intends to decline to issue a modified designation for the health care institution if the Department determines that the application or the health care institution does not comply with the applicable requirements in this Article.
- J. 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. Is not eligible for designation under R9-25-1302(A) or (B); or
 - 3. Fails to comply with an applicable requirement in A.R.S. Title 36, Chapter 21.1 or this Article.
- **K.** 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.
- L. If the Department intends to dedesignate a health care institution, the Department shall send to the owner a written notice that complies with A.R.S. Title 41, Chapter 6, Article 10.
- M. An owner who receives a written notice in subsection (A)(2), (B)(3), (E)(3), (G)(2), (I)(3), or (J) may file a written notice of appeal with the Department that complies with A.R.S. Title 41, Chapter 6, Article 10.

R9-25-1308. Trauma Center Responsibilities (A.R.S. §§ 36-2202(A)(4), 36-2208(A), 36-2209(A)(2), 36-2221, and 36-2225(A)(4), (5), and (6))

- **A.** The owner of a trauma center shall ensure that:
 - 1. If designation is based on:
 - a. Verification, the trauma center meets the applicable standards of the verifying national verification organization; or
 - 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:
 - a. The trauma center and to personnel members present in the trauma center; and
 - 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 ensure that the trauma center:
 - 1. Except as provided in subsection (D), establishes a trauma registry of patients receiving trauma care who meet the criteria specified in subsection (C)(1) that contains the information required in R9-25-1309, as applicable for the specific Level of the trauma center:
 - 2. Appoint Appoints an individual to act as trauma registrar to coordinate trauma registry activities;
 - 3. If necessary to comply with subsections (C)(2) and (3), provides sufficient additional individuals to assist with trauma registry activities;
 - 4. Establishes a performance improvement program for the trauma service to develop and implement processes to improve trauma care parameters;
 - 5. If required according to Table 13.1 for the Level of the trauma center, establishes as part of the performance improvement program, established according to subsection (B)(4), a multidisciplinary peer review committee to review the quality of trauma care provided by the trauma center, including information from the trauma registry, and suggest methods to improve the quality of trauma care;
 - 6. Establishes, documents, and implements policies and procedures for the trauma registry established according to subsection (B)(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;
- b. Collection of the information required in R9-25-1309 about the patients specified in subsection (C)(1) receiving trauma care;
- c. Submission to the Department of the information required in subsection (C)(2);
- d. Review of information in the trauma center's trauma registry; and
- e. Performance improvement activities required in R9-25-1310; and
- 7. Establishes, documents, and implements policies and procedures for the performance improvement program established according to subsection (B)(4), including:
 - a. A list of the positions of personnel members who have defined roles in the performance improvement program and, if applicable, a list of positions that are dedicated to performance improvement activities for patients receiving trauma care from the trauma center;
 - b. The qualifications, skills, and knowledge required of the personnel members in the positions specified according to subsection (B)(6)(a) (B)(7)(a);
 - c. The role each personnel member specified according to subsection (B)(6)(a)
 (B)(7)(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;
 - f. If an issue related to trauma care or to trauma care parameters is identified:
 - How a plan to address the issue is developed to reduce the chance of the issue recurring in the future;
 - ii. How the plan is documented;
 - iii. The mechanism and criteria by which the plan is reviewed and approved;
 - iv. How the plan is implemented; and
 - v. How implementation of the plan and future recurrences are monitored;
 - g. If applicable, the composition, duties, responsibilities, and frequency of meetings of the multidisciplinary peer review committee established according to subsection (B)(5);
 - h. If applicable, how the multidisciplinary peer review committee collaborates with the trauma center's quality management program; and
 - i. How changes proposed by the performance improvement program are reviewed

by the trauma center's quality management program.

- C. The owner of a trauma center shall ensure that:
 - 1. The trauma registry, established according to subsection (B)(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 an 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
 - Transferred from one health care institution to another health care institution 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. At the initial encounter with the patient, the patient had:
 - (1) An injury or injuries to specific body parts,
 - (2) Unspecified multiple injuries,
 - (3) Injury of an unspecified body region,
 - (4) A burn or burns to specific body parts,
 - (5) Burns assessed through Total Body Surface Area percentages, or
 - (6) Traumatic Compartment Syndrome; 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;
 - 2. The following information is submitted to the Department, in a Department-provided format, according to subsection (C)(3):
 - a. The name and physical address of the trauma center;

