

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 2. ARIZONA COMMISSION ON THE ARTS

PREAMBLE

- 1. Sections Affected**

Article 2	<u>Rulemaking Action</u>
R2-2-201	New Article
R2-2-202	New Section
R2-2-203	New Section
R2-2-204	New Section
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 41-982(B)(5) and 41-983.02(B)
Implementing statutes: A.R.S. §§ 41-983.01 and 41-983.02
- 3. The effective date of the rules:**

January 9, 2002
- 4. A list of all previous notices appearing in the Register addressing the final rule:**

Notice of Rulemaking Docket Opening: 7 A.A.R. 2659, June 22, 2001
Notice of Proposed Rulemaking: 7 A.A.R. 3200, August 3, 2001
- 5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

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E-mail:	mlakinhayes@ArizonaArts.org
- 6. An explanation of the rule, including the agency's reasons for initiating the rule:**

These rules set forth procedures to be followed by the Arizona Commission on the Arts ["Commission"], its staff, and grant review panels in receiving, considering, and reviewing applications for, and distribution of, general operating support grants from the Arizona Arts Trust Fund. The proposed rule was initiated by the Commission as mandated by the Arizona Legislature when it established the Arizona arts program.
- 7. A reference to any study that the agency relied on in its evaluation of or justification for the proposed rule, and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:**

None
- 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 public subdivision of the state:**

Not applicable

Arizona Administrative Register
Notices of Final Rulemaking

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

The summary anticipates that several state agencies will experience a minimal increase in staff time; that cities, counties, and non-profit arts organizations receiving grants will experience minimal to substantial increase in revenue; that public and private employment by cities, counties, and non-profit organizations receiving grants will increase; and that small businesses and consumers will experience no direct impact.

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

Grammatical and organizational changes recommended by Council staff have been made to the rules.

11. A summary of the principal comments and the agency's response to them:

None

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

None

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

None

14. Was this rule previously adopted as an emergency rule:

No

15. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 2. ARIZONA COMMISSION ON THE ARTS

ARTICLE 2. GRANTMAKING PROCEDURES FOR GRANTS FROM THE ARIZONA ARTS TRUST FUND

Section

R2-2-201. Definitions

R2-2-202. Eligibility

R2-2-203. Criteria

R2-2-204. Process for Obtaining A Grant from the Arizona Arts Trust Fund

ARTICLE 2. GRANTMAKING PROCEDURES FOR GRANTS FROM THE ARIZONA ARTS TRUST FUND

R2-2-201. Definitions

In this Article, unless the context otherwise requires:

"Applicant" means an organization that applies for a grant.

"Application" means the documentation and material that an applicant submits to request a grant.

"Arizona Arts Trust Fund" means the fund created by A.R.S. § 41-983.01 and funded with \$15 from each annual filing fee submitted to the Arizona Corporation Commission by for-profit corporations.

"Arizona Arts Trust Fund Grant" means a general operating support grant that includes funds derived from the Arizona Arts Trust Fund.

"Board member" means a trustee of a non-profit organization elected or appointed according to that organization's bylaws.

"Commission" means the Arizona Commission on the Arts, a state agency, consisting of fifteen members appointed by the Governor.

"Commissioner" means one of 15 Governor-appointed members of the Commission responsible for the administration of the Arizona Arts Program and the Arizona Arts Endowment Fund.

"Criteria" means the established and published standards used to evaluate an application to determine whether a grant award is recommended.

"Denial conference" means the method by which an applicant that was not recommended for a grant may request a review of their application.

"Fiscal agent" means any Arizona organization, designated 501(c)(3) tax exempt by the Internal Revenue Service, that accepts grant funds on behalf of an organization not meeting the nonprofit tax-exempt requirements.

"General operating support" means a grants program administered by the Commission that provides funds to organizations to be used for administrative or artistic expenses, or both.

Arizona Administrative Register
Notices of Final Rulemaking

“Grant” means an award of financial support to an organization, for the purposes requested in the application.

“Grant conditions” means specific requirements, agreed to by the grantee in writing, that must be met or undertaken to receive a grant.

“Grant deadline” means the published date by which an application must be postmarked or hand-delivered to the Commission to be considered for a grant.

“Grant review panel” means a group of citizens appointed by the Commission to review and make recommendations on public policy and applications for grants.

“Grant review panel chair” means a Commissioner who serves as a non-voting member of the panel to ensure that state law is followed and that there is an open, fair process for the review of applications by the grant review panel.

“Grant review panel comments” means documented comments made by the grant review panelists during the application review process that become the public record of the process after the final grants are awarded.

“Grant review panelist” means an individual serving on the grant review panel.

“Grantee” means an organization receiving grant funds.

“Guidelines” means information published annually describing the Commission’s grant program, including the application process, forms and formats, eligibility requirements, and criteria.

“Legal requirements” means the federal and state standards and regulations including those regarding fair labor, civil rights, accessibility, age discrimination, lobbying with appropriated monies, accounting records, and other published requirements to which organizations accepting a grant must adhere.

“Match” means an applicant’s financial contribution to a project, in addition to a grant, that demonstrates the community support of the project.

“Non-profit organization” means a school, governmental unit, or corporation that is exempt from taxation under Section 501(c)(3) of the Internal Revenue Code.

“Substantial interest” has the same meaning as in A.R.S. § 38-502.

“Underserved populations” means persons who are members of ethnic or racial minorities, have disabilities, or are from communities outside the metropolitan areas of Phoenix and Tucson.

R2-2-202. Eligibility

To be eligible to receive an Arizona Arts Trust Fund grant under this Article, an applicant shall meet the following requirements:

1. Be based in Arizona;
2. Be a city or county government, be designated as a nonprofit 501(c)(3) organization by the Internal Revenue Service, or be an unincorporated organization using an Arizona-based nonprofit 501(c)(3) organization as a fiscal agent;
3. Submit no more than the maximum allowable number of grant applications per year as published in the Commission’s guidelines;
4. Match grant funds with applicant funds as required by the Commission; and
5. Have the production, presentation, or service of the arts as its primary mission.

R2-2-203. Criteria

A. The following criteria shall be used by the grant review panels and the Commission for reviewing general operating support grants and granting funds from the Arizona Arts Trust Fund:

1. Artistic quality and creativity;
2. Ability of the applicant organization’s programs to serve the needs of the community, including potential public exposure and public benefit, and efforts to reach artists and audiences from culturally diverse groups;
3. Managerial and administrative ability of the applicant organization to carry out arts programming and properly administer funds granted;
4. Appropriateness of the applicant organization’s budget to carry out its proposed programs; and
5. History of the applicant organization in producing, presenting or serving the arts.

B. Further, the Commission shall also take into consideration in approving grants:

1. Whether the applicant represents underserved populations;
2. The applicant’s employment of, or contracting with, artists who are members of racial or ethnic minorities; and
3. Inclusion of racial or ethnic minority members on applicant organizations’ governing boards.

Arizona Administrative Register
Notices of Final Rulemaking

R2-2-204. Process for Obtaining a Grant from the Arizona Arts Trust Fund

- A.** The Commission shall establish an annual grant deadline and publish grant guidelines by January 15th of each year. Applications shall be postmarked or delivered by 5:00 p.m. on the grant deadline date. Late applications shall not be filed by the Commission but shall be returned without review.
- B.** An applicant shall submit a narrative and budget that comply with the grant guidelines and address the criteria in R2-2-203. The Commission shall provide the forms and formats for the narrative and budget to the applicant. An applicant may submit supplemental information including slides, videotapes, audio recordings, press coverage, and print or other materials that document the artistic work of the applicant.
- C.** The Commission shall conduct a grant review process:
1. The Commission shall appoint grant review panels. Each panel shall be assigned a specific group of grant applications to review. The Commission shall appoint three to seven community members to serve on each of the grant review panels. Grant review panelists shall be appointed by the Commission for one year and may serve no more than three consecutive years on the same panel. No more than two members of any panel shall serve on the panel for the second and third years.
 2. Grant review panelists shall hold a grant review panel meeting. Grant review panelists shall read all the applications assigned to their panel prior to the grant review panel meeting. Upon request, grant review panelists shall attend events of the applicant or speak with a representative of the applicant to be informed about the applicant organization. At the grant review panel meeting, grant review panelists shall contribute to the discussion of the applications; rate applications based on the facts in the applications and their own professional judgments about the merit of the applications, in relation to the criteria in R2-2-203; and provide policy and procedural suggestions for the Commission.
 3. If a grant review panelist has a substantial interest in any application, the panelist shall declare the interest verbally and in writing and shall not participate in the discussion of or the vote on the application.
 4. The grant review panel chair shall chair the grant review panel meeting and shall ensure that the discussion relates to the required criteria, that Commission policies and open meeting laws under A.R.S. 38-431 et seq. are followed, and that all grant review panelists have an opportunity to speak.
- D.** Following the grant review panel process, Commissioners shall receive grant review panelists' recommendations and grant review panel comments for each application. At the Commission meeting following the Commissioners' receipt of grant review panelists' recommendations, the Commissioners shall discuss the recommendations of the grant review panels and shall vote to accept, reject, or modify the recommendations of the grant review panels.
- E.** All applicants shall be notified in writing of the Commission's decisions. Any applicant that is not recommended for funding may request and shall be provided a denial conference. The Commission shall establish and publish in its grant guidelines the process for requesting and receiving a denial conference. The Commission shall not provide a denial conference based on dissatisfaction with the amount of a grant.
- F.** All applicants shall accept in writing the grant's legal requirements and grant conditions before grant funds are released.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

- | | |
|------------------------------------|---------------------------------|
| <u>1. Sections Affected</u> | <u>Rulemaking Action</u> |
| R4-23-110 | Amend |
| Article 2 | Amend |
| R4-23-202 | Amend |
| R4-23-203 | Amend |
| R4-23-204 | Amend |
| R4-23-205 | Amend |
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
- Authorizing statutes: A.R.S. §§ 32-1904(A)(1), (2), and (5) and 32-1904(B)(7), (10), and (11)
- Implementing statutes: A.R.S. §§ 32-1922, 32-1924(A), (B), (D), (E), and (F), 32-1925(A), (B), (C), and (E)(1), 32-1931, 32-1935, 32-1936, and 32-1937
- 3. The effective date of the rules:**
- January 10, 2002
- 4. A list of all previous notices appearing in the Register addressing the final rule:**
- Notice of Rulemaking Docket Opening: 7 A.A.R. 977, February 23, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 3718, August 31, 2001

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

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

This rulemaking increases the pharmacist license and pharmacy permit fees. The biennial licensure fee for a pharmacist is increased from \$110 to \$145. The biennial permit fee for a pharmacy is increased from \$300 to \$400. The fee increase is necessary to accommodate an ever increasing budget. Additional changes in Sections R4-23-202 and R4-23-203 will clarify the requirements and procedures for licensure by examination and reciprocity. Board staff pointed out that the examination fee in R4-23-205 was only being required of applicants for licensure by examination and not applicants by reciprocity. A.R.S. § 32-1922(A)(5) mandates an examination fee for all pharmacist licensure applicants. This rulemaking decreases the examination fee for initial taking of the AZPLEX examination from \$100 to \$50. NAPLEX and AZPLEX are computer-based examinations that are approved by the Board and administered through the National Association of Boards of Pharmacy. The use of the NAPLEX and AZPLEX allows applicants a choice between many locations in this and other states for taking the examinations. This decreases the time needed to become licensed. During the five-year rule review approved on September 9, 1997, the Board determined that R4-23-204 should be amended by moving definitions in subsection (B) into R4-23-110. Other changes are made to comply with the current Administrative Procedure Act and to make the rules more clear, concise, and understandable.

The Board believes that approval of these rules will benefit the public health and safety by establishing clear standards governing pharmacist licensure and continuing education. The Board further believes that the fee increase is necessary to cover an increasing budget and support a Board staff dedicated to protecting public health and safety.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

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 rule will impact the Board, pharmacists, and pharmacies. Some of the changes to the rule have no economic impact, but rather provide more clear, concise, and understandable language.

After conferring with the Joint Legislative Budget Committee, the Board determined that a fee increase for pharmacists and pharmacies is necessary to provide a needed budget increase to cover the costs of adding one new compliance officer and two non-pharmacist inspectors to the staff. A continuing increase in the number of pharmacies, drug wholesalers, nonprescription drug retailers, and other drug outlets in the state has put extreme pressure on the existing Board staff. The number of pharmacies in the state as of June 30, 2000 was 870. That is an increase of 21% since June 30, 1986 when there were 721 pharmacies in Arizona. The number of pharmacists with active in-state licenses as of June 30, 2000 was 3629. That is an increase of 57% since June 30, 1986 when there were 2315 active in-state pharmacists. The Board employed four full-time compliance officers in 1986 and currently employs only four full-time compliance officers. The Board has lost four compliance officers in the last four years because pharmacist compliance officer's salaries have not keep pace with the pharmacist salaries offered by community and hospital pharmacies. The 2001 Arizona Legislature approved the Board's 2002-2004 biennial budget to include a salary increase for pharmacist compliance officers and one additional compliance officer and two non-pharmacist inspectors. To support this budget increase, the Board approved a fee increase (within the allowed statutory maximum) for the pharmacist license and pharmacy permit. The pharmacist licensure fee increases to \$145 biennially from \$110 biennially. The pharmacy permit fee increases to \$400 biennially from \$300 biennially. The increased fees will not go into effect until the first renewal period after the effective date of the final rule.

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

At the request of G.R.R.C. staff, the Board made minor grammar, style, format, and punctuation changes. A written comment by the Arizona Pharmacy Association prompted the Board to make a nonsubstantive change in R4-23-204(C)(1)(b). The words "a statement of credit or" are inserted before the words "a certificate" in R4-23-

Arizona Administrative Register
Notices of Final Rulemaking

204(C)(1)(b) of the final rule. A Board member noticed that the heading of Article 2 uses the word “registration” and that word is not used in any of the Sections in the Article. Instead the word “licensure” is used throughout the Sections of Article 2. The Board approved the nonsubstantive change to the heading of Article 2 to “Pharmacist Licensure” instead of “Pharmacist Registration”.

11. A summary of the principal comments and the agency response to them:

There was one written comment received from the Arizona Pharmacy Association. The written comment asked that the words “a statement of credit or” be inserted before the words “a certificate” in R4-23-204(C)(1)(b) because the American Council of Pharmaceutical Education (ACPE) has changed how they define a certificate of credit for pharmacy continuing education. ACPE guidelines for documentation of continuing education credit state that any program that provides a minimum of 15 contact hours in a particular subject (for example, diabetes, asthma, etc.) qualifies to be a certificate-type program and the participant receives a certificate. For any program that provides at least one contact hour of instruction, the participant receives a statement of credit. The Board agreed with the comment and made the nonsubstantive change in the final rule.

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 approved as an emergency rule?

No

15. 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 2. PHARMACIST REGISTRATION LICENSURE

Section

R4-23-202. Licensure by Examination

R4-23-203. Licensure by Reciprocity

R4-23-204. Continuing Education Requirements

R4-23-205. Fees

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

“Active ingredient” means any component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug, that are present in the finished drug product in a modified form, and that furnish the specified activity or effect.

“Approved course in pharmacy law” means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations.

“Approved Provider” means an individual, institution, organization, association, corporation, or agency that is approved by the American Council on Pharmaceutical Education (ACPE) in accordance with ACPE’s policy and procedures or by the Board as meeting criteria indicative of the ability to provide quality continuing education.

“Authentication of product history” means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

“Container” means:

A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or

A metal receptacle designed to contain liquefied or vaporized compressed medical gas and used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

“Continuing education” means a structured learning process required of a licensed pharmacist to maintain licensure that includes study in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology, characteristics and therapeutics of disease status; or pharmacy practice.

Arizona Administrative Register
Notices of Final Rulemaking

“Continuing education activity” means continuing education obtained through an institute, seminar, lecture, conference, workshop, mediated instruction, programmed learning course, or postgraduate study in an accredited college or school of pharmacy.

“Continuing education unit” or “CEU” means 10 contact hours of participation in a continuing education activity sponsored by an Approved Provider.

“Contact hour” means 50 minutes of participation in a continuing education activity sponsored by an Approved Provider.

“Correctional facility” has the same meaning as in A.R.S. §§ 13-2501 and 31-341.

“Mediated instruction” means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.

“MPJE” means Multistate Pharmacy Jurisprudence Examination.

“NABP” means National Association of Boards of Pharmacy.

