NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION
PERSONNEL ADMINISTRATION

[R05-395]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R2-5-101	Amend
R2-5-416	Amend
R2-5-417	Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 38-651, 38-651.01, 38-653, and 41-763(2) and (6)

Implementing statutes: A.R.S. §§ 38-651.02 and 41-783

3. The effective date of the rules:

December 5, 2005

4. A list of all previous notices appearing in the *Register* addressing the final rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 1397, April 9, 2004

Notice of Proposed Rulemaking: 11 A.A.R. 1348, April 8, 2005

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

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6. An explanation of the rule, including the agency's reason for initiating the rule:

This rulemaking updates the definitions of the terms "child," "class," "eligible dependent," "essential function," and "knowledge, skills, and abilities" to conform to current usage in Title 2, Chapter 5. The rulemaking broadens the meaning of "class series" to provide an incumbent retention point protection when a position is reclassified or reassigned to a class series within five years before a reduction in force. The amendments to Article 1 amend existing definitions to provide clarity, to conform to current practice, to include in rule an eligibility provision for a child who is disabled, to reformat the definitions of "child" and "eligible dependent" to enhance readability, and to make technical corrections. The rulemaking adds definitions for the terms "limited position" and "qualified life event."

Language is added to R2-5-416 to articulate a requirement that an application must be submitted timely to add an eligible dependent due to a qualified life event, establish program eligibility for a university retiree who returns to work under A.R.S. § 38-766.01, and delineate dependent eligibility in rule.

A.R.S. § 38-651.02 allows the Arizona Department of Administration (ADOA) to offer additional group life and group accidental death and dismemberment insurance to officers and employees at the employee's expense in an amount up to three times the employee's annual salary. Rule R2-5-417(B) is amended to provide flexibility and accommodate contractual changes.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not 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 agency did not review any study relevant to the rule.

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

Not applicable

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

The proposed rulemaking affects State Service employees only and will not have an impact on small businesses and consumers. The impact will be upon employees receiving the benefits of the rules. Any financial impact or administrative expenses should be covered by ordinary operating funds.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

A portion of the proposed new language to R2-5-416(A)(1), which would have specified the health benefits coverage date for a new employee, has been removed from the Notice of Final Rulemaking. The proposed language would not have adequately addressed each of the plans administered by the Department, nor did the language address the effective date of a qualified life event, which may vary depending on the event.

Other minor, non-substantive, and stylistic changes were made between publication of the notice of proposed rulemaking and this notice of final rulemaking, where appropriate.

11. A summary of the comments made regarding the rule and the agency response to them:

An oral proceeding was not scheduled regarding these rules, thus, no oral comments were received. As part of the initial rulemaking process, the agency solicited input from ADOA Personnel Managers and staff assigned to the satellite Human Resources (HR) offices. Following submission of the Notice of Proposed Rulemaking, representatives from three agency HR offices submitted suggestions relative to clarity and style.

Two individuals responding from the same agency submitted comments regarding the proposed new language defining "class series." One of the comments received noted that the definition for "repromotion" includes the term "grade" instead of "pay grade," which is defined in the rules, and recommended the definition be revised for consistency. Two of the three agencies responding submitted comments regarding the proposed amendment to R2-5-416(A)(1), which was removed from the final rulemaking. Based on the comments received, the agency made clarifying, non-substantive changes to the final rule, where appropriate.

One of the parties commenting suggested that definitions be added for the following terms: "break time," "call back," "disciplinary action," and "job duties." The agency does not believe these additional definitions are necessary. R2-5-502(B)(2) addresses breaks during the work period. The term "call back" is not utilized in this Chapter, therefore, a definition is not necessary. "Disciplinary actions" are listed in Article 8 of these rules. The agency believes the term "job duties" is self-explanatory.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

Not applicable

14. Was this rule previously made as an emergency rule?

No.

15. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION
PERSONNEL ADMINISTRATION

ARTICLE 1. GENERAL

Section
R2-5-101. Definitions

ARTICLE 4. BENEFITS

Section
R2-5-416. Health Benefit Plan
R2-5-417. Life Insurance and ~~Short-term~~ Disability Income Insurance Plans

ARTICLE 1. GENERAL

R2-5-101. Definitions

The following words and phrases have the defined meanings unless otherwise clearly indicated by the context.

1. "Agency" means a department, board, office, authority, commission, or other governmental budget unit of the state.
2. "Agency head" means the chief executive officer of an agency.
3. "Appeal" means a request for a review by the Personnel Board of a disciplinary action under ~~to~~ A.R.S. § 41-782.
4. "Applicant" means a person who seeks appointment to a position in state service.
5. "Appointment" means the offer to and the acceptance by a person of a position in state service.
6. "Base salary" means an employee's salary excluding overtime pay, shift differential, bonus pay, special performance adjustment previously granted, or pay for other allowance or special incentive pay program.
7. "Business day" means the hours between 8:00 a.m. and 5:00 p.m. Monday through Friday, excluding observed state holidays.
8. "Candidate" means a person whose knowledge, skills, and abilities ~~(KSAs)~~ meet the requirements of a position and who may be considered for employment.
9. "Cause" means any of the reasons for disciplinary action provided by A.R.S. § ~~41-771~~ 41-770 or these rules.
10. "Child" means:
    a. For purposes of R2-5-416(C), pertaining to the health benefit plan, R2-5-418(B), pertaining to the retiree health benefit plan, and R2-5-419(C), pertaining to the health benefit plan for former elected officials, ~~each~~ an unmarried ~~natural, adopted, foster, or stepchild who is less than age 19, or less than age 25 if a full-time student, and who resides, or is placed by court order, in the household of the employee, the retired employee, or the former elected official;~~ person who falls within one or more of the following categories:
        i. A natural child, adopted child, or stepchild who is younger than age 19 or younger than age 25 if a full-time student;
        ii. A child who is younger than age 19 for whom the employee-member, retiree, or former elected official has court-ordered guardianship;
        iii. A foster child who is younger than age 19;
        iv. A child who is younger than age 19 and placed in the employee-member's, retiree's, or former elected official's home by court order pending adoption; or
        v. A natural child, adopted child, or stepchild who was disabled prior to age 19 and continues to be disabled under 42 USC 1382c and for whom the employee-member, retiree, or elected official had custody prior to age 19.
    b. For purposes of R2-5-417(C) and (D), pertaining to the life and disability income insurance plan, and R2-5-421(B), pertaining to the life insurance plan for former elected officials, ~~each~~ an unmarried ~~natural, adopted, foster, or stepchild who is less than age 19, or less than the age of 25 if a full-time student, and who resides or is placed by court order in the household of the employee or the former elected official;~~ person who falls within one or more of the following categories:
        i. A natural child, adopted child, or stepchild who is younger than age 19 or younger than age 25 if a full-time student;
        ii. A child who is younger than age 19 for whom the employee or former elected official has court-ordered

guardianship;
iii. A foster child who is younger than age 19;
iv. A child who is younger than age 19 and placed in the employee's or former elected official's home by court order pending adoption; or
v. A natural child, adopted child, or stepchild who was disabled prior to age 19 and continues to be disabled under 42 USC 1382c and for whom the employee or former elected official had custody prior to age 19; or

c. For purposes of R2-5-207(D), pertaining to the employment of relatives, R2-5-404, pertaining to sick leave, R2-5-410, pertaining to bereavement leave, the term includes a natural child, adopted child, foster child, or stepchild; and

d. For purposes of R2-5-411, pertaining to parental leave, the term includes a ~~each~~ natural child, adopted child, foster child, or stepchild.

11. "Class" means a group of positions ~~sufficiently similar as to duties performed, scope of discretion and responsibility, knowledge, skills, and abilities required and other characteristics that~~ with the same title and pay grade ~~apply to~~ because each position in the group has similar duties, scope of discretion and responsibility, required knowledge, skills and abilities, or other job-related characteristics.
12. "Class series" means:
    a. For purposes of R2-5-902(B), pertaining to the administration of reduction in force, and R2-5-903(A), pertaining to a temporary reduction in force, a group of related classes that is listed in the Arizona Department of Administration, Human Resources Division, Occupational Listing of Classes as a subsection of the occupational group~~.~~; and
    b. For purposes of R2-5-902(D), pertaining to the calculation of retention points for length of service, a group of related classes that is listed in the Arizona Department of Administration, Human Resources Division, Occupational Listing of Classes as a subsection of the occupational group, including a position that has been reclassified or reassigned to the class series within five years before the effective date of the reduction in force.
13. "Class specification" means a description of the type and level of duties and responsibilities of the positions assigned to a class.
14. "Clerical pool appointment" means the non-competitive, temporary placement of a qualified individual in a clerical position.
15. "Competition" means the process leading to the identification of candidates for employment or promotional consideration that includes an evaluation of knowledge, skills, and abilities and the development of a hiring list in accordance with these rules.
16. "Covered employee" means an employee in state service who is subject to the provisions of these rules.
17. "Covered position" means a position in state service, as ~~provided by~~ defined in A.R.S. § 41-762.
18. "Days" means calendar days.
19. "Demotion" means a change in the assignment of an employee from a position in one class to a position in another class ~~having~~ with a lower pay grade ~~resulting~~ that results from disciplinary action for cause.
20. "Department" means the Arizona Department of Administration.
21. "Director" means the Director of the Arizona Department of Administration, and the Director's designee with respect to personnel administration.
22. "Eligible dependent" means ~~a dependent eligible for employee benefits under Section 125 of the Internal Revenue Code.~~ the employee-member's, retiree's, or former elected official's spouse under Arizona law or an unmarried child who falls within one or more of the following categories:
    a. A natural child, adopted child, or stepchild who is younger than age 19 or younger than age 25 if a full-time student;
    b. A child who is younger than age 19 for whom the employee-member, retiree, or former elected official has court-ordered guardianship;
    c. A foster child who is younger than age 19;
    d. A child who is younger than age 19 and placed in the employee-member's, retiree's, or former elected official's home by court order pending adoption; or
    e. A natural child, adopted child, or stepchild who was disabled prior to age 19 and continues to be disabled under 42 USC 1382c and for whom the employee-member, retiree, or former elected official had custody prior to age 19.
23. "Emergency appointment" means an appointment made without regard to the recruitment, evaluation, referral, or selection requirements of these rules in response to a governmental emergency.
24. "Entrance salary" means the minimum rate of the ~~salary plan~~ pay grade established for a specific class.
25. "Essential job function" means the ~~physical, mental, and environmental demands of a position's basic job duties that an employee~~ fundamental job duties of a position that an applicant or employee must be able to perform, with or without a reasonable accommodation.
26. "Evaluation" means the procedure used to determine the relative knowledge, skills, and abilities of an applicant.

27. "Flexible or cafeteria employee benefit plan" means a plan providing benefits to eligible employees that meets the requirements of Section 125 of the Internal Revenue Code.
28. "FLSA" means the federal Fair Labor Standards Act.
29. "FLSA exempt" means a position that is not entitled to overtime compensation under the FLSA.
30. "FLSA non-exempt" means a position that is entitled to overtime compensation under the FLSA.
31. "FMLA" means the federal Family and Medical Leave Act.
32. "Good standing" means the status of a former employee at the time of separation from state service for reasons other than disciplinary action or anticipated disciplinary action.
33. "Grievance" means a formal complaint filed by an employee, using the procedure established in Article 7 of these rules, that alleges discrimination, noncompliance with these rules, or concerns other work-related matters that directly and personally affect the employee.
34. "Human Resources Employment Database" means the database ~~containing~~ that contains the resume of an applicant interested in employment within state service.
35. "Incumbent" means the officer or employee who currently ~~holding~~ holds an office or position.
36. "Institution" means a facility that provides supervision or care for residents on a 24-hour per day, 7-day per week, basis.
37. "Knowledge, skills, and abilities ~~(KSAs)~~" means ~~familiarity with or possession of information and the capability to perform tasks through a variety of manual, physical, intellectual, or interpersonal activities and a natural talent or acquired expertise to perform the functions of a specific position~~ the qualifications and personal attributes required to perform a job that are generally demonstrated through qualifying service, education, or training.
    a. Knowledge is a body of information applied directly to the performance of a function;
    b. Skill is an observable competence to perform a learned psychomotor act; and
    c. Ability is competence to perform an observable behavior or a behavior that results in an observable product.
38. "Limited appointment" means an appointment to a position that is funded for at least six months but not more than 36 months.
39. "Limited position" means a position in state service that is established for at least six months but not more than 36 months based on the duration of funding.