- b. The date the trauma registry information is being submitted to the Department;
- c. The total number of patients whose trauma registry information is being submitted;
- d. 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;
- f. The name, title, e-mail address, telephone number, and, if available, fax number 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;
- h. The information from the trauma registry for patients identified during the quarter specified according to subsection (C)(2)(d); and
- Updated information for any patients identified during the previous quarter,
 including the patient's name, medical record number, and admission date; and
- 3. The information required in subsection (C)(2) is submitted:
 - a. For patients identified between January 1 and March 31, so that the information in subsections (C)(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 (C)(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 (C)(2)(a) through (h) is received by the Department by January 2 of the following calendar year; and
 - d. For patients identified between October 1 and December 31, so that the information in subsections (C)(2)(a) through (h) is received by the Department by April 1 of the following calendar year.
- D. Trauma centers under the same governing authority, as defined in A.R.S. § 36-401, may establish a single, centralized trauma registry and submit to the Department consolidated information from the trauma registry, according to subsections (C)(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
- b. Use the information contributed by the trauma center to the centralized trauma registry when complying with performance improvement program requirements in this Section.
- E. 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:
 - 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:
 - a. EMS received by a patient;
 - b. Length of stay longer than two hours in the emergency department before transfer;
 - c. Instances of trauma team activation to determine if trauma team activation was timely and appropriate;
 - d. Instances where trauma care was provided to a patient but trauma team activation did not occur;
 - e. Time from notification of a surgeon on the trauma team that a patient described in subsection (H)(6)(b)(i) is in the emergency department to when the surgeon arrives in the emergency department;
 - f. Documentation of the nursing services provided to a patient;
 - g. Instances and reasons for transfer of a patient;
 - h. Instances and reasons for transfer to a hospital not designated as a trauma center;
 - For a hospital designated as a Level I trauma center, Level I Pediatric trauma center, Level II trauma center, or Level II Pediatric trauma center, instances and reasons for diversion, as defined in A.A.C. R9-10-201, of a patient requiring trauma care;
 - j. Instances of and circumstances related to the death of a patient;
 - k. Instances related to the assessment of child maltreatment;
 - k.l. Other patient outcomes;
 - <u>+m.</u> Trauma care parameters for pediatric patients, including pediatric-specific measures; and
 - m.n. The completeness and timeliness of trauma data submission.

- F. In addition to the requirements in subsections (A) through (E), the owner of a trauma center designated based on meeting the applicable standards specified in this Section and Table 13.1 shall:
 - 1. Ensure that a trauma service is established if required by Table 13.1;
 - 2. 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;
 - c. Continuing education or continuing medical education requirements for each personnel member of the trauma team;
 - 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 have the qualifications, skills, and knowledge required in the 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 or board-eligible 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;
 - 6. 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 external trauma-related continuing medical education during the term of the designation;
 - b. If the trauma center's designation is for a one-year period, at least 16 hours of external trauma-related continuing medical education during the term of the designation; and
 - c. If the trauma center is designated as a Level I Pediatric trauma center or Level II Pediatric trauma center, at least 12 of the 48 hours required in subsection (F)(6)(a) or four of the 16 hours required in subsection (F)(6)(b) in pediatric trauma-related continuing medical education;
 - Appoint an individual to act as trauma program manager to coordinate trauma service activities;
 - 8. If the trauma center is required by Table 13.1 to have a multidisciplinary peer review

- committee, ensure that each surgeon on the trauma team designated according to subsection (F)(3) attends at least 50% of the meetings of the multidisciplinary peer review committee;
- 9. If the trauma center provides surgical services, ensure that policies and procedures for operating rooms and an operating room team are established, documented, and implemented that include:
 - a. The availability of an operating room for trauma care;
 - b. The composition of an operating room team;
 - c. The qualifications, skills, and knowledge required of each personnel member of an operating room team;
 - d. The roles and responsibilities of each personnel member of an operating room team;
 - e. If an operating room team is not on the premises of the health care institution 24 hours a day, under what circumstances the operating room team is notified to come to the trauma center; and
 - f. How the operating room team is notified;
- 10. 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 or boardeligible; and
 - iii. Each physician assistant or registered nurse practitioner who is responsible for <u>providing trauma care to</u> patients in an emergency department in the absence of an emergency physician; or
 - b. Have held certification in a trauma critical care course:
 - i. Each general surgeon other than the trauma medical director, and
 - ii. Each emergency medicine physician who is board-certified or boardeligible;
- 11. If the trauma center is designated as a Level I trauma center, Level I Pediatric trauma center, Level II trauma center, or Level II Pediatric trauma center, ensure that each of the trauma team personnel members required in Table 13.1(C)(2) and (C)(3)(a) through (f) are board-certified or board-eligible;
- 12. If the trauma center is designated as a Level I Pediatric trauma center, ensure that the following trauma team members are fellowship-trained:

- a. The surgeon credentialed for pediatric trauma care required in Table 13.1(C)(2)(a)(iii),
- b. The pediatric emergency medicine physician required in Table 13.1(C)(2)(c),
- c. The pediatric-credentialed orthopedic surgeon required in Table 13.1(C)(3)(b),
- d. The pediatric-credentialed neurosurgeon required in Table 13.1(C)(3)(d), and
- e. The pediatric-credentialed critical care medicine physician required in Table 13.1(C)(3)(f);
- 13. If the trauma center is designated as a Level II Pediatric trauma center, ensure that:
 - a. The pediatric-credentialed critical care medicine physician required in Table 13.1(C)(3)(f) is fellowship-trained, and
 - b. A fellowship-trained pediatric emergency medicine physician:
 - <u>i.</u> <u>provides supervision Provides direction</u> for pediatric emergency trauma care and <u>oversight of the treatment of pediatric patients as part of the performance improvement program, and</u>
 - <u>ii.</u> <u>is Is</u> appointed as a liaison to the multidisciplinary peer review committee established according to subsection (B)(5); and
- 14. If the trauma center is not designated as a Level I Pediatric trauma center or Level II Pediatric trauma center and annually provides trauma care to 100 or more injured children younger than 15 years of age who meet one or more of the criteria in subsection (C)(1)(c), ensure that the trauma center:
 - a. Complies with subsection (F)(13) and Table 13.1(C)(2)(a)(iii), (3)(b), (3)(d), and (3)(f) and (F)(2); and
 - b. Has a:
 - i. Pediatric emergency department area,
 - ii. Pediatric intensive care area, and
 - iii. Pediatric-specific trauma performance improvement program.
- G. In addition to the requirements in subsections (A) through (E), the owner of a trauma center designated based on meeting the applicable standards specified in this Section and Table 13.1 shall ensure that the trauma center:
 - Establishes, documents, and implements a patient transfer plan, consistent with A.A.C.
 R9-10-211, that include includes:
 - a. The criteria for transferring a patient,
 - b. The health care institution to which a patient meeting specific criteria will be transferred,

- c. The personnel members who are responsible for coordinating the transfer of a patient, and
- d. The process for transferring a patient;
- 2. Participates in state, local, or regional trauma-related activities such as:
 - a. The State Trauma Advisory Board, established by A.R.S. § 36-2222;
 - A regional emergency medical services coordinating council described in A.R.S.
 § 36-2222(A)(3);
 - c. Trauma Registry Users Group, established by the Department;
 - d. Trauma Managers Workgroup, established by the Department; or
 - e. Injury Prevention Council;
- 3. Participates in injury prevention programs specific to the trauma center's patient population at the national, regional, state, or local levels;
- 4. Except for a Level IV trauma center, conducts trauma care continuing education activities for physicians, trauma center personnel members, and EMCTs;
- 5. If <u>required for</u> the trauma center holds a designation as a Level I trauma center, Level I Pediatric trauma center, Level II trauma center, or Level II Pediatric trauma center according to Table 13.1, establishes and maintains:
 - a. An injury prevention program:
 - i. Independently or in collaboration with other health care institutions, health advocacy groups, or the Department; and
 - ii. That includes:
 - Designating a prevention coordinator who serves as the trauma center's representative for injury prevention and injury control activities;
 - (2) Carrying out injury prevention and injury control activities, including activities specific to the patient population;
 - (3) Conducting injury control studies;
 - (4) Monitoring the progress and effect of the injury prevention program; and
 - (5) Providing injury prevention and injury control information resources for the public; and
 - b. An educational outreach program:
 - Independently or in collaboration with other health care institutions, health advocacy groups, or the Department;