ARTICLE 2. PHARMACIST REGISTRATION LICENSURE

R4-23-202. Licensure by Examination

A. Eligibility: To be eligible for licensure as a pharmacist by examination, a person shall:

1. Have an undergraduate ~~or first professional~~ degree in pharmacy from a school or college of pharmacy whose professional degree program, at the time the person graduates, is accredited by the American Council on Pharmaceutical Education; or
2. Qualify under the requirements of A.R.S. § 32-1922(C); and
- ~~2.3. Complete not less than 1500 hours of intern training as specified in R4-23-303.~~

B. Application:

1. An applicant for licensure by examination shall file with the Board office:
 - a. A completed application for licensure by examination form, ~~at least 30 days before the date of the AZPLEX, and~~
 - b. A completed NAPLEX registration form ~~for the NAPLEX at least 30 days before the applicant’s preferred NAPLEX testing window or ensure receipt of an Official official NABP Score Transfer Report score transfer report~~ through the Board ~~Office office~~ online computer link with NABP indicating the applicant’s score on the NAPLEX taken in another jurisdiction, and
 - c. A completed AZPLEX registration form.
2. The Board ~~Office office~~ shall deem an application ~~form~~ or registration form received on the date that the Board ~~Office office~~ stamps on the form as the form is delivered to the Board ~~Office and office~~. The Board office shall deem a score transfer received on the date that the NABP transmits the applicant’s Official official NABP Score Transfer Report score transfer report through the online computer link to the Board ~~Office office~~.
3. An applicant for licensure by examination shall:
 - a. Make application ~~for licensure by examination~~ on a form furnished by the Board, and
 - b. ~~shall submit~~ Submit with the application for licensure by examination form:
 - i. The documents specified in the application form, and
 - ii. The examination fee specified in R4-23-205(C)(1)(a). ~~The fee shall be paid~~ made payable to the Arizona State Board of Pharmacy by money order or certified or personal check.
4. An applicant for licensure by examination shall:
 - a. Make ~~the~~ NAPLEX and AZPLEX registration on ~~a form~~ forms furnished by the Board or NABP; and
 - b. ~~shall submit~~ Submit with the registration ~~form~~ forms:
 - i. The documents specified in the registration ~~form~~ forms; and
 - ii. The examination fee specified by ~~NABP~~. ~~The fee shall be~~ and made payable to NABP by money order, certified check, or bank draft.
5. The Board shall deem ~~a~~ an application for licensure by examination or a NAPLEX or AZPLEX registration or ~~AZPLEX application for licensure by examination~~ to be invalid after 12 months from the date the Board ~~Office office~~ determines an application or registration form is complete. An applicant whose application or registration form is invalid and who wishes to continue licensure procedures, shall submit a new application ~~form~~ or registration form and fee.

C. Passing grade; notification; re-examination:

1. To pass the required examinations, an applicant shall obtain a score of at least 75 on both the NAPLEX and ~~75% on~~ the AZPLEX.
2. ~~The NABP will forward~~ Board office shall:
 - a. Retrieve an applicant’s NAPLEX and AZPLEX score ~~to the Board~~ from the NABP online database no later than 2 two weeks after the applicant’s examination date; and
 - b. ~~The Board Office shall~~ Mail the an applicant’s NAPLEX and AZPLEX score ~~to an~~ the applicant no later than 7 seven days after the Board ~~Office office~~ receives the applicant’s score from NABP.
3. ~~The Board Office shall mail an applicant’s AZPLEX score to the applicant no later than 14 days after the applicant takes the examination.~~

Arizona Administrative Register
Notices of Final Rulemaking

- 4.3. An applicant who fails the NAPLEX or AZPLEX may apply to ~~take a subsequent~~ retake the examination within the 12-month period defined in subsection(B)(5). An applicant applying to ~~take a subsequent~~ retake an examination shall submit to the Board ~~Office~~ office a completed NAPLEX or AZPLEX registration form and pay the examination fee specified by NABP. ~~The fee shall be~~ and made payable to NABP by money order, certified check, or bank draft. An applicant who fails the NAPLEX or AZPLEX ~~3~~ three times shall petition the Board for permission before retaking the examination.
5. ~~An applicant who fails the AZPLEX may apply for reexamination within the 12-month application period defined in subsection(B)(5). An applicant applying for reexamination shall submit to the Board Office a written request to retake the AZPLEX including the examination date preferred by the applicant and pay the examination fee specified in R4-23-205(C) (1)(b). The fee shall be paid to the Arizona State Board of Pharmacy by money order or certified or personal check. An applicant who fails the AZPLEX 3 times shall petition the Board for permission before retaking the examination.~~
- D. NAPLEX score transfer:
1. An applicant who receives a passing score on the NAPLEX taken in another jurisdiction shall, ~~complete the licensure procedure~~ within 12 months from the date the Board office receives the applicant's ~~Official~~ official NABP ~~Score Transfer Report~~ score transfer report from the NABP, ~~by making~~ make application for licensure according to subsection (B)(3). After 12 months, an applicant may ~~apply~~ reapply for licensure in ~~Arizona~~ this state under the provisions of ~~R4-23-202(B)~~ subsection (B) or R4-23-203(B).
 2. An applicant who takes the NAPLEX in another jurisdiction and fails the examination may apply for licensure in ~~Arizona~~ this state under the provisions of ~~R4-23-202(B)~~ subsection (B).
- E. Licensure: The Board ~~Office~~ office shall issue a certificate of licensure to a successful applicant upon receipt of the licensure fee specified in R4-23-205(A)(1)(a). The Board ~~Office~~ office shall:
1. Provide a receipt for payment of the licensure fee to an applicant who delivers a payment in person, or
 2. ~~mail~~ Mail a receipt for payment of the licensure fee to ~~the~~ an applicant within ~~+~~ one working day of receiving the payment by mail or other delivery service.
- F. Time-frames for licensure by examination:
1. The Board ~~Office~~ office shall ~~finish~~ complete an administrative completeness review within 20 days from the date of receipt of an application or registration form.
 - a. The Board ~~Office~~ office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the application or registration form.
 - b. If the application or registration form is incomplete, the Board ~~Office~~ office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The 20-day time-frame for the Board ~~Office~~ office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board ~~Office~~ office with all missing information.
 - c. If the Board ~~Office~~ office does not provide the applicant with notice regarding administrative completeness, the application or registration form shall be deemed complete 20 days after receipt by the Board ~~Office~~ office.
 2. An applicant with an incomplete application or registration form shall submit all of the missing information within 30 days of service of the notice of incompleteness.
 - a. If an applicant cannot submit all missing information within 30 days of service of the notice of incompleteness, the applicant may ~~obtain an extension by submitting~~ send a written request for an extension to the Board ~~Office~~ office post marked or delivered no later than 30 days from service of the notice of incompleteness.
 - b. The written request for an extension shall document the reasons the applicant is unable to meet the 30-day deadline.
 - c. The Board ~~Office~~ office shall review the request for an extension of the 30-day deadline and grant the request if the Board ~~Office~~ office determines that an extension of the ~~30-day~~ deadline will enable the applicant to assemble and submit the missing information. An extension of the ~~30-day~~ deadline shall be for no more than 30 days. The Board ~~Office~~ office shall notify the applicant in writing of its decision to grant or deny the request for an extension. An applicant who requires an additional extension shall submit an additional written request in accordance with this subsection.
 3. If an applicant fails to submit a complete application or registration form within the time allowed, the Board ~~Office~~ office shall close the applicant's file. An applicant, whose file is closed and who later wishes to obtain a license, shall apply again in accordance with subsection (B).
 4. ~~From the date on which the administrative completeness review of an application or registration form is finished, the~~ The Board Office office shall complete a substantive review of the applicant's qualifications in no more than 20 days from the date on which the administrative completeness review of an application or registration form is complete.
 - a. If an applicant is found to be ineligible for licensure by examination, the Board ~~Office~~ office shall issue a written notice of denial to the applicant.
 - b. If an applicant is found to be eligible to take the NAPLEX, the Board ~~Office~~ office shall issue a written notice of eligibility to the applicant and the NABP.

Arizona Administrative Register
Notices of Final Rulemaking

- c. If an applicant is found to be eligible to take the AZPLEX, the Board ~~Office~~ office shall issue a written notice of eligibility to the applicant and the NABP.
 - d. If the Board ~~Office~~ office finds deficiencies during the substantive review of an application or registration form, the Board ~~Office~~ office shall issue a written request to the applicant for additional documentation.
 - e. The 20-day time-frame for a substantive review of eligibility to take the NAPLEX or AZPLEX is suspended from the date of a written request for additional documentation until the date that all documentation is received. The applicant shall submit the additional documentation in accordance with subsection (F)(2).
 - f. If the applicant and the Board ~~Office~~ office mutually agree in writing, the 20-day substantive review time-frame may be extended once for no more than 10 days.
5. For the purpose of A.R.S. § 41-1072 ~~et seq.~~ et seq., the Board establishes the following time-frames for licensure by examination.
- a. Administrative completeness review time-frame: 20 days.
 - b. Substantive review time-frame: 20 days.
 - c. Overall time-frame: 40 days.

R4-23-203. Licensure by Reciprocity

A. Eligibility: A person is eligible for licensure by reciprocity who:

1. Is licensed as a pharmacist in a jurisdiction that provides reciprocity to Arizona licensees;
2. Has passed the NABPLEX or NAPLEX with a score of 75 or better or was licensed by examination in another jurisdiction having essentially the same standards for licensure as ~~Arizona~~ this state at the time the pharmacist was licensed;
3. Provides evidence to the Board of having completed the required secondary and professional education and training specified in R4-23-202(A);
4. Has engaged in the practice of pharmacy for at least ~~+~~ one year or has met the internship requirements of ~~Arizona~~ A.A.C. Title 4, Chapter 23, Article 3 within the year immediately before the date of application; and
5. Has actively practiced as a pharmacist for 400 or more hours within the last calendar year. ~~If this requirement is not met, an applicant may qualify for licensure by reciprocity by obtaining or has~~ an Arizona graduate intern license and completing has completed 400 hours of internship training in an approved internship training site.

B. Application:

1. ~~A person who is eligible and wishes to be licensed~~ An applicant for licensure by reciprocity shall file with the Board office:
 - a. ~~an application~~ A completed application for licensure by reciprocity form ~~at least 20 days before the date of the AZPLEX ; and~~
 - b. A completed AZPLEX registration form.
2. The Board ~~Office~~ office shall deem an application ~~for licensure by reciprocity or registration form~~ received on the date that the Board ~~Office~~ office stamps on the application or registration form as the form is delivered to the Board ~~Office~~ office.
3. An applicant for licensure by reciprocity shall:
 - a. ~~Make application for licensure by reciprocity~~ Make application for licensure by reciprocity on a form furnished by the Board, ~~and~~
 - b. ~~shall submit~~ Submit with the application for licensure by reciprocity form:
 - i. The documents specified in the application form, and
 - ii. The reciprocity and examination fee specified in R4-23-205(B) and (C). ~~The fee shall be paid and made payable to the Arizona State Board of Pharmacy by money order or certified or personal check and entitles the applicant to 1 sitting of the AZPLEX.~~
4. An applicant for licensure by reciprocity shall:
 - a. Make AZPLEX registration on a form furnished by the Board or NABP; and
 - b. Submit with the registration form:
 - i. The documents specified in the registration form; and
 - ii. The examination fee specified by and made payable to NABP by money order, certified check, or bank draft.
- 4-5. The Board ~~office~~ office shall deem an application for licensure by reciprocity form or AZPLEX registration invalid after 12 months from the date the Board ~~Office~~ office determines an application or registration form is complete. An applicant whose application or registration form is invalid and who wishes to continue licensure procedures, shall submit a new application or registration form and fee.

C. Passing grade; notification; re-examination:

1. To pass the required examination, an applicant shall obtain a score of at least 75% on the AZPLEX.
2. The Board ~~office~~ office shall:
 - a. Retrieve an applicant's AZPLEX score from the NABP online database no later than two weeks after the applicant's examination date; and
 - b. Mail an applicant's AZPLEX score to the applicant no later than 14 seven days after the applicant takes the examination Board office receives the applicant's score from NABP.

Arizona Administrative Register
Notices of Final Rulemaking

3. ~~If~~ An applicant who fails the AZPLEX, ~~the applicant may apply for reexamination to retake the examination~~ within the 12-month ~~application period defined specified~~ in subsection ~~(B)(4) (B)(5)~~. An applicant applying for reexamination ~~to retake an examination~~ shall submit to the Board ~~Office office~~ a ~~written request to retake the AZPLEX including the examination date preferred by the applicant~~ completed AZPLEX registration form and pay the examination fee specified in R4-23-205(C)(1)(b). The fee shall be paid to the Arizona State Board of Pharmacy by money order or certified or personal check ~~by and made payable to NABP by money order, certified check, or bank draft~~. An applicant who fails the AZPLEX ~~3~~ three times shall petition the Board for permission before retaking the examination.
- D. Licensure: The Board ~~office~~ shall issue a certificate of licensure to a successful applicant upon receipt of the licensure fee specified in R4-23-205(A)(1)(a). The Board ~~Office office~~ shall:
1. Provide a receipt for payment of the licensure fee to an applicant who delivers a payment in person; or
 2. mail Mail a receipt for payment of the licensure fee to an applicant within ~~±~~ one working day of receiving the payment by mail or other delivery service.
- E. Time-frames for licensure by reciprocity: The Board ~~Office office~~ shall follow the time-frames established for licensure by examination in R4-23-202(F).

R4-23-204. Continuing Education Requirements

- A. General: In accordance with A.R.S. § 32-1925(G), ~~no renewal of license shall be issued by the Board shall not renew a license~~ unless the applicant has, during the two years preceding the application for renewal, participated in 30 contact hours (3.0 CEU's) of continuing education ~~activities activity~~ sponsored by an Approved Provider as defined in ~~(B)(5) of this section~~ R4-23-110, ~~of which at least three contact hours (0.3 CEU's) of which shall be are approved courses on in pharmacy law. Pharmacists Subject to A.R.S. § 32-1937, a pharmacist licensed for less than 24 months shall accrue obtain~~ continuing education units in an amount determined by multiplying 1.25 hours times the number of months between the date of their initial licensure and the next license renewal date ~~of their application for renewal of their license~~.

B. Definitions:

1. ~~Continuing education shall include study in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology, characteristics and therapeutics of disease status; and pharmacy practice.~~
2. ~~Continuing education activities shall consist of institutes, seminars, lectures, conferences, workshops, various forms of mediated instruction, or programmed learning courses. Postgraduate studies in an accredited college of pharmacy shall be considered as continuing education activities.~~
3. ~~A continuing education unit (CEU) is equivalent to ten contact hours of participation in a continuing education activity sponsored by an Approved Provider.~~
4. ~~A contact hour is equivalent to 50 minutes of participation in a continuing education activity sponsored by an Approved Provider.~~
5. ~~“Approved Provider” means an individual, institution, organization, association, corporation or agency that has been approved by the American Council on Pharmaceutical Education (A.C.P.E.) in accordance with its policy and procedures, or by the Board as having met criteria indicative of the ability to provide quality continuing education.~~
6. ~~Mediated instruction refers to learning transmitted via intermediate mechanisms such as audio and/or visual tape, telephonic transmission, etc.~~
7. ~~“Approved course in pharmacy law” means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules or regulations.~~

~~B.~~ Acceptance of continuing education units (CEU's). ~~±~~ The Board shall:

1. Only accept continuing education units (CEU's) for continuing education activities ~~provided the activities are sponsored by an Approved Provider;~~
2. Only accept continuing education units (CEU's) accrued during the two-year period immediately ~~prior to before~~ renewal shall be considered acceptable for licensure renewal;
3. ~~No continuing education units (CEU's) may be~~ Not allow CEU's accrued in a biennial renewal period in as excess of the 3.0 CEU's required and to be carried forward to the succeeding biennial renewal period;
4. ~~Any~~ Allow a pharmacist who leads, instructs, or lectures to ~~groups a group~~ of health professionals on pharmacy-related topics in continuing education activities sponsored by an Approved Provider ~~shall be granted continuing education units (CEU's) for such time expended during actual presentation, upon documentation to the Board to receive CEU's for a presentation by following the same attendance procedures as any other attender of the continuing education activity; and~~
5. Any pharmacist whose primary responsibility is the education of health professionals shall ~~Not be granted continuing education units (CEU's) for~~ accept as CEU's the performance of normal teaching duties within ~~the a~~ learning institution: by a pharmacist whose primary responsibility is the education of health professionals.

~~B.C.~~ Continuing education records of continuing education units (and reporting CEU's): ~~±~~ Each individual Δ pharmacist is responsible for shall:

1. maintaining and preserving Maintain continuing education records that:

Notices of Final Rulemaking

- a. ~~which verify~~ Verify the continuing education activities ~~in which he or she has the pharmacist participated in~~ during the preceding five years; ~~and~~
 2. b. ~~The records shall consist~~ Consist of the a statement of credit or a certificate issued by the an Approved Provider at the conclusion of each a continuing education activity; ~~or documentation in the case of a leader, instructor or lecturer.~~
- ~~E.~~ Reporting of continuing education units (CEU's):
- 1.2. ~~At the time a pharmacist is required to renew his or her license the pharmacist shall of licensure renewal, attest to participating in continuing education, pursuant to (A) of this section, the number of CEU's the pharmacist participated in during the renewal period on the biennial renewal application form; and~~
 - 2.3. ~~In the event a pharmacist is When requested by the Board office, to submit proof of continuing education participation and fails to do so within 20 days of the request, the licensee shall be advised he or she is non-compliant and shall be required to appear before the Board.~~
- D. The Board may revoke, suspend, or place on probation the license of a pharmacist who fails to comply with continuing education participation, recording, or reporting requirements of this Section.
- ~~F.E.~~ In the event that A pharmacist who is aggrieved by any decision of the Board or its administrative staff concerning continuing education units, ~~he~~ may request a hearing before the Board.

