

Notices of Proposed Rulemaking

10. The time, place and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled where, when, or how persons may request an oral proceeding on the proposed rule:

Written comment will be accepted at the Board office, 5060 N. 19th Ave., #416, Phoenix, AZ, 85015 on a business day between the hours of 8:00 a.m. and 5:00 p.m. until 5:00 p.m. on June 7, 2004. An oral proceeding is not scheduled but may be requested.

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

Not applicable

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

Not applicable

13. The full text of the rules as follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 7. BOARD OF CHIROPRACTIC EXAMINERS

ARTICLE 5. LICENSES

Section

R4-7-502. Procedures for Processing Initial License and Specialty Certification Applications

ARTICLE 5. LICENSES

R4-7-502. Procedures for Processing Initial License and Specialty Certification Applications

- A.** An applicant may obtain a license or specialty certification application package at the Board Office on business days, or by requesting that the Board mail one to an address specified by the applicant. An applicant shall pay the Board a non-refundable \$10 fee for each license application package. The \$10.00 fee does not apply to specialty certification application package.
- B.** A completed license application package ~~they have~~ shall be submitted to the Board office on business days. The Board shall deem the license application package received by on the date that the Board Board's date stamps stamp, when on the package as the package is delivered to the Board office.
- C.** To complete a license application package, an applicant shall provide the following information and documentation:
1. Two identical photographs, ~~measuring three inches by four inches~~, showing the applicant's full front face as the applicant will appear at the time of the examination and a description of identifying characteristics, if any;
 2. The applicant's full ~~current~~ name and any former names;
 3. The applicant's current home and all office addresses, current home and all office phone numbers, all current office fax numbers, and any previous home or office address or addresses for the past five years;
 4. The type of license and certification for which application is made;
 5. All fees required by A.R.S. §§ 32-921(D) and (E) and ~~32-922.0(E)~~; 32-922.02(E);
 6. A record of education requirements described in A.R.S. § 32-921(B) including the applicant's chiropractic college transcript and the applicant's certificate of attainment of passing scores for Parts I, II, III, and IV of the examination, conducted by the National Board of Chiropractic Examiners;
 7. Any record of being convicted of, pleading guilty to or pleading nolo contendere to a misdemeanor or a felony, even if the record of the conviction or plea was sealed or expunged or the conviction was set aside or forgiven, and any record of an arrest, investigation, indictment, or charge within the last 12 months. The applicant shall submit any record of being refused a license to practice chiropractic or any other health care profession in this or any other state, and any record of a formal sanction taken against the applicant's license in this or any other state; and provide a current copy of a self-query from The National Practitioner Data Bank (NPDB) and Healthcare Integrity and Protection Data Bank (HIPDB);
 8. A completed fingerprint card;
 9. A list of all other states or jurisdictions in which the applicant is or has been licensed or certified to practice chiropractic or any other health care profession with a verification of good standing for each ~~current~~ license or certification submitted directly by the licensing agency of the other states or jurisdictions;
 10. The name and professional designation of the owner or owners of the clinic or office at which the applicant will be employed;
 11. The applicant's social security number;
 12. The applicant's notarized signature, attesting to the truthfulness of the information provided by the applicant;
 13. A score of ~~60%~~ 75% or higher on the Arizona Jurisprudence Examination. The applicant may not sit for the Arizona Jurisprudence Examination until the application package is otherwise complete.

- D. Within 25 business days of receiving a license application package, the Board shall notify the applicant in writing that the package is either complete or incomplete. If the package is incomplete, the notice shall specify what information is missing. If the Board does not provide notice to the applicant, the license application package shall be deemed complete after the passage of 25 business days.
- E. An applicant with an incomplete license application package shall supply the missing information within 60 calendar days from the date of the notice. An applicant who is unable to supply the missing information within 60 calendar days may submit a written request to the Board for an extension of time in which to provide a complete application package. The request for an extension of time shall be submitted to the Board office before the 60-day deadline for submission of a complete application package, and shall state the reason that the applicant is unable to comply with the 60-day requirement and the amount of additional time requested. The Board shall grant a request for an extension of time if the Board finds that the reason the applicant was unable to comply with the 60-day requirement was due to circumstances beyond the applicant's control and that compliance can reasonably be expected to be remedied during the extension of time.
- F. If an applicant fails to submit a complete license application package within the time permitted, the Board shall close the applicant's file. An applicant whose file has been closed and who later wishes to become licensed, shall apply anew.
- G. After receiving all missing information as specified in subsection (E), the Board shall notify the applicant that the license application package is complete.
- H. The Board shall render a licensing decision no later than 120 business days after receiving a completed license application package. The Board shall deem a completed license application package received on the postmarked date of the notice advising the applicant that the package is complete.
- I. An applicant seeking initial licensure by reciprocity under A.R.S. § 32-922.01 shall submit an application to the Board and shall comply with all provisions of R4-7-502 except that the applicant is not required to submit proof of obtaining a passing score on Part IV of the examination conducted by the National Board of Chiropractic Examiners.
- J. An applicant seeking initial certification in a specialty under A.R.S. § 32-922.02 shall submit an application to the Board and shall comply with all provisions of R4-7-502 except for subsection (C).
- K. To complete a specialty certificate application package, an applicant shall provide the following information and documentation:
 - 1. The applicant's full current name;
 - 2. The applicant's current office address and current office phone number;
 - 3. The applicant's Arizona chiropractic license number;
 - 4. All fees required by A.R.S. § 32-922.02(E);
 - 5. A record of education requirements described in A.R.S. § 32-922.02 and the applicant's certificate of attainment of passing scores of the examination for the specialty, conducted by the National Board of Chiropractic Examiners;
 - 6. The applicant's notarized signature, attesting to the truthfulness of the information provided by the applicant;
- ~~J.~~ For the purpose of A.R.S. § 41-1073, the Board establishes the following time-frames for initial licenses and specialty certifications:
 - 1. Administrative completeness review time-frame: 25 business days.
 - 2. Substantive review time-frame: 120 business days.
 - 3. Overall time-frame: 145 business days.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

- 1. **Sections Affected**

R4-23-110	<u>Rulemaking Action</u>
R4-23-411	Amend
	New Section
- 2. **The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
 - Authorizing statute: A.R.S. § 32-1904(A)(1)
 - Implementing statute: A.R.S. § 32-1901(21) and (66)
- 3. **A list of all previous notices appearing in the Register addressing the proposed rulemaking:**
 - Notice of Rulemaking Docket Opening: 9 A.A.R. 5603, December 26, 2003

Notices of Proposed Rulemaking

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

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302
Telephone: (623) 463-2727, ext. 131
Fax: (623) 934-0583
E-mail: rxcop@cox.net

5. An explanation of the rules, including the agency's reasons for initiating the rules:

The Board received numerous inquiries from pharmacies, pharmacists, and pharmacy educators regarding the expanding role of pharmacists in the health care delivery system, specifically whether a pharmacist may administer immunizations. The Board's Assistant Attorney General advised the Board that Arizona pharmacists have statutory authority to dispense and administer immunizations on the prescription order of a medical practitioner for a specific patient. The Board was advised to write rules to set the standards for a pharmacist to administer immunizations. The proposed rules amend R4-23-110 to add new definitions for "eligible patient" and "pharmacist administered immunizations training program." The proposed rules include a new Section (R4-23-411 Pharmacist Administered Immunizations) that details the standards for pharmacist authorization to administer immunizations, pharmacist qualifications, immunization training programs, recordkeeping and reporting, confidentiality, and renewal of authorization to administer immunizations. The proposed rules include necessary style, format, grammar, and punctuation changes to comply with the rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public, pharmacists, and pharmacies by clearly establishing the standards for pharmacist administered immunizations.

6. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on or 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, any analysis of the study and other supporting material:

None

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

Not applicable

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

The proposed rules will impact the Board, pharmacists, and pharmacies. The proposed rules will have moderate economic impact on the Board. The impact on the Board will be usual rulemaking-related costs which are minimal. The major impact on the Board will be the costs of processing and issuing pharmacist administered immunization certifications. The Board estimates that from 30 to 50 pharmacists may seek certification at an initial cost to the Board of \$1230 to \$2050. The cost of renewing the certification would be minimal because it would be tied to the pharmacist's biennial license renewal. The cost to the Board to approve a pharmacist administered immunizations training program would be minimal and would involve Board staff time receiving and processing training program applications for Board approval. The Board's compliance costs may increase minimally. The costs to a pharmacist to be certified to administer immunizations will not come from the Board directly. The Board will not charge a fee to issue pharmacist administered immunization certifications. A pharmacist will have to pay the costs to meet the qualifications for authorization to administer immunizations. The qualifications include: a current, unrestricted license to practice pharmacy in Arizona, successful completion of an approved pharmacist administered immunizations training program, and current certification in basic cardiopulmonary resuscitation. The Board does not have figures for the cost of the training program and costs for CPR training vary. The Board estimates that these costs may vary from a couple hundred dollars to a thousand dollars. The proposed rules will have no direct economic impact on the public. The public will benefit from increased access to immunization services provided by pharmacists, and there will be a cost to the public for the service.

The public, Board, pharmacists, and pharmacies benefit from rules that are clear, concise, and, understandable. The proposed rules benefit the public, the Board, and the pharmacy community by clearly establishing the standards for pharmacist administered immunizations.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131
Fax: (623) 934-0583
E-mail: rxcop@cox.net

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

Comments may be written or presented orally. Written comments must be received by 5 p.m., Tuesday, June 1, 2004. An oral proceeding is scheduled for:

Date: June 1, 2004
Time: 10:00 a.m.
Location: 4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed above.

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

Not applicable

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

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-411. ~~Reserved~~ Pharmacist Administered Immunizations

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

- “Active ingredient” No change
- “Alternate physician” No change
- “Approved course in pharmacy law” No change
- “Authentication of product history” No change
- “AZPLEX” No change
- “Batch” No change
- “Beyond-use date” No change
- “Biological safety cabinet” No change
- “Certified pharmacy technician” No change
- “Class 100 environment” No change
- “Community pharmacy” No change
- “Component” No change
- “Computer system audit” No change
- “Contact hour” No change
- “Container” No change
- “Continuing education” No change
- “Continuing education activity” No change
- “Continuing education unit” or “CEU” No change

- “Correctional facility” No change
- “CRT” No change
- “Current good compounding practices” No change
- “Current good manufacturing practice” No change
- “Cytotoxic” No change
- “Day” No change
- “DEA” No change
- “Delinquent license” No change
- “Dietary supplement” No change
- “Dispensing pharmacist” No change
- “Drug sample” No change
- “Drug therapy management” No change
- “Drug therapy management agreement” No change
- “Eligible patient” means a patient who is determined eligible to receive an immunization by a pharmacist using professional judgment after a consultation with the patient regarding the patient’s current health condition, recent chronic health condition, and allergies.
- “Extreme emergency” No change
- “FDA” No change
- “Immediate notice” No change
- “Inactive ingredient” No change
- “Pharmacist administered immunizations training program” means an immunization training program for pharmacists that meets the requirements of R4-23-411(C).
- “Internal test assessment” No change
- “Limited-service correctional pharmacy” No change
- “Limited-service long-term care pharmacy” No change
- “Limited-service mail-order pharmacy” No change
- “Limited-service nuclear pharmacy” No change
- “Limited-service pharmacy permittee” means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.
- “Long-term care consultant pharmacist” No change
- “Long-term care facility” or “LTCF” No change
- “Lot” No change
- “Lot number” or “control number” No change
- “Materials approval unit” No change
- “Mediated instruction” No change
- “MPJE” No change
- “NABP” No change
- “NABPLEX” No change
- “NAPLEX” No change
- “Other designated personnel” No change
- “Outpatient” No change
- “Outpatient setting” No change
- “Patient profile” No change
- “Pharmaceutical care” No change
- “Pharmacy law continuing education” No change
- “Pharmacy permittee” means a person who holds a current pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1934, and A.A.C. R4-23-606 and R4-23-652.
- “Pharmacy technician” No change
- “Prepackaged drug” No change
- “Proprietor” means the owner of a business permitted by the Board under A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1934.
- “Provider pharmacy” No change
- “Radiopharmaceutical” No change
- “Radiopharmaceutical quality assurance” No change
- “Radiopharmaceutical services” No change
- “Red C stamp” No change
- “Remodel” No change
- “Remote drug storage area” No change
- “Resident” No change

- “Responsible person” No change
- “Score transfer” No change
- “Sight-readable” No change
- “Single-drug audit” No change
- “Single-drug usage report” No change
- “Sterile pharmaceutical product” No change
- “Strength” No change
- “Supervision” No change
- “Supervisory physician” No change
- “Supplying” No change
- “Support personnel” means an individual, working under the supervision of a pharmacist, trained to perform clerical duties associated with the practice of pharmacy, including cashiering, bookkeeping, pricing, stocking, delivering, answering non-professional telephone inquiries, and documenting third-party reimbursement. Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, graduate intern, pharmacy technician, or ~~certified~~ pharmacy technician trainee.
- “Transfill” No change
- “Wholesale distribution” No change
- “Wholesale distributor” No change

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Reserved Pharmacist Administered Immunizations

- A.** Authority to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations. If a pharmacist meets the qualifications and standards specified by this Section and is granted authorization by the Board, the pharmacist may administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations and, in an emergency, epinephrine to eligible patients eighteen years of age and older upon receipt of a valid prescription order. The Board may issue a certificate authorizing this function to the pharmacist who meets the qualifications established in subsection (B). The authority to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations is valid only for a pharmacist holding a certificate for pharmacist administered immunizations and may not be delegated to any other pharmacist or employee.
- B.** Qualifications for authorization to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations. The Board may issue a certificate authorizing the administration of hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations to a pharmacist who meets the following qualifications:
 - 1. Current, unrestricted licensure to practice pharmacy in this state;
 - 2. Successful completion of an approved training program as outlined in this Section; and
 - 3. Current certification in basic cardiopulmonary resuscitation.
- C.** Standards for a Board-approved pharmacist administered immunizations training program. An institution desiring to offer a training program for pharmacists to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations shall submit an application to the Board for approval. The Board shall grant approval to an applicant training program that meets the following requirements:
 - 1. The training program is based on the course requirements outlined in subsection (D);
 - 2. The training program is offered in an institution accredited by the Accreditation Council on Pharmacy Education;
 - 3. A completion certificate is awarded to a pharmacist who successfully completes the training program. The certificate shall include:
 - a. The name and location of the institution,
 - b. The date of completion,
 - c. The full name of the person who completed the program,
 - d. The signature of the faculty member in charge of the course, and
 - e. The date the certificate was awarded; and
 - 4. Records are maintained which include documentation of the following:
 - a. Each person enrolled in the program, including documentation of performance and the date the person failed or completed the program;
 - b. Each faculty member teaching the program, including qualifications;
 - c. The course of study; and
 - d. A list of graduates of the program who were awarded certificates and the dates of certification.To maintain ongoing approval, an applicant shall submit an evaluation of the program standard’s compliance with this subsection to the Board every two years.
- D.** Training program requirements. A training program for pharmacists to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations shall include the following course of study:

Notices of Proposed Rulemaking

1. Basic immunology and the human immune response;
 2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
 3. Response to an emergency situation as a result of the administration of an immunization, including administering epinephrine based on a patient-specific prescription order received before administration of an immunization;
 4. Administration of intramuscular injections;
 5. Other immunization administration methods; and
 6. Recordkeeping and reporting requirements specified in subsection (E).
- E.** Recordkeeping and reporting requirements. In addition to filing the prescription order as required in A.R.S. § 32-1964, a pharmacist granted authorization under this Section to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations shall maintain in the pharmacy for a minimum of seven years the following documentation regarding each immunization administered:
1. The name, address, and date of birth of the patient;
 2. The date of administration and site of injections;
 3. The name, dose, manufacturer's lot number, and expiration date of the vaccine;
 4. The name and address of the patient's primary health care provider, as identified by the patient;
 5. The name of the pharmacist administering the immunization;
 6. A record of the pharmacist's consultation with a patient determining that the patient is an eligible patient as defined in R4-23-110;
 7. The date that the written report was sent to the patient's primary health care provider;
 8. Consultation or other professional information provided to the patient; and
 9. The name of the vaccine information sheet provided to the patient.
- The pharmacist shall provide a written report to the patient's primary health care provider of documentation required in subsections (E)(1) through (E)(9) within 14 days of the immunization. The required records specified in this subsection shall be available in the pharmacy for inspection by the Board or its designee.
- F.** Confidentiality of records maintained. The required records identified in subsection (E) that include specific patient information are confidential records. A pharmacist, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.
- G.** Renewal of a certificate for pharmacist administered immunizations. A certificate authorizing a pharmacist to administer hepatitis, influenza, meningococcal, pneumonia, smallpox, and tetanus toxoid immunizations shall be renewed biennially by November 1. Any pharmacist desiring to renew the certificate shall provide proof of the following:
1. Current certification in basic cardiopulmonary resuscitation, and
 2. Completion of a minimum of two contact hours (0.2 CEU) of continuing education related to immunizations. A pharmacist may use the continuing education hours required in this subsection to satisfy the continuing education requirements for pharmacist license renewal.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

**CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSING**

PREAMBLE

<u>1. Sections Affected</u>	<u>Rulemaking Action</u>
R9-10-201	Amend
R9-10-203	Amend
R9-10-204	Amend
R9-10-206	Amend
R9-10-207	Amend
R9-10-208	Amend
R9-10-209	Amend
R9-10-212	Amend
R9-10-213	Amend
R9-10-218	Amend
R9-10-219	Amend
R9-10-220	Amend
R9-10-222	Amend

Notices of Proposed Rulemaking

R9-10-228	Amend
R9-10-229	Amend
R9-10-230	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. §§ 36-132(A) and 36-136(F)

Implementing statutes: A.R.S. §§ 36-405 and 36-406

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 1716, April 30, 2004

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

Name: Kathleen Phillips, Rules Administrator
Address: Arizona Department of Health Services
1740 W. Adams, Suite 202
Phoenix, AZ 85007
Telephone: (602) 542-1264
Fax: (602) 364-1150
E-mail: kphilli@hs.state.az.us

or

Name: Kathy McCanna, Program Manager
Address: Arizona Department of Health Services
150 N. 18th Ave., Suite 450
Phoenix, AZ 85007
Telephone: (602) 364-2841
Fax: (602) 364-4764
E-mail: kmccann@hs.state.az.us

5. An explanation of the rules, including the agency's reasons for initiating the rules:

A.R.S. § 36-132(A) requires the Arizona Department of Health Services (Department) to license and regulate health care institutions in Arizona. A.R.S. § 36-405(A) requires the Director of the Department to adopt rules establishing minimum standards and requirements for the construction, modification and licensure of health care institutions necessary to assure the public health, safety and welfare. It further requires that the standards and requirements relate to the construction, equipment, sanitation, staffing for medical, nursing, and personal care services, and recordkeeping pertaining to the administration of medical, nursing, and personal care services according to generally accepted practices of health care. A.R.S. § 36-405(A) also requires that the Director use the current standards adopted by the Joint Commission on Accreditation of Hospitals and the Commission on Accreditation of the American Osteopathic Association or those adopted by any recognized accreditation organization approved by the Department as guidelines in prescribing minimum standards and requirements.

The Department promulgated rules that became effective October 1, 2002 for hospitals, a classification of health care institutions. After the rules were implemented, the Department and affected stakeholders identified technical or clarifying changes that needed to be made to the rules. The Department established a task force to review and discuss changes to the rules. Based on the recommendations from the task force, the Department submitted a notice of proposed rulemaking to the Secretary of State that was published in the Arizona Administrative Register on June 20, 2003. During the comment period several additional issues were identified. Subsequently, a supplemental proposed rulemaking was submitted and published on December 12, 2003. Additional issues were again identified that would require another supplemental proposed rulemaking. Because the Department determined that making another supplemental proposed rulemaking would be too confusing, the Department decided to terminate the rulemaking and submit a proposed rulemaking that includes the changes previously identified as a result of the comment period for the terminated rulemaking. This rulemaking does not change the tuberculosis testing requirements currently in effect.

6. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on or 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, any analysis of the study and other supporting material:

None

Notices of Proposed Rulemaking

7. 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

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

The Department and licensed hospitals will bear any costs associated with the rules. Because the rules require additional policies and procedures and additions to a hospital's quality management plan and to staff orientation, the hospital may incur a one-time cost for development and minimal costs for implementation of the new requirements. The Department may experience an increase in survey time for Department personnel to review the additional policies and procedures. In addition, hospitals may experience an increase in staffing costs due to changes in the nurse-to-patient ratio for patients who receive intensive care services.

The rules will provide a benefit to the Department, licensed hospitals, nurses, and patients. The rules provide for clarification that will make it easier for hospital personnel to comply with the rules and easier for Department personnel to survey and determine compliance with the rules. Nurses may benefit from a decrease in patient assignments and stress associated with inadequate staffing. Nurse staffing based on acuity as well as increased nurse-to-patient ratio for intensive care patients will have a positive effect on patient health and safety and help decrease the incidence of negative patient outcomes. In addition, the rules provide more flexibility for special hospitals providing patients with clinical laboratory services, radiology, and diagnostic imaging services and more staff flexibility for hospitals with nurseries providing care to neonates receiving no treatment.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Kathleen Phillips, Rules Administrator
Address: Arizona Department of Health Services
1740 W. Adams, Suite 202
Phoenix, AZ 85007
Telephone: (602) 542-1264
Fax: (602) 364-1150
E-mail: kphilli@hs.state.az.us
or
Name: Kathy McCanna, Program Manager
Address: Arizona Department of Health Services
150 N. 18th Ave., Suite 450
Phoenix, AZ 85007
Telephone: (602) 364-2841
Fax: (602) 364-4764
E-mail: kmccann@hs.state.az.us

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceeding:

Date: June 11, 2004
Time: 10:00 a.m.
Location: Arizona Department of Health Services
1740 W. Adams, Room 411
Phoenix, AZ 85007

A person may submit written comments on the proposed rules no later than the close of record, 5:00 p.m., June 11, 2004, to either of the individuals listed in items #4 and #9.

A person with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting Nancy Sylvester by telephone at (602) 364-3959 or by email at nsylves@hs.state.az.us. A request should be made as early as possible to allow time to arrange the accommodation.

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

Not applicable

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

Not applicable

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSING

ARTICLE 2. HOSPITALS

Section

R9-10-201.	Definitions
R9-10-203.	Administration
R9-10-204.	Quality Management
R9-10-206.	Personnel
R9-10-207.	Medical Staff
R9-10-208.	Nursing Services
R9-10-209.	Patient Rights
R9-10-212.	Transport
R9-10-213.	Transfer
R9-10-218.	Clinical Laboratory Services and Pathology Services
R9-10-219.	Radiology Services and Diagnostic Imaging Services
R9-10-220.	Intensive Care Services
R9-10-222.	Perinatal Services
R9-10-228.	Medical Records
R9-10-229.	Infection Control
R9-10-230.	Environmental Services

ARTICLE 2. HOSPITALS

R9-10-201. Definitions

No change

1. No change
2. No change
3. ~~“Acuity” means a determination of the level and type of nursing services, based on the patient’s illness or injury, that are required to meet the needs of the patient~~ a patient’s need for hospital services based on the patient’s medical condition.
4. “Acuity plan” means a method for establishing nursing personnel requirements by unit based on a patient’s acuity.
- ~~4.5.~~ No change
- ~~5-6.~~ No change
- ~~6-7.~~ No change
- ~~7-8.~~ No change
- ~~8-9.~~ No change
- ~~9-10.~~ “Assessment” means an analysis of a patient’s current medical condition and need for hospital services.
- ~~10-11.~~ No change
12. “Attending physician’s designee” means a physician, a physician assistant, a registered nurse practitioner, or a medical staff member who has clinical privileges and is authorized by medical staff bylaws to act on behalf of the attending physician.
- ~~11-13.~~ No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- ~~12-14.~~ No change
 - a. No change
 - b. No change
 - c. No change
- ~~13-15.~~ No change
- ~~14-16.~~ No change

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~~15-17~~. No change

~~16-18~~. No change

~~17-19~~. No change

~~18-20~~. No change

~~19-21~~. No change

~~20-22~~. No change

~~21-23~~. No change

24. "Critically ill inpatient" means an inpatient whose severity of medical condition requires the nursing services of specially trained registered nurses for:

a. Continuous monitoring and multi-system assessment.

b. Complex and specialized rapid intervention, and

c. Education of the patient or patient's representative.

~~22-25~~. No change

~~23-26~~. No change

~~24-27~~. No change

~~25-28~~. No change

~~26-29~~. No change

~~27-30~~. No change

~~28-31~~. No change

~~29-32~~. No change

~~30-33~~. No change

~~31-34~~. No change

~~32-35~~. No change

~~33-36~~. No change

~~34-37~~. No change

~~35-38~~. No change

~~36-39~~. No change

~~37-40~~. No change

~~38-41~~. No change

~~39-42~~. No change

~~40-43~~. No change

~~41-44~~. No change

~~42-45~~. No change

~~43-46~~. No change

~~44-47~~. No change

~~45-48~~. No change

~~46-49~~. No change

~~47-50~~. No change

~~48-51~~. No change

~~49-52~~. No change

~~50-53~~. No change

~~51-54~~. No change

a. No change

b. No change

~~52-55~~. No change

53-56. "Intensive care services" means hospital services provided to ~~an~~ a critically ill inpatient who requires the services of especially trained nursing and other personnel members as specified in hospital policies and procedures.

~~54-57~~. No change

~~55-58~~. No change

a. No change

b. No change

~~56-59~~. No change

60. "Medical condition" means the state of a patient's physical or mental health, including the patient's illness, injury, or disease.

~~57-61~~. No change

~~58-62~~. No change

~~59-63~~. No change

~~60-64~~. No change

~~61-65~~. No change

~~62-66~~.No change

~~63-67~~.No change

~~64-68~~.No change

a. No change

b. No change

~~65-69~~.No change

~~66-70~~.No change

~~67-71~~.No change

~~68-72~~.No change

~~69-73~~.No change

~~70-74~~.No change

~~71-75~~.No change

~~72-76~~.No change

~~73-77~~. “Order” means an instruction to provide medical services, as authorized by the governing authority, to a patient by:

a. A medical staff member;~~;~~

b. An individual licensed under A.R.S. Title 32 or authorized by a hospital within the scope of the individual’s license;~~;~~ or

c. A physician who is not a medical staff member.

~~74-78~~.No change

~~75-79~~.No change

~~76-80~~.No change

a. No change

b. No change

~~77-81~~.No change

~~78-82~~.No change

~~79-83~~.No change

~~80-84~~. “~~Patient~~ Patient’s representative” means a patient’s legal guardian, an individual acting on behalf of a patient with the written consent of the patient, or a surrogate as defined in A.R.S. § 36-3201.

~~81-85~~.No change

~~82-86~~.No change

~~83-87~~.No change

~~84-88~~.No change

a. No change

b. No change

~~85-89~~.No change

~~86-90~~.No change

~~87-91~~.No change

~~88-92~~.No change

~~89-93~~.No change

~~90-94~~.No change

~~91-95~~.No change

~~92-96~~.No change

~~93-97~~.No change

~~94-98~~.No change

~~95-99~~.No change

~~96-100~~.No change

~~97-101~~.No change

~~98-102~~.No change

~~99-103~~.No change

~~100-104~~.No change

~~101-105~~.No change

~~102-106~~.No change

~~103-107~~.No change

~~104-108~~.No change

~~105-109~~.No change

a. No change

b. No change

~~106-110~~.No change

~~107-111~~.No change

~~108-112~~. No change

- a. No change
- b. No change
- c. No change

~~109-113~~. No change

~~110-114~~. "Transfer" means a hospital discharging a patient and sending the patient to another hospital for inpatient medical services licensed health care institution as an inpatient or resident without the intent intending that the patient will be returned to the sending hospital.

~~111-115~~. No change

~~112-116~~. No change

~~113-117~~. "Treatment" means a procedure or method to cure, improve, or palliate an injury, an illness, or a disease a medical condition.

~~114-118~~. No change

~~115-119~~. No change

- a. No change
- b. No change
- c. No change

~~116-120~~. No change

~~117-121~~. No change

~~118-122~~. No change

~~119-123~~. No change

R9-10-203. Administration

A. No change

- 1. No change
- 2. No change
- 3. No change
 - a. No change
 - b. No change
- 4. No change
- 5. No change
- 6. No change
- 7. No change
- 8. No change
- 9. No change
- 10. No change
- 11. No change
- 12. No change
- 13. No change

B. No change

- 1. No change
- 2. No change
- 3. No change
- 4. No change

C. No change

- 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. Include how a personnel member may submit a complaint relating to patient care;
 - ~~d~~-e. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - e- f. No change
 - ~~f~~- g. No change
 - i. No change
 - ii. No change

- iii. No change
- iv. No change
- ~~g-h~~ No change
- ~~h-i~~ No change
- ~~i-j~~ No change
- ~~j-k~~ No change
- ~~k-l~~ No change
- ~~l-m~~ No change
- ~~m-n~~ No change
- 2. No change
 - a. No change
 - b. Cover acuity, including a process for obtaining sufficient nursing personnel to meet the needs of patients at all times;
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - ii. No change
 - i. No change
 - j. No change
- 3. No change
- 4. No change
- 5. No change
 - a. No change
 - b. No change
- 6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
- D. No change
 - 1. No change
 - 2. No change

R9-10-204. Quality Management

- A. No change
 - 1. No change
 - 2. No change
- B. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. A method to make changes or take action as a result of the identification of a concern about the delivery of hospital services; ~~and~~
 - e. A method to identify, document, and evaluate occurrences of exceeding licensed capacity, as described in R9-10-203(C)(5), including the actions taken for resolving occurrences of exceeding licensed capacity; and
 - e. ~~f~~ No change
 - 2. No change
 - a. An identification of each concern about the delivery of hospital services; and

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- b. Any changes made or actions taken as a result of the identification of a concern about the delivery of hospital services;
- 3. The acuity plan required in R9-10-208(C)(2) is reviewed and evaluated every 12 months and the results are documented and reported to the governing authority; and
- 3-4. ~~The report reports~~ required in ~~subsection~~ subsections (B)(2) and (3) and the supporting documentation for the ~~report reports~~ are:
 - a. No change
 - b. No change

R9-10-206. Personnel

No change

- 1. No change
- 2. ~~Personnel assigned to provide~~ A personnel member who provides medical services or nursing services ~~demonstrate demonstrates~~ competency and proficiency according to criteria established in hospital policies and procedures for each type of unit and each type of patient to which the personnel member is assigned;
- 3. No change
 - a. No change
 - b. No change
 - c. No change
- 4. Orientation occurs within the first 30 days of providing hospital services or volunteer service and includes:
 - a. Informing personnel about Department rules for licensing and regulating hospitals and how the rules may be obtained;
 - b. Reviewing the process by which a personnel member may submit a complaint about patient care to a hospital; and
 - c. ~~information determined~~ Providing the information required by hospital policies and procedures;
- 5. No change
 - a. No change
 - b. No change
- 6. No change
- 7. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
- 8. No change
- 9. No change
 - a. No change
 - b. No change
 - c. No change
- 10. No change
- 11. No change
 - a. No change
 - b. No change

R9-10-207. Medical Staff

A. No change

- 1. No change
- 2. No change
- 3. No change
- 4. No change
- 5. No change
- 6. No change
- 7. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change

- f. No change
- g. No change
- h. No change
- i. No change
- j. No change
- k. No change
- l. No change
- m. No change
 - i. No change
 - ii. No change
 - iii. No change
- 8. No change
- B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 3. No change
 - a. No change
 - b. No change

R9-10-208. Nursing Services

- A.** No change
 - 1. No change
 - 2. No change
- B.** No change
- C.** No change
 - 1. No change
 - 2. An acuity plan is established, and documented, to determine the types and numbers of nursing personnel necessary to provide nursing services to meet the needs of the patients; and implemented that includes:
 - a. A method that establishes the types and numbers of nursing personnel that are required for each unit in the hospital;
 - b. An assessment of a patient's need for nursing services made by a registered nurse providing nursing services directly to the patient; and
 - c. A policy and procedure stating the steps a hospital will take to obtain the nursing personnel necessary to meet patient acuity;
 - 3. ~~The acuity plan in subsection (C)(2) is implemented;~~ Registered nurses, including registered nurses providing nursing services directly to a patient, are knowledgeable about the acuity plan and implement the acuity plan established under subsection (C)(2);
 - 4. If licensed capacity in an organized service is exceeded or patients are kept in areas without licensed beds, nursing personnel are assigned according to the specific rules for the organized service in this Chapter;
 - ~~4-5.~~ No change
 - ~~5-6.~~ No change
 - ~~6-7.~~ No change
 - ~~7-8.~~ No change
 - ~~8-9.~~ No change
 - ~~9-10.~~ No change
 - ~~10-11.~~ No change
 - ~~11-12.~~ No change
 - ~~12-13.~~ No change
 - a. No change
 - b. No change
 - c. No change
 - ~~13- 14.~~ No change

- ~~14-~~ 15. No change
- ~~15-~~ 16. No change
- ~~16-~~ 17. No change

R9-10-209. Patient Rights

A. No change

- 1. No change
 - a. No change
 - b. No change
- 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - i. ~~The hospital's health care directives policies and procedures~~ Proposed medical procedures, alternatives to the medical procedures, associated risks, and possible complications;
 - ii. No change
 - iii. The hospital's patient grievance policies and procedures, including the telephone number of hospital personnel to contact about grievances, and the Department's telephone number if the hospital is unable to resolve the patient's grievance; and
 - iv. Except as authorized by the Health Insurance Portability and Accountability Act of 1996, proposed involvement of the patient in research, experimentation, or education, if applicable; ~~and~~
 - ~~v. Proposed medical procedures, alternatives to the medical procedures, associated risks, and possible complications;~~
- 3. A patient or the patient's representative is provided a description of the hospital's health care directives policies and procedures:
 - a. If an inpatient, at the time of admission; or
 - b. If an outpatient:
 - i. Before the performance of any invasive procedure, except phlebotomy for obtaining blood for diagnostic purposes; or
 - ii. If the hospital services include a planned series of treatment, at the start of each series;
- ~~3-~~ 4. No change
 - a. No change
 - b. No change
- ~~4-~~ 5. No change
- ~~5-~~ 6. No change

B. The requirements in subsections (A)(2)(a), (A)(2)(d)(i), (A)(3), and (A)(4) shall not apply in an emergency.

R9-10-212. Transport

A. No change

- 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. Specify how a medical staff member explains the risks and benefits of a transport ~~and obtains consent from~~ to the patient or the patient's representative based on the:
 - i. No change
 - ii. No change
- 2. No change
 - a. Consent for transport by the patient or the patient's representative or why consent could not be obtained;
 - ~~a-b.~~ No change
 - ~~b-c.~~ No change
 - ~~e-d.~~ No change
 - ~~d-e.~~ No change
 - ~~e-f.~~ No change

B. No change

- 1. No change
 - a. No change

b. Require an assessment of the patient by a registered nurse or a medical staff member upon arrival of the patient and before the patient is returned to the sending hospital unless the receiving hospital is a satellite facility, as defined in A.R.S. § 36-422, and does not have a registered nurse or a medical staff member at the satellite facility;

c. No change

d. No change

2. No change

a. No change

b. No change

c. No change

d. No change

e. No change

f. No change

C. No change

R9-10-213. Transfer

A. No change

1. No change

a. No change

b. No change

c. Specify how the sending hospital personnel members communicate medical record information that is not provided at the time of the transfer; and

d. Specify how a medical staff member explains the risks and benefits of a transfer to the patient or the patient's representative based on the:

i. Patient's medical condition, and

ii. Mode of transfer;

~~2. Except in an emergency, a medical staff member obtains informed consent for the transfer;~~

~~3. In an emergency, documentation of informed consent or why informed consent could not be obtained is included in the medical record;~~

~~4. One of the following accompanies the patient during transfer to the receiving hospital:~~

~~a. No change~~

~~b. No change~~

~~i. No change~~

~~ii. No change~~

~~iii. No change~~

~~iv. No change~~

~~v. No change~~

~~vi. No change~~

~~vii. No change~~

~~5. Consent for transfer by the patient or the patient's representative, except in an emergency:~~

~~a. The acceptance of the patient by and communication with an individual at the receiving hospital health care institution;~~

~~b. The date and the time of the transfer to the receiving hospital health care institution;~~

~~c. No change~~

~~d. No change~~

B. A sending hospital and a receiving hospital that are licensed at separate locations and have the same Medicare number issued by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services are exempt from subsections (A)(1)(c), ~~(A)(4)~~ (A)(2) and ~~(A)(5)(a)~~ (A)(3)(a).

R9-10-218. Clinical Laboratory Services and Pathology Services

No change

1. No change

2. No change

3. No change

4. A special hospital whose patients' diagnoses or treatment requires patients require clinical laboratory services provides the services within the special hospital 24 hours a day;

a. Is able to provide clinical laboratory services when needed by the patients,

b. Obtains specimens for clinical laboratory services without transporting the patients from the special hospital's

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- premises, and
- c. Has the examination of the specimens performed by a clinical laboratory on the special hospital's premises or by arrangement with a clinical laboratory not on the premises;
- 5. No change
- 6. No change
- 7. No change
 - a. No change
 - i. No change
 - ii. No change
 - b. No change
- 8. No change
- 9. No change
- 10. No change
 - a. No change
 - b. No change
 - c. No change
- 11. No change
 - a. No change
 - b. No change
- 12. No change

R9-10-219. Radiology Services and Diagnostic Imaging Services

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. A hospital that provides surgical services has radiology services and diagnostic imaging services on the hospital's premises to meet the needs of patients;
 - ~~4-5.~~ No change
 - ~~5-6.~~ Except as provided in subsection (A)(4), A a special hospital whose patients' diagnoses or treatment requires patients require radiology services and diagnostic imaging services is able to provide the radiology services and diagnostic imaging services or has a documented plan to provide the services to meet the needs of a patient when needed by the patients:
 - a. On the special hospital's premises, or
 - b. By arrangement with a radiology and diagnostic imaging facility that is not on the special hospital's premises.
- B. No change
 - 1. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - 2. No change
 - 3. A radiologist prepares a documented radiologic or diagnostic imaging patient report is prepared that includes:
 - a. No change
 - b. No change
 - c. A medical staff member's or radiologist's interpretation of the image;
 - d. No change
 - e. The adverse reaction to the radiopharmaceutical, if any; and
 - 4. A radiologic or diagnostic imaging patient report is included in the patient's medical record; and,
 - ~~5.~~ A radiologic or diagnostic image is maintained by the hospital for at least 12 months from the date of the imaging.

R9-10-220. Intensive Care Services

- A. No change
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change

4. No change
5. No change
 - a. With a minimum of one registered nurse assigned for every ~~three~~ two patients; and
 - b. According to an acuity plan as required in R9-10-208;
6. Each intensive care unit has a policy and procedure that provides for meeting the needs of the patients at all times;
- ~~6-7.~~ No change
- ~~7-8.~~ No change
- ~~8-9.~~ Nursing personnel assigned to an intensive care unit are At least one registered nurse assigned to a patient in an intensive care unit is qualified in advanced cardiopulmonary resuscitation specific to the age of the patients in the intensive care unit patient;
- ~~9-10.~~ No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
- ~~10-11.~~ No change

C. No change

R9-10-222. Perinatal Services

A. No change

1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
7. No change
8. No change
9. No change
10. No change
11. No change
 - a. No change
 - b. No change
12. No change
 - a. No change
 - b. No change
13. No change
14. No change
15. No change
16. A minimum of one registered nurse is on duty in a nursery at all times when there is a neonate in a the nursery except as provided in subsection (A)(17);
17. A nursery occupied only by neonates who are placed in the nursery for the convenience of the mother and who do not require treatment as defined in this Article, is staffed by a licensed nurse;
- ~~17-18.~~ No change
- ~~18-19.~~ No change

B. No change

R9-10-228. Medical Records

A. No change

1. No change

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2. No change
 - a. No change
 - b. No change
 - c. No change
3. No change
 - a. No change
 - b. No change
 - c. No change
4. No change
5. No change
6. No change
7. No change
 - a. No change
 - b. No change
8. No change
 - a. No change
 - b. No change
9. No change
10. No change
 - a. No change
 - b. ~~According to A.R.S. § 12-2297; maintained for seven years from the date of patient discharge unless the patient is less than 18 years of age, in which case the record is maintained for three years after the patient's 18th birthday or at least seven years after the last date the child received hospital services, whichever date occurs last;~~
11. No change
12. No change
- B.** No change
 1. No change
 2. No change
- C.** No change
 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 2. No change
 - a. No change
 - b. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 3. No change
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
 9. No change
 10. No change
 11. No change
 12. No change
 13. No change
 14. No change
 15. No change
 - a. No change
 - b. No change
 - c. No change

d. No change

e. No change

D. No change

1. No change

a. No change

b. No change

c. No change

d. No change

e. No change

2. No change

a. No change

b. No change

c. No change

i. No change

ii. No change

iii. No change

iv. No change

3. No change

4. No change

5. No change

6. No change

7. No change

a. No change

b. No change

c. No change

d. No change

e. No change

E. No change

1. No change

2. No change

3. No change

4. No change

5. No change

6. No change

R9-10-229. Infection Control

A. No change

1. No change

2. No change

a. No change

i. No change

ii. No change

iii. No change

iv. No change

v.

b. No change

i. No change

ii. No change

iii. No change

c. No change

i. No change

ii. No change

d. No change

3. No change

4. No change

a. No change

b. No change

c. No change

5. No change

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- a. No change
- b. No change
- c. No change
- 6. No change
- 7. No change
 - a. No change
 - b. No change
 - c. No change
- 8. No change
- 9. No change
 - a. No change
 - b. No change
 - c. No change
- 10. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

B. No change

R9-10-230. Environmental Services

No change

- 1. No change
- 2. No change
 - a. No change
 - b. No change
- 3. No change
- 4. No change
- 5. No change
- 6. No change
 - a. No change
 - b. No change
 - c. No change
- 7. No change

NOTICE OF PROPOSED RULEMAKING

TITLE 20. COMMERCE, BANKING, AND INSURANCE

CHAPTER 5. INDUSTRIAL COMMISSION OF ARIZONA

PREAMBLE

- 1. Sections Affected** **Rulemaking Action**
R20-5-120 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. §§ 23-107(A)(1) and 23-921(B)
Implementing statutes: A.R.S. §§ 23-942, 23-943, and 23-907
- 3. A list of all previous notices appearing in the Register addressing the proposed rules:**
Notice of Rulemaking Docket Opening: 10 A.A.R. 1631, April 23, 2004
Notice of Formal Rulemaking Advisory Committee: 6 A.A.R. 2493, June 30, 2000
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**
Name: Andrew F. Wade, Esq.
Address: Legal Division
Industrial Commission of Arizona
800 W. Washington, Suite 303

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Phoenix, AZ 85007

Telephone: (602) 542-5781

Fax: (602) 542-6783

E-mail: awade@ica.state.az.us

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

R20-5-120 became effective March 1, 1987. The original purpose of Rule 120 was to provide a mechanism for Industrial Commission Administrative Law Judges (ALJ's) to review and approve compromise and settlement agreements in workers' compensation cases. Although not formalized in agency rules, guidelines for approval were subsequently developed using factors set forth in important workers' compensation cases decided by the Arizona courts. The proposed rule formalizes some existing practices and establishes required standards for defendant employers and carriers, injured workers, and ALJ's to follow in the development and approval of settlement agreements pertaining to workers' compensation cases before the Industrial Commission of Arizona.

6. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on or 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, any analysis of the study and other supporting material:

None

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

The proposed amendments do not diminish a previous grant of authority of a political subdivision of this state.

8. The preliminary summary of the economic, small business, and consumer impact statement:

The proposed rule's impact on the development, submission and approval of settlement agreements in the workers' compensation context is not as substantial as a review of the current rule would lead one to conclude. The proposed rule establishes objective standards for defendant employers and carriers, injured workers, and the Industrial Commission to follow in the development and approval of settlement agreements. The existing settlement rule has little, if any, formal guidance concerning the content or standards for approval of settlement agreements. However, those in the workers' compensation community have been practicing many of the standards formalized in the proposed rule as informal "guidelines" for many years. As a consequence, no measurable impact on the actual practices of those involved in workers' compensation matters is expected.

Injured workers who do not have an attorney would not be expected to encounter any increased costs, other than the potential cost of a notary public to notarize their signature on the settlement agreement. Most attorneys who represent injured workers do so on a contingent fee basis - generally a percentage of the benefits received as their fee. The customary percentage is not expected to change as a consequence of the proposed rule. Therefore, an injured worker who has an attorney should not experience any increase in costs or legal fees as a result of the implementation of the proposed rule.

For businesses who have workers' compensation insurance coverage with an insurance carrier, the larger insurance carriers have opined that there will be zero to minimal impact on their policy premiums and little if any impact on settlement practices. Some employers may experience some expense associated with the time necessary to review and approve a settlement agreement and appear at any hearing on the matter. This may be no more than the time incurred in reviewing and approving settlement agreements under the present rule.

Although some businesses who self-insure for workers' compensation claims and an association representing self-insured employers have speculated that the proposed rule might increase litigation costs, the actual impact on self-insured employers would likely be similar to the impact experienced by insurance carriers.

The Industrial Commission does not expect any significant change or increased costs as a consequence of the proposed rule.

Although there will be costs associated with the implementation of the proposed rule, the intent of the proposed rule is to recognize established practices and establish formal procedures and standards to enable ALJ's to effectively and consistently review proposed settlement agreements. This will further the goal of assuring that all settlement agreements are informative and not overreaching to the injured worker, particularly to a worker who is not represented by legal counsel. In the long term, injured workers will be the primary beneficiaries of the proposed rule. Given the importance of establishing fair and impartial standards for settlement agreements to protect the injured worker, the *potential* costs are outweighed by the benefit to the worker and the general public.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Andrew F. Wade, Esq.

Address: Legal Division
Industrial Commission of Arizona

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800 W. Washington, Suite 303
Phoenix, AZ 85007

Telephone: (602) 542-5781
Fax: (602) 542-6783
E-mail: awade@ica.state.as.us

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Date: June 24, 2004

Time: 1:30 p.m.

Location: Industrial Commission of Arizona
First Floor Auditorium
800 W. Washington
Phoenix, AZ 85007

Nature: Oral and written comments will be accepted on or before the date set forth in this item.

11. Any other matters prescribed by statute, that are applicable to the specific rule or class of rules:

None.

12. Incorporation by reference and their location in the rules:

None.

13. The full text of the rules follows:

TITLE 20. COMMERCE, BANKING, AND INSURANCE

CHAPTER 5. THE INDUSTRIAL COMMISSION OF ARIZONA

ARTICLE 1. WORKERS' COMPENSATION PRACTICE AND PROCEDURE

Section

R20-5-120. ~~Settlement Agreements, Compromises and Releases~~

ARTICLE 1. WORKERS' COMPENSATION PRACTICE AND PROCEDURE

R20-5-120. Settlement Agreements, ~~Compromises and Releases~~

- A.** Subject to commission approval and other applicable law, parties appearing before the commission may settle any bona fide dispute, including a bona fide dispute concerning:
1. A worker's entitlement to receive any benefits; and
 2. The amount, extent, or duration of benefits that a worker is entitled to receive.
- B.** For purposes of this Section, "bona fide dispute" means a legitimate good faith dispute between the parties on each contested issue.
- C.** A settlement agreement that settles any dispute related to a worker's compensation claim is unenforceable and void unless an administrative law judge approves the settlement agreement and issues an award under subsection (D).
- D.** Except as provided in subsection (E), within 20 days after a proposed settlement agreement is filed with the commission, an administrative law judge shall:
1. Review the proposed settlement agreement.
 2. Review any documents submitted with the proposed settlement agreement.
 3. Review the applicable commission's claims file, and
 4. Issue an award under A.R.S. § 23-942 approving or disapproving the proposed settlement agreement.
- E.** Upon its own motion, or request of a party, an administrative law judge may set an expedited conference or hearing to consider the proposed settlement agreement, if the request is received before the administrative law judge issues an award under A.R.S. § 23-942.
- F.** An administrative law judge shall not approve a proposed settlement agreement if a preponderance of the evidence demonstrates any of the following:
1. The proposed settlement agreement lacks the information or documentation required under subsection (H);
 2. The proposed settlement agreement does not present or resolve a bona fide dispute. In determining whether the proposed settlement agreement presents or resolves a bona fide dispute, the administrative law judge shall consider:
 - a. The type of benefit in dispute;
 - b. The amount of benefit in dispute; and

- c. Any credit taken under subsection (J);
- 3. The claimant does not understand the proposed settlement agreement or does not understand the nature and extent of a right given up;
- 4. The proposed settlement agreement is a result of coercion, duress, fraud, misrepresentation, or an undisclosed additional agreement; or
- 5. The proposed settlement agreement is contrary to law or the requirements of this Section.
- G.** If an administrative law judge issues an award under subsection (D) and a party requests review under A.R.S. § 23-943, the administrative law judge shall hold a hearing to consider additional evidence or argument if:
 - 1. A hearing was not held under subsection (E) and a party requests a hearing before the administrative law judge issues a decision upon review under A.R.S. § 23-943;
 - 2. The administrative judge determines that a hearing would assist the judge in issuing a decision upon review under A.R.S. § 23-943; or
 - 3. The party has not filed a written waiver of review of the award issued under A.R.S. § 23-942.
- H.** Form of a proposed settlement agreement.
 - 1. A request for approval of a proposed settlement agreement shall be made by filing:
 - a. A written original proposed settlement agreement signed by all parties or their authorized representatives;
 - b. A notarized statement signed by the claimant that contains the information required under subsection (I); and
 - c. Except as provided in A.R.S. § 23-907(M), if an uninsured employer is not represented by an attorney, a notarized statement signed by the uninsured employer stating that:
 - i. The uninsured employer has read the proposed settlement agreement;
 - ii. The uninsured employer understands the proposed settlement agreement;
 - iii. The contents of the proposed settlement agreement are true and correct; and
 - iv. The settlement agreement is not a result of coercion, duress, fraud, misrepresentation, or an undisclosed additional agreement.
 - 2. A proposed settlement agreement required under subsection (H)(1)(a) shall contain the following information:
 - a. The names of the parties;
 - b. The claimant's date of injury;
 - c. A statement of the procedural and factual history of the claim;
 - d. A statement of each bona fide dispute and the parties' current respective positions concerning each dispute;
 - e. The terms of the proposed settlement agreement, including a statement describing the consideration paid to resolve each bona fide dispute;
 - f. A statement of any credit taken, including if applicable, the type, amount, and duration of the credit; and
 - g. Other information the administrative law judge may request to ensure that the proposed settlement agreement meets the requirements of this Section.
- I.** The statement required under subsection (H)(1)(b) shall contain the following acknowledgements and agreements by the claimant:
 - 1. The claimant understands the proposed settlement agreement;
 - 2. The claimant understands the right to a hearing before an administrative law judge and understands that by signing the settlement agreement the claimant gives up the right to the current hearing, including the right to:
 - a. Testify;
 - b. Call witnesses on the claimant's behalf;
 - c. Cross-examine witnesses who might be called by other parties; and
 - d. File documents in support of the claimant's position;
 - 3. The claimant understands that now is the time to litigate each bona fide dispute and that by signing the settlement agreement there will be no hearing before the commission;
 - 4. The claimant has a financial incentive to litigate each bona fide dispute pending before the commission; and
 - 5. The settlement agreement is not a result of coercion, duress, fraud, misrepresentation, or an undisclosed additional agreement.
- J.** If the only issue is the compensability of a claim, the parties may negotiate, without limitation, the nature and scope of credits contained in the proposed settlement agreement.
- K.** Once a claim is compensable, the nature and scope of credits contained in the proposed settlement agreement shall comply with this subsection.
 - 1. A party shall not assert a credit against the claimant's entitlement to medical benefits if the bona fide dispute being resolved under the proposed settlement agreement is the claimant's entitlement to disability benefits;
 - 2. A party may negotiate a full credit against future disability benefits if the bona fide dispute being resolved under the proposed settlement agreement is the claimant's entitlement to any disability benefits;
 - 3. If the parties agree that the claimant is entitled to receive permanent disability benefits and the bona fide dispute being resolved under the proposed settlement agreement is the amount of permanent disability benefits that the claim-

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ant is entitled to receive, then:

- a. A party may negotiate a full credit against future disability benefits in the amount of the settlement that represents the difference in the parties' positions; and
 - b. A party may negotiate a prorated credit against future permanent disability benefits in the amount of the settlement that represents the defendant's position concerning the claimant's entitlement to permanent disability benefits. This credit shall be prorated over the claimant's life expectancy calculated from the date the claimant's medical condition last became stationary.
4. A party may negotiate a credit against medical and disability benefits alleged to be causally related to a specific physical or mental condition if the worker's compensation claim has been accepted for benefits and the bona fide dispute being resolved under the proposed settlement agreement is whether the specific physical or mental condition is compensable. This credit may be applied only if a party is later deemed responsible for medical and disability expenses causally related to the specific physical or mental condition in dispute under the proposed settlement agreement.
 5. A party may negotiate a credit against the claimant's entitlement to future supportive medical care if the bona fide dispute being resolved under the proposed settlement agreement is the claimant's entitlement to supportive medical care. The credit shall not apply to any surgical, diagnostic, or consultation expense incurred within 15 days of the claimant filing a petition to reopen the claim under A.R.S. § 23-1061(H).
 6. A party may negotiate a credit as provided in subsection (J)(5) if the parties agree that the claimant is entitled to receive supportive medical care and the bona fide dispute being resolved under a proposed settlement agreement is the extent of or duration of supportive medical care. The credit asserted under this subsection shall be reduced by any amount personally paid by the claimant to obtain supportive care identified in the proposed settlement agreement as the defendant's position concerning the claimant's entitlement to supportive care.
 7. A party may negotiate a credit against future active medical care for a specific compensable condition identified in the proposed settlement agreement if the bona fide dispute being resolved under the proposed settlement agreement is the necessity for, or reasonableness of, future active medical care for the identified compensable condition.
 8. A party shall not assert a credit against future medical or disability benefits causally related to a compensable physical or mental condition except as provided in this subsection;
 9. A party shall not assert a credit against future active or supportive medical care for an unknown condition or condition not identified in the proposed settlement agreement.
 10. The consideration and credit asserted for resolution of each bona fide dispute shall be separately stated if a proposed settlement agreement contains the resolution of more than one bona fide dispute; and
 11. Consideration paid or a credit provided for under the proposed settlement agreement shall not be used as an offset against benefits a claimant is entitled to receive under a worker's compensation claim that is not the subject of the proposed settlement agreement.
- L.** The effective date of an approved proposed settlement agreement is the date an administrative law judge issues an award under subsection (D).
- A.** No settlement agreement, compromise, or waiver of rights of a workers' compensation claim, will be valid unless approved by the Commission.
- B.** The acceptance of any payments or the signing of a settlement agreement, compromise, release or waiver of rights, unless approved by the Commission, shall not release the employer or his insurance carrier from any obligation imposed by the Workers' Compensation Law.
- C.** The carrier or employer shall not be entitled to a credit for any sums paid to an employee under a settlement agreement which has not been approved by the Commission.