~~39~~40."Manifest error" means an act or failure to act that is, or clearly has caused, a mistake.

~~40~~41."Mobility assignment" means the assignment of a permanent status employee to an uncovered position or to a covered or uncovered position in another state agency.

~~41~~42."Original probation" means the specified period following initial appointment to state service in a regular or limited position for evaluation of the employee's work.

~~42~~43."Original probationary appointment" means the initial appointment to a regular or limited position in state service.

~~43~~44."Parent" means, for purposes of ~~R2-5-403(E)~~ R2-5-403, pertaining to ~~donation of~~ annual leave, ~~R2-5-404(A)~~ R2-5-404, pertaining to sick leave, and R2-5-410, pertaining to bereavement leave, birth parent, adoptive parent, stepparent, foster parent, grandparent, parent-in-law, or anyone who can be considered "in loco parentis."

~~44~~45."Participant" means an employee who is enrolled in the state's insurance ~~programs~~ program.

~~45~~46."Part-time" means, for purposes of R2-5-402, pertaining to holidays, R2-5-403, pertaining to annual leave, R2-5-404, pertaining to sick leave, R2-5-902, pertaining to reduction in force, and R2-5-903, pertaining to temporary reduction in force, employment scheduled for less than 40 hours per week.

~~46~~47."Pay grade" means a salary range in a state service salary plan.

~~47~~48."Pay status" means an employee is eligible to receive pay for work or for a compensated absence.

~~48~~49."Permanent status" means the standing an employee achieves after the completion of an original probation or a promotional probation.

~~49~~50."Plan" means a flexible or cafeteria employee benefit plan.

~~50~~51."Plan administrator" means the Director~~,~~ of the Arizona Department of Administration.

~~51~~52."Promotion" means a permanent change in assignment of an employee from a position in one class to a position in another class ~~having~~ that has a higher pay grade.

~~52~~53."Promotional probation" means the specified period of employment following promotion of a permanent status employee for evaluation of the employee's work.

~~53~~54."Qualified" means ~~possessing~~ an individual possesses the knowledge, skills, and abilities required of a specific position, as described in the class ~~specifications~~ specification, ~~plus~~ and any unique characteristics required for the position.

55. "Qualified life event" means a change in an employee's family, employment status, or residence including but not limited to:
    a. Changes in the employee's marital status such as marriage, divorce, legal separation, annulment, or death of spouse;
    b. Changes in dependent status such as birth, adoption, placement for adoption, death, or dependent eligibility due to age, marriage, or student status;

c. Changes in employment status or work schedule that affect benefits eligibility for the employee, spouse, or dependent; or

d. Changes in residence that affect available plan options for the employee, spouse, or dependent.

~~54~~56."Reclassification" means changing the classification of a position ~~when~~ if a material and permanent change in duties or responsibilities occurs.

~~55~~57."Reduction" means the non-appealable movement of an employee from one position to another in a lower pay grade as a result of a reduction in force.

~~56~~58."Reemployment" means the appointment of a former permanent status employee who was separated by a reduction in force.

~~57~~59."Regular position" means a full-time equivalent (FTE) position in state service.

~~58~~ 60. "Reinstatement" means the appointment of a former permanent status employee who resigned, was separated in good standing, or was separated without prejudice within two years from the effective date of separation.

~~59~~61."Repromotion" means the promotion of an employee who was reduced in pay grade due to a reduction in force to the pay grade held before the reduction in force or to an intervening pay grade.

~~60~~62."Reversion" means the return of an employee on promotional probation to a position in the class in which the employee held permanent status immediately before the promotion.

~~61~~63."Rules" means the rules contained in ~~the Arizona Administrative Code~~ A.A.C., Title 2, Chapter 5.

~~62~~64."Separation without prejudice" means ~~the~~ a non-disciplinary removal from state service, without appeal rights, of an employee in good standing ~~from state service~~.

~~63~~65."Special detail" means the temporary assignment of a permanent status employee to a covered position in the same agency.

~~64~~66."State service" ~~means the same as at~~ is defined in A.R.S. § 41-762.

~~65~~67."Surviving spouse" means the husband or wife, as provided by law, of a current or former elected official, or active or retired officer or employee who survives upon the death of the elected official, officer, or employee.

~~66~~68."Temporary appointment" means an appointment made for a maximum of 1,500 hours in any one position per agency in each calendar year.

~~67~~69."Transfer" means the movement of an employee from one position in state service to another position in state service in the same pay grade.

~~68~~70."Uncovered position" means a position that is exempt under A.R.S. § 41-771 and not subject to the provisions of these rules.

~~69~~71."Underfill" means the appointment of a person to a class with a pay grade that is lower than the pay grade for the allocated class for that position.

~~70~~72."Voluntary pay grade decrease" means a change in assignment, at the request of an employee, to a position in a class with a lower pay grade.

ARTICLE 4. BENEFITS

R2-5-416. Health Benefit Plan

A. Eligibility.

1. ~~All~~ A state ~~employees~~ employee, except ~~those~~ an employee listed in subsection (A)(2), and ~~their~~ the employee's eligible dependents may participate in the health benefit plan, if ~~they comply~~ the employee complies with the contractual requirements of the selected health benefit plan. An eligible employee may enroll in a health benefit plan at any time within the first ~~30~~ 31 days of employment or during an open enrollment period specified by the Director. To add an eligible dependent due to a qualified life event, ~~An~~ an eligible employee ~~may~~ shall submit an application for enrollment within 31 days of ~~a~~ the ~~family status~~ qualified life event.
2. The following categories of employees are not eligible to participate in the health benefit plan:
   a. An employee who works fewer than 20 hours per week;
   b. An employee in a temporary, emergency, or clerical pool position;
   c. A patient or inmate employed in a state institution;
   d. A non-state employee, officer, or enlisted personnel of the National Guard of Arizona;
   e. An employee in a position established for rehabilitation purposes;
   f. An employee of any state college or university:
      i. Who works fewer than 20 hours per week;
      ii. Who is engaged to work for ~~fewer~~ less than six months; or
      iii. For whom contributions are not made to a state retirement plan. This disqualification does not apply to a non-immigrant alien employee, an employee participating in a medical residency training program, ~~or~~ a Cooperative Extension employee on federal appointment, or a retiree who returns to work under A.R.S. § 38-766.01.

B. Eligibility exception. An employee who is on leave without pay may continue to participate in the health benefit plan

under the conditions in:
1. R2-5-405 for employees on leave without pay due to industrial illness or injury;
2. R2-5-413 for employees on medical leave without pay; or
3. R2-5-414 for employees on leave without pay for any other reason.

C. Dependent eligibility. Dependents eligible to participate in the health benefit plan include an ~~employee's~~ employee-member's spouse as provided by law and each qualifying child.

D. Enrollment of dependents. An eligible employee may enroll eligible dependents at the time of the employee's original enrollment, within 31 days of a ~~family status~~ qualified life event, or at open enrollment.

R2-5-417. Life Insurance and ~~Short-term~~ Disability Income Insurance Plans

A. Eligibility.
1. ~~All~~ A state ~~employees~~ employee, except ~~those~~ an employee listed in subsection (A)(2), may participate in the life insurance and short-term disability income insurance plans.
2. The following categories of employees are not eligible to participate in the life insurance and short-term disability income insurance plans:
   a. An employee who works fewer than 20 hours per week;
   b. An employee in a temporary, ~~or~~ emergency, or clerical pool position;
   c. A patient or inmate employed in a state institution;
   d. A non-state employee, officer, or enlisted personnel of the National Guard of Arizona;
   e. An employee in a position established for rehabilitation purposes;
   f. An employee of any state college or university:
      i. Who works fewer than 20 hours per week;
      ii. Who is engaged ~~in~~ to work for ~~fewer~~ less than six months; or
      iii. For whom contributions are not made to a state retirement plan. This disqualification does not apply to an employee participating in a medical residency training program, ~~or~~ a Cooperative Extension employee on federal appointment, or a retiree who returns to work under A.R.S. § 38-766.01.

B. Supplemental insurance coverage. In addition to the basic life insurance provided at no cost to an employee, an eligible employee may elect to purchase additional group life insurance. The employee may purchase ~~in~~ an amount of insurance that does not ~~to~~ exceed three times the employee's annual base salary, rounded down to the nearest $5,000, or ~~$200,000~~ the maximum amount established by the Director, whichever is less.

C. Dependent coverage. An eligible employee may elect to purchase group life insurance for the employee's spouse and each ~~qualifying~~ child in an amount established by the Director. ~~The employee may contact a representative of the Human Resources Benefits Section or the employee's agency personnel liaison for details.~~

D. Long-term disability coverage. The monthly benefit paid under the disability portion of a plan provided under A.R.S. § 38-651 may be reduced by payments the employee receives or is eligible to receive in the same month as determined by the terms and conditions of the plan.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES

[R05-394]

PREAMBLE

1. Sections Affected	Rulemaking Action
Article 13	New Article
R9-25-1301	New Section
R9-25-1302	New Section
R9-25-1303	New Section
R9-25-1304	New Section
R9-25-1305	New Section
R9-25-1306	New Section
R9-25-1307	New Section
R9-25-1308	New Section
R9-25-1309	New Section
R9-25-1310	New Section

R9-25-1311	New Section
R9-25-1312	New Section
R9-25-1313	New Section
R9-25-1314	New Section
R9-25-1315	New Section
Table 1	New Table
Exhibit I	New Exhibit

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4), (5), and (6)

Implementing statute: A.R.S. § 36-2225(A)(4), (5), and (6)

3. The effective date of the rules:

October 6, 2005

The rules will take effect immediately upon filing with the Office of the Secretary of State after approval by the Governor's Regulatory Review Council, as authorized under A.R.S. § 41-1032(A)(4).

ADHS is requesting an immediate effective date under A.R.S. § 41-1032(A)(4) because the rules will provide a benefit to the public, and a penalty is not associated with a violation of the rules. ADHS believes that the establishment of a formal state designation process is a cornerstone in the development of a more cohesive and effective state emergency medical services (EMS) and trauma system. Official determination of the resources and capabilities possessed by health care institutions providing trauma services will enable health care providers, including EMS providers, to ensure that each trauma patient is cared for at a health care institution with the resources and capabilities that match the patient's treatment needs, resulting in the best and most cost-effective care possible for the patient and in the best and most cost-effective use of the health care institution's resources. A state designation process will help to develop Arizona's EMS and trauma system so that trauma patients are treated in the most appropriate settings for the needs, and fewer trauma patients with severe trauma injuries will be unable to obtain the level of care needed in a timely manner because of a lack of resources. ADHS believes that developing and enhancing the Arizona EMS and trauma system through trauma center designation will result in many trauma patients' having better outcomes and even in the survival of some trauma patients who might not have survived in the absence of a developed EMS and trauma system.

4. A list of all previous notices appearing in the *Register* addressing the final rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 3192, August 13, 2004

Notice of Public Meeting on Open Rulemaking Docket: 10 A.A.R. 4854, December 3, 2004

Notice of Proposed Rulemaking: 11 A.A.R. 2354, June 24, 2005

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

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Telephone:	(602) 542-1264
Fax:	(602) 364-1150
E-mail:	phillik@azdhs.gov

6. An explanation of the rule, including the agency's reason for initiating the rule:

A.R.S. § 36-2225 requires the Arizona Department of Health Services (ADHS) to develop and administer a statewide emergency medical services (EMS) and trauma system to implement the Arizona EMS and trauma system plan. As

part of developing the statewide EMS and trauma system, ADHS is required by A.R.S. § 36-2225 to adopt rules to establish standards for a trauma center designation and dedesignation process for health care institutions that provide trauma care. A.R.S. § 36-2225 expressly authorizes ADHS to adopt rules allowing for designation based on: (1) a health care institution's verification as a trauma facility by a national verification organization, (2) a determination by a national verification organization that a health care institution meets the state standards established by rule for designation as a trauma center, or (3) a determination by ADHS that a health care institution meets the state standards established by rule for designation as a trauma center. A.R.S. § 36-2225 defines "national verification organization" to mean the American College of Surgeons Committee on Trauma (ACS) or another nationally recognized organization that verifies the ability of health care institutions to provide trauma services at various levels. Currently, ACS is the only national verification organization in existence.