R4-23-205. Fees

- A. Licensure fees:**
1. Pharmacist:
 - a. Initial licensure [Prorated according to A.R.S. § 32-1925(B)]: ~~\$110~~ 145.
 - b. Licensure renewal: ~~\$110~~ 145.
 2. Pharmacy or graduate intern: \$10.
- B. Reciprocity fee: \$300.**
- C. Examination fees: \$50.**
1. ~~AZPLEX:~~
 - a. ~~Initial: \$100.~~
 - b. ~~Retake: \$50.~~
 2. ~~NAPLEX: specified by and made payable to NABP according to R4-23-202(B)(4).~~
- D. Vendor permit fees (Resident and nonresident):**
1. Pharmacy: ~~\$300~~ 400 biennially (Including hospital, and limited service). (~~Including hospital, and limited service.~~)
 2. Drug wholesaler or manufacturer:
 - a. Manufacturer: \$1000 biennially.
 - b. Full service drug wholesaler: \$1000 biennially.
 - c. Nonprescription drug wholesaler: \$500 biennially.
 3. Drug packager or repackager: \$1000 biennially.
 4. Nonprescription drug, retail:
 - a. Category I (30 or fewer items): \$100 biennially
 - b. Category II (more than 30 items): \$200 biennially
 5. Compressed medical gas distributor: \$200 biennially
 6. Compressed medical gas supplier: \$100 biennially
- E. Other Fees:**
1. Wall certificate.
 - a. Pharmacist: \$20.
 - b. Pharmacy intern: \$10.
 - c. Relief Pharmacist: \$10.
 2. Duplicate of any Board-issued license, registration, certificate, or permit: \$10.
 3. Certification of electronic security system: \$25.
- F. Fees are not refunded under any circumstances except for the Board's failure to comply with its established licensure or permit time-frames under A.R.S. § 41-1077.**
- G. Penalty fee. Renewals submitted after expiration date are subject to penalty fees as provided in A.R.S. § 32-1925.**

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

Arizona Administrative Register
Notices of Final Rulemaking

1. Sections Affected

	<u>Rulemaking Action</u>
R4-23-110	Amend
R4-23-205	Amend
Article 3	Amend
R4-23-301	Amend
R4-23-302	Amend
R4-23-303	Amend
R4-23-304	Amend
R4-23-305	Amend

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

Authorizing statutes: A.R.S. § 32-1904(A)(1) and (5) and 32-1904(B)(7) and (10)

Implementing statutes: A.R.S. §§ 32-1923, 32-1924(C), 32-1925(A), (B), (C), and (E)(2), and 32-1926

3. The effective date of the rules:

January 10, 2002

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

Notice of Rulemaking Docket Opening: 6 A.A.R. 4758, December 22, 2000

Notice of Proposed Rulemaking: 7 A.A.R. 3520, August 17, 2001

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

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@qwest.net

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

Beginning in May of 1994, discussions within the agency centered on what to do with pharmacy intern preceptors, which are pharmacists who supervise pharmacy interns. Before 1985, the Board issued pharmacy intern preceptor wall certificates. Since 1986 the Board has issued no preceptor wall certificates and has had no formal preceptor approval or recognition procedure. The Board has not enforced the current rules' standards for pharmacy intern preceptors or monitored preceptor's practices. Existing rule R4-23-302 mentions a pharmacy intern preceptor application, but no such form exists. A docket was opened in March of 1995 to draft proposed rules for regulating interns and pharmacy intern preceptors. The draft rules have undergone many changes as a result of input from pharmacists, educators, and the agency. The proposed rules are a result of that effort. A lack of agreement between the Board, both Arizona colleges of pharmacy and interested pharmacists and other rulemaking priorities resulted in the automatic termination of the docket in August 1999 and again in November 2000. A new docket was opened on December 22, 2000. The rules address format, style, and grammatical changes necessary under the current Administrative Procedure Act (APA) and other necessary language changes to provide a clear, concise, and understandable document.

The rules amend the definition of "supervision" in R4-23-110 by adding the term "graduate intern" and specific reference to supervision for intern training. Existing rule defines the pharmacy intern fee of \$10 in R4-23-205(E)(1)(b). The proposed rules increase the fee to \$20 biennially for initial licensure and \$20 biennially for licensure renewal. The pharmacy intern wall certificate fee of \$10 in subsection R4-23-205(E)(1)(b) is repealed and the fee for issuance of a wall certificate is included with initial licensure. The increase in fee is necessary to provide a rapid licensure process. R4-23-301 addresses intern licensure and under the APA, any licensing activity requires implementing time-frame rules. However, the APA allows an agency to forego establishing separate time-frame rules if the time-frame is seven days or less. The Board staff determined that a licensure time-frame of less than seven days was possible and desirable. The intern licensure fee has not been increased in over 20 years. The new fee, which includes a wall certificate, will partially offset the increased staff time to decrease the intern application process time and the increase in postage necessary to comply with the under seven-day time-frame. Other changes to R4-23-301 address the prerequisites for licensure as a pharmacy intern and graduate intern, experiential training, and notification of training.

The heading of R4-23-302 is amended to read: "Training Site and Pharmacy Intern Preceptors". Besides the necessary format, style, and grammar changes, R4-23-302 is amended to establish the qualifications and requirements of an intern training site and establish the qualifications, privileges, and responsibilities of a pharmacy intern preceptor.

R4-23-303 is amended by adding necessary format, style, and grammar changes.

The proposed rules amend R4-23-304 to add the designation "graduate intern" where applicable and deletes the requirement that a preceptor file a final report. Quarterly intern training report requirements are established in subsection (B).

The proposed rules amend R4-23-305 by adding necessary citations to other Sections and other necessary format, style, and grammar changes.

The Board believes that approval of these rules will benefit the public health and safety by establishing clear standards governing pharmacy interns, graduate interns, and pharmacy intern preceptors. The Board further believes that regulation and enforcement are necessary to produce confident, well-trained pharmacists.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

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 rules' impact on established Board of Pharmacy procedures and office-related costs is moderate. The estimated additional cost to the Secretary of State's office is minimal. This additional cost stems from Secretary of State's staff time publishing the rules.

The Board's postage costs will increase to accommodate the less than seven-day time-frame for issuance of an intern license. This increase in postage cost will be minimal. The estimated cost to issue an initial intern license, as of October 4, 2001, is \$41.08 (\$4.69 for material and \$36.39 for labor). The estimated cost to issue an intern renewal certificate, as of October 4, 2001, is \$46.64 (\$3.00 for material and \$43.64 for labor). Based on June 30, 2001 figures for intern licenses issued, the total cost to issue intern licenses was \$17,365. The approximate costs to issue an initial intern license or an intern renewal certificate are more than four times the existing intern licensure fee and more than two times the proposed intern licensure fee. The Board has always lost money when licensing interns.

The maximum statutory fee for intern licensure is \$25. It has never made sense to increase the fee because interns on average are licensed for three years or less; historically the number of interns has been relatively low, although it has increased considerably in the last few years; and intern licensure is necessary to produce licensed pharmacists. The difference between intern license revenue and cost to issue intern licenses (\$3,284) was not as noticeable in 1992, when the Board issued 88 new intern licenses and renewed one-half or 39 of the existing 78 intern licenses for a total of 166 intern licenses. But, the difference (\$10,855) is more noticeable in 2001, when the Board issued 249 new intern licenses and renewed one-half or 153 of the existing 306 intern licenses for a total of 555 intern licenses.

The increased intern license fee will reduce the revenue/cost difference by \$1,530 to \$9,325, using 2001 figures. The increased intern licensure fee does produce increased Board revenues, but still does not fully cover the Board's cost for intern licensure. However, the Board requirement that all interns have a license provides the benefit of Board oversight, control, and accountability of an intern's activities.

For pharmacy interns and graduate interns, the main economic impact is the increase in licensure fee. This small increase of \$10 to an already small fee is offset by the benefit of almost immediate licensure. This allows an intern to start work almost immediately, thus increasing an intern's income. By being able to work several days earlier than before, the intern can earn back several times the increased cost of the licensure fee. The average intern earns from \$12 to \$25 per hour. Under existing rule, the initial cost of intern licensure was \$10 biennially for licensure fee and \$10 for wall certificate fee or a total initial cost of \$20, and the total cost of intern licensure renewal was \$10 biennially for the licensure renewal fee. The proposed rules impose a total initial intern licensure cost of \$20 biennially and involves no actual fee increase over existing rule. The proposed rules impose a total intern licensure renewal fee of \$20 biennially which is a fee increase of \$10 biennially or \$5 per year. By working one eight-hour day earlier, an intern earning the low end of the wage scale (\$12/hour) will make \$96 which easily offsets the \$5 annual increase in intern licensure fee. There has been no increase in the intern licensure fee in over 20 years, and the Board does not feel this small increase is outrageous or burdensome, especially since even this small increase will cover less than half of the Board's costs to license an intern.

The rules may have a minimal economic impact on Arizona pharmacies. The proposed rules allow the use of a two to one intern to pharmacist ratio instead of the one to one ratio that exists in previous rule. A pharmacy may be able to reduce personnel costs by better utilization of personnel with the new ratio. The Board cannot quantify this benefit to pharmacies.

The rules will have no economic impact on the public. The citizens of Arizona will benefit from minimum standards of training for pharmacists that should produce more confident, newly licensed pharmacists.

Arizona Administrative Register
Notices of Final Rulemaking

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

At the request of the Secretary of State and G.R.R.C. staff, the Board made minor grammar, style, format, and punctuation changes where necessary. Because the Board has not collected any fee and no one has requested certification of an electronic security system since approval of subsection R4-23-205(E)(3) on April 1, 1995 and to comply with A.R.S. § 41-1008 which became effective on July 1, 1999 and requires specific statutory fee authority, the Board repealed subsection R4-23-205(E)(3). In response to written comment received by the Board and after some discussion, the Board made a nonsubstantive change in subsection R4-23-302(C)(5). At the request of the commentor, the word "specific" is deleted from subsection R4-23-302(C)(5). Based on written comment, G.R.R.C. staff recommendations, and to improve the clarity and understandability of the rule regarding the pharmacist to intern ratio, the Board made nonsubstantive changes to R4-23-302(E) including the standards the Board will use to grant exceptions to the ratio.

11. A summary of the principal comments and the agency response to them:

The Board received a written comment from the National Association of Chain Drug Stores (NACDS) voicing two concerns about the proposed rulemaking. The first concern involved subsections R4-23-302(C)(4) and (5). The NACDS believes that the proposed requirement that all pharmacy intern preceptors hold faculty positions in the experiential training program of a Board-approved college or school of pharmacy or receive specific Board approval as a pharmacy intern preceptor is unreasonably restrictive. The Board agreed to delete the word "specific" from subsection 302(C)(5) as requested by the NACDS, but the Board does not agree that the requirement in subsection 302(C)(4) is unreasonably restrictive. To become an adjunct faculty member of either of Arizona's two Board-approved colleges of pharmacy, a pharmacist need only voice an interest, go through the particular college's eight-hour training program for pharmacy intern preceptors, and comply with the college's intern training and recordkeeping standards. The college's training standards coincide with the Board's training standards. The Board does not believe it is unreasonable to require intern training to be reasonably uniform no matter where the training occurs. The use of pharmacy intern preceptors who strive to meet the same intern training standards used by both colleges of pharmacy will give the Board confidence in the skills and abilities of the interns who seek licensure as pharmacists in Arizona. Additionally, a pharmacist who is not an adjunct faculty member of a Board-approved college of pharmacy may seek specific approval from the Board as a pharmacy intern preceptor.

The second concern involved subsection R4-23-302(E). While the NACDS appreciates the Board's proposal to increase the intern to pharmacist ratio to 2:1 from 1:1, the NACDS does not believe that the rules should have a ratio of 2:1 only for community pharmacy practice settings, while practice settings directed by a Board-approved school do not have any required ratio. Although the comment is unclear, the NACDS believes that a community pharmacy practice setting and a practice setting affiliated with a school should have the same 2:1 ratio or both should have no required ratio. The NACDS believes that, in this time of changes and new beginnings in community practice endeavors, it does not seem appropriate to limit intern and preceptor involvement in community pharmacy. The Board does not agree that the rule will limit intern and preceptor involvement in community pharmacy and the NACDS does not explain why it believes this to be true, but the Board does believe that a ratio is necessary to ensure appropriate training and oversight of interns by pharmacists in practice settings that are not directed by a Board-approved school. The Board believes that the colleges' experiential intern training programs are in a position to determine and control intern training, including the appropriate intern to pharmacist ratio, in any pharmacy practice setting. In practice, the college experiential training programs only exceed the 2:1 ratio in non-pharmacy settings. Such settings include the training of pharmacy interns on hospital rounds with physicians and pharmacy interns answering phone questions for the poison control center. The use of a intern to pharmacist ratio exceeding 2:1 in a community pharmacy practice setting is also limited by the pharmacy space requirements of R4-23-609, which require a minimum of 300 square feet for three people with an additional 60 square feet for each additional person. The goal of a school experiential training program is to produce well-trained, competent pharmacists. The Board and the college experiential training programs believe that the use of a intern to pharmacist ratio that exceeds 2:1 in the average pharmacy does not meet that goal. The Board is changing subsection R4-23-302(E) by removing the words "noncommunity pharmacy", which will mean that any pharmacy practice setting (community or noncommunity) directed by a Board-approved college or school of pharmacy experiential training program will not have a required ratio. This is not a substantial change because in actual practice the ratio will not be exceeded except in certain non-pharmacy settings, such as on hospital rounds and at the poison control center. This does not preclude a community pharmacy practice site that is not associated with a college or school of pharmacy experiential training program from petitioning the Board for a waiver of the pharmacist to intern ratio. In considering a request to exceed the ratio, the Board would consider pharmacy space limitations and whether exceeding the ratio poses a safety risk to the public health.

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 approved as an emergency rule?

No

15. 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 2. PHARMACIST LICENSURE

Section

R4-23-205. Fees

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section

R4-23-301. ~~General~~ Intern Licensure

R4-23-302. ~~Training place~~ Site and Pharmacy Intern Preceptors

R4-23-303. Training Time

R4-23-304. Reports

R4-23-305. Miscellaneous Intern Training Provisions

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

“Supervision” means a pharmacist is present, assumes legal responsibility, and has direct oversight of activities relating to acquiring, preparing, distributing, and selling prescription medications by pharmacy interns, graduate interns, pharmacy technicians, or certified pharmacy technicians and when used in connection with the intern training requirements means that, in a pharmacy where intern training occurs, a pharmacy intern preceptor assumes the primary responsibility of teaching the intern during the entire period of the training.

ARTICLE 2. PHARMACIST LICENSURE

R4-23-205. Fees

A. Licensure fees:

1. Pharmacist:

a. Initial licensure [Prorated according to A.R.S. § 32-1925(B)]: \$110.

b. Licensure renewal: \$110.

2. Pharmacy or graduate intern:

a. Initial licensure [prorated according to A.R.S. § 32-1925(B)]: \$4020.

b. Licensure renewal: \$20.

B. Reciprocity fee: \$300.

C. Examination fees:

1. AZPLEX:

a. Initial: \$100.

b. Retake: \$50.

2. NAPLEX: specified by and made payable to NABP according to R4-23-202(B)(4).

D. Vendor permit fees (Resident and nonresident):

1. Pharmacy: \$300 biennially. (Including community, hospital, and limited service.)

2. Drug wholesaler or manufacturer:

a. Manufacturer: \$1000 biennially.

b. Full service drug wholesaler: \$1000 biennially.

c. Nonprescription drug wholesaler: \$500 biennially.

3. Drug packager or repackager: \$1000 biennially.

4. Nonprescription drug, retail:

a. Category I (30 or fewer items): \$100 biennially.

b. Category II (more than 30 items): \$200 biennially.

5. Compressed medical gas distributor: \$200 biennially.

6. Compressed medical gas supplier: \$100 biennially.

E. Other Fees:

1. Wall certificate.

Arizona Administrative Register
Notices of Final Rulemaking

- a. Pharmacist: \$20.
- b. ~~Pharmacy intern:~~ \$10.
- e-b. Relief pharmacist: \$10.
- 2. Duplicate of any Board-issued license, registration, certificate, or permit: \$10.
- 3. ~~Certification of electronic security system:~~ \$25.
- F. Fees are not refunded under any circumstances except for the Board's failure to comply with its established licensure or permit time-frames under A.R.S. § 41-1077 R4-23-202, R4-23-202, or R4-23-602.
- G. Penalty fee. Renewals Renewal applications submitted after the expiration date are subject to penalty fees as provided in A.R.S. § 32-1925.