- ii. That includes providing education to physicians, trauma center personnel members, EMCTs, and the general public; and
- iii. That may include education about:
 - (1) Injury prevention,
 - (2) Trauma care,
 - (3) Other topics specific to the patient population,
 - (4) Criteria for assessing a patient who may require trauma care, and
 - (5) Criteria for the transfer of a patient requiring trauma care; and
- 6. If the trauma center holds a designation as a Level I trauma center or Level I Pediatric trauma center:
 - Establishes and maintains, either independently or in collaboration with other hospitals, a residency program or fellowship 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;
 - c. Conducts or participates in research related to trauma and trauma care; and
 - d. Maintains an Institutional Review Board, established consistent with 45 CFR Part 46, to review biomedical and behavioral research related to trauma and trauma care involving human subjects, conducted, funded, or sponsored by the trauma center, in order to protect the rights of the human subjects of such research.
- H. In addition to the requirements in subsections (A) through (E), the owner of a trauma center designated based on meeting the applicable standards specified in this Section and Table 13.1 shall:
 - 1. Ensure the presence of a surgeon at all operative procedures;
 - 2. If the trauma center provides emergency medicine, neurosurgery, orthopedic surgery, anesthesiology, critical care, or radiology as an organized service, ensure that:
 - A physician from the organized service is appointed to act as a liaison between the organized service and the trauma center's trauma service;
 - b. The physician in subsection (H)(2)(a) completes:
 - 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;
 - 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
- iii. If the trauma center is designated as a Level I Pediatric trauma center or Level II Pediatric trauma center, at least 12 of the 48 hours required in subsection (H)(2)(b)(i) or four of the 16 hours required in subsection (H)(2)(b)(ii) in pediatric trauma-related continuing medical education; and
- c. If the trauma center is required by Table 13.1 to have a multidisciplinary peer review committee, ensure the physician in subsection (H)(2)(a) attends at least 50% of the meetings of the multidisciplinary peer review committee;
- 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. Except for a Level IV trauma center, the formulation of blood products to be available during an event requiring multiple blood transfusions for a patient or patients; and
 - b. For a Level IV trauma center, the expedited release of blood products during an event requiring multiple blood transfusions for a patient or patients;
- 5. Ensure that the patient transfer plan required in subsection (G)(1) includes processes for transferring a patient needing:
 - a. Acute hemodialysis or pediatric trauma care to a hospital providing the required service if the trauma center is designated as a:
 - i. Level III or Level IV trauma center; or
 - ii. Level II trauma center and does not provide, as applicable, acute hemodialysis or pediatric trauma care;
 - b. Burn care as an organized service, acute spinal cord management, microvascular surgery, or replant surgery to a hospital providing the required service if the trauma center is designated as a:
 - i. Level III or Level IV trauma center; or
 - Level I or Level II trauma center and does not provide, as applicable,
 burn care as an organized service, acute spinal cord management,
 microvascular surgery, or replant surgery; or
 - c. Another service that the trauma center is not authorized or not able to provide to

a hospital providing the required service;

- 6. Except for a Level IV trauma center or as provided in subsection (I), require that:
 - An emergency medicine physician is present in the emergency department at all times;
 - b. A surgeon on the trauma team is present in the emergency department:
 - i. For a patient:
 - (1) If an adult, with a systolic blood pressure less than 90 mm Hg or, if a child, with confirmed age-specific hypotension;
 - (2) With respiratory compromise, respiratory obstruction, or intubation;
 - (3) Who is transferred from another hospital and is receiving blood to maintain vital signs;
 - (4) Who has a gunshot wound to the abdomen, neck, or chest;
 - (5) Who has a Glasgow Coma Scale score less than 8 associated with an injury attributed to trauma; or
 - (6) Who is determined by an emergency department physician to have an injury that has the potential to cause prolonged disability or death; and
 - ii. No later than the following times:
 - (1) For a Level I trauma center, Level I Pediatric trauma center, Level II trauma center, or Level II Pediatric trauma center, within 15 minutes after notification or at the time the patient arrives in the emergency department, whichever is later; or
 - (2) 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; and
 - c. One of the following anesthesia personnel members is available for an operative procedure on a patient at the indicated time point:
 - i. For a Level I trauma center, Level I Pediatric trauma center, Level II trauma center, or Level II Pediatric trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department or in an operating room area awaiting the patient no later than 15 minutes after patient arrival in the emergency department; and