A.R.S. § 36-2222(E)(1) requires the State Trauma Advisory Board (STAB) to make recommendations to ADHS on the initial and long-term processes for the verification and designation of trauma center levels, including the evaluation of trauma center criteria.

A.R.S. §§ 36-2225 and 36-2222(E)(1) were created by Laws 2004, Ch. 292, which became effective on August 25, 2004. A.R.S. § 36-2225 was then amended by Laws 2005, Ch. 52, effective April 11, 2005, to include the language regarding a national verification organization and the permissible bases for designation.

ADHS has been working on the rules for trauma center designation with STAB and the STAB Verification/Designation Work Group (STAB Work Group) since August 2004. Combined, STAB and the STAB Work Group include representation from the Arizona Department of Public Safety, the four EMS Regional Councils, the seven currently self-designated Level I trauma facilities, ACS, the Arizona Fire District Association, the Arizona Hospital and Healthcare Association, Indian Health Services, the American College of Emergency Physicians, a statewide rehabilitation facility, urban and rural advanced life support base hospitals that are not trauma centers, the Arizona Ambulance Association, the American Association of Retired Persons, Phoenix Fire Department, a tribal health organization, and Phoenix Children's Hospital.

After obtaining STAB Work Group approval and STAB approval of draft rules for trauma center designation in November 2004, ADHS solicited public comment on the draft rules through mass mailing and mass e-mailing to potentially interested persons, presented information at EMS Regional Council meetings, and held a public meeting on an open rulemaking docket to obtain oral comment. After revising the draft rules as a result of input received and further internal review, ADHS again worked with the STAB Work Group and STAB to finalize and obtain their approval of revised draft rules before proceeding to the formal rulemaking process.

As a result of this cooperative effort, ADHS has created rules for trauma center designation that represent the recommendations of STAB and the STAB Work Group; that meet the needs of the EMS, hospital, and urgent care communities; and that will protect and enhance public health and public health preparedness in Arizona.

The rules in the new 9 A.A.C. 25, Article 13 provide standards and establish the process for the designation of health care institutions as trauma centers at four different Levels. Designation represents a formal determination by ADHS that a health care institution has the resources and capabilities necessary to provide trauma services at a particular Level and is a trauma center. Designation as a Level I trauma center requires the most resources and capabilities, and designation as a Level IV the least.

Under the new rules, designation is voluntary. An owner is not required to obtain designation as a prerequisite to providing trauma services at the owner's health care institution and is not required to demonstrate the need for a trauma center in its health care institution's geographic area as part of the designation process. ADHS believes that this is consistent with ADHS's statutory authority because A.R.S. § 36-2225 does not indicate that designation is mandatory and does not prohibit a health care institution from providing trauma services if it is not a designated trauma center. Although the designation process is similar to a licensing process, the voluntary nature of designation results in its not being a "license" as defined in A.R.S. § 41-1001.

The rules allow for designation at a particular Level (Level I through Level IV) based on ACS verification at the same Level or based on a health care institution's meeting the state standards for the Level. The rules prescribe the state standards for Level I, II, III, and IV trauma centers in Exhibit I. The determination that a health care institution meets the state standards for designation as a Level I, II, or III trauma center is made through an ACS site visit. This means that an owner who desires to obtain designation as a Level I, II, or III trauma center for the owner's health care institution must arrange and pay for an ACS site visit. If ACS is requested to conduct a site visit as a "combined visit," ACS will make separate determinations of (1) eligibility for ACS verification and (2) whether a health care institution meets the state standards for designation. The determination that a health care institution meets the state standards for designation as a Level IV trauma center is made through an on-site survey of the health care institution conducted by ADHS.

The state standards for designation prescribed in Exhibit I are modeled after ACS's criteria for verification contained in the ACS publication *Resources for Optimal Care of the Injured Patient: 1999*, as subsequently amended by ACS, and are very similar to the standards adopted as guidelines in the Arizona EMS and Trauma System Plan for 2002-2005. Having ACS perform the site visits for designation as a Level I, II, or III trauma center, whether designation is based on ACS verification or on meeting the state standards, is consistent with the recommendations made by STAB

and the STAB Work Group. STAB and the STAB Work Group also recommended that designation be available at all Levels based on ACS verification at the same Level.

In addition to establishing standards and a process for regular designation as a Level I, II, III, or IV trauma center, the rules establish a provisional designation to allow designation as a Level I, II, or III trauma center to be granted for a health care institution that has not compiled sufficient data related to the trauma services provided to be eligible to obtain an ACS site visit. This could be because the health care institution has not been providing organized trauma services or because it has only recently begun providing organized trauma services.

The rules also establish a grace period to allow each of the state's seven currently self-designated Level I trauma facilities to obtain initial designation as a Level I trauma center without first obtaining ACS verification as a Level I trauma facility or documentation from ACS establishing that the trauma facility meets the state standards for designation as a Level I trauma center.

In addition, the rules establish a process for modification of designation if a trauma center's owner desires to obtain a designation that requires fewer resources and capabilities than the trauma center's current designation.

ADHS believes that the establishment of a formal state designation process is a cornerstone in the development of a more cohesive and effective state EMS and trauma system. Official determination of the resources and capabilities possessed by health care institutions providing trauma services will enable health care providers, including EMS providers, to ensure that each trauma patient is cared for at a health care institution with the resources and capabilities that match the patient's treatment needs, resulting in the best and most cost-effective care possible for the patient and in the best and most cost-effective use of the health care institution's resources. The following quoted material, from the U.S. Department of Health and Human Services Health Resources and Services Administration, the American Trauma Society, and the American Association for the Surgery of Trauma publication *When it Matters Most: Trauma Centers, Part of Your Community, There to Save Lives*, explains the concept well:

> Trauma centers must be part of a larger Trauma System to ensure the right patient is taken to the right hospital in the right amount of time to give them the greatest chance of survival. The Emergency Medical System (EMS)—911 dispatchers, emergency medical technicians on ambulances and helicopters—works to identify the severity of injury and takes those with less life-threatening injuries to emergency rooms and the most severely injured to a Trauma Center.
>
> Trauma Systems are designed to take maximum advantage of the "golden hour"—the sixty critical minutes when a life hangs in the balance. Getting full-fledged trauma care within an hour after the injury occurred can mean the difference between life or death—or whether you fully recover.
>
> . . . .
>
> Each year, nearly 150,000 Americans die from injuries. Injury is the leading cause of death and disability among children and adults in the country. Does having a well-organized, viable system of trauma care in your area make a difference? By any measure, the answer is yes.
>
> Trauma Systems can reduce the preventable death rate by 20-30 percent; some say even up to 50 percent. For example, studies of Trauma Systems in the United States, where the most severely injured patients are directed to specialized Trauma Centers showed that the benefit of an organized system of trauma care can reduce the risk of death by greater than 50 percent among seriously injured trauma patients. As an added benefit, these survivors have shorter hospital stays, freeing up resources for other needs.

A state designation process will help to develop Arizona's EMS and trauma system so that trauma patients are treated in the most appropriate settings for their needs, and fewer trauma patients with severe trauma injuries will be unable to obtain the level of care needed in a timely manner because of a lack of resources. ADHS believes that developing and enhancing the Arizona EMS and trauma system through trauma center designation will result in many trauma patients' having better outcomes and even in the survival of some trauma patients who might not have survived in the absence of a developed EMS and trauma system.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not 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:

ADHS has read and is relying on information in American College of Surgeons Committee on Trauma, *Resources for Optimal Care of the Injured Patient: 1999* (1998). Although ADHS does not believe that this ACS publication is a study as that term is used in the Administrative Procedure Act, ADHS believes that a number of ACS's recommendations in the publication are based upon information derived from studies. The publication is available to purchase from ACS at 633 N. Saint Clair St., Chicago, IL 60611-3211 or http://www.facs.org/trauma/index.html.

ADHS has read and is relying on information in U.S. Department of Health and Human Services Health Resources and Services Administration, American Trauma Society, and American Association for the Surgery of Trauma, *When it Matters Most: Trauma Centers, Part of Your Community, There to Save Lives* (2004). Although ADHS does not believe that this publication is a study, the publication refers to studies. The publication is available, free of charge,

from the American Trauma Society at 8903 Presidential Parkway, Suite 512, Upper Marlboro, MD 20772, or at http://www.amtrauma.org/uploads/1089662159249.pdf.

ADHS has read and, consistent with the recommendations of STAB and the STAB Work Group, is not relying on information in the following studies presented to ADHS as justification for allowing pediatric-only Level I trauma centers to have trauma surgeons on call and able to arrive at a trauma center within a 15-20 minute response time rather than requiring a trauma surgeon or senior surgical resident to be in-house at all times at a pediatric Level I trauma center:

Michael L. Nance, MD, et al., *Blunt Renal Injuries in Children Can Be Managed Nonoperatively: Outcome in a Consecutive Series of Patients*, 57 J. TRAUMA 474 (2004), available to purchase at http://www.jtrauma.com; and

Barbara A. Gaines, MD, & Henri R. Ford, MD, *Abdominal and Pelvic Trauma in Children*, 30 CRITICAL CARE MED. S416 (2002), available to purchase at http://www.ccmjournal.com.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule 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:

The rules will result in costs to ADHS, members of STAB, members of the STAB Work Group, and each owner who applies for trauma center designation for the owner's health care institution. The rules may also result in costs to the Arizona Health Care Cost Containment System (AHCCCS). ADHS does not believe that any other person will incur costs as a result of the new rules.

The rules will benefit ADHS, members of STAB and the STAB Work Group, each owner who obtains trauma center designation for the owner's health care institution, EMS providers, trauma patients and their loved ones, and ACS. ADHS does not believe that any other persons will benefit from the new rules.

As used in this summary, "minimal" means less than $1,000; "moderate" means $1,000 to $9,999; "substantial" means $10,000 or more; and "significant" means meaningful or important, but not easily subject to quantification.

ADHS has incurred substantial costs from the rulemaking process, and each member of STAB and the STAB Work Group who actively participated in the rulemaking process has incurred moderate costs from the time spent. Each member of STAB and the STAB Work Group also received a significant benefit from the rulemaking process because ADHS was receptive to STAB and STAB Work Group suggestions throughout the rulemaking process and created rules consistent with the groups' recommendations.

ADHS believes that the existence of a trauma center designation process in Arizona will result in no burden to a very minimal burden to AHCCCS from adjusting its operations so that Trauma and Emergency Services Fund monies are distributed only to designated Level I trauma centers and from processing additional applications for and distributing monies to any Level I trauma centers beyond the seven currently self-designated Level I trauma facilities. Because the seven currently self-designated Level I trauma facilities are receiving Trauma and Emergency Services Fund monies for unrecovered trauma center readiness costs from AHCCCS, and AHCCCS will no longer distribute these monies to non-designated trauma facilities after ADHS begins designating trauma centers, the existence of a trauma center designation process in Arizona may result in a substantial impact to the owners of the seven currently self-designated Level I trauma facilities. If any of the seven owners does not obtain designation as a Level I trauma center, that owner will incur a substantial cost from the loss of eligibility for the Trauma and Emergency Services Fund monies. For FY2004, each of these owners received more than $1 million from this Fund for unrecovered trauma center readiness costs.

ADHS believes that the existence of a trauma center designation process in Arizona may result in a substantial cost to University Medical Center (UMC), if UMC does not obtain designation as a trauma center or ACS verification. UMC has been designated as a trauma center by the Pima County Board of Supervisors. In the absence of a state designation process, ADHS believes that UMC's designation by the Pima County Board of Supervisors made UMC eligible to bill for trauma team activations on the UB-92 form using revenue code 068X. A health care institution may only bill for trauma team activations using revenue code 068X if the health care institution has either ACS verification or designation from the state or local government authority authorized to designate. Because the Arizona Legislature has provided the statutory authority for trauma center designation to ADHS, not the counties, ADHS believes that having a state designation process in place will render UMC ineligible to bill for trauma team activations using revenue code 068X, unless UMC obtains designation from ADHS or ACS verification. A representative of the National Foundation for Trauma Care estimated that, depending on patient volume and the trauma center Level, billing for trauma team activations using revenue code 068X could result in an additional $500,000 in annual reimbursement for a trauma facility.