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-301. General Intern Licensure

- A. ~~In general: Registration as a pharmacy intern may only be granted by the Board so the applicant may obtain practical experience in the practice of pharmacy. Registration as a pharmacy intern shall not be granted beyond the time necessary to complete the minimum practical experience as a pharmacy intern, as required by R4-23-303(A), unless such permission is specifically granted by the Board. Licensure as a pharmacy intern or graduate intern is for the purpose of complementing the individual's academic or experiential education in preparation for licensure as a pharmacist. An applicant may request a waiver of intern licensure requirements by submitting a written request and appearing in person at a Board meeting.~~
- B. The prerequisites for licensure as a pharmacy intern are:
 - 1. Current enrollment, in good standing, in a Board-approved college or school of pharmacy; or
 - 2. Graduation from a college or school of pharmacy that is not approved by the Board; and
 - 3. Proof that the applicant received:
 - a. A passing score on the Foreign Pharmacy Graduate Equivalency Examination (FPGEE); or
 - b. Acceptance to take the FPGEE; or
 - 4. By order of the Board if the Board determines the applicant needs intern training.
- C. If the Board determines that a pharmacy intern licensee stops attending pharmacy school classes before graduation under circumstances indicating the licensee does not intend to continue the licensee's pharmacy education, the licensee shall surrender the pharmacy intern license no later than 30 days after the date of the last attended class. A student re-entering a pharmacy program who wishes to continue internship training shall reapply for pharmacy intern licensure.
- D. The prerequisites for licensure as a graduate intern are:
 - 1. Graduate from a Board-approved college or school of pharmacy, and
 - 2. Apply for licensure as a pharmacist by examination or reciprocity, or
 - 3. By order of the Board if the Board determines that the applicant needs intern training.
- ~~B.E. Practical experience: Experiential training. Practical experience in intern Intern training activities shall include, but not be limited to, the activities and services encompassed by the term "practice of pharmacy" as defined in A.R.S. § 32-1901, pertaining to drugs devices and medical care: distribution, dispensing, manufacturing, providing information, monitoring, modifying, keeping records, making reports and experience in clinical pharmacy.~~
- ~~C.E. Out-of-state experience: experiential training. Practical experience in intern An intern shall receive credit for intern training received in a outside this state other than Arizona may be allowed by the Board if in the opinion of the Board determines that the intern training requirements of the state jurisdiction in which the experience training was received are equal to the minimum standards requirements for intern training in Arizona this state. The An applicant seeking for such credit in for intern training received outside this state shall furnish a transcript certified copy of the records of intern training from:~~
 - 1. ~~The The board of pharmacy of the state in which the experience was obtained or the intern licensing agency of the other jurisdiction where the training was received; or~~
 - 2. In a jurisdiction without an intern licensing agency, the director of the applicant's Board-approved college or school of pharmacy's experiential training program.
- ~~D.G. Management required to verify intern's qualifications: The An owner, manager, or pharmacist-in-charge shall not permit a person to act as a pharmacy or graduate intern until there has been verification the owner, manager, or pharmacist-in-charge verifies that the person is currently registered licensed by the Board as a pharmacy or graduate intern.~~
- E. Registration: An applicant for registration as a pharmacy intern shall not be approved until the applicant shall have been accepted for registration in an accredited college of pharmacy.
- ~~F.H. Intern application: An applicant for registration licensure as a pharmacy intern or graduate intern shall:~~
 - 1. Ensure that the applicant's college or school of pharmacy provides documentation to the Board of the applicant's current enrollment or graduation; and
 - 2. File an application on a form furnished by the Board, that includes:
 - a. Applicant's name, address, mailing address, if different, telephone number, and social security number;

- b. Name and address of college or school of pharmacy attending or attended, degree anticipated or received, and anticipated date or date of graduation;
- c. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
- d. Whether the applicant has ever had an intern license revoked, suspended, or denied in this state or any other jurisdiction, and if so, indicate where and when;
- e. A recent photograph of the applicant that is no larger than 2-1/2" x 3" with the applicant's signature on the front;
- f. If the applicant graduated from an unapproved college or school of pharmacy, a verification of acceptance to take the FPGEE or an original Foreign Pharmacy Graduate Equivalency Committee (FPGEC) certification document;
- g. Date signed and applicant's verified signature; and
- h. The initial licensure fee specified in R4-23-205. If accepted, the applicant shall pay a biennial registration fee prorated from date of registration to June 30 of even-numbered years. The fee is not refunded under any circumstances. The intern certificate shall be kept in good standing by payment of a biennial fee July 1 of even-numbered years, provided, however, the intern training time shall be no longer than six years from the time of enrollment in a college of pharmacy, without providing proof to the Board that he is intending and working toward becoming a pharmacist.

I. Licensure. Within seven business days of receipt of a completed application, fees, and other information specified in subsection (H), the Board office shall issue a determination. If the application is complete, the Board office shall issue a license number and mail a current renewal receipt to an applicant. An applicant who is issued a license number may begin practice as a pharmacy intern or graduate intern. The initial licensure fee shall include the issuance of a wall certificate. The Board office shall mail the wall certificate to the licensee within 14 days of issuing the license number.

G.I. License renewal. An intern license shall be kept in good standing by payment of the biennial renewal fee specified in R4-23-205. If a pharmacy intern fails to graduate from a Board-approved college or school of pharmacy within six years from the date the Board issues the intern license, the intern is not eligible for relicensure as an intern unless the intern obtains Board approval as specified in A.R.S. § 32-1923(E). Failure to pay renewal fee: If the biennial renewal fee is not paid by July 1 ~~November 1~~ of an even-numbered the renewal year specified in A.R.S. § 32-1925, the intern registration license is delinquent suspended and the licensee shall pay a penalty as provided in A.R.S. § 32-1925 and 32-1931 is required to vacate the suspension.

H.K. Notification of training:

1. A pharmacy intern who is employed as an intern outside the experiential training program of a Board-approved college or school of pharmacy or a graduate intern shall notify the Board within ten days of starting or terminating training, or changing place of training in accordance with A.R.S. § 32-1926(A) site.
2. The director of a Board-approved college or school of pharmacy's experiential training program shall provide the Board an intern training report as specified in R4-23-304(B)(3).

R4-23-302. Training place Site and Pharmacy Intern Preceptors

A. Training place: To receive credit for intern training hours, a pharmacy or graduate intern shall train in a site that:

1. A pharmacy operating under a pharmacy credit from the Board, employing a pharmacy intern preceptor Holds a valid Arizona pharmacy permit and employs a pharmacy intern preceptor who supervises the intern; or
2. Other pharmaceutical specialties, such as wholesale drug companies, drug manufacturers, medical care clinics and others Is an alternative training site. For purposes of this Section, the term alternative training site is a non-pharmacy training site established and monitored by a Board-approved college or school of pharmacy or other non-pharmacy site where practical experience in pharmacy may be obtained as listed in subsection (B) of related activities are performed and where an intern gains experience as specified in R4-23-301(E).

B. Cancellation of approval of training place. The Board may disapprove or cancel approval of shall inform a pharmacy or other place to train pharmacy interns alternative training site that an intern will not get credit for training received at the site if in the opinion of the Board determines that a the pharmacy or other place of alternative training site fails to comply with drug laws and regulations provide experiential training as specified in R4-23-301(E) or violates A.R.S. Chapter 18 Title 32 or Chapter 27 Title 36 or the federal act.

C. Preceptor Pharmacy intern preceptor. To be a pharmacy intern preceptor, a pharmacist shall:

1. A pharmacist who has been actively engaged in the practical experience of pharmacy in Arizona for one year as listed in R4-23-301(B) may make application, on a form to be provided by the Board, to be a pharmacy intern preceptor. Hold a current unrestricted pharmacist license;
2. Have a minimum of one year of experience as an actively practicing pharmacist before acting as a pharmacy intern preceptor;
- 2-3. If a pharmacist Any preceptor applicant who has been found guilty of violations of the laws and regulations pertaining to drugs, devices or poisons, or of gross immorality, shall be eligible as a pharmacy preceptor only by special permission from the Board. violating any federal or state law relating to the practice of pharmacy, drug or device dis-

Arizona Administrative Register
Notices of Final Rulemaking

tribution or recordkeeping, or unprofessional conduct, enter into an agreement satisfactory to the Board that places restrictions on the pharmacist's license; and

4. Hold a faculty position in the experiential training program of a Board-approved college or school of pharmacy; or
 5. Be approved by the Board as being otherwise qualified as a pharmacy intern preceptor.
- D.** ~~Cancellation~~ Revocation of preceptorship privileges. The right to be a pharmacy intern preceptor may be revoked Board shall revoke a pharmacy intern preceptor's privilege to train pharmacy or graduate interns if the Board finds determines that the a pharmacy intern preceptor has failed to comply with drug laws and regulations fails to provide experiential training as specified in R4-23-301(E) or violates A.R.S. Chapter 18 Title 32 or Chapter 27 Title 36 or the federal act. R4-23-104 applies to revocation of preceptor privileges.
- E.** Intern to notify Board. An intern must notify the Board when he begins training and when he leaves his training position.
- F.** Supervision defined: The term "supervision" as used in connection with the intern training requirements shall mean that, in the pharmacy where intern training is being obtained, a pharmacy preceptor shall be in personal contact with, and actually giving instructions to, the intern obtaining practical experience during the entire period of such training.
- G.**~~E.~~ Preceptor-intern ratio: The ratio of intern to full-time pharmacy preceptor employed in any Intern Training Place, where more than one intern is employed must not be greater than one intern to each pharmacy preceptor at any one time. A preceptor may train more than one pharmacy intern at different times. Pharmacist-intern ratio. A pharmacy intern preceptor may supervise the training of more than one pharmacy or graduate intern during a calendar quarter. The ratio of pharmacist to intern shall not exceed one pharmacist to two interns in a community pharmacy or limited-service pharmacy setting unless approved by the Board. In considering a request to exceed the ratio, the Board will consider pharmacy space limitations and whether exceeding the ratio poses a safety risk to the public health. Subject to R4-23-609 and the safety of public health, there is no pharmacist to intern ratio in a practice setting directed by a Board-approved college or school of pharmacy experiential training program.
- H.** Willingness to train interns: Evaluation of training. The owner and pharmacy preceptor in an Intern Training Place shall cooperate with the Board of Pharmacy in developing intern training and shall report to the Board from time to time as requested by the Board on the progress and aptitude of any intern under their supervision.
- I.**~~F.~~ Preceptor responsibilities. The Board holds the pharmacy preceptor responsible for the actions of the pharmacy intern he is training. Therefore, the preceptor should determine the degree of skill possessed by the intern and develop a training program whereby the intern will be able to improve upon and develop his ability in the actual practice of pharmacy. A pharmacy intern preceptor assumes the responsibilities of a teacher and mentor in addition to those of a pharmacist. A preceptor shall thoroughly review pharmacy policy and procedure with each intern. A preceptor is responsible for the pharmacy related actions of an intern during the specific training period. A preceptor shall give an intern the opportunity for skill development and provide an intern with timely and realistic feedback regarding their progress.
- J.** Sufficient time to instruct: The pharmacy preceptor shall allow sufficient time to instruct the intern in the practical aspects of pharmacy and to review and discuss his progress frequently.
- K.** ~~Preceptor continuing education: The preceptor shall continue his own professional education by reading the available pharmacy journals, magazines and other trade publications. He shall also attend seminars, meetings or other functions which may, in the opinion of the Board, be required to remain an informed and competent pharmacy preceptor~~

R4-23-303. Training time

- A.** Training. The minimum hours of internship training required for licensure by examination shall be 1,500, hours, all of which must be accumulated A pharmacy intern shall accumulate all 1500 hours of internship training after the intern has been enrolled enrolling in a college of pharmacy as prescribed in R4-23-301(D)(B) and after the receiving a Board-issued pharmacy intern license has accepted the intern's application. Time spent in college clinical programs or demonstration projects which have been approved by the Board shall be credited. The Board shall credit a pharmacy intern with no more than 500 hours of internship training will be approved for one per calendar quarter. (See R4-23-304 for reports required.)
- B.** Start of training and limitation of credit. Practical experience as a pharmacy intern shall be computed from the date of registration as a pharmacy intern. To receive credit as internship training, the practical experience shall be credited only when it has been obtained take place in a pharmacy or other place approved and authorized by the Board for training interns an alternative training site as specified in R4-23-302(A) and under an approved the supervision of a pharmacy intern preceptor, except for a non-pharmacy site as part of a Board-approved college or school of pharmacy experiential training program. In no event The Board shall credit no more than 500 hours practical experience internship training as a pharmacy or graduate intern be approved for training received in any pharmacy specialty other than an approved intern training place in an alternative training site specified in R4-23-302(A)(2).

R4-23-304. Reports

- A.** Change of employment or mailing address. A pharmacy intern or graduate intern shall notify the Board within ten 10 days of change of employment or mailing address.
- B.** Quarterly reports.
1. A pharmacy intern who is a graduate of a college or school of pharmacy that is not approved by the Board or is a graduate intern shall file on forms supplied by provide the Board quarterly intern training reports of such training for

Arizona Administrative Register
Notices of Final Rulemaking

the duration of his training. ~~Such reports~~ A quarterly intern training report shall be filed October 1, January 1, April 1 and July 1 for the preceding quarter, whether the intern was in training or not during the quarter. ~~The A quarterly intern training report reports shall be is~~ delinquent if not received at the Board's office 30 days after being the due date. The Board ~~will~~ shall write the intern to acknowledge receipt of the reports and notify the intern of the remaining hours of training required. A quarterly intern training report shall include:

- a. Intern's name, address, and license number;
- b. Training site name and address;
- c. Pharmacy intern preceptor's name and license number;
- d. Whether the report is for the first quarter (Jan.-Mar.), second quarter (Apr.-June), third quarter (July-Sept.), or fourth quarter (Oct.-Dec.);
- e. Number of intern training hours per week, specified by week ending date (month, day, year) and total number of intern training hours for the quarter; and
- f. Date signed and pharmacy intern preceptor's signature verifying that the pharmacy intern preceptor has been actively engaged in the practice of pharmacy for at least one year and that the pharmacy intern preceptor supervised the intern training of the pharmacy or graduate intern identified in the quarterly intern training report.

2. A pharmacy intern seeking credit for intern training hours received outside an approved college or school of pharmacy's experiential training program shall provide the Board a quarterly intern training report as specified in subsection (B)(1)
3. After graduation and before sitting for the NAPLEX or AZPLEX, a pharmacy intern who is a graduate of a Board-approved college or school of pharmacy shall ensure that the director of the Board-approved college or school of pharmacy's experiential training program provides the Board an intern training report that includes:
 - a. A list of all training sites where training occurred during any part of the entire training program including addresses and telephone numbers;
 - b. The dates and number of training hours experienced, by training site and total;
 - c. The name of the pharmacy intern preceptor, if applicable, for each training site; and
 - d. The date signed and experiential training program director's signature verifying that the pharmacy intern successfully completed the experiential training program.

~~C.~~ Preceptor's final report: Upon completion of the year's intern training, the last preceptor under whom this experience was obtained shall file a report describing this training and giving the preceptor's opinion on the ability of the intern to practice pharmacy without supervision. If the preceptor's report is not satisfactory, the Board may require further training before allowing the intern to take the practical examination.

R4-23-305. Miscellaneous intern training provisions

Experience in lieu of intern training: Intern training is ordinarily only credited for experience gained while training under a pharmacist, or limited credit given for training in wholesale drug companies, drug manufacturers, and other pharmaceutical specialties which may not be under a pharmacist. However, the Board may accept three years' experience as a pharmacist in another jurisdiction as the equivalent of the 1,500 hours of intern training required. To prevent losing a loss of intern hour credit and before beginning training, an intern should may ask the Board whether the if a training place is approved and if credit will be given hour credit for hour trained site meets the requirements specified in R4-23-301(E) and R4-23-302(A).
Note: Intern training should be practical; research and college studies are not considered that kind of "practical".

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

**CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)
ADMINISTRATION**

PREAMBLE

1. Sections Affected

R9-22-101
R9-22-107
Article 4
R9-22-401
R9-22-402
R9-22-403
R9-22-404
R9-22-405
R9-22-406
Article 6

Rulemaking Action

Amend
Amend
Repeal
Repeal
Repeal
Repeal
Repeal
Repeal
Repeal
Amend

Arizona Administrative Register
Notices of Final Rulemaking

R9-22-601	Amend
R9-22-602	Repeal
R9-22-602	New Section
R9-22-603	Repeal
R9-22-603	New Section
R9-22-604	Amend
R9-22-605	New Section
R9-22-606	New Section
R9-22-701	Amend
R9-22-709	Amend
R9-22-714	Repeal
R9-22-714	New Section
R9-22-716	Amend
R9-22-719	New Section

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

Authorizing statute: A.R.S. § 36-2906

Implementing statutes: A.R.S. §§ 36-2903, 36-2904, and 36-2906

3. The effective date of the rules:

January 10, 2002

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

Notice of Rulemaking Docket Opening: 7 A.A.R. 3050, July 13, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 3738, August 31, 2001

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

Name: Cheri Tomlinson, Federal and State Policy Administrator

Address: 801 East Jefferson
Mail Drop 4200
Phoenix, AZ 85034

Telephone: (602) 417-4198

Fax: (602) 256-6756

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

These rules define the contracts/request for proposal (RFP) process for AHCCCS' acute care program. The Administration is amending these rules to make the rules more clear, concise, and understandable by:

- repealing Article 4 and relocating the provisions of Article 4 to Article 6,
- grouping like concepts to provide clarity and conciseness to the rule language,
- deleting language that appropriately exists in contract rather than rule according to A.R.S. § 41-1005(A)(16),
- clarifying language that does not clearly present policies or procedures, and
- updating citations to documents incorporated in the rule, as needed.

Following is an explanation of the changes:

9 A.A.C. 22, Article 1, Definitions

The Administration modified, added, or deleted definitions to improve the clarity and conciseness of the rule language.

9 A.A.C. 22, Article 4, Contracts, Administration, and Standards

This Article is repealed. The Administration believes that Chapter 22 needs to model Chapter 28 for which the Administration has combined the contract and RFP process as the two content areas are so intertwined. The provisions of Article 4 are grouped with like concepts in Article 6 or deleted because they are more appropriately housed in contract per A.R.S. § 41-1005(A)(16).

9 A.A.C. 22, Article 6, RFP and Contract Process

R9-22-601 The Administration moved subsections "B" through "F" to R9-22-602.

R9-22-602 The Administration amended this Section with R9-22-601(B through F) and R9-22-401 to delineate the RFP process and make it more clear, concise, and understandable.

R9-22-603 The Administration moved the provisions of this Section to R9-22-601.

Notices of Final Rulemaking

R9-22-604 The Administration amended the content of this Section to improve the clarity and conciseness of the rule language.

R9-22-605 The Administration added "Waiver of Contractor's Subcontract with Hospitals" as a new Section, which mirrors the repealed R9-22-403(C).

R9-22-606 The Administration added "Contract Compliance Sanction" as a new Section, which mirrors R9-22-406 except for the addition of A.R.S. citations.

9 A.A.C. 22, Article 7, Standards for Payments

The Administration revised those Sections in Article 7 that pertain to contract.

R9-22-701 The Administration deleted subsections "B", "C", and "D" because the provisions are more appropriately housed in contract per A.R.S. § 41-1005(A)(16).

R9-22-709 The Administration made minor changes to improve clarity.

R9-22-714 The Administration added "Payments to Providers" as a new Section to clarify the prerequisite for provider payment.

R9-22-716 The Administration amended the language to improve clarity and conciseness and to strike those areas which are already included in contract.

R9-22-719 The Administration added "Contractor Performance Measure Outcomes" as a new Section. This Section allows the Administration to retain a specified percentage of capitation reimbursement to distribute to contractors based on their performance outcomes under A.R.S. § 36-2904.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

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 contractors, members, providers, and AHCCCS are nominally impacted by the changes to the rule language. These rules define the contracts/request for proposal (RFP) process for AHCCCS' acute care program. The Administration is amending these rules to make the rules more clear, concise, and understandable by:

- repealing Article 4 and relocating the provisions of Article 4 to Article 6,
- grouping like concepts to provide clarity and conciseness to the rule language,
- deleting language that appropriately exists in contract rather than rule according to A.R.S. § 41-1005(A)(16),
- clarifying language that does not clearly present policies or procedures, and
- updating citations to documents incorporated in the rule, as needed.

It is anticipated that the private sector, including small businesses or political subdivisions will not be impacted since the proposed rule language changes are intended to streamline and clarify the existing rules. The Administration, contractors, and providers will benefit because the changes provide greater flexibility and clarification of the rule.

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

The only changes to the proposed rule are grammatical and technical changes suggested by G.R.R.C. staff.

11. A summary of the principal comments and the agency response to them:

On October 2, 2001, the Administration simultaneously conducted public hearings in Phoenix, Yuma, and Sierra Vista. The Phoenix site was linked by videoconference with Tucson and Flagstaff. The Administration received no oral or written comments prior to close of record at 5 p.m. on October 2, 2001.

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 adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

**CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)
ADMINISTRATION**

ARTICLE 1. DEFINITIONS

Section

- R9-22-101. Location of Definitions
- R9-22-107. Standard for Payments Related Definitions

ARTICLE 4. ~~CONTRACTS, ADMINISTRATION, AND STANDARDS~~ REPEALED

Section

- R9-22-401. ~~General~~ Repealed
- R9-22-402. ~~Contracts~~ Repealed
- R9-22-403. ~~Subcontracts~~ Repealed
- R9-22-404. ~~Contract Amendments; Mergers; Reorganizations~~ Repealed
- R9-22-405. ~~Suspension, Denial, Modification, or Termination of Contract~~ Repealed
- R9-22-406. ~~Contract Compliance Sanction Alternative~~ Repealed

ARTICLE 6. ~~REQUEST FOR PROPOSALS (RFP)~~ RFP AND CONTRACT PROCESS

Section

- R9-22-601. General Provisions
- R9-22-602. ~~Request for Proposals (RFP); Contract Award~~ RFP
- R9-22-603. ~~Contract Records~~ Contract Award
- R9-22-604. Contract or Proposal Protests; Appeals
- R9-22-605. ~~Repealed~~ Waiver of Contractor's Subcontract with Hospitals
- R9-22-606. Contract Compliance Sanction

ARTICLE 7. STANDARDS FOR PAYMENTS

Section

- R9-22-701. Scope of the Administration's Liability; ~~Payments to Contractors~~
- R9-22-709. Contractor's Liability to Hospitals for the Provision of Emergency and Subsequent Care
- R9-22-714. ~~Contractor risk retention fund (AHCCCS-assembled networks)~~ Payments to Providers
- R9-22-716. Specialty Contracts
- R9-22-719. Contractor Performance Measure Outcomes

ARTICLE 1. DEFINITIONS

R9-22-101. Location of Definitions

A. Location of definitions. Definitions applicable to this Chapter are found in the following:

Definition	Section or Citation
"Accommodation"	R9-22-107
"Act"	R9-22-114
"Active case"	R9-22-109
"Acute mental health services"	R9-22-112
"ADHS"	R9-22-112
"Administration"	A.R.S. § 36-2901
"Administrative law judge"	R9-22-108
"Administrative review"	R9-22-108
"Adverse action"	R9-22-114
"Affiliate <u>Affiliated</u> corporate organization"	R9-22-106
"Aged"	42 U.S.C. 1382c(a)(1)(A) and R9-22-115
"Aggregate"	R9-22-107
"AHCCCS"	R9-22-101
"AHCCCS inpatient hospital day or days of care"	R9-22-107
"Ambulance"	R9-22-102
"Ancillary department"	R9-22-107
"Annual assessment period"	R9-22-109

Arizona Administrative Register

Notices of Final Rulemaking

“Annual assessment period report”	R9-22-109
“Annual enrollment choice”	R9-22-117
“Appellant”	R9-22-114
“Applicant”	R9-22-101
“Application”	R9-22-101
“Assignment”	R9-22-101
“Authorized representative”	R9-22-114
“Auto-assignment algorithm”	R9-22-117
“Baby Arizona”	R9-22-114
“Behavior management services”	R9-22-112
“Behavioral health evaluation”	R9-22-112
“Behavioral health medical practitioner”	R9-22-112
“Behavioral health professional”	R9-22-112 <u>R9-20-101</u>
“Behavioral health service”	R9-22-112
“Behavioral health technician”	R9-22-112 <u>R9-20-101</u>
“Behavior management services”	R9-22-112
“BHS”	R9-22-114
“Billed charges”	R9-22-107
“Blind”	R9-22-115
“Board-eligible for psychiatry”	R9-22-112
“Burial plot”	R9-22-114
“Capital costs”	R9-22-107
“Capped fee-for-service”	R9-22-101
“Caretaker relative”	R9-22-114
“Case”	R9-22-109
“Case record”	R9-22-101 and R9-22-109
“Case review”	R9-22-109
“Cash assistance”	R9-22-114
“Categorically-eligible”	R9-22-101
“Certified psychiatric nurse practitioner”	R9-22-112
“Clean claim”	A.R.S. § 36-2904
“Clinical supervision”	R9-22-112
“CMDP”	R9-22-117
“CMS”	R9-22-101
“Complainant”	R9-22-108
“Continuous stay”	R9-22-101
“Contract”	R9-22-101
“Contractor”	A.R.S. § 36-2901
“Copayment”	R9-22-107
“Corrective action plan”	R9-22-109
“Cost-to-charge ratio”	R9-22-107
“Covered charges”	R9-22-107
“Covered services”	R9-22-102
“CPT”	R9-22-107
“CRS”	R9-22-114
“Cryotherapy”	R9-22-120
“Date of notice”	R9-22-108
“Day”	R9-22-101
“DCSE”	R9-22-114
“De novo hearing”	R9-22-112 <u>42 CFR 431.201</u>
“Dentures”	R9-22-102
“Department”	A.R.S. § 36-2901
“Dependent child”	R9-22-114
“DES”	R9-22-101
“Diagnostic services”	R9-22-102
“Director”	R9-22-101
“Disabled”	R9-22-115
“Discussions”	R9-22-106
“Disenrollment”	R9-22-117

Arizona Administrative Register
Notices of Final Rulemaking

“District”	R9-22-109
“DME”	R9-22-102
“DRI inflation factor”	R9-22-107
“E.P.S.D.T. services”	R9-22-102
“Eligible person”	A.R.S. § 36-2901
“Emergency medical condition”	Section 1903(v) of the Social Security Act
“Emergency medical services”	R9-22-102
“Encounter”	R9-22-107
“Enrollment”	R9-22-117
“Enumeration”	R9-22-101
“Equity”	R9-22-101
“Error”	R9-22-109
“FAA”	R9-22-114
“Facility”	R9-22-101
“Factor”	R9-22-101
“FBR”	R9-22-101
“FESP”	R9-22-101
“Finding”	R9-22-109
“First-party liability”	R9-22-110
“Foster care maintenance payment”	41 U.S.C. 675(4)(A) 42 U.S.C. 675(4)(A)
“Federal poverty level” (“FPL”)	A.R.S. § 1-215
“FQHC”	R9-22-101
“Grievance”	R9-22-108
“GSA”	R9-22-101
“Health care practitioner”	R9-22-112
“Hearing”	R9-22-108
“Hearing aid”	R9-22-102
“Home health services”	R9-22-102
“Homebound”	R9-22-114
“Hospital”	R9-22-101
“ICU”	R9-22-107
“IHS”	R9-22-117
“TMD”	R9-22-112
“Income”	R9-22-114
“Inmate of a public institution”	42 CFR 435.1009
“Interested party”	R9-22-106
“LEEP”	R9-22-120
“License” or “licensure”	R9-22-101
“Mailing date”	R9-22-114
“Management evaluation review”	R9-22-109
“Medical education costs”	R9-22-107
“Medical expense deduction”	R9-22-114
“Medical record”	R9-22-101
“Medical review”	R9-22-107
“Medical services”	R9-22-101 A.R.S. § 36-401
“Medical supplies”	R9-22-102
“Medical support”	R9-22-114
“Medically necessary”	R9-22-101
“Medicare claim”	R9-22-107
“Medicare HMO”	R9-22-101
“Member”	R9-22-101 A.R.S. § 36-2901
“Mental disorder”	R9-22-112 A.R.S. § 36-501
“New hospital”	R9-22-107
“Nursing facility” (“NF”)	R9-22-101 42 U.S.C. 1396r(a)
“NICU”	R9-22-107
“Noncontracting provider”	A.R.S. § 36-2901
“Nonparent caretaker relative”	R9-22-114
“Notice of Findings”	R9-22-109
“OAH”	R9-22-108

Notices of Final Rulemaking

“Occupational therapy”	R9-22-102
“Offeror”	R9-22-106
“Ownership interest”	<u>42 CFR 455.101</u>
“Operating costs”	R9-22-107
“Outlier”	R9-22-107
“Outpatient hospital service”	R9-22-107
“Ownership change”	R9-22-107
“Partial Care”	R9-22-112
“Party”	R9-22-108
“Peer group”	R9-22-107
“Performance measures”	R9-22-109
“Pharmaceutical service”	R9-22-102
“Physical therapy”	R9-22-102
“Physician”	R9-22-102
“PPC”	<u>R9-22-107</u>
“Post-stabilization care services”	42 CFR 438.114 <u>42 CFR 422.113</u>
“Practitioner”	R9-22-102
“Pre-enrollment process”	R9-22-114
“Preponderance of evidence”	R9-22-109
“Prescription”	R9-22-102
“Primary care provider”	R9-22-102
“Primary care provider services”	R9-22-102
“Prior authorization”	R9-22-102
“Private duty nursing services”	R9-22-102
“Proposal”	R9-22-106
“Prospective rates”	R9-22-107
“Prospective rate year”	R9-22-107
“Prudent layperson standard”	42 U.S.C. 1396u-2
“Psychiatrist”	R9-22-112
“Psychologist”	R9-22-112
“Psychosocial rehabilitation services”	R9-22-112
“Qualified alien”	A.R.S. § 36-2903.03
“Quality management”	R9-22-105
“Radiology services”	R9-22-102
“Random sample”	R9-22-109
“RBHA”	R9-22-112
“Rebasing”	R9-22-107
“Referral”	R9-22-101
“Rehabilitation services”	R9-22-102
“Reinsurance”	R9-22-107
“Resources”	R9-22-114
“Respiratory therapy”	R9-22-102
“Respondent”	R9-22-108
“Responsible offeror”	R9-22-106
“Responsive offeror”	R9-22-106
“Review”	R9-22-114
“Review period”	R9-22-109
“RFP”	R9-22-106
“Scope of services”	R9-22-102
“SDAD”	R9-22-107
“Section 1115 Waiver”	A.R.S. § 36-2901
“Service location”	R9-22-101
“Service site”	R9-22-101
“SESP”	R9-22-101
“S.O.B.R.A.”	R9-22-101
“Specialist”	R9-22-102
“Specified relative”	R9-22-114
“Speech therapy”	R9-22-102
“Spendthrift restriction”	R9-22-114

Arizona Administrative Register
Notices of Final Rulemaking

“Spouse”	R9-22-101
“SSA”	PL. 103-296, Title I <u>42 CFR 1000.10</u>
“SSI”	R9-22-101 <u>42 CFR 435.4</u>
“SSN”	R9-22-101
“Sterilization”	R9-22-102
“Subcontract”	R9-22-101
“Summary report”	R9-22-109
“SVES”	R9-22-114
“Third-party”	R9-22-110
“Third-party liability”	R9-22-110
“Tier”	R9-22-107
“Tiered per diem”	R9-22-107
“Title IV-D”	R9-22-114
“Title IV-E”	R9-22-114
“Title XIX”	<u>42 U.S.C. 1396</u>
“Title XXI”	<u>42 U.S.C. 1397aa</u>
“Tolerance level”	R9-22-109
“Total inpatient hospital days”	R9-22-107
“Utilization management”	R9-22-105
“WWHP”	R9-22-120

B. General definitions. In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

- “AHCCCS” means the Arizona Health Care Cost Containment System, which is composed of the Administration, contractors, and other arrangements through which health care services are provided to a member.
- “Applicant” means a person who submits or whose authorized representative submits, a written, signed, and dated application for AHCCCS benefits.
- “Application” means an official request for AHCCCS medical coverage made under this Chapter.
- “Assignment” means enrollment of a member with a contractor by the Administration.
- “Capped fee-for-service” means the payment mechanism by which a provider of care is reimbursed upon submission of a valid claim for a specific AHCCCS-covered service and equipment provided to a member. A payment is made in accordance with an upper, or capped, limit established by the Director.
- “Case record” means ~~the~~ an applicant’s or member’s file and all documents in the file that are used to establish eligibility.
- “Categorically-eligible” means a person who is eligible under A.R.S. §§ 36-2901(i), (ii), or (iii) and 36-2934.
- “CMS” means the Centers for Medicare and Medicaid Services.
- “Continuous stay” means the period during which a member receives inpatient hospital services without interruption beginning with the date of admission and ending with the date of discharge or date of death.
- “Contract” means a written agreement entered into between a person, an organization, or other entity and the Administration to provide health care services to a member under A.R.S. Title 36, Chapter 29, and ~~these rules~~ this Chapter.
- “Day” means a calendar day unless otherwise specified ~~in the text~~.
- “DES” means the Department of Economic Security.
- “Director” means the Director of the Administration or the Director’s designee.
- “Eligible person” means ~~the~~ a person as defined in A.R.S. § 36-2901.
- “Enumeration” means the assignment of a specific nine-digit identification number to a person by the Social Security Administration.
- “Equity” means the county assessor full cash or market value of a resource minus valid liens, encumbrances, or both.
- “Facility” means a building or portion of a building licensed or certified by the Arizona Department of Health Services as a health care institution, under A.R.S. Title 36, Chapter 4, to provide a medical service, a nursing service, or other health care or health-related ~~services~~ service.
- “Factor” means an organization, a collection agency, a service bureau, or a person who advances money to a provider for accounts receivable that the provider assigns, sells, or otherwise transfers, including transfers through the use of a power of attorney, to the organization, the collection agency, the service bureau, or the person that receives an added fee or a deduction of a portion of the face value of the accounts receivable in return for the advanced money. The term “factor” does not include a business representative, such as a bailing agent or an accounting firm described ~~within these rules~~ in this Chapter, or a health care institution.
- “FBR” means Federal Benefit Rate, the maximum monthly Supplemental Security Income payment rate for a member or a married couple.
- “FESP” means a federal emergency services program covered under R9-22-217, to treat an emergency medical condition for a member who is determined eligible under A.R.S. § 36-2903.03(D).

Arizona Administrative Register
Notices of Final Rulemaking

“FQHC” means federally qualified health center.

“GSA” means a geographical service area designated by the Administration within which a contractor ~~of record~~ provides, directly or through a subcontract, a covered health care service to a member enrolled with that contractor of record.

“Hospital” means a health care institution that is licensed as a hospital by the Arizona Department of Health Services under A.R.S. Title 36, Chapter 4, Article 2, and certified as a provider under Title XVIII of the Social Security Act, as amended, or is currently determined, by the Arizona Department of Health Services as the CMS designee, to meet the requirements of certification.

~~“Inmate of a public institution” means a person defined by 42 CFR 435.1009.~~

“License” or “licensure” means a nontransferable authorization that is awarded based on established standards in law, is issued by a state or a county regulatory agency or board, and allows a health care provider to lawfully render a health care service lawfully.

“Medical record” means all documents that relate to medical and behavioral health services provided to a member by a physician or other licensed practitioner of the healing arts and that are kept at the site of the provider.

~~“Medical services” means health care services provided to a member by a physician, a practitioner, a dentist, or by a health professional and technical personnel under the direction of a physician, a practitioner, or a dentist.~~

“Medically necessary” means a covered service provided by a physician or other licensed practitioner of the healing arts ~~and~~ within the scope of practice under state law to prevent disease, disability, ~~and~~ or other adverse health conditions or their progression, ~~or~~ or prolong life.

“Medicare HMO” means a health maintenance organization that has a current contract with Centers for Medicare and Medicaid for participation in the Medicare program under 42 CFR 417(L).

~~“Member” is defined in A.R.S. § 36-2901.~~

~~“NF” means a nursing facility defined in 42 U.S.C. 1396r(a).~~

~~“Noncontracting provider” is defined in A.R.S. § 36-2901.~~

“Referral” means the process by which a member is directed by a primary care provider or an attending physician to another appropriate provider or resource for diagnosis or treatment.

“Service location” means ~~any~~ a location at which a member obtains ~~any~~ a covered health care service provided by a ~~contractor of record~~ physician or other licensed practitioner of the healing arts under the terms of a contract.

“Service site” means a location designated by a contractor ~~of record~~ as the location at which a member is to receive covered health care services.

“SESP” means state emergency services program covered under R9-22-217 to treat an emergency medical condition for a qualified alien or noncitizen who is determined eligible under A.R.S. § 36-2901.06.

“S.O.B.R.A.” means Section 9401 of the Sixth Omnibus Budget Reconciliation Act, 1986, amended by the Medicare Catastrophic Coverage Act of 1988, 42 U.S.C. 1396a(a)(10)(A)(i)(IV), 42 U.S.C. 1396a(a)(10)(A)(i)(VI), and 42 U.S.C. 1396a(a)(10)(A)(i)(VII).

“Spouse” means ~~the husband or wife~~ a person who has entered into a contract of marriage, recognized as valid by Arizona.

~~“SSA” means Social Security Administration under P.L. 103-296, Title I.~~

~~“SSI” means Supplemental Security Income under Title XVI of the Social Security Act, as amended.~~

“SSN” means social security number.

“Subcontract” means an agreement entered into by a contractor with any of the following:

A provider of health care services who agrees to furnish covered services to a member;

A marketing organization; or

Any other organization or person who agrees to perform any administrative function or service for a contractor specifically related to securing or fulfilling the contractor’s obligation to the Administration under the terms of a contract.

R9-22-107. Standard for Payments Related Definitions

In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

1. “Accommodation” means ~~the~~ bed and board services provided to a patient during an inpatient hospital stay and includes the cost of all staffing, supplies, and equipment. The accommodation is ~~typically~~ semi-private except when the member must be isolated for medical reasons. Other types of accommodation include hospital routine medical/surgical units, intensive care units, and any other specialty care unit in which bed and board are provided.
2. “Aggregate” means the combined amount of hospital payments for covered services provided within and outside the service area.
3. “AHCCCS inpatient hospital day or days of care” means the period of time beginning with the day of admission and includes each day of an inpatient stay for an eligible person, including the day of death, but excluding the day of discharge, provided that all medical necessity and medical review requirements are met.

Arizona Administrative Register
Notices of Final Rulemaking

4. "Ancillary department" means the department of a hospital that provides ancillary services and outpatient services, which are defined in the Medicare Provider Reimbursement Manual.
5. "Billed charges" means charges that a hospital includes on a claim for providing hospital services to an eligible person or member consistent with the rates and charges filed by the hospital with the Arizona Department of Health Services.
6. "Capital costs" means capital-related costs, which are defined in the Medicare Provider Reimbursement Manual, Chapter 28, such as building and fixtures, and movable equipment.
7. "Clean claim" ~~has the meaning in A.R.S. § 36-2904.~~
8. "Copayment" means a monetary amount, specified by the Director, that a member pays directly to a contractor or provider at the time covered services are rendered.
9. "Cost-to-charge ratio" means a hospital's costs for providing covered services divided by the hospital's covered charges for the same services.
10. "Covered charges" means billed charges that represent medically necessary, reasonable, and customary items of expense for AHCCCS-covered services that meet medical review criteria of the Administration or contractor.
11. "CPT" means current procedural terminology, the manual published and updated by the American Medical Association, which is a nationally accepted listing of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians and provides a uniform language ~~that will~~ to accurately designate medical, surgical, and diagnostic services.
12. "DRI inflation factor" means the Data Resources Inc., Health Care Financing Administration-~~type~~-hospital input price index for prospective hospital reimbursement, which is published by DRI/McGraw-Hill.
13. "Encounter" means a record of medical service, submitted by a contractor and processed by AHCCCS, that is rendered by a provider registered with AHCCCS to a member who is enrolled with the contractor on the date of service, and for which the contractor incurs any financial liability.
14. "ICU" means the intensive care unit of a hospital.
15. "Medical education costs" means direct hospital costs for intern and resident salaries, ~~fringes fringe benefits, and~~ program costs, nursing school education, and paramedical education, which ~~is~~ are defined in the Medicare Provider Reimbursement Manual, Chapter 28.
16. "Medical review" means a review involving clinical judgment of a claim or a request for a service before or after it is paid or rendered to ensure that services provided to an eligible person or member are medically necessary ~~and~~ covered services and that required authorizations are obtained by the provider. The criteria for medical review are established by the Administration or contractor based on medical practice standards that are updated periodically to reflect changes in medical care.
17. "Medicare claim" means a claim for Medicare covered services for an eligible person or member with Medicare coverage.
18. "New hospital" means ~~any~~ a hospital for which Medicare Cost Report (Health Care Finance Administration form-2552) data and claim and encounter data are not available for hospital rate development from any owner or operator of the hospital, during either the initial prospective rate year or rebasing.
19. "NICU" means the neonatal intensive care unit of a hospital that ~~has been~~ is classified as a Level II or Level III perinatal center by the Arizona Perinatal Trust.
20. "Operating costs" means an AHCCCS allowable accommodation and ancillary department hospital costs excluding capital and medical education costs.
21. "Outlier" means a hospital claim or encounter in which the AHCCCS inpatient hospital days of care have operating costs per day that meet the criteria described in R9-22-712.
22. "Outpatient hospital service" means a service provided in an outpatient hospital setting that does not result in an admission.
23. "Ownership change" means a change in a hospital's owner, lessor, or operator as defined in 42 CFR 489.18(A).
24. "Peer group" means hospitals that share a common, stable, and independently definable characteristic or feature that significantly influences the cost of providing hospital services.
"PPC" means prior period coverage. PPC is the period of time, prior to the member's enrollment, during which a member is eligible for covered services. The time-frame is the first day of the month of application or the first eligible month, whichever is later to the day a member is enrolled with a contractor.
25. "Prospective rates" means inpatient or outpatient hospital rates defined by the Administration in advance of a payment period and representing full payment for covered services excluding any quick-pay discounts, slow-pay penalties, non-categorical discounts, and ~~1st first-~~ and ~~3rd third-~~ party payments regardless of billed charges or individual hospital costs.
26. "Prospective rate year" means the period from October 1 of each year to September 30 of the following year, except for the initial prospective rate year, which is between March 1, 1993, and September 30, 1994.

- 27. "Rebasing" means the process by which new Medicare Cost Report data (HCFA-2552); and AHCCCS claim; and encounter data are collected and analyzed to reset periodically the inpatient hospital tiered per diem rates or the outpatient hospital cost-to-charge ratios.
- 28. "Reinsurance" means a risk-sharing program provided by the Administration to contractors for the reimbursement of certain contract service costs incurred by a member or eligible person beyond a certain monetary threshold.
- 29. "SDAD" means same day admit and discharge, which is a hospital stay with the admit and discharge occurring on the same calendar day.
- 30. "Tier" means a grouping of inpatient hospital services into levels of care based on diagnosis, procedure or revenue codes, peer group, or NICU classification level, or any combination of these items.
- 31. "Tiered per diem" means a payment structure in which payment is made on a per-day basis depending upon the tier into which an AHCCCS inpatient hospital day of care is assigned.
- 32. "Total inpatient hospital days" means the total number of days, including all hospital subprovider and nursery days, from the Medicare Cost Report for all payors. Observation days and swing bed days are not included.

ARTICLE 4. ~~CONTRACTS, ADMINISTRATION, AND STANDARDS~~ REPEALED

R9-22-401. General Repealed

- ~~A. A contract to provide services under AHCCCS shall be established between the Administration and a qualified provider of health care in conformance with the requirements in this Article. A contract and a subcontract entered into according to this Article is a public record and shall be on file with the Administration as specified in selected provisions of 42 and 45 CFR, as of October 1, 1995. These citations are incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~B. A contractor shall not knowingly have a director, an officer, a partner, or a person with ownership of more than 5% of a contractor's equity who has been debarred or suspended by any federal agency specified in 42 U.S.C. 1396u-2, as of August 5, 1997, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.~~
- ~~C. The Administration shall certify a contractor as a risk-bearing entity as specified in A.R.S. § 36-2903, as specified in RFP and contract, and as specified in 42 U.S.C. 1396b(m), as of August 5, 1997, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.~~

R9-22-402. Contracts Repealed

- ~~A. Each contract between the Administration and a contractor shall be in writing and contain at least the following information:
 - 1. The method and amount of compensation or other consideration to be received by the contractor.
 - 2. The name and address of the contractor.
 - 3. The population to be covered by the contract.
 - 4. The amount, duration, and scope of medical services to be provided, or for which compensation will be paid.
 - 5. The term of the contract, including the beginning and ending dates, as well as methods of extension, renegotiation, and termination.
 - 6. A provision that the Director or the Secretary of the U.S. Department of Health and Human Services may evaluate, through inspection or other means, the quality, appropriateness, or timeliness of services performed under the contract.
 - 7. A description of patient, medical, and cost recordkeeping systems and a provision that the Director or the Secretary of the U.S. Department of Health and Human Services may audit and inspect any of the contractor's records that pertain to services performed and determinations of amounts payable under the contract. These records shall be maintained by the contractor for 5 years from the date of final payment or, for records relating to costs and expenses to which the Administration has taken exception, 5 years after the date of final disposition or resolution of the exception.
 - 8. A provision to retain a specified percentage of periodic payments to the contractor, provide a reserve fund, or use another means to adjust the payments made to the contractor, based on utilization efficiency, including incentives for maintaining quality care and minimizing unnecessary inpatient services. This provision applies only to capped fee-for-service and AHCCCS-assembled network contractors and providers participating in a risk retention fund under R9-22-714.
 - 9. A provision that the contractor maintain all forms, records, and statistical information required by the Director for purposes of audit and program management. This material, including files, correspondence, and related information pertaining to services rendered or claims for payments is subject to inspection and copying by the Administration and the U.S. Department of Health and Human Services during normal business hours at the place of business of the person or organization maintaining the materials.
 - 10. A provision that the contractor safeguard information.
 - 11. Any activities to be performed by the contractor affecting categorically eligible members that are related to 3rd-party liability requirements prescribed in 42 CFR 433, Subpart D, as of October 1, 1995, which is incorporated by reference~~

Arizona Administrative Register
Notices of Final Rulemaking

and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

12. Functions that may be subcontracted, including a provision that any subcontract meets the requirements of 42 CFR 434.6(b), as of October 1, 1995, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
 13. A provision that the contractor arrange for the collection of any required co-payment.
 14. A provision that the contractor will not bill or attempt to collect from a member for any covered service except as may be authorized by statute or these rules.
 15. A provision that the contract will not be assigned or transferred without the prior written approval of the Director.
 16. Procedures for enrollment or re-enrollment of the covered population.
 17. Procedures and criteria for terminating the contract.
 18. A provision that any cost-sharing requirements imposed for services furnished to members comply with 42 CFR 447.50 through 447.58, as of October 1, 1995, which are incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
 19. A provision that specifies the actuarial basis for computation of capitation fees.
 20. Procedures for terminating enrollment and choice of health professional.
 21. A provision that a contractor provide an internal grievance procedure that:
 - a. Is approved in writing by the Administration;
 - b. Provides prompt resolution; and
 - c. Ensures the participation of persons with authority to provide prompt resolution.
 22. A provision that the contractor maintain an internal quality management system consistent with A.R.S. § 36-2903 and R9-22-522.
 23. A provision that the contractor submit marketing plans, procedures, and materials to the Administration for approval under R9-22-505 before implementation.
 24. A statement that all representations made by a contractor or authorized representative are truthful and complete to the best of their knowledge.
 25. A provision that the contractor is responsible for all tax obligations, Worker's Compensation insurance, and all other applicable insurance coverage, for itself and its employees, and that the Administration has no responsibility or liability for any of the taxes or insurance coverage.
 26. A provision that the contractor agrees to comply with all applicable statutes and rules.
 27. A provision that the contractor agrees to comply with the requirements regarding laboratory tests as specified in A.R.S. § 36-2903.
- B.** Each contract shall include all provisions necessary to ensure compliance with the applicable requirements of 42 CFR 434, Subpart C, as of October 1, 1995, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

R9-22-403. Subcontracts Repealed

- A.** Approval. Any subcontract entered into by a contractor to provide covered services to AHCCCS members or any amendment to a subcontract shall be subject to review and approval by the Director. No subcontract alters the legal responsibility of a contractor to the Administration to ensure that all activities under the contract are carried out.
- B.** Subcontracts. Each subcontract shall be in writing and include:
1. That the subcontract is to be governed by, and construed in accordance with all laws, rules, and contractual obligations of the contractor.
 2. Provision to notify the Administration in the event the subcontract is amended or terminated.
 3. Provision that assignment or delegation of the subcontract is voidable unless prior written approval is obtained from the Administration.
 4. Provision to hold harmless the state, the Director, the Administration, and members in the event the contractor cannot or will not pay for covered services performed by the subcontractor.
 5. Provision that the subcontract and subcontract amendments are subject to review and approval by the Director as set forth in these rules and that a subcontract or subcontract amendment may be terminated, rescinded, or cancelled by the Director for a violation of these rules.
 6. Provision to hold harmless and indemnify the state, the Director, the Administration, and members against claim, liabilities, judgments, costs and expenses with respect to third parties, which may accrue against the state, the Director, the Administration, or members, through the negligence of the subcontractor.
 7. Provision that members are not to be held liable for payment to providers in the event of contractor's bankruptcy, in compliance with 42 CFR 434, Subpart C, as of October 1, 1995, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

8. ~~The requirements contained in R9-22-402(A)(1) through (A)(7), (A)(9), (A)(10), (A)(14), (A)(15), (A)(17), and (A)(24) through (A)(26) but substituting the term "subcontractor" wherever the term "contractor" is used.~~
- C. ~~Waiver. A contractor may submit a written request to the Administration requesting a waiver of the requirement that the contractor subcontract with a hospital in the contractor's service area. The request shall set forth the reasons a waiver is believed to be necessary and shall state all efforts the contractor has made to secure a subcontract. For good cause shown, the Administration may waive the hospital subcontract requirement. The Administration shall consider the following criteria in deciding whether to waive the hospital subcontract requirement:~~
1. ~~The number of hospitals in the service area.~~
 2. ~~The extent to which the contractor's primary care physicians have staff privileges at noncontracting hospitals in the service area.~~
 3. ~~The size and population of, and the demographic distribution within, the service area.~~
 4. ~~Patterns of medical practice and care within the service area.~~
 5. ~~Whether the contractor has diligently attempted to negotiate a hospital subcontract in the service area.~~
 6. ~~Whether the contractor has any subcontracts in adjoining service areas with hospitals that are reasonably accessible to the contractor's members in the service area.~~
 7. ~~Whether the contractor's members can reasonably be expected to receive all covered services in the absence of a hospital subcontract.~~

R9-22-404. Contract Amendments, Mergers, Reorganizations Repealed

~~Any merger, reorganization, or change in ownership of a contractor shall require that the contractor submit the contract between the Administration and the contractor for amendment and prior approval by the Director. Additionally, any merger, reorganization, or change in ownership of a subcontractor that is related to or affiliated with the contractor shall constitute a contract amendment which requires the prior approval of the Director. To be effective, contract amendments shall be in writing and executed by the Director.~~

R9-22-405. Suspension, Denial, Modification, or Termination of Contract Repealed

- A. ~~General. The Director may suspend, deny, refuse or fail to renew, or terminate a contract or subcontract for good cause which may include the following reasons:~~
1. ~~Submitting any misleading, false, or fraudulent information with a claim for payment.~~
 2. ~~Submitting false information for the purpose of obtaining greater compensation than that to which the contractor is legally entitled.~~
 3. ~~Submitting an inaccurate or incomplete representation in the bidding process.~~
 4. ~~Failing to disclose or make available to the Administration, or its authorized representatives, records of services provided to eligible persons or members and records of payment made for the services.~~
 5. ~~Submitting false information for the purpose of obtaining authorization to provide services requiring authorization.~~
 6. ~~Over-providing services or delivering unnecessary services by inducing or otherwise causing an eligible person or member to receive services or items not required by the person or member or by directly furnishing the services or items.~~
 7. ~~Providing any services in violation of or not authorized by or otherwise precluded by licensure, certification, or other law.~~
 8. ~~Breaching the terms or conditions of a contract.~~
 9. ~~Having a member of the board, administrator, manager, or participating physician of a contractor convicted of a felony.~~
 10. ~~Giving or accepting a rebate, kickback, or fee or portion of a fee, or charging for referral of an eligible person or member.~~
 11. ~~Violating any provision of A.R.S. Title 36, Chapter 29, Title XIX of the Social Security Act, as amended, or any state or federal rule promulgated under those statutes.~~
 12. ~~Demonstrating an inability to perform obligations under a contractor agreement by prior conduct.~~
 13. ~~Being determined to have substantially breached a previous or existing contract agreement with another state agency.~~
 14. ~~Being previously found ineligible to participate in federal or state assembled medical programs by the Administration or any other state or federal governmental agency.~~
 15. ~~Failing to reimburse a subcontracting or noncontracting provider utilized by referral for the provision of medically necessary health care services to the contractor's members within 60 days of receipt of a valid claim unless a different period is specified by contract, or failing to ensure that future claims will be paid.~~
 16. ~~Failing to reimburse a noncontracting provider or nonprovider for the provision of emergency medical services provided to the contractor's members within 60 days of receipt of a valid claim, or failing to ensure that future claims will be timely paid.~~
 17. ~~Failing to provide and maintain quality health care service to eligible persons and members, as determined by standards established by state and federal statute or regulations.~~

Arizona Administrative Register
Notices of Final Rulemaking

18. Being determined to be endangering or to have endangered either, by omission or commission, the health, safety, or well-being of an eligible person or member.
 19. Becoming insolvent, or filing proceedings in bankruptcy or reorganization under the United States Code, or assigning rights or obligations under the contract without the prior written consent of the Administration.
 20. Failing or refusing to comply with the reporting or disclosure requirement of 42 CFR 455, Subpart B, as of October 1, 1995, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
 21. Being determined to have committed fraud or abuse in accordance with 42 CFR 455, Subpart A, as of October 1, 1995, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
 22. Being convicted of a criminal offense related to involvement in any program under Medicare, Medicaid, or Title XX of the Social Security Act of any person who has an ownership or control interest in the contractor or subcontractor, or is an agent or managing employee of the contractor or subcontractor.
 23. Failing to conform to and abide by the applicable laws or rules of Arizona, the United States federal government and the Administration.
- B.** Modification and termination of the contract without cause. The contract may be modified or terminated at any time by mutual consent of the Administration and contractor. Additionally, the Administration may terminate or suspend the contract in whole or in part without cause effective 30 days after mailing written notice of termination or suspension by certified mail, return receipt requested, to the contractor.
- C.** Notification. The Director shall provide the contractor written notice of intent to suspend, deny, fail to renew, or terminate a contract or related subcontract. The notice shall be provided to affected principals, enrolled members and other interested parties, and shall include the effective date of, and reason for, the action.
- D.** Records. All medical, financial, and other records shall be retained by a terminated contractor in accordance with federal and state laws and rules. Medical records or copies of medical records may be required to be submitted to the Director, or designee, within 10 working days of the effective date of contract termination.

R9-22-406. ~~Contract Compliance Sanction Alternative Repealed~~

- A.** Instead of using the sanctioning authority prescribed in R9-22-405, the Director may impose 1 or more of the following sanctions upon a contractor that violates any provision of these rules or of an AHCCCS contract:
1. Suspend any or all further member enrollment, by choice or assignment, for a period of time commensurate with the nature, term, and severity of the violation.
 2. Withhold a percentage of the contractor's capitation prepayment, commensurate with the nature, term, and severity of the violation.
- B.** The Director shall provide a contractor with written notice specifying the sanction alternative, grounds for the sanction, and either the length of suspension or the amount of prepayment to be withheld.
- C.** Nothing contained in this Section shall be construed to prevent the Administration from imposing sanctions provided for by contract.

ARTICLE 6. ~~REQUEST FOR PROPOSALS (RFP) RFP AND CONTRACT PROCESS~~

R9-22-601. General Provisions

- A.** This Article applies to the expenditure of all public monies by the Administration for covered services under Articles 2 and 12 except as otherwise provided by law. The Administration shall ensure that it has conflict-of-interest safeguards for officers and employees of the state with responsibilities relating to contracts specified in 42 U.S.C. 1396u-2(d)(3), August 5, 1997, incorporated by reference and on file with the Administration and the Secretary of State. This incorporation by reference contains no future editions or amendments.
- B.** If it is deemed by the Administration to be in the best interest of the state, the Administration may cancel an RFP or reject any and all proposals, in whole or in part, as specified in the RFP. The reasons for cancellation or rejection shall be part of the contract file. An offeror shall have no right to damages for any claims against the state, the state's employees, or agents if an RFP is cancelled or if a proposal is rejected in whole or in part.
- C.** The Administration may conduct an investigation of a person or organization who has ownership or management interests defined within 42 CFR 455.101, in corporate offerors and affiliated corporate organizations of an offeror. 42 CFR 455.101, September 30, 1986, is incorporated by reference and on file with the Administration and the Secretary of State. This incorporation by reference contains no future editions or amendments.
- D.** A proposal may be opened publicly and the name of the offeror announced and recorded. All other information contained in a proposal shall be confidential. A proposal shall be open for public inspection after contract award unless the Administration determines that disclosure is not in the best interest of the state.
- E.** Failure by an offeror to supply information requested by the Administration is sufficient basis for rejection of the offeror's proposal by the Administration.
- F.** Disclosure of information pertaining to an offeror's proposal by the offeror to any other offeror or person prior to contract award is prohibited and may be grounds for rejecting a proposal.

- A. The Director has full operational authority to adopt rules for the RFP process and the award of contracts under A.R.S. § 36-2906.
- B. This Article applies to the expenditure of all public monies by the Administration for covered services under Articles 2 and 12 of this Chapter except as otherwise provided by law. The Administration shall establish conflict-of-interest safeguards for officers and employees of this state with responsibilities relating to contracts that comply with 42 U.S.C. 1396u-2(d)(3).
- C. The Administration shall award contracts under A.R.S. §§ 36-2904 and 36-2906 to provide services under A.R.S. § 36-2907.
- D. The Administration is exempt from the procurement code under A.R.S. § 41-2501.
- E. The Administration and contractors shall retain all contract records for five years under A.R.S. § 36-2903 and dispose of the records under A.R.S. § 41-2550.

R9-22-602. Request for Proposals (RFP); Contract Award RFP

- A. RFP content. The following items shall be included in an RFP:
 - 1. The instructions and information to an offeror concerning the proposal submission requirements, including:
 - a. The deadline for submitting a proposal;
 - b. The address of the office at which a proposal is to be received;
 - c. The period during which the RFP shall remain open, and
 - d. Any special instructions and information;
 - 2. The service description, covered populations, geographic coverage, and a delivery or performance schedule;
 - 3. The contract terms and conditions, including bonding or other security requirements, if applicable;
 - 4. The factors used to evaluate a proposal;
 - 5. The location of and method of obtaining documents that are incorporated by reference;
 - 6. A requirement that the offeror acknowledge receipt of all RFP amendments issued by the Administration;
 - 7. The type of contract to be used and a copy of a proposed contract form or provisions;
 - 8. The length of the contract service;
 - 9. A requirement for cost or pricing data;
 - 10. The minimum RFP requirements; and
 - 11. A provision requiring an offeror to certify that the submission of a proposal does not involve collusion or other anti-competitive practices.
- B. Evaluation of a proposal:
 - 1. The Administration shall evaluate a proposal based on the evaluation factors listed in the RFP.
 - 2. The Administration may initiate discussions with a responsive and responsible offeror to clarify and assure full understanding of an offeror's proposal. The Administration shall provide an offeror fair treatment with respect to discussion and revision of a proposal. The Administration shall not disclose information derived from a proposal submitted by a competing offeror.
 - 3. The Administration may issue a written request for best and final offers. The request shall state the date, time, and place for the submission of best and final offers.
 - 4. Best and final offers may be requested only once unless the Administration determines that it is advantageous to the state to request additional best and final offers. The written request for best and final offers shall inform the offeror that if the offeror does not submit a notice of withdrawal or a best and final offer, the immediate previous offer shall be construed as the offeror's best and final offer.
 - 5. The Administration shall provide written notification to an offeror whose proposal is rejected. The rejection notice shall be part of the contract file and public record.
- C. Contract award. The Administration shall award the contract to the responsible and responsive offeror whose proposal is deemed most advantageous to the state. If the Administration determines that multiple contracts are in the best interest of the state, the Administration may award multiple contracts. The contract file shall contain the basis on which the award is made.
- A. RFP content. The Administration shall include the following items in any RFP under this Article:
 - 1. Instructions and information to an offeror concerning the proposal submission including:
 - a. The deadline for submitting a proposal.
 - b. The address of the office at which a proposal is to be received.
 - c. The period during which the RFP remains open, and
 - d. Any special instructions and information;
 - 2. The scope of covered services under Article 2 of this Chapter and A.R.S. §§ 36-2906 and 36-2907, covered populations, geographic coverage, service and performance requirements, and a delivery or performance schedule;
 - 3. The contract terms and conditions, including bonding or other security requirements, if applicable;
 - 4. The factors used to evaluate a proposal;
 - 5. The location and method of obtaining documents that are incorporated by reference in the RFP;
 - 6. A requirement that the offeror acknowledge receipt of all RFP amendments issued by the Administration;

Arizona Administrative Register
Notices of Final Rulemaking

7. The type of contract to be used and a copy of a proposed contract form or provisions;
8. The length of the contract service;
9. A requirement for cost or pricing data;
10. The minimum RFP requirements; and
11. A provision requiring an offeror to certify that a submitted proposal does not involve collusion or other anti-competitive practices.

B. Proposal process.

1. After the deadline for submitting proposals, the Administration may open a proposal publicly and announce and record the name of the offeror. The Administration shall keep all other information contained in a proposal confidential. The Administration shall open a proposal for public inspection after contract award unless the Administration determines that disclosure is not in the best interest of the state.
2. The Administration shall evaluate a proposal based on the GSA and the evaluation factors listed in the RFP.
3. The Administration may initiate discussions with a responsive and responsible offeror to clarify and assure full understanding of an offeror's proposal. The Administration shall provide an offeror fair treatment with respect to discussion and revision of a proposal. The Administration shall not disclose information derived from a proposal submitted by a competing offeror.
4. The Administration shall allow for the adjustment of covered services by expansion, deletion, segregation, or combination in order to secure the most financially advantageous proposals for the state.
5. The Administration may conduct an investigation of a person or organization who has ownership or management interests in corporate offerors or affiliated corporate organizations of an offeror.
6. The Administration may issue a written request for best and final offers. The Administration shall state in the request the date, time, and place for the submission of best and final offers.
7. The Administration shall not request best and final offers more than once unless the Administration determines that it is advantageous to the state to request additional best and final offers. The Administration shall state in the written request for best and final offers that if the offeror does not submit a notice of withdrawal or a best and final offer, the Administration shall take the most recent offer as the offeror's best and final offer.

C. Proposal rejection.

1. The Administration may reject an offeror's proposal if the offeror fails to supply the information requested by the Administration.
2. The offeror shall not disclose information pertaining to its proposal to any other offeror prior to contract award. The offeror may disclose proposal information to a person other than another offeror if the recipient agrees to keep the information confidential until contract award. Disclosure in violation of this subsection may be grounds for rejecting a proposal.
3. The Administration shall provide written notification to an offeror whose proposal is rejected. The rejection notice shall be part of the contract file and a public record.
4. If the Administration determines that it is in the best interest of the state, the Administration may reject any and all proposals, in whole or in part, under the RFP. The reasons for rejection shall be part of the contract file. An offeror shall have no right to damages for any claims against the state, the state's employees, or agents if a proposal is rejected in whole or in part.

D. Proposal cancellation. If the Administration determines that it is in the best interest of the state, the Administration may cancel a RFP. The reasons for cancellation shall be part of the contract file. An offeror shall have no right to damages for any claims against the state, the state's employees, or agents if a RFP is cancelled.

R9-22-603. ~~Contract Records~~ Contract Award

~~All contract records shall be retained for a period of 5 years and disposed of under A.R.S. § 41-2550.~~

The Administration shall award a contract to the responsible and responsive offeror whose proposal is determined most advantageous to the state under A.R.S. § 36-2906. If the Administration determines that multiple contracts are in the best interest of the state, the Administration may award multiple contracts. The contract file shall contain the basis on which the award is made.

R9-22-604. Contract or Proposal Protests; Appeals

~~**A.** Grievances related to contract performance. This Section shall not apply to grievances related to contract performance. Any contract performance grievance shall be governed by R9-22-804.~~

~~**B.** Resolution of a proposal protest. The procurement officer issuing an RFP shall have the authority to resolve proposal protests. An appeal from the decision of the procurement officer shall be made to the Director.~~

~~**C.** Filing of a protest.~~

- ~~1. An interested party may file a protest with the procurement officer regarding:
 - a. An RFP issued by the Administration,
 - b. A proposed award, or
 - e. An award of a contract.~~

Arizona Administrative Register
Notices of Final Rulemaking

2. The protest shall be in writing and shall include the following information:
 - a. The name, address, and telephone number of the protester;
 - b. The signature of the protester or protester's representative;
 - c. Identification of an RFP or contract number;
 - d. A detailed statement of the legal and factual grounds of the protest including copies of any relevant documents; and
 - e. The relief requested.
- D.** Time for filing a protest.
 1. A protest based on alleged improprieties in an RFP shall be filed before the due date for receipt of proposals.
 2. A protest alleging improprieties that do not exist in the original RFP but are subsequently incorporated into the RFP before the due date for receipt of proposals shall be filed prior to the amended due date for receipt of proposals.
 3. In cases other than those covered in subsections (D)(1) and (2), a protest shall be filed within 10 days after the protester knows or should have known the basis of the protest.
- E.** Stay of procurements during the protest. If a protest is filed before the contract award, the procurement officer may issue a written stay of the contract award if:
 1. A reasonable probability exists that the protest will be sustained, and
 2. The stay of the contract award is not contrary to the best interest of the state.
- F.** Decision by the procurement officer.
 1. The procurement officer shall issue a written decision within 14 days after a protest has been filed. The decision shall contain an explanation of the basis of the decision.
 2. The procurement officer shall furnish a copy of the decision to the protester by:
 - a. Certified mail, return receipt requested; or
 - b. Any method that provides evidence of receipt.
 3. The Administration may extend, for good cause, the time limit for decisions in subsection (F)(1) for a time not to exceed 30 days. The procurement officer shall notify the protester in writing that the time for the issuance of a decision has been extended and the date by which a decision shall be issued.
 4. If the procurement officer fails to issue a decision within the time limits in subsection (F)(1) or (3) the protester may proceed as if the procurement officer issued an adverse decision.
- G.** Remedies.
 1. If the procurement officer sustains the protest in whole or in part and determines that the RFP, proposed contract award, or contract award does not comply with applicable statutes and rules, the procurement officer shall order an appropriate remedy.
 2. In determining an appropriate remedy, the procurement officer shall consider all the circumstances of the procurement or proposed procurement, including:
 - a. Seriousness of the procurement deficiency;
 - b. Degree of prejudice to other interested parties or to the integrity of the RFP process;
 - c. Good faith of the parties;
 - d. Extent of performance;
 - e. Costs to the state, and
 - f. Urgency of the procurement.
 3. An appropriate remedy may include 1 or more of the following:
 - a. Terminate the contract;
 - b. Reissue the RFP;
 - c. Issue a new RFP;
 - d. Award a contract consistent with statutes, rules, and the terms of the RFP; or
 - e. Any relief determined necessary to ensure compliance with applicable statutes and regulations.
- H.** Appeals to the Director.
 1. An interested party shall file an appeal from a decision by the procurement officer with both the Director and the procurement officer within 5 days from the date the decision is received. The date the decision is received shall be determined according to R9-22-604(F)(2).
 2. The appeal shall contain:
 - a. The information required in subsection (C)(2);
 - b. A copy of the decision of the procurement officer;
 - c. The alleged factual or legal error in the decision of the procurement officer on which the appeal to the Director is based, and
 - d. A request for hearing unless the interested party requests that the Director's decision be based solely upon the contract record.
- I.** Stay of contract award during an appeal to the Director. If an appeal is filed before a contract award and the contract award is stayed by the procurement officer under subsection (E), the filing of an appeal to the Director shall automatically con-

Arizona Administrative Register
Notices of Final Rulemaking

~~tinue the stay unless the Director issues a written determination that the contract award is necessary to protect the best interest of the state.~~

- ~~**J.** Dismissal. No appeal hearing shall be scheduled, and the Director shall dismiss an appeal with a written determination if:~~
- ~~1. The appeal does not state a basis for protest;~~
 - ~~2. The appeal is untimely under subsection (H), or~~
 - ~~3. The appeal is moot.~~
- ~~**K.** Hearing. Hearings requested under this rule shall be conducted under Article 8.~~
- A.** Disputes related to contract performance. This Section does not apply to a dispute related to contract performance. A contract performance dispute is governed by Article 8 of this Chapter.
- B.** Resolution of a proposal protest. The procurement officer issuing a RFP shall have the authority to resolve proposal protests. An appeal from the decision of the procurement officer shall be made to the Director.
- C.** Filing of a protest.
1. A person may file a protest with the procurement officer regarding:
 - a. A RFP issued by the Administration.
 - b. A proposed award, or
 - c. An award of a contract.
 2. A protester shall submit a written protest and include the following information:
 - a. The name, address, and telephone number of the protester;
 - b. The signature of the protester or protester's representative;
 - c. Identification of a RFP or contract number;
 - d. A detailed statement of the legal and factual grounds of the protest including copies of any relevant documents;
and
 - e. The relief requested.
- D.** Time for filing a protest.
1. A protester filing a protest alleging improprieties in a RFP shall file the protest before the due date for receipt of proposals.
 2. A protester filing a protest alleging improprieties that do not exist in the original RFP but are subsequently incorporated into the RFP before the due date for receipt of proposals shall file the protest prior to the amended due date for receipt of proposals.
 3. In cases other than those covered in subsections (D)(1) and (2), a protester shall file a protest within 10 days after the protester knows or should have known the basis of the protest.
- E.** Stay of procurement during the protest. If a protester files a protest before the contract award, the procurement officer may issue a written stay of the contract award. In considering whether to issue a written stay of contract, the procurement officer shall consider but is not limited to considering whether:
1. A reasonable probability exists that the protest will be sustained, and
 2. The stay of the contract award is in the best interest of the state.
- F.** Stay of contract award during an appeal to the Director. The Director shall automatically continue the stay of a contract award if:
1. An appeal is filed before a contract award, and
 2. The procurement officer issues a stay of the contract award under subsection (E), unless
 3. The Director issues a written determination that the contract award is necessary to protect the best interest of the state.
- G.** Decision by the procurement officer.
1. The procurement officer shall issue a written decision within 14 days after a protest has been filed. The decision shall contain an explanation of the basis of the decision.
 2. The procurement officer shall furnish a copy of the decision to the protester by:
 - a. Certified mail, return receipt requested; or
 - b. Any other method that provides evidence of receipt.
 3. The Administration may extend, for good cause, the time-limit for decisions in subsection (F)(1) for a time not to exceed 30 days. The procurement officer shall notify the protester in writing that the time for the issuance of a decision has been extended and the date by which a decision shall be issued.
 4. If the procurement officer fails to issue a decision within the time-limits in subsection (F)(1) or (3), the protester may proceed as if the procurement officer issued an adverse decision.
- H.** Remedies.
1. If the procurement officer sustains the protest in whole or in part and determines that the RFP, proposed contract award, or contract award does not comply with applicable statutes and rules, the procurement officer shall order an appropriate remedy.
 2. In determining an appropriate remedy, the procurement officer shall consider all the circumstances of the procurement or proposed procurement, including:
 - a. Seriousness of the procurement deficiency.

Notices of Final Rulemaking

- b. Degree of prejudice to other interested parties or to the integrity of the RFP process.
 - c. Good faith of the parties.
 - d. Extent of performance.
 - e. Costs to the state, and
 - f. Urgency of the procurement.
3. An appropriate remedy may include one or more of the following:
- a. Terminating the contract;
 - b. Reissuing the RFP;
 - c. Issuing a new RFP;
 - d. Awarding a contract consistent with statutes, rules, and the terms of the RFP; or
 - e. Any relief determined necessary to ensure compliance with applicable statutes and rules.

I. Appeals to the Director.

- 1. A person may file an appeal about a procurement officer's decision with both the Director and the procurement officer within five days from the date the decision is received. The date the decision is received shall be determined under subsection (F)(2).
- 2. The appeal shall contain:
 - a. The information required in subsection (C)(2).
 - b. A copy of the procurement officer's decision.
 - c. The alleged factual or legal error in the decision of the procurement officer on which the appeal to the Director is based, and
 - d. A request for hearing unless the person requests that the Director's decision be based solely upon the contract record.

J. Dismissal. The Director shall not schedule a hearing and shall dismiss an appeal with a written determination if:

- 1. The appeal does not state a basis for protest.
- 2. The appeal is untimely under subsection (H)(1), or
- 3. The appeal is moot.

K. Hearing. Hearings under this Section shall be conducted under R9-22-802 of this Chapter.

R9-22-605. Repealed Waiver of Contractor's Subcontract with Hospitals

If a contractor is unable to obtain a subcontract with a hospital, the contractor may request in writing a waiver from the Administration as allowed by A.R.S. § 36-2906. The contractor shall state in the request the reasons a waiver is believed to be necessary and all efforts the contractor has made to secure a subcontract. The Administration shall consider the following criteria in deciding whether to grant the waiver:

- 1. The number of hospitals in the GSA.
- 2. The extent to which the contractor's physicians have staff privileges at noncontracting hospitals in the service area.
- 3. The size and population of, and the demographic distribution within, the service area.
- 4. Patterns of medical practice and care within the service area.
- 5. Whether the contractor has diligently attempted to negotiate a hospital subcontract with local hospitals capable of serving members in the service area.
- 6. Whether the contractor has any subcontracts in adjoining service areas with hospitals that are reasonably accessible to the contractor's members in the service area, and
- 7. Whether the contractor's members can reasonably be expected to receive all covered services in the absence of a hospital subcontract.

R9-22-606. Contract Compliance Sanction

A. The Director may impose one or more of the following sanctions upon a contractor that violates any provision of this Chapter or of a contract:

- 1. Suspend any or all further member enrollment, by choice or assignment, for a period of time commensurate with the nature, term, and severity of the violation.
- 2. Withhold a percentage of the contractor's capitation prepayment, commensurate with the nature, term, and severity of the violation.

B. The Director shall consider the nature, severity, and length of the violation when determining a sanction.

C. The Director shall provide a contractor with written notice specifying grounds for the sanction which are commensurate with the nature, term, and severity of the violation and one or more of the following:

- 1. Length of suspension.
- 2. Amount to be forfeited, or
- 3. Prepayment to be withheld.

D. Nothing contained in this Section shall be construed to prevent the Administration from imposing sanctions as provided in contract under A.R.S. § 36-2903.

ARTICLE 7. STANDARDS FOR PAYMENTS

R9-22-701. Scope of the Administration's Liability, ~~Payments to Contractors~~

- A.** The Administration shall bear no liability for providing covered services to or completing a plan of treatment for any member or eligible person beyond the date of eligibility termination, ~~of the individual's eligibility or enrollment.~~
- B.** ~~The Administration shall make all payments to a contractor in accordance with the terms and conditions of the contract executed between the contractor and the Administration and in accordance with these rules.~~
- C.** ~~The Administration shall bear no liability for subcontracts that a contractor executes with other parties for the provision of administrative or management services, medical services, or covered health care services, or for any other purpose. A contractor shall indemnify and hold the Administration harmless from any and all liability arising from the contractor's subcontracts, shall bear all costs of defense of any litigation over the liability, and shall satisfy in full any judgment entered against the Administration in litigation involving the contractor's subcontracts.~~
- D.** ~~The Administration shall make capitation payments monthly to a contractor who meets the requirements in A.R.S. § 36-2903(N).~~

R9-22-709. Contractor's Liability to Hospitals for the Provision of Emergency and Subsequent Care

- A.** ~~For purposes of program and contractor liability, A contractor is liable for the cost of services for an emergency medical or acute mental health condition of a member shall be subject to reimbursement only until the member's condition is stabilized and the member is transferable, or until the member is discharged following stabilization subject to the requirements of A.R.S. § 36-2909(E) 36-2909 and Article 2 of these rules this Chapter.~~
- B.** Subject to subsection (A), if a member cannot be transferred following stabilization to a facility that has a subcontract with the contractor of record, the contractor of record shall pay for all appropriately documented, prior authorized, and medically necessary treatment provided to the member before the ~~date of discharge~~ discharge date or transfer ~~in accordance with payment standards in under R9-22-705.~~
- C.** If a member refuses transfer from a ~~nonprovider~~ noncontracting provider or noncontracting hospital to a hospital affiliated with the member's contractor of record, neither the Administration nor the contractor shall be liable for any costs incurred after the date of refusal if:
 - 1. After consultation with the member's contractor of record, the member continues to refuse the transfer; and
 - 2. The member has been provided and signs a written statement, before the ~~date of transfer of liability~~ the member is liable for payment, informing the member of the medical and financial consequences of refusing to transfer. If the member refuses to sign a written statement, a statement signed by 2 two witnesses indicating that the member was informed may be substituted.

R9-22-714. ~~Contractor risk retention fund (AHCCCS-assembled networks) Payments to Providers~~

~~Contractor risk pools may be established by the Administration for AHCCCS-assembled networks as follows:~~

- ~~1. Fifteen percent of the total capitation to be paid to primary care contractors may be retained by the Administration. If the Administration determines to do so, to prevent over utilization or other misuse of the system, 10% shall be deposited into an inpatient risk pool fund and 5% shall be deposited into a specialty care risk pool fund. Hospital utilization and the frequency of referrals shall be monitored on a monthly basis to compare actual utilization experience with targeted utilization. Utilization targets shall be identified in each network. If actual utilization is below such utilization targets, the entire amount within risk pools shall be returned to the primary care contractors on a quarterly basis. If actual utilization exceeds targets, the costs associated with such excess utilization shall be deducted by the Administration from the risk pools on a dollar for dollar basis. Any residual funds remaining in a risk pool shall be distributed to the primary care contractor on a quarterly basis.~~
- ~~2. Ten percent of the capitation paid to specialty care providers may be withheld by the Administration and deposited into an inpatient risk pool fund. If the Administration determines to do so to prevent over utilization or other misuse of the system, hospital utilization shall be monitored on a monthly basis to compare actual utilization experience with targeted utilization. Hospital utilization targets shall be identified in each network. If actual utilization is below utilization targets, the entire amount in the inpatient risk pool shall be returned to the specialty care contractor following the close of the contract year. If actual utilization exceeds targets, costs associated with excess utilization shall be deducted by the Administration from the risk pool on a dollar for dollar basis. Any residual funds remaining in the risk pool shall be distributed to the specialty care contractor, on a quarterly basis.~~
- A.** As a prerequisite for receiving reimbursement for covered services provided to a member, a provider shall sign a provider agreement with the Administration that establishes the terms and conditions of participation and payment under A.R.S. § 36-2904.
- B.** This subsection does not apply to reimbursement of emergency services and services provided during PPC under Article 2 of this Chapter.

R9-22-716. Specialty Contracts

~~The Director may at any time negotiate or contract on behalf of providers, noncontracting providers, and the Administration for specialized hospital and medical services including, but not limited to, neonatology, neurology, cardiology, and burn care.~~

Notices of Final Rulemaking

If the Director contracts for specialized services, contractors of record may be required to include the services within their delivery networks and make contractual modifications necessary to carry out this Section. Specialty contractors shall take precedence over all other contractual arrangements between contractors of record and their subcontractors. Specialty contractors may require interim payments to specialty contractors on behalf of contractors of record for contract services received by members. Interim payments to specialty contractors may be deducted from capitation payments, performance bonds, or other monies for payment on behalf of contractors of record. If the Administration and a hospital that performed a transplant surgery on an eligible person do not have a contracted rate, the system shall not reimburse the hospital more than the contracted rate established by the Administration.

The Director may contract with entities for specialized hospital and medical services including:

1. Neonatology.
2. Neurology.
3. Cardiology.
4. Burn care under A.R.S. § 36-2903.01, and
5. Transplant services.

R9-22-719. Contractor Performance Measure Outcomes

The Administration may retain a specified percentage of capitation reimbursement to distribute to contractors based on their performance measure outcomes under A.R.S. § 36-2904. The Administration shall notify contractors 60 days prior to a new contract year if this methodology is implemented. The Administration shall specify the details of the reimbursement methodology in contract.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

**CHAPTER 28. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)
ARIZONA LONG-TERM CARE SYSTEM**

PREAMBLE

1. Sections Affected

R9-28-101
Article 6
R9-28-601
R9-28-602
R9-28-603
R9-28-603
R9-28-604
R9-28-604
R9-28-605
R9-28-605
R9-28-606
R9-28-606
R9-28-607
R9-28-608
R9-28-701
R9-28-707
R9-28-710
R9-28-714
R9-28-715

Rulemaking Action

Amend
Amend
Amend
Amend
Repeal
New Section
Repeal
New Section
Repeal
New Section
Repeal
New Section
Repeal
Repeal
Amend
Amend
Repeal
New Section
New Section

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

Authorizing statutes: A.R.S. §§ 36-2932 and 36-2944
Implementing statutes: A.R.S. §§ 36-2932 and 36-2944

3. The effective date of the rules:

January 10, 2002

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

Notice of Rulemaking Docket Opening: 7 A.A.R. 3050, July 13, 2001
Notice of Proposed Rulemaking: 7 A.A.R. 3757, August 31, 2001

Arizona Administrative Register
Notices of Final Rulemaking

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

Name: Cheri Tomlinson, Federal & State Policy Administrator
Address: 801 East Jefferson
Mail Drop 4200
Phoenix, AZ 85034
Telephone: (602) 417-4198
Fax: (602) 256-6756

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

These rules define the contracts/request for proposal (RFP) process for AHCCCS' long term care program. The Administration is amending these rules to make the rules more clear, concise, and understandable by:

- grouping like concepts to provide clarity and conciseness to the rule language,
- deleting language that appropriately exists in contract rather than rule according to A.R.S. § 41-1005(A)(16),
- clarifying language that does not clearly present policies or procedures, and
- updating citations to documents incorporated in the rule, as needed.

Following is an explanation of the changes:

9 A.A.C. 28, Article 1, Definitions

The Administration modified, added, or deleted definitions to improve the clarity and conciseness of the rule language.

9 A.A.C. 28, Article 6, RFP and Contract Process

Amend

- R9-28-601 The Administration amended R9-28-601 to mirror the general provisions in R9-22-601 in content.
- R9-28-602 The Administration amended the title to "RFP" as well as adding an A.R.S. citation and correcting an A.A.C. citation.

New Section

The Administration added the following as new Sections to mirror 9 A.A.C. 22, Article 6:

- R9-28-603 "Contract Award," which refers to A.R.S. § 36-2944 and A.A.C. R9-22-603 for content.
- R9-28-604 "Contractor Proposal Protests; Appeals," which refers to A.A.C. R9-22-604 for content.
- R9-28-605 "Waiver of Contractor's Subcontract with Hospitals," which refers to A.A.C. R9-22-605 for content.
- R9-28-606 "Contract Compliance Sanction," which refers to A.A.C. R9-22-606 and the CFR and U. S. Code for content.

Repeal

- R9-28-607 The Administration has repealed this Article because it is more appropriately housed in contract per A.R.S. § 41-1005(A)(16).
- R9-28-608 The Administration has repealed this Section. Subsection "A" is already in rule in Article 4. Subsection "B" is incorporated in R9-28-606.

9 A.A.C. 28, Article 7, Standards for Payments

The Administration revised those Articles in Article 7 that pertained to contract.

- R9-28-701 The Administration amended the Article to contain only language that is appropriate to rule. The balance of the language was struck because it is more appropriately housed in contract per A.R.S. § 41-1005(A)(16).
- R9-28-707 The Administration amended the Article to refer the reader to A.R.S. § 36-2989, A.A.C. R9-22-709, R9-28-705 and Article 2 of Chapter 28 for content.
- R9-28-710 The Administration repealed this Article because the content is more appropriately housed in contract per A.R.S. § 41-1005(A)(16).
- R9-28-714 The Administration added "Payments to Providers" as a new Section which clarifies the prerequisite for provider payment and refers the reader to A.A.C. R9-22-714 for content.
- R9-28-716 The Administration added "Specialty Contracts" as a new Section which directs the reader to A.A.C. R9-22-716 for content.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

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 contractors, members, providers, and AHCCCS are nominally impacted by