- ii. 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 operating room area awaiting the patient no later than 30 minutes after patient arrival in the emergency department;
- 7. For a clinical capability required for the trauma center according to Table 13.1(C)(3), require that the on-call radiologist, critical care medicine physician, or surgical specialist is available to provide medical services, as applicable to the specialist, for a patient requiring trauma care within 45 minutes after notification; and
- 8. For personnel members assigned to an operating room team according to subsection (F)(9), require that the personnel members on the operating room team are on the premises of the trauma center while on duty or:
 - a. For a Level I trauma center, Level I Pediatric trauma center, Level II trauma center, Level II Pediatric trauma center:
 - i. Are available to provide operative services for a patient requiring trauma care within 15 minutes after notification or patient arrival at the trauma center, whichever is later; and
 - ii. Have response times and patient outcomes monitored through the performance improvement program; and
 - b. For a Level III trauma center or Level IV trauma center, if the Level IV trauma center provides surgical services:
 - i. Are available to provide operative services for a patient requiring trauma care within 30 minutes after notification or patient arrival at the trauma center, whichever is later; and
 - ii. Have response times and patient outcomes monitored through the performance improvement program.
- I. The Department shall consider a trauma center designated based on meeting the applicable standards specified in this Section and Table 13.1 to be in compliance with subsection (H)(6)(a), (b), or (c), as applicable, if the trauma center has documentation showing that:
 - 1. The individual required to be present at the indicated location and within the indicated time period was present 80% or more of the time, and
 - 2. The trauma center monitors the rate of compliance with subsection (H)(6) and patient outcomes through the performance improvement program.
- J. The requirement in subsection (H)(6)(b) 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 (H)(6)(b)(i) while awaiting the arrival of the surgeon on the trauma team, as required in subsection (H)(6)(b)(ii)(1) or (2).
- K. 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:
 - Include in the ALS base hospital's trauma registry at least the information required in R9-25-1309(A) for each patient who meets one or more of the criteria in subsections (C)(1)(a) through (c), and
 - 2. Comply with the submission requirements in subsections (C)(2) and (3).

Table 13.1. Arizona Trauma Center Standards (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

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E = Essential and required

I(P) = Level I Pediatric trauma center II(P) = Level II Pediatric trauma center

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

Child life = A program of support to injured children and their families to reduce stress and anxiety by:

 Explaining medical equipment and procedures to children in a non-threatening and age-appropriate manner.

b. Explaining a diagnosis to a child in an age-appropriate manner, and

c. Helping children and their families develop strategies to cope with the diagnosis and expected outcome

				Levels						
	Trauma Facilities Criteria			I(P)	П	II(P)	Ш	IV		
Α.		Institutional Organization								
	1.	Trauma service	Е	Е	Е	Е	Е	-		
	2.	Trauma program medical director	Е	E	Е	Е	E	-		
***********	3,	Trauma multidisciplinary peer review committee	Е	Е	Е	E	Е	_		
	<u>4.</u>	Injury prevention program (R9-25-1308(G)(5)(a))	E	<u>E</u>	<u>E</u>	E		=		
	<u>5.</u>	Injury prevention activities (R9-25-1308(G)(3))	<u>E</u>	E	E	E	<u>E</u>	E		
	<u>6.</u>	Educational outreach program (R9-25-1308(G)(5)(b))	E	E	E	E	=	=		
	<u>7.</u>	Educational outreach activities (R9-25-1308(G)(4))	E	E	E	E	E	-		
	<u>8.</u>	Child maltreatment assessment capability	E	E	E	E	E	E		
B.		Hospital Departments/Divisions/Sections						•		
	1.	Surgery	E	Е	Е	Е	Е	-		
	2.	Neurosurgery	E	Е	Е	Е	-	-		
***************************************	3.	Orthopedic surgery	Е	Е	Е	Е	E	-		
	4.	Emergency medicine	Е	Е	Е	Е	Е	-		
	5.	Pediatric emergency department area	-	Е	-	Е	-	-		
	6.	Anesthesia	Е	Е	Е	Е	E	-		
C.	·	Clinical Capabilities								
	1.	Written on-call schedule for each component of the trauma service if a team member is not in-house	Е	Е	Е	Е	Е	E		
	2.	Physician specialist available 24 hours/day		•	•					
		a. General surgeon	E	Е	Е	Е	Е	-		
		i. Published back-up schedule	Е	Е	Е	Е	-	-		
		ii. Dedicated to single hospital when on-call	Е	Е	Е	Е	-	-		
			·	4				. 2		