Having a state trauma center designation process in Arizona will result in a significant benefit to ADHS, owners who obtain trauma center designation for their health care institutions, EMS providers, and trauma patients and their loved ones because establishing a formal trauma center designation process is a cornerstone in developing a cohesive and effective statewide EMS and trauma system.

An owner of a health care institution who applies for designation as a Level I, II, or III trauma center will incur a substantial cost from obtaining an ACS site visit to obtain either ACS verification or an ACS determination that the owner's health care institution meets the state standards for designation. The estimated cost of an ACS site visit, conducted by two surgeons, is approximately $12,700 (including the ACS administrative verification fee, an honorarium for each surgeon, the travel expenses for each surgeon, and the cost of a dinner meeting). In addition to the actual costs associated with the site visit itself, an owner will also incur costs from the administrative process of applying and coordinating the site visit with ACS.

ADHS will receive a substantial benefit from having ACS conduct the site visits for designation as a Level I, II, or III trauma center. For ADHS to conduct these site visits, ADHS would need to obtain the services and pay for the travel expenses of at least one out-of-state trauma surgeon and would need to use staff time to arrange travel and coordinate site visits with the surgeon and applicants. ADHS believes that trauma patients and their loved ones will also receive a significant benefit from having ACS conduct the site visits for designation as a Level I, II, or III trauma center because ACS is the leading national authority on the resources and capabilities necessary to operate an effective trauma facility. ACS's involvement in the designation process for Level I, II, and III trauma centers should enhance Arizona's trauma system.

ACS will receive a moderate benefit from each application for designation as a Level I, II, or III trauma center, from the $2,800 ACS administrative verification fee received for a site visit.

An owner who chooses to obtain ACS verification as a Level IV trauma facility to obtain designation as a Level IV trauma center will incur a substantial cost from the ACS site visit, as described above. An owner who chooses to obtain designation as a Level IV trauma center based on meeting the state standards will incur only a minimal cost from the time spent preparing for, and with ADHS during, an ADHS on-site survey. Allowing for designation as a Level IV trauma center without ACS involvement represents a potentially substantial benefit to an owner who desires to obtain designation as a Level IV trauma center. ADHS, however, will incur substantial costs as a result of this. To implement this, ADHS is establishing a position for and will employ one grade 21 FTE surveyor to conduct on-site surveys. ADHS estimates that the annual cost of employing one grade 21 FTE is $36,547-61,895 in salary plus approximately another $12,182-20,632 in employee-related expenses, for a total cost of approximately $48,729-82,527. This employee will also conduct investigations, which may include announced or unannounced on-site surveys.

Allowing an owner of one of the seven currently self-designated Level I trauma facilities to obtain designation as a Level I trauma center without first obtaining either ACS verification as a Level I trauma facility or documentation issued by ACS stating that the owner's health care institution meets the state standards for a Level I trauma center, under the grace period Section, may result in a substantial benefit to each of the six currently self-designated Level I trauma facilities that do not already hold ACS verification, because each is eligible to obtain designation as a Level I trauma center without first paying for an ACS site visit. This will probably not result in a benefit to St. Joseph's Hospital and Medical Center (St. Joe's), because St. Joe's already holds ACS verification as a Level I trauma facility and thus is already eligible to obtain regular designation as a Level I trauma center based on its ACS verification.

The grace period Section also allows an owner of one of the seven currently self-designated Level I trauma facilities to choose to meet the state standards for a Level II trauma center, rather than those for a Level I trauma center, during the term of the initial Level I designation granted under the grace period Section. This may result in a substantial benefit to each of the six currently self-designated Level I trauma facilities that do not currently hold ACS verification because each will be able to obtain initial designation as a Level I trauma center without having the resources and capabilities required only for Level I trauma centers (most of which would result in a substantial cost individually). The grace period will allow these trauma centers time to come into compliance with those requirements for a Level I trauma center that are not currently met.

Allowing an owner whose health care institution has not produced at least 12 consecutive months of data related to trauma services provided at the health care institution, and who cannot yet comply with the eligibility requirements for regular designation as a Level I, II, or III trauma center, to obtain an 18-month provisional designation will result in a substantial benefit to each owner who wants to begin providing organized trauma services or whose health care institution has been providing organized trauma services for only a short period of time and who desires to obtain designation as a Level I, II, or III trauma center. ACS will not perform a site visit for verification or a combined visit unless a health care institution has been providing trauma services and can provide trauma-related data for at least the past 9-12 months. Also, at least in the central region of Arizona, regional protocols require EMS providers to take trauma patients only to specified trauma facilities. Once designation begins, these protocols will require EMS providers in the central region to take trauma patients only to designated trauma centers. This would make it impossible for a new trauma facility to establish the trauma-related data necessary to obtain an ACS site visit. Without an ACS site visit, it is not possible to obtain designation as a Level I, II, or III trauma center. The rules eliminate this dilemma by creating a shorter term provisional designation that allows a health care institution to be designated (and thus to receive trauma patients from EMS providers) so that it can establish the trauma-related data necessary to obtain the ACS site visit necessary to obtain regular designation. The rule's allowing for an extension of provisional designation will also result in a substantial benefit to each owner that holds a provisional designation that will expire on its face before an ACS site visit of the owner's trauma center has been completed.

The rules provide that regular designation issued based on ACS verification expires on the expiration date of the ACS verification and that regular designation issued based on meeting the state standards expires after three years. ACS verification is good for three years. For renewal of designation as a Level I, II, or III trauma center, an owner is again required to provide documentation of either ACS verification or ACS's determination that the owner's health care institution meets the state standards. This will result in a substantial cost to an owner who applies for renewal of designation as a Level I, II, or III trauma center, from obtaining an ACS site visit either for re-verification or an ACS determination that the owner's health care institution meets the state standards. The cost of an ACS site visit for re-verification, conducted by two surgeons, is approximately $12,100 (including the $2,200 ACS administrative re-verification fee, an honorarium for each surgeon, the travel expenses for each surgeon, and the cost of a dinner meeting). In addition to the actual costs associated with the site visit itself, an owner will also incur costs from the administrative process of applying and coordinating the site visit with ACS. For the reasons stated previously, this will result in a substantial overall benefit to ADHS and a moderate benefit to ACS per renewal application.

Allowing an owner who desires to obtain a designation that requires fewer resources and capabilities than the current designation to obtain modified designation at a state Level consistent with the resources and capabilities that the owner intends to have at the trauma center will result in a substantial benefit to an owner who is unable to maintain the resources and capabilities necessary for the current designation, but who desires to have the owner's trauma center remain designated, because ADHS does not require an ACS site visit to issue modified designation. The owner is instead required to attest that the owner will ensure, and then to ensure, that the owner's trauma center meets the state standards for the Level of the modified designation.

The rules require the owner of a trauma center to ensure that the owner's trauma center meets the state standards or, if applicable, the ACS standards. This will result in a substantial cost to each owner who holds designation as a trauma center because the state standards and ACS standards require a number of resources and capabilities, at a substantial cost. The extent of the cost depends upon which resources and capabilities already exist at an owner's health care institution. Because designation is voluntary, however, it is an owner's decision to obtain designation that will actually result in the costs to the owner, not the rule itself. This requirement will result in a significant benefit to ADHS and to trauma patients and their loved ones because it will help to ensure that only committed owners whose trauma centers meet the applicable standards for designation will be designated.

The rules require the owner of a trauma center to ensure that data related to the trauma services provided are submitted to ADHS's Trauma Registry as required by ADHS. This will result in no cost to a substantial cost to the owner of a trauma center. A.R.S. § 36-2221(A) already requires each acute care hospital that provides in-house 24-hour daily dedicated trauma surgical services to submit to ADHS a uniform data set for trauma patients as prescribed by ADHS. Thus, the seven currently self-designated Level I trauma facilities are already statutorily required to provide, and are providing, data to the Trauma Registry and should incur no additional costs as a result of this provision. In addition, A.R.S. § 36-2221 provides that advanced life support base hospitals that are not trauma centers may also submit this data to the Trauma Registry. Each owner of a trauma center whose health care institution is not currently submitting data to the Trauma Registry will incur a minimal-to-substantial cost from the rule. The costs will depend primarily on whether computer hardware needs to be purchased and the additional staff time necessary to comply with the rule. ADHS is currently in the process of standardizing the data set to be used and assisting currently submitting entities with a transition to a standardized data set, which should help to minimize the costs resulting from this provision. ADHS will also incur a substantial cost from this rule because ADHS pays for Trauma Registry software, technical support, and training for Trauma Registry participants.

The rules also require the owner of a trauma center to ensure that the owner and the trauma center staff comply with the applicable provisions of A.R.S. Title 36, Chapter 21.1 and the new rules and with all applicable federal and state laws relating to confidentiality of information. This should result in no cost to an owner because the owner and the trauma center staff should already be complying with all applicable laws. This may result in a substantial cost, however, if an owner fails to ensure compliance.

The rules also require ADHS to comply with all applicable federal and state laws relating to confidentiality of information, which should result in no impact to ADHS because ADHS is already obligated to comply with these laws.

Finally, the rules prescribe the state standards (the resources and capabilities required) for designation as a Level I, II, III, or IV trauma center. Meeting the state standards for designation may result in a substantial cost to the owner of a health care institution, depending on which resources and capabilities already exist at the owner's health care institution. Because designation is voluntary, however, the cost of meeting the prescribed state standards is the direct result of an owner's choice to pursue designation for the owner's health care institution, not the direct result of the rules themselves. The state standards for designation will result in a significant benefit to ADHS and to trauma patients and their loved ones because the state standards will help to ensure that trauma patients are being taken to appropriate health care institutions that have the resources and capabilities necessary to provide quality trauma services.

ADHS does not believe that any small businesses will be subject to the rules or that there is a less intrusive or less costly alternative method of achieving the purpose of the rulemaking.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

ADHS made the following changes from the proposed rules to the final rules:

In R9-25-1301(1), ADHS changed "for purposes of" to read "for the purpose of."

In R9-25-1310(C), ADHS deleted ", unless subsection (F) applies,".

ADHS deleted R9-25-1310(F) in its entirety.

In R9-25-1311(A)(2), ADHS deleted ", unless subsection (D) applies,".

ADHS deleted R9-25-1311(D) in its entirety.

In footnote 10 to Exhibit I, ADHS changed each reference to "trauma director" to read "trauma medical director."

ADHS made minor grammatical and stylistic changes in response to suggestions from Governor's Regulatory Review Council staff.

11. A summary of the comments made regarding the rule and the agency response to them:

Rulemaking Process Generally	
Public Comment	**ADHS Response**
The Arizona Hospital and Healthcare Association (AzHHA) expressed its gratitude to ADHS for the work put into the rulemaking process, including the numerous revisions to the draft rules that ADHS made at the request of stakeholders. AzHHA praised ADHS's efforts to involve stakeholders early in the process and its willingness to work with AzHHA to resolve its regulatory and legal concerns, particularly ADHS's responsiveness to concerns previously submitted relating to the use of the term "substantial compliance." AzHHA thanked ADHS staff for the tremendous amount of work put into drafting the rules and the staff's willingness to listen to the concerns of stakeholders. AzHHA stated that it is confident that the rules have benefited greatly from the collaborative approach.	ADHS appreciates the support.
Trauma Center Designation and Trauma System Development Generally	
Public Comment	**ADHS Response**
The Arizona Emergency Nurses Association (AzENA) stated that "there seem to be some concerns with the new 'voluntary credentialing' from the American College of Surgeons [Committee on Trauma] (ACS) that will cost facilities an estimated $12,000 in up-front costs as well as reimbursement for uninsured trauma victims for those facilities that are not part of the 'voluntary credentialing.'" AzENA went on to state: "Many of the recommendations set about by the STAB Work Group for trauma center designation is not much different then what the majority of hospitals are doing currently. The difference with the introduction of this rulemaking policy is that any facility that desires a designation of LEVEL I must arrange and fund a visit from ACS to continue to receive that designation as well as to receive reimbursement from AHCCCS . . . . It further stipulates that all facilities regardless of the trauma designation will not receive any sort of reimbursement for uninsured patients that may be brought to their facilities.	ADHS interprets AzENA's statements regarding ACS as a criticism of the rules' requiring, for designation as a Level I, II, or III trauma center, that a health care institution have either ACS verification or an ACS determination that the health care institution meets the state standards. Having ACS conduct the site visits to determine eligibility for designation as a Level I, II, or III trauma center is consistent with ADHS's express statutory authority under A.R.S. § 36-2225 and with the recommendations of the STAB Work Group and STAB, the advisory body statutorily charged with making recommendations to ADHS on the initial and long-term processes for the verification and designation of trauma center levels, including the evaluation of trauma center criteria. Like STAB, ADHS believes that ACS's involvement will enhance Arizona's trauma system. ACS is the leading national authority on the resources and capabilities necessary to operate an effective trauma facility and has the resources and expertise to conduct these site visits. For ADHS to conduct these site visits, ADHS would need to contract for the services of at least one out-of-

Trauma patients need to be taken to the most appropriate facility to take advantage of the 'Golden Hour,' the sixty minutes that are most critical to saving a patients life. In this state with our vast open spaces and a total area of 114,006 square miles that golden hour to trauma treatment is not realistic even with medical air transportation. Emergency Nurses across the state who work in the small urban hospitals and rural hospitals can begin life saving treatment such as CPR with intubation, administration of blood, insertion of chest tubes as well as other treatments prior to a flight crew arriving. AzENA asks . . . ADHS . . . to develop a statewide trauma system that will benefit the entire state of Arizona."	state trauma surgeon and would need to use a great deal of staff time and resources to arrange and pay for travel and to coordinate site visits with the surgeon and with applicants. A health care institution owner who wishes to obtain designation without arranging and paying for an ACS site visit may apply for designation as a Level IV trauma center, which does not require ACS involvement. ADHS was cognizant of the expense of an ACS site visit when it determined that designation as a Level IV trauma center should be available without ACS involvement. ADHS believes that the other comments made by AzENA concern areas over which ADHS does not have control. ADHS interprets AzENA's statement regarding AHCCCS reimbursement as a criticism of the definition of "Level I trauma center" in A.A.C. R9-22-2101(F)(2) as "any acute care hospital designated by the Arizona Department of Health Services as a level I trauma center." ADHS does not have the authority to change that rule, which was adopted by AHCCCS to carry out its duties under A.R.S. § 36-2903.07, which was created by Proposition 202, a voter-approved initiative. A.R.S. § 36-2903.07 restricts payment of those funds to level I trauma centers. ADHS interprets the statement regarding reimbursement for uninsured patients as a criticism of the requirement that a health care institution have either ACS verification or designation from the governmental authority with jurisdiction to designate in order to bill for trauma activations on the UB-92 form using revenue code 068X. ADHS does not have the authority to change this requirement, which was adopted by the National Uniform Billing Committee, the organization that adopted and periodically updates the UB-92 form. ADHS agrees with AzENA that small urban hospitals and rural hospitals are important components of an effective EMS and trauma system, particularly in Arizona, a vast state with very concentrated population in some urban areas and very scattered population in more rural areas. ADHS hopes that the owners of such hospitals will choose to have them designated so that ADHS, Regional Councils, health care providers, EMS providers, and the public will be more familiar with their trauma-related resources and capabilities. Because of the voluntary nature of designation, however, these hospitals will be able to continue providing valuable trauma services and will continue to be important components of the EMS and trauma system even if they do not become designated as trauma centers. ADHS has not made any changes in response to these comments.

A Board Member of AzENA and a representative from Casa Grande Regional Medical Center expressed concern and requested clarification concerning the financial impact for non-trauma-center rural facilities that will receive trauma patients. The concern was that there will not be monies available from AHCCCS and other payers to reimburse these rural facilities if the rural facilities are not designated trauma centers.	ADHS explained that AHCCCS currently provides monies, from a fund created through a voter-approved Proposition, only to Level I trauma facilities. The money is currently going only to the seven self-designated Level I trauma facilities because they are the only facilities that are eligible under the AHCCCS rule for administration of that money (R9-22-2101). If any of the seven self-designated Level I trauma centers does not obtain designation once designation is in place, it will no longer receive those monies from AHCCCS because it will no longer be eligible under the AHCCCS rule for administration of that money. This does not affect most health care institutions, only those self-designated Level I trauma facilities. ADHS did not make any changes in response to this comment.
A representative from Casa Grande Regional Medical Center requested information about eligibility to bill for trauma activations and asked if local designation would make a health care institution eligible to bill for trauma activations.	ADHS explained that, according to the National Foundation for Trauma Care and information published by the Centers for Medicare and Medicaid Services, a health care institution can only bill for trauma activations on the UB-92 form using revenue code 068X if the health care institution is either ACS verified as a trauma facility or has designation granted by whatever governmental authority has jurisdiction over designation. ADHS is currently aware of one trauma facility that has local designation and one trauma facility that has ACS verification. ADHS is not aware of any other health care institution in Arizona that would currently be eligible to bill using revenue code 068X. ADHS believes that because the Legislature has given the authority to designate to ADHS and not local jurisdictions, once designation is in place, it is designation by ADHS that will make a health care institution eligible to bill using revenue code 068X. Thus, the locally designated trauma facility will need to obtain ADHS designation (or ACS verification) to remain eligible to bill for trauma activations using revenue code 068X. ADHS believes that, especially for smaller rural facilities, designation as a Level IV trauma center is a good option because it does not involve an ACS site visit and would still make a health care institution eligible to bill using revenue code 068X. ADHS has not made any changes in response to this comment.
R9-25-1302. Eligibility for Designation	
Public Comment	**ADHS Response**
AzHHA stated that it appreciates ADHS's two-pronged approach to eligibility, i.e., the adoption of both ACS verification standards and state standards as qualifying trauma center criteria.	ADHS appreciates the support.

R9-25-1303. Grace Period for Self-Designated Level I Trauma Facilities	
Public Comment	**ADHS Response**
AzHHA stated that it is confident that the grace period requirements will allow for a safe and effective transition from the current self-designated system to a formal system of designation and is grateful to ADHS for including these in the rules.	ADHS appreciates the support.
R9-25-1305. Eligibility for Provisional Designation; Provisional Designation Process	
Public Comment	**ADHS Response**
AzHHA stated that provisional designation will permit the trauma system to expand while still protecting public health and safety.	ADHS appreciates the support.
R9-25-1309. Modification of Designation	
Public Comment	**ADHS Response**
AzHHA stated that provisions allowing a trauma center to modify its designation will allow for an efficient change in status when a facility is faced with resource or capability constraints.	ADHS appreciates the support.
R9-25-1310. On-Site Survey for Designation as a Level IV Trauma Center Based on Meeting the State Standards; and R9-25-1311. Investigations	
Public Comment	**ADHS Response**
As proposed, R9-25-1310(F) and R9-25-1311(D) require ADHS to provide a trauma center with the opportunity to correct deficiencies identified unless ADHS determines that the deficiencies are a "direct risk to any person; the public health, safety, or welfare; or the environment." AzHHA stated that it understands ADHS's reasons for including these provisions, but believes that hospitals should always be permitted to correct deficiencies. Also, AzHHA is concerned that the term "direct risk" is not defined and could be subject to multiple interpretations. Thus, AzHHA recommended that ADHS eliminate the provision beginning with "unless the Department determines" or, at a minimum, insert "that is not correctable" at the end of that provision. AzHHA explained that the latter recommendation would permit a hospital to correct any deficiency unless ADHS determines that the deficiency poses a direct risk and is not correctable.	ADHS does not intend to prevent any health care institution from correcting deficiencies identified during an on-site survey or investigation, particularly deficiencies that could pose a risk to any person; the public health, safety, or welfare; or the environment. Indeed, ADHS would always encourage a health care institution to correct identified deficiencies, even if ADHS believes that it is appropriate to deny or revoke the health care institution's designation. Thus, in response to AzHHA's comments, and to clarify ADHS's intentions relating to correcting deficiencies, ADHS is: • Revising R9-25-1310(C) by deleting ", unless subsection (F) applies,"; • Deleting R9-25-1310(F) in its entirety; • Revising R9-25-1311(A)(2) by deleting ", unless subsection (D) applies,"; and • Deleting R9-25-1311(D) in its entirety. As a result, both R9-25-1310 and R9-25-1311 will require ADHS to send a request for a written corrective action plan along with a list of any deficiencies identified during an on-site survey or investigation.

R9-25-1311. Investigations	
Public Comment	**ADHS Response**
AzHHA expressed concern regarding the potential for duplicative investigations with medical facilities licensure. AzHHA believes that there are several trauma center designation requirements that are also regulated by ADHS's medical licensing division (e.g., facility resources, performance improvement, and medical staff issues). AzHHA stated that it recognizes and acknowledges a hospital's obligation under both sets of regulations, but is concerned that a trauma center designation complaint would trigger two separate ADHS investigations, which would create an unnecessary administrative burden and unfairly penalize hospitals that elect to participate in the trauma center designation program. AzHHA stated that it understands from previous conversations with ADHS that ADHS does not intend to have duplicative investigations and intends for the division that receives a complaint to investigate if the complaint falls within its jurisdiction and then, if the complaint also falls within the jurisdiction of another division, to forward the findings of the investigation to the other division. AzHHA requested that ADHS minimize the administrative burden to the health care institution to the extent possible by not treating the findings of another division as a complaint that requires a separate investigation, by requiring one division to accept a plan of correction submitted to another division for the same issue, or by otherwise consolidating the investigation process. AzHHA stated that it believes a substantive policy statement may be in order so that hospitals fully understand how this investigation process will work and what impact participation in the trauma designation program may have on their medical facility licenses.	ADHS intends to have complaints investigated by the ADHS Division that appears to have jurisdiction over the issues included in the complaint, whether the Public Health Services Division or the Licensing Division, and anticipates that findings will be shared between the Divisions when deficiencies identified in one Division's investigation appear to fall within the jurisdiction of the other Division. ADHS does not intend to duplicate efforts or to create unnecessary burdens for health care institutions or ADHS and is in the process of creating internal operating instructions to streamline these investigation processes to the extent possible and to coordinate the efforts of the Divisions to ensure consistent application of the rules and to minimize the administrative burden to both ADHS and the health care institutions. ADHS is amenable to receiving further suggestions from AzHHA concerning those internal processes, but does not believe that those internal processes are appropriate subject matter for a substantive policy statement. ADHS did not make any changes in response to this comment.
AzHHA expressed concern because R9-25-1311(A) requires ADHS to investigate a complaint alleging a trauma center is not meeting ACS standards, if designation is based on ACS verification, and "meeting the ACS standards" is defined as "being operated in compliance with each applicable criterion for verification as required by ACS for verification." AzHHA stated that because ACS specifications for compliance are not delineated in the rule, it is unclear what those requirements are and, subsequently, what thresholds of non-compliance trigger an investigation and ultimately a deficiency notice. AzHHA requested that, for the sake of clarity, ADHS consider developing a substantive policy statement outlining the compliance specifications and what, if any, role the ACS would play in the investigative process.	In determining whether a trauma center is meeting the ACS standards, when designation is based on ACS verification, ADHS will apply the ACS standards that were in effect at the time the trauma center's ACS verification was granted. This ensures that the trauma center is held to one set of standards throughout the designation period, which runs concurrently with the verification period, and that the trauma center owner is already aware of the standards, which would have been received from ACS during the verification process. ADHS does not intend to have ACS directly involved in investigations, but may consult with ACS if necessary to resolve any issues regarding interpretation of an ACS criterion. ADHS does not believe that a substantive policy statement is necessary to clarify this position, because it is consistent with the

	plain language of the definition of "Meet the ACS standards," "meeting the ACS standards," or "meets the ACS standards" in R9-25-1301: "be operated, being operated, or is operated in compliance with each applicable criterion for verification **as required by ACS for verification**" (emphasis added). To be consistent with the definition, a standard must have been the standard that was applied by ACS at the time that the verification upon which designation is based was granted. ADHS has not made any changes in response to this comment.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously made as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES

ARTICLE 13. TRAUMA CENTER DESIGNATION

Section

ARTICLE 13. TRAUMA CENTER DESIGNATION

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

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

1. "ACS" means the American College of Surgeons Committee on Trauma.
2. "ACS site visit" means an on-site inspection of a trauma facility conducted by ACS for the purpose of determining compliance with ACS trauma facilities criteria, or ACS trauma facilities criteria and state standards, at the Level of designation sought.
3. "Administrative completeness time period" means the number of days from the Department's receipt of an application until the Department determines that the application contains all of the items of information required by rule to be submitted with an application.
4. "ATLS" means the ACS Advanced Trauma Life Support Course.
5. "Available" means accessible for use.
6. "Chief administrative officer" means an individual assigned to control and manage the day-to-day operations of a health care institution on behalf of the owner or the body designated by the owner to govern and manage the health care institution.
7. "CME" means continuing medical education courses for physicians.
8. "Comply with" means to satisfy the requirements of a stated provision.
9. "CT" means computed tomography.
10. "Current" means up-to-date and extending to the present time.
11. "CVP" means central venous pressure.
12. "Department" means the Arizona Department of Health Services.
13. "Designation" means a formal determination by the Department that a health care institution has the resources and capabilities necessary to provide trauma services at a particular Level and is a trauma center.
14. "EMS" means emergency medical services.
15. "Health care institution" has the same meaning as in A.R.S. § 36-401.
16. "Hospital" has the same meaning as in A.A.C. R9-10-201.
17. "ICU" means intensive care unit.
18. "In compliance with" means satisfying the requirements of a stated provision.
19. "In-house" means on the premises at the health care institution.
20. "ISS" means injury severity score, the sum of the squares of the abbreviated injury scale scores of the three most severely injured body regions.
21. "Major resuscitation" means a patient:
    a. If an adult, with a confirmed blood pressure < 90 at any time or, if a child, with confirmed age-specific hypotension;
    b. With respiratory compromise, respiratory obstruction, or intubation, if the patient is not transferred from another health care institution;
    c. Who is transferred from another hospital and is receiving blood to maintain vital signs;
    d. Who has a gunshot wound to the abdomen, neck, or chest;
    e. Who has a Glasgow Coma Scale score < 8 with a mechanism attributed to trauma; or
    f. Who is determined by an emergency physician to be a major resuscitation.
22. "Meet the ACS standards," "meeting the ACS standards," or "meets the ACS standards" means be operated, being operated, or is operated in compliance with each applicable criterion for verification as required by ACS for verification.
23. "Meet the state standards," "meeting the state standards," or "meets the state standards" means be operated, being operated, or is operated in compliance with each applicable criterion listed in Exhibit I at least as frequently or consistently as required by the minimum threshold stated for the criterion in Exhibit I or at least 95% of the time, whichever is less.
24. "On-call" means assigned to respond and, if necessary, come to a health care institution when called by health care institution personnel.
25. "Owner" means one of the following:
    a. For a health care institution licensed under 9 A.A.C. 10, the licensee;
    b. For a health care institution operated under federal or tribal laws, the administrative unit of the U.S. government or sovereign tribal nation operating the health care institution.
26. "Person" means:
    a. An individual;
    b. A business organization such as an association, cooperative, corporation, limited liability company, or partnership; or
    c. An administrative unit of the U.S. government, state government, or a political subdivision of the state.
27. "Personnel" means an individual providing medical services, nursing services, or health-related services to a patient.

28. "PGY" means postgraduate year, a classification for residents in postgraduate training indicating the year that they are in during their post-medical-school residency program.
29. "Self-designated Level I trauma facility" means a health care institution that as of July 1, 2004, met the definition of a Level I trauma center under A.A.C. R9-22-2101(F)(1).
30. "SICU" means surgical intensive care unit.
31. "Signature" means:
    a. A handwritten or stamped representation of an individual's name or a symbol intended to represent an individual's name, or
    b. An "electronic signature" as defined in A.R.S. § 44-7002.
32. "Substantive review time period" means the number of days after completion of the administrative completeness time period during which the Department determines whether an application and owner comply with all substantive criteria required by rule for issuance of an approval.
33. "Transfer agreement" means a written contract between the owners of two health care institutions in which one owner agrees to have its health care institution receive a patient from the other owner's health care institution if the patient falls within specified criteria related to diagnosis, acuity, or treatment needs.
34. "Trauma center" has the same meaning as in A.R.S. § 36-2225.
35. "Valid" means that a license, certification, or other form of authorization is in full force and effect and not suspended or otherwise restricted.
36. "Verification" means formal confirmation by ACS that a health care institution has the resources and capabilities necessary to provide trauma services as a Level I, Level II, Level III, or Level IV trauma facility.
37. "Working day" means the period between 8:00 a.m. and 5:00 p.m. on a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.

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

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

tution under federal or tribal law; and

b. Comply with one of the following:

i. Hold current verification for the health care institution as a Level IV trauma facility; or

ii. Demonstrate, during an on-site survey of the health care institution conducted by the Department as described in R9-25-1310, that the health care institution meets the state standards for a Level IV trauma center.

B. To be eligible to retain designation for a health care institution, an owner shall:

1. Maintain a current and valid regular license for the health care institution to operate, if applicable; and
2. Comply with the trauma center responsibilities in R9-25-1313.

R9-25-1303. Grace Period for Self-Designated Level I Trauma Facilities (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

A. Within 90 days after the effective date of this Article, the owner of a self-designated Level I trauma facility who desires to obtain designation for the self-designated Level I trauma facility as a Level I trauma center under this Article shall apply for initial designation as a Level I trauma center under R9-25-1304.

B. An owner who applies for designation based on eligibility under this Section shall attest to one of the following in the application for initial designation:

1. That the owner's health care institution will meet the state standards for a Level I trauma center during the initial designation period, or
2. That the owner's health care institution will meet the state standards for a Level II trauma center during the initial designation period.

C. For an application submitted by an owner described under subsection (A), the Department shall waive the eligibility requirement of R9-25-1302(A)(1)(b) and grant designation as a Level I trauma center if the other requirements for designation are met.

D. An owner who obtains designation based on eligibility under this Section shall, during the term of the designation, ensure that the owner's trauma center meets the state standards that were the subject of the owner's attestation described in subsection (B).

E. An owner described under subsection (A) who obtains initial designation as a Level I trauma center and who desires to retain designation shall apply for renewal of designation under R9-25-1306.

F. To obtain renewal of designation under R9-25-1306, an owner described under subsection (A) shall comply with R9-25-1302(A)(1)(b)(i) or (ii) and R9-25-1306.

G. During the term of an initial designation granted to an owner based on eligibility under this Section, the Department may:

1. Investigate the owner's trauma center, as provided under R9-25-1311; and
2. Revoke the owner's designation, as provided under R9-25-1312.

H. This Section expires on January 1, 2009.

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

A. An owner applying for initial designation shall submit to the Department an application including:

1. An application form provided by the Department containing:
   a. The name, address, and main telephone number of the health care institution for which the owner seeks designation;
   b. The owner's name, address, and telephone number and, if available, fax number and e-mail address;
   c. The name and telephone number and, if available, fax number and e-mail address of the chief administrative officer for the health care institution for which the owner seeks designation;
   d. The designation Level for which the owner is applying;
   e. If the owner holds verification for the health care institution for which designation is sought, the Level of verification held and the effective and expiration dates of the verification;
   f. The asserted basis for designation:
      i. The owner holds verification for the health care institution,
      ii. The owner's health care institution meets the state standards, or
      iii. The owner is eligible for the grace period under R9-25-1303;
   g. Unless the owner is an administrative unit of the U.S. government or a sovereign tribal nation, the hospital or health care institution license number for the health care institution for which designation is sought;
   h. If applying for designation as a Level I, Level II, or Level III trauma center, the name and telephone number and, if available, fax number and e-mail address of the health care institution's trauma medical director;
   i. The name, title, address, and telephone number of the owner's statutory agent or the individual designated by the owner to accept service of process and subpoenas;
   j. Attestation that the owner knows all applicable requirements in A.R.S. Title 36, Chapter 21.1 and this Article;
   k. Attestation that the information provided in the application, including the information in the documents attached to the application form, is accurate and complete; and

l. The dated signature of:
i. If the owner is an individual, the individual;
ii. If the owner is a corporation, an officer of the corporation;
iii. If the owner is a partnership, one of the partners;
iv. If the owner is a limited liability company, a manager or, if the limited liability company does not have a manager, a member of the limited liability company;
v. If the owner is an association or cooperative, a member of the governing board of the association or cooperative;
vi. If the owner is a joint venture, one of the individuals signing the joint venture agreement;
vii. If the owner is a governmental agency, the individual in the senior leadership position with the agency or an individual designated in writing by that individual; and
viii. If the owner is a business organization type other than those described in subsections (A)(1)(l)(ii) through (vi), an individual who is a member of the business organization;

2. Unless the owner is an administrative unit of the U.S. government or a sovereign tribal nation, a copy of the current regular hospital or health care institution license issued by the Department for the health care institution for which designation is sought;
3. If applying for designation based on verification, documentation issued by ACS establishing that the owner holds current verification for the health care institution at the Level of designation sought and showing the effective and expiration dates of the verification; and
4. If applying for designation as a Level I, Level II, or Level III trauma center based on meeting the state standards, current documentation issued by ACS establishing that the owner's health care institution meets the state standards listed in Exhibit I for the Level of designation sought.

B. The Department shall process an application as provided in R9-25-1315.
C. The Department shall approve designation if the Department determines that an owner is eligible for designation as described in R9-25-1302.

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

A. The owner of a health care institution may apply for one 18-month provisional designation as a Level I, Level II, or Level III trauma center if:
1. When the owner applies for provisional designation, the owner's health care institution has not produced at least 12 consecutive months of data related to trauma services provided at the health care institution; and
2. The owner cannot comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b).

B. To be eligible to obtain provisional designation for a health care institution, an owner shall:
1. Comply with one of the following:
a. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
b. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
2. Make the attestations described in subsection (C)(2).

C. An owner applying for provisional designation shall submit to the Department an application including:
1. An application form that contains the information and items listed in R9-25-1304(A)(1)(a) through (A)(1)(d), (A)(1)(g) through (A)(1)(l), and (A)(2); and
2. Attestation that:
a. The owner's health care institution has the resources and capabilities necessary to meet the state standards for the Level of designation sought and will meet the state standards for the Level of designation sought during the term of the provisional designation; and
b. During the term of the provisional designation, the owner will:
i. Ensure that the trauma center meets the state standards;
ii. Apply for verification for the trauma center; and
iii. Provide to the Department, within 30 days after applying for verification, documentation issued by ACS establishing that the owner has applied for verification.

D. The Department shall process an application submitted under this Section as provided in R9-25-1315.
E. The Department shall approve provisional designation if the Department determines that an owner is eligible for provisional designation as described in subsection (B).
F. To be eligible to retain provisional designation for a health care institution, an owner shall:
1. Comply with subsection (B)(1)(a) or (b);
2. Comply with the trauma center responsibilities in R9-25-1313;
3. Apply for verification for the trauma center; and
4. Provide to the Department, within 30 days after applying for verification, documentation issued by ACS establishing

that the owner has applied for verification.

G. An owner who holds provisional designation and who desires to retain designation shall, before the expiration date of the provisional designation:
1. If the owner can comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for initial designation under R9-25-1304; or
2. If the owner cannot comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for an extension of the provisional designation under subsection (H).

H. An owner who holds provisional designation and who will not be able to comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b) on the expiration date of the provisional designation may apply to the Department, on a form provided by the Department, for one 180-day extension of the provisional designation and shall include with the application documentation issued by ACS showing the owner's progress in obtaining an ACS site visit.

I. The Department shall grant an extension if an owner provides documentation issued by ACS:
1. Establishing that the owner has applied for verification; and
2. Showing the owner's progress in obtaining an ACS site visit.

J. The Department may:
1. Investigate, as provided under R9-25-1311, a trauma center that is the subject of a provisional designation; and
2. Revoke, as provided under R9-25-1312, a provisional designation.

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

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

B. The Department shall process an application as provided in R9-25-1315.

C. The Department shall renew designation if the Department determines that the owner is eligible to retain designation as described in R9-25-1302(B).

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

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

A. The Department shall issue initial designation or renewal of designation:
1. When based on verification, with a term beginning on the date of issuance and ending on the expiration date of the verification upon which designation is based; and
2. When based on meeting the state standards or eligibility under R9-25-1303, with a term beginning on the date of issuance and ending three years later.

B. The Department shall issue a provisional designation with a term beginning on the date of issuance and ending 18 months later and an extension of provisional designation with a term beginning on the expiration date of the provisional designation and ending 180 days later.

C. The Department shall issue a modified designation with a term beginning on the date of issuance and ending on the expiration date of the designation issued before the application for modification of designation under R9-25-1309.

D. If an owner submits an application for renewal of designation as described in R9-25-1306 before the expiration date of the current designation, or submits an application for extension of provisional designation as described in R9-25-1305 before the expiration date of the provisional designation, the current designation does not expire until the Department has made a final determination on the application for renewal of designation or extension of provisional designation.

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

A. At least 30 days before the date of a change in a trauma center's name, the owner of the trauma center shall send the Department written notice of the name change.

B. At least 90 days before a trauma center ceases to offer trauma services, the owner of the trauma center shall send the

Department written notice of the intention to cease offering trauma services and the desire to relinquish designation.

C. Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:
1. For a notice described in subsection (A), issue an amended designation that incorporates the name change but retains the expiration date of the current designation; or
2. For a notice described in subsection (B), send the owner written confirmation of the voluntary relinquishment of designation, with an effective date consistent with the written notice.

D. An owner of a trauma center shall notify the Department in writing within three working days after:
1. The trauma center's hospital or health care institution license expires or is suspended, revoked, or changed to a provisional license;
2. A change in the trauma center's verification status; or
3. A change in the trauma center's ability to meet the state standards or, if designation is based on verification, to meet the ACS standards, that is expected to last for more than one week.

E. An owner of a trauma center who obtains verification for the trauma center during a term of designation based on meeting the state standards may obtain a new initial designation based on verification, with a designation term based on the dates of the verification, by submitting an initial application as provided in R9-25-1304.

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

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

B. The Department shall process an application as provided in R9-25-1315.

C. The Department shall issue a modified designation if the Department determines that, with the changes being made in the trauma center's resources and operations, the trauma center will meet the state standards for the Level of designation requested.

D. An owner who obtains modified designation shall, during the term of the modified designation, ensure that the owner's trauma center meets the state standards that were the subject of the owner's attestation described in subsection (A)(6).

E. The Department may:
1. Investigate, as provided under R9-25-1311, a trauma center that is the subject of a modified designation; and
2. Revoke, as provided under R9-25-1312, a modified designation.

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

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

A. Before issuing initial or renewal designation to an owner applying for designation as a Level IV trauma center based on meeting the state standards, the Department shall complete an announced on-site survey of the owner's health care institution that includes:
1. Reviewing equipment and the physical plant;
2. Interviewing personnel; and
3. Reviewing:
   a. Medical records;
   b. Patient discharge summaries;
   c. Patient care logs;
   d. Personnel rosters and schedules;
   e. Performance-improvement-related documents other than peer review documents privileged under A.R.S. §§ 36-

445.01 and 36-2403, including reports prepared as required under R9-10-204(B)(2) and the supporting documentation for the reports; and

f. Other documents relevant to the provision of trauma services as a Level IV trauma center and that are not privileged under federal or state law.

B. A Department surveyor shall make a verbal report of findings to an owner upon completion of an on-site survey.

C. Within 30 days after completing an on-site survey, the Department shall send to an owner a written report of the Department's findings, including a list of any deficiencies identified during the on-site survey and a request for a written corrective action plan.

D. Within 10 days after receiving a request for a written corrective action plan, an owner shall submit to the Department a written corrective action plan that includes for each identified deficiency:

1. A description of how the deficiency will be corrected, and
2. A date of correction for the deficiency.

E. The Department shall accept a written corrective action plan if it:

1. Describes how each identified deficiency will be corrected, and
2. Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.

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

A. If the Department determines based upon Trauma Registry data collected by the Department or receives a complaint alleging that a trauma center is not meeting the state standards or, if designation is based on verification, is not meeting the ACS standards, the Department shall conduct an investigation of the trauma center.

1. The Department may conduct an announced or unannounced on-site survey as part of an investigation.
2. Within 30 days after completing an investigation, the Department shall send to the owner of the trauma center investigated a written report of the Department's findings, including a list of any deficiencies identified during the investigation and a request for a written corrective action plan.

B. Within 10 days after receiving a request for a written corrective action plan, an owner shall submit to the Department a written corrective action plan that includes for each identified deficiency:

1. A description of how the deficiency will be corrected, and
2. A date of correction for the deficiency.

C. The Department shall accept a written corrective action plan if it:

1. Describes how each identified deficiency will be corrected, and
2. Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.

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

A. The Department may deny or revoke designation if an owner:

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

B. In determining whether to deny or revoke designation, the Department shall consider:

1. The severity of each violation relative to public health and safety;
2. The number of violations;
3. The nature and circumstances of each violation;
4. Whether each violation was corrected, the manner of correction, and the duration of the violation; and
5. Whether the violations indicate a lack of commitment to having the trauma center meet the state standards or, if applicable, the ACS standards.

C. If the Department denies or revokes designation, the Department shall send to the owner a written notice setting forth the information required under A.R.S. § 41-1092.03.

1. An owner may file a written notice of appeal with the Department within 30 days after receiving a notice of denial or revocation, as provided in A.R.S. § 41-1092.03.
2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

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

The owner of a trauma center shall ensure that:

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

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

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

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

A. The application processing time periods for each type of approval granted by the Department under this Article are listed in Table 1 and may be extended through a written agreement between an owner and the Department.

B. The Department shall, within the administrative completeness time period specified in Table 1, review each application submitted for administrative completeness.

1. If an application is incomplete, the Department shall send to the owner a written notice listing each deficiency and the information or items needed to complete the application.
2. If an owner fails to submit to the Department all of the information or items listed in a notice of deficiencies within the time period specified in Table 1, the Department shall consider the application withdrawn.

C. After determining that an application is administratively complete, the Department shall review the application for substantive compliance with the requirements for approval.

1. The Department shall complete its substantive review of each application, and send an owner written notice of approval or denial, within the substantive review time period specified in Table 1.
2. As part of the substantive review for an application for initial designation or renewal of designation as a Level IV trauma center based on meeting the state standards, the Department shall conduct an announced on-site 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 on-site survey of the health care institution or trauma center.
6. If an owner fails to submit to the Department all of the information or items listed in a written request for additional information, including, if applicable, a corrective action plan, within the time period specified in Table 1, the Department shall deny the application.

D. In applying this Section, the Department shall:

1. In calculating an owner's time to respond, begin on the postmark date of a notice of deficiencies or written request for additional information and end on the date that the Department receives all of the information or documents requested in the notice of deficiencies or written request for additional information; and
2. In calculating the Department's time periods, not include any time during which the Department is waiting for an owner to submit information or documents to the Department as requested by the Department in a notice of deficiencies or written request for additional information.

E. If the Department denies an application, the Department shall send to the owner a written notice of denial setting forth the information required under A.R.S. § 41-1092.03.

1. An owner may file a written notice of appeal with the Department within 30 days after receiving the notice of denial, as provided in A.R.S. § 41-1092.03.
2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

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

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

EXHIBIT I. ARIZONA TRAUMA CENTER STANDARDS (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

E = Essential and required

Trauma Facilities Criteria	Levels			
	I	**II**	**III**	**IV**
A. Institutional Organization				
1. Trauma program	E	E	E	-
2. Trauma service	E	E	E	-
3. Trauma team	E	E	E	E
4. Trauma program medical director[1]	E	E	E	-
5. Trauma multidisciplinary committee	E	E	E	-
6. Trauma coordinator/trauma program manager[2]	E	E	E	E
B. Hospital Departments/Divisions/Sections				
1. Surgery	E	E	E	-
2. Neurological surgery	E	E	-	-
a. Neurosurgical trauma liaison	E	E	-	-
3. Orthopaedic surgery	E	E	E	-
a. Orthopaedic trauma liaison	E	E	E	-
4. Emergency medicine	E	E	E	-
a. Emergency medicine liaison[3]	E	E	E	-

5. Anesthesia	E	E	E	-
C. Clinical Capabilities				
1. Published on-call schedule for each listed specialty required in (C)(2) and (3)	E	E	E	-
2. Specialty immediately available 24 hours/day				
a. General surgery[4]	E	E	E	-
i. Published back-up schedule	E	E	-	-
ii. Dedicated to single hospital when on-call	E	E	-	-
b. Anesthesia[5]	E	E	E	-
c. Emergency medicine[6]	E	E	E	-
3. On-call and promptly available 24 hours/day[7]				
a. Cardiac surgery[8]	E	-	-	-
b. Hand surgery	E	E	-	-
c. Microvascular/replant surgery	E	-	-	-
d. Neurologic surgery	E	E	-	-
i. Dedicated to one hospital or back-up call	E	E	-	-
e. Obstetrics/gynecologic surgery	E	-	-	-
f. Ophthalmic surgery	E	E	-	-
g. Oral/maxillofacial surgery[9]	E	E	-	-
h. Orthopaedic surgery	E	E	E	-
i. Dedicated to one hospital or back-up call	E	E	-	-
i. Plastic surgery	E	E	-	-
j. Critical care medicine	E	E	-	-
k. Radiology	E	E	E	-
l. Thoracic surgery	E	E	-	-
D. Clinical Qualifications				
1. General/Trauma Surgeon				
a. Board certification[10]	E	E	E	-
b. 16 hours CME/year[11]	E	E	-	-
c. ATLS certification[12]	E	E	E	E
d. Multidisciplinary peer review committee attendance > 50%[13]	E	E	E	-
2. Emergency Medicine[3]				
a. Board certification[10]	E	E	-	-
b. Trauma education – 16 hours CME/year[11]	E	E	-	-
c. ATLS certification[12]	E	E	E	E
d. Multidisciplinary peer review committee attendance > 50%[13]	E	E	E	-
3. Neurosurgery				
a. Board certification	E	E	-	-
b. 16 hours CME/year[11]	E	E	-	-
c. 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. Facilities/Resources/Capabilities				
1. Volume Performance[14]	E	-	-	-
2. Presence of surgeon at resuscitation (immediately available)[15]	E	E	-	-
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	E	E	E	-
b. Resuscitation Equipment for Patients of All Ages				
i. Airway control and ventilation equipment	E	E	E	E
ii. Pulse oximetry	E	E	E	E
iii. Suction devices	E	E	E	E
iv. Electrocardiograph-oscilloscope-defibrillator	E	E	E	E
v. Internal paddles	E	E	E	-
vi. CVP monitoring equipment	E	E	E	-
vii. Standard intravenous fluids and administration sets	E	E	E	E
viii. Large-bore intravenous catheters	E	E	E	E
ix. Sterile Surgical Sets for				
(1) Airway control/cricothyrotomy	E	E	E	E
(2) Thoracostomy	E	E	E	E
(3) Venous cutdown	E	E	E	E
(4) Central line insertion	E	E	E	-
(5) Thoracotomy	E	E	E	-
(6) Peritoneal lavage	E	E	E	-
x. Arterial catheters	E	E	-	-
xi. Drugs necessary for emergency care	E	E	E	E
xii. X-ray availability 24 hours/day	E	E	E	-
xiii. Broselow tape	E	E	E	E
xiv. Thermal Control Equipment				
(1) For patient	E	E	E	E
(2) For fluids and blood	E	E	E	E
xv. Rapid infuser system	E	E	E	E
xvi. Qualitative end-tidal CO_2 determination	E	E	E	E
c. Communication with EMS vehicles	E	E	E	E
d. Capability to resuscitate, stabilize, and transport pediatric patients[17]	E	E	E	E
6. Operating Room				
a. Immediately available 24 hours/day	E	E	-	-
b. Personnel				
i. In-house 24 hours/day[18]	E	-	-	-

ii. Available 24 hours/day[19]	-	E	E	-
c. Age-Specific Equipment				
i. Cardiopulmonary bypass	E	-	-	-
ii. Operating microscope	E	-	-	-
d. Thermal Control Equipment				
i. For patient	E	E	E	E
ii. For fluids and blood	E	E	E	E
e. X-ray capability including C-arm image intensifier	E	E	E	-
f. Endoscopes, bronchoscope	E	E	E	-
g. Craniotomy instruments	E	E	-	-
h. Equipment for long bone and pelvic fixation	E	E	E	-
i. Rapid infuser system	E	E	E	E
7. Postanesthetic Recovery Room (SICU is acceptable)				
a. Registered nurses available 24 hours/day	E	E	E	-
b. Equipment for monitoring and resuscitation	E	E	E	E
c. Intracranial pressure monitoring equipment	E	E	-	-
i. Pulse oximetry	E	E	E	E
ii. Thermal control	E	E	E	E
8. Intensive or Critical Care Unit for Injured Patients				
a. Registered nurses with trauma training	E	E	E	-
b. Designated surgical director or surgical co-director	E	E	E	-
c. Surgical ICU service physician in-house 24 hours/day[20]	E	-	-	-
d. Surgically directed and staffed ICU service[20]	E	E	-	-
e. Equipment for monitoring and resuscitation	E	E	E	-
f. Intracranial pressure monitoring equipment	E	E	-	-
g. Pulmonary artery monitoring equipment	E	E	E	-
9. Respiratory Therapy Services				
a. Available in-house 24 hours/day	E	E	-	-
b. On-call 24 hours/day	-	-	E	-
10. Radiological Services (Available 24 hours/day)				
a. In-house radiology technologist	E	E	-	-
b. Angiography	E	E	-	-
c. Sonography	E	E	E	-
d. Computed tomography	E	E	E	-
i. In-house CT technician	E	E	-	-
e. Magnetic resonance imaging	E	-	-	-
11. Clinical Laboratory Service (Available 24 hours/day)				
a. Standard analyses of blood, urine, and other body fluids, including micro-sampling when appropriate	E	E	E	E
b. Blood typing and cross-matching	E	E	E	-
c. Coagulation studies	E	E	E	E

d. Comprehensive blood bank or access to a community central blood bank and adequate storage facilities	E	E	E	-
e. Blood gases and pH determinations	E	E	E	E
f. Microbiology	E	E	E	-
12. Acute Hemodialysis				
a. In-house	E	-	-	-
b. Transfer agreement	-	E	E	E
13. Burn Care—Organized				
a. In-house or transfer agreement with burn center	E	E	E	E
14. Acute Spinal Cord Management				
a. In-house or transfer agreement with regional acute spinal cord injury rehabilitation center	E	E	E	E
F. Rehabilitation Services				
1. Transfer agreement to an approved rehabilitation facility	E	E	E	E
2. Physical therapy	E	E	E	-
3. Occupational therapy	E	E	-	-
4. Speech therapy	E	E	-	-
5. Social Services	E	E	E	-
G. Performance Improvement				
1. Performance improvement programs	E	E	E	E
2. Trauma Registry				
a. In-house	E	E	E	E
b. Participation in state, local, or regional registry	E	E	E	E
3. Audit of all trauma deaths	E	E	E	E
4. Morbidity and mortality review	E	E	E	E
5. Trauma conference – multidisciplinary	E	E	E	-
6. Medical nursing audit	E	E	E	E
7. Review of prehospital trauma care	E	E	E	-
8. Review of times and reasons for trauma-related bypass	E	E	-	-
9. Review of times and reasons for transfer of injured patients	E	E	E	E
10. Performance improvement personnel dedicated to care of injured patients	E	E	-	-
H. Continuing Education/Outreach				
1. Outreach activities[21]	E	E	-	-
2. Residency program[22]	E	-	-	-
3. ATLS provide/participate[23]	E	-	-	-
4. Programs provided by hospital for:				
a. Staff/community physicians (CME)	E	E	E[24]	-
b. Nurses	E	E	E	-
c. Allied health personnel	E	E	E	-
d. Prehospital personnel provision/participation	E	E	E	-
I. Prevention				

1. Prevention program[25]	E	E	-	-
2. Collaboration with existing national, regional, state, and community programs[26]	E	E	E	E
J. Research				
1. Research program[27]	E	-	-	-
2. Trauma registry performance improvement activities	E	E	E	-
3. Identifiable Institutional Review Board process	E	-	-	-
4. Extramural education presentations	E[28]	-	-	-
K. Additional Requirements for Trauma Centers Represented as Caring for Pediatric Trauma Patients[29]				
1. Trauma surgeons credentialed for pediatric trauma care	E	E	-	-
2. Pediatric emergency department area	E	E	-	-
3. Pediatric resuscitation equipment in all patient care areas	E	E	-	-
4. Microsampling	E	E	E	-
5. Pediatric-specific performance improvement program	E	E	E	E
6. Pediatric intensive care unit	E[30]	E[31]	-	-

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

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

[3] This does not apply if emergency medicine physicians do not participate in the care of a hospital's trauma patients.

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

1. For a Level I trauma center, a PGY 4 or 5 surgery resident or a trauma surgeon is on the hospital premises at all times; and
2. For all major resuscitations in a Level I, II, or III trauma center:
   a. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
   b. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department:
      i. For a Level I or II trauma center, no later than 15 minutes after patient arrival; or
      ii. For a Level III trauma center, no later than 30 minutes after patient arrival.

The minimum threshold for compliance with #2 is 80%.
A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

[5] For this criterion, "immediately available" means that:

1. For a Level I trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is on the hospital premises at all times;
2. For a Level II trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department no later than 15 minutes after patient arrival;
3. For a Level III trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department no later than 30 minutes after patient arrival; and
4. For a Level I, II, or III trauma center, an anesthesiologist is present for all surgeries.

[6] For this criterion, "immediately available" means that an emergency medicine physician is physically present in the emergency department at all times. However, if emergency medicine physicians do not participate in the care of a hospital's trauma patients, an emergency medicine physician is not required to be immediately available 24 hours per day.

[7] For the criteria in (C)(3)(a)-(l), "promptly available" means that:
1. A physician specialist is present in the emergency department no later than 45 minutes after notification, based on patient need; or
2. For hand surgery and microvascular/replant surgery, the owner has transfer agreements to ensure that a patient in need of hand surgery or microvascular/replant surgery can be expeditiously transferred to a health care institution that has a hand surgeon or microvascular/replant surgeon on the premises.

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

[9] This criterion is satisfied by a dentist or physician authorized by the hospital to perform oral and maxillofacial surgery. If a physician, the individual shall be a plastic surgeon or an otolaryngologist.

[10] In a Level I or II trauma center, a non-board-certified physician may be included in the trauma service if the physician:
1. If a surgeon, is in the examination process by the American Board of Surgery;
2. If the trauma medical director, is a Fellow of ACS;
3. Unless the trauma medical director, complies with the following:
   a. Has a letter written by the trauma medical director demonstrating that the health care institution's trauma program has a critical need for the physician because of the physician's individual experience or the limited physician resources available in the physician's specialty;
   b. Has successfully completed an accredited residency training program in the physician's specialty, as certified by a letter from the director of the residency training program;
   c. Has current ATLS certification as a provider or instructor, as established by documentation;
   d. Has completed 48 hours of trauma CME within the past three years, as established by documentation;
   e. Has attended at least 50% of the trauma quality assurance and educational meetings, as established by documentation;
   f. Has been a member or attended local, regional, and national trauma organization meetings within the past three years, as established by documentation;
   g. Has a list of patients treated over the past year with accompanying ISS and outcome for each;
   h. Has a quality assurance assessment by the trauma medical director showing that the morbidity and mortality results for the physician's patients compare favorably with the morbidity and mortality results for comparable patients treated by other members of the trauma service; and
   i. Has full and unrestricted privileges in the physician's specialty and in the department with which the physician is affiliated; or
4. Complies with the following:
   a. Has provided exceptional care of trauma patients, as established by documentation such as a quality assurance assessment by the trauma medical director;
   b. Has numerous publications, including publication of excellent research;
   c. Has made numerous presentations; and
   d. Has provided excellent teaching, as established by documentation.

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

[11] This criterion applies only to the trauma medical director, the emergency medicine liaison, the neurosurgical trauma liaison, and the orthopaedic trauma liaison. This criterion is satisfied by an average of 16 hours annually, or 48 hours over three years, of verifiable external trauma-related CME. External CME includes programs given by visiting professors or invited speakers and teaching an ATLS course.

[12] Among the trauma surgeons, only the trauma medical director is required to have current ATLS certification. The other trauma surgeons are required to have held ATLS certification at one time. Among the emergency medicine physicians, only non-board-certified physicians are required to have current ATLS certification. The other emergency medicine physicians are required to have held ATLS certification at one time.

[13] Among the trauma surgeons, 50% attendance is required for each member of the trauma surgical core group. In the other specialty areas, 50% attendance is required only for the emergency medicine liaison, the neurosurgical trauma liaison, and the orthopaedic trauma liaison.

[14] Except for Level I trauma centers that care only for pediatric patients, each Level I trauma center shall satisfy one of the following volume performance standards:
1. 1200 trauma admissions per year,

2. 240 admissions with ISS > 15 per year, or
3. An average of 35 patients with ISS > 15 for the trauma panel surgeons per year.

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

[15] For this criterion, "immediately available" means that for all major resuscitations in a Level I or II trauma center:

1. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
2. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department no later than 15 minutes after patient arrival.

The minimum threshold for compliance with this criterion is 80%.
A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

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

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

The minimum threshold for compliance with this criterion is 80%.
A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

[17] A trauma center that does not admit pediatric patients shall be capable of resuscitating, stabilizing, and transporting pediatric trauma patients.

[18] A Level I trauma center shall have a complete operating room team in the hospital at all times, so that an injured patient who requires operative care can receive it in the most expeditious manner. The members of the operating room team shall be assigned to the operating room as their primary function; they cannot also be dedicated to other functions within the institution.

[19] A Level II trauma center shall have a complete operating room team available when needed. The need to have an in-house operating room team depends on a number of things, including the patient population served, the ability to share responsibility for operating room coverage with other hospital staff, prehospital communication, and the size of the community served by the trauma center. If an out-of-house operating room team is used, then this aspect of care shall be monitored by the performance improvement program.

[20] This requirement may be satisfied by a physician authorized by the hospital to admit patients into the intensive care unit as the attending physician or to perform critical care procedures.

[21] This requirement is met through having an independent outreach program or participating in a collaborative outreach program. "Collaborative outreach program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating hospitals educate the general public or current or prospective physicians, nurses, prehospital providers, or allied health professionals regarding injury prevention, trauma triage, interfacility transfer of trauma patients, or trauma care.

[22] A Level I trauma center shall have a functional and documented teaching commitment. This requirement may be met through:

1. A trauma fellowship program; or
2. Active participation with one of the following types of residency programs in emergency medicine, general surgery, orthopaedic surgery, or neurosurgery:
   a. An independent residency program;
   b. A regional residency rotation program; or
   c. A collaborative residency program that includes multiple hospitals, with each non-sponsor participating hospital hosting at least one rotation.

[23] This requirement is met through participating in the provision of ATLS courses and having ATLS instructors on staff.

[24] When a Level III trauma center is in an area that contains a Level I or Level II trauma center, this is not required.

[25] This requirement is met through having an independent prevention program or participating in a collaborative prevention program. "Collaborative prevention program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating health care institutions promote injury prevention through primary, secondary, or tertiary prevention strategies. An independent or collaborative prevention program shall include:

1. Conducting injury control studies,
2. Monitoring the progress and effect of the prevention program,
3. Providing information resources for the public, and
4. Each participating hospital's designating a prevention coordinator who serves as the hospital's spokesperson for prevention and injury control activities.

[26] This requirement is met through participating in a prevention program organized at the national, regional, state, or local community level.

[27] This requirement is met through having an independent research program or participating in a collaborative research program. "Collaborative research program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating hospitals systematically investigate issues related to trauma and trauma care.
Injury control studies are considered to be research program activities if they have a stated focused hypothesis or research question.

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

29 A trauma center is required to comply with the requirements of (K)(1) through (6), in addition to the requirements in (A) through (J), if the trauma center is represented as caring for pediatric trauma patients. "Represented as caring for pediatric trauma patients" means that a trauma center's availability or capability to care for pediatric trauma patients is advertised to the general public, health care providers, or emergency medical services providers through print media, broadcast media, the Internet, or other means such as the EMSystem® administered by the Department.

[30] The trauma center shall have a PICU available on-site.

[31] This requirement may be satisfied by a transfer agreement.