	•									
	iii. Surgeon credentialed for pediatric trauma care	-	E	-	Е	_	-			
	b. Emergency medicine physician	E	Е	Е	Е	E	-			
	c. Pediatric emergency medicine physician	-	E	-	_	-	-			
3.	Specialist on-call and available 24 hours/day									
	a. Orthopedic surgeon	E	Е	Е	Е	E	-			
	b. Pediatric-credentialed orthopedic surgeon	-	Е	-	Е	-	-			
	c. Neurosurgeon	Е	Е	Е	Е	_	-			
	d. Pediatric-credentialed neurosurgeon	-	E	-	Е	_	_			
	e. Critical care medicine physician	Е	Е	Е	Е	_	-			
	f. Pediatric-credentialed critical care medicine physician	-	Е	-	Е	-	-			
	g. Radiologist	Е	Е	Е	Е	E				
	h. Hand surgeon	E	E	Е	Е	-	-			
	i. Ophthalmic surgeon	Е	E	Е	E	-	-			
	j. Plastic surgeon	Е	Е	Е	Е	-	~			
	k. Thoracic surgeon	E	Е	Е	E	-	-			
	l. Cardiac surgeon	Е	Е	-	-	-	-			
	m. Obstetrics/gynecologic surgeon	E	Е	-	-	-	-			
	n. Oral/maxillofacial surgeon (plastic surgeon, otolaryngologist, or oral/maxillofacial surgeon)	Е	Е	Е	Е	-	-			
4.	Qualified anesthesia personnel member on-call and a	available 24 l	nours/day							
	a. Physician or certified nurse anesthetist	Е	E	Е	Е	E	-			
	Physician or certified nurse anesthetist with a pediatric credential	-	Е	-	Е	-	•			
5.	Volume performance standards:									
	 a. 1200 trauma admissions per year, b. 240 admissions with ISS > 15 per year, or c. Average of 35 patients with ISS > 15 for each trauma team surgeon per year 	E	-	-	-	1	_			
	d. 200 trauma admissions < 15 years of age per year	ar, -	Е	-	-	-	-			
D.	Facilities/Resources/Capabilities			***************************************			1			
1.	Emergency department									
***	a. Designated physician director	E	Е	Е	Е	E	-			
	b. Personnel members with pediatric-specific trauma-related training	-	Е	-	Е	_	-			
	c. Resuscitation equipment for patients of all sizes	3				•				
	i. Airway control and ventilation equipment	E	Е	Е	E	Е	Е			
			1							

ii. Pulse oximetry	E	E	E	E	E	Е
iii. Suction devices	E	Е	Е	Е	Е	Е
iv. Electrocardiograph-oscilloscope-defibrillator	E	Е	E	E	Е	E
v. Color-coded, length-based tool to assist with medication dosing and equipment selection for children	Е	E	Е	E	E	E
vi. Central venous pressure monitoring equipment	Е	E	Е	Е	E	-
vii. Standard intravenous fluids and administration sets	E	Е	Е	Е	Е	E
viii. Large-bore intravenous catheters	E	Е	E	E	E	E
ix. Sterile surgical sets for:	,			<u> </u>		
(1) Airway control/cricothyrotomy	Е	Е	Е	Е	E	Е
(2) Thoracostomy	Е	Е	Е	Е	Е	Е
(3) Central line insertion	Е	Е	Е	Е	Е	-
(4) Thoracotomy	Е	Е	Е	E	Е	-
x. Arterial catheters	Е	Е	Е	Е	_	-
xi. X-ray availability 24 hours/day	Е	Е	Е	E	Е	-
xii. Thermal control equipment						
(1) For patient	Е	Е	Е	E	E	E
(2) For fluids and blood	Е	Е	Е	Е	Е	E
xiii. Rapid infusion system/capability	Е	E	Е	Е	E	Е
xiv. Qualitative end-tidal CO2 monitoring	Е	E	E	Е	Е	E
d. Communication with EMS personnel	Е	Е	Е	E	Е	E
e. Capability to resuscitate, stabilize, and transfer pediatric patients	Е	Е	Е	E	E	Е
2. Operating room						
a. Immediately available 24 hours/day	Е	Е	E	E	_	-
b. Size-specific equipment		•				
i. Cardiopulmonary bypass	E	Е		-	-	-
ii. Operating microscope	E	E	_	_	_	-
c. Thermal control equipment			•			
i. For patient	Е	Е	Е	Е	Е	E
ii. For fluids and blood	Е	Е	Е	Е	Е	E
d. X-ray capability including C-arm image intensifier	E	Е	E	Е	Е	-
e. Endoscopes, bronchoscope						
	E	Е	E	Е	E	-

							ı
	h. Equipment for long bone and pelvic fixation	Е	Е	Е	Е	Е	-
	i. Rapid infusion system/capability	Е	Е	Е	Е	E	Е
3.	Postanesthesia recovery room or surgical ICU						
	a. Registered nurses available 24 hours/day	E	Е	Е	Е	Е	Е
	b. Equipment for monitoring and resuscitation	Е	Е	Е	Е	Е	Е
	c. Intracranial pressure monitoring equipment	E	Е	Е	Е	-	-
	d. Pulse oximetry	Е	Е	Е	Е	Е	Е
	e. Thermal control equipment	,					
	i. For patient	Е	Е	Е	E	Е	E
	ii. For fluids and blood	Е	Е	Е	Е	Е	E
4.	ICU or critical care unit for injured patients						
	a. Pediatric ICU	-	Е	-	Е	-	-
	b. Registered nurses with trauma-related training	E	Е	Е	Е	Е	-
	c. Registered nurses with pediatric-specific trauma- related training	-	E		Е	-	7
	d. Designated surgical director or surgical co- director	Е	Е	Е	E	Е	-
	e. Physician (fourth year of residency training or higher) assigned to surgical ICU service and inhouse 24 hours/day	E	Е	-	-	_	-
	f. Physician (fourth year of residency training or higher) with a pediatric credential assigned to surgical ICU service and in-house 24 hours/day	_	Е	-	-		_
***************************************	g. Surgically directed and staffed ICU service	E	Е	E	Е	-	-
	h. Equipment for monitoring and resuscitation	E	E	Е	Е	Е	-
	i. Intracranial pressure monitoring equipment	Е	E	Е	Е	_	-
5.	Respiratory therapy services (Available 24 hours/day)						
	a. Available in-house	E	Е	Е	Е	_	-
	b. On-call and available within 45 minutes after notification	_	-	-	+	Е	
6.	Radiological services (Available 24 hours/day)		· · · · · · · · · · · · · · · · · · ·			•	,
	a. In-house radiology technologist	Е	Е	Е	Е	-E	-
	b. Radiology technologist on-call and available within 45 minutes after notification	-	-	-	***	_	Е
	c. Resuscitation equipment for patients of all sizes, as specified in subsection (D)(1)(c)(i) to (v)	E	Е	Е	Е	Е	Е
	d. Angiography	Е	Е	Е	Е	-	-
	e. Sonography	E	Е	Е	Е	Е	-
	f. Computed tomography (CT)	Е	Е	E	Е	Е	-
		•	•		**		

		i. In-house CT technician	Е	Е	Е	E	_	-
		ii. CT technician on-call and available within 45 minutes after notification	<u>-</u>	_	-	-	E	_
		f. Magnetic resonance imaging	Е	Е	Е	Е	-	
	7.	Clinical laboratory service (Available 24 hours/day)						
		a. Standard analyses of blood, urine, and other body fluids	Е	Е	Е	Е	Е	E
		b. Blood typing and cross-matching	E	Е	Е	Е	Е	-
		c. Coagulation studies	Е	Е	Е	Е	E	Е
		d. Comprehensive blood bank or access to a community central blood bank and adequate storage facilities	Е	Е	E	Е	Е	-
		e. Blood gases and pH determinations	Е	Е	Е	Е	Е	Е
		f. Microbiology	Е	Е	Е	E	E	1
	8.	Child maltreatment assessment capability	E	E	E	£	E	E
E.		Rehabilitation Services Specific to the Patient Pop	ulation					
	1.	Physical therapy	Е	Е	Е	Е	Е	-
	2.	Occupational therapy	Е	Е	Е	Е	-	_
	3.	Speech therapy	Е	Е	Е	Е	-	-
F.		Social Services Specific to the Patient Population			, <u>, , , , , , , , , , , , , , , , , , ,</u>			
	1.	Social services	E	Е	Е	Е	Е	-
	2.	Child life program	-	E	-	E	-	-
G.		Performance Improvement	••••	•	•	•		
***************************************	1.	Multidisciplinary peer review committee	E	Е	Е	Е	Е	-
	2.	Performance improvement personnel dedicated to the trauma service	Е	Е	Е	E	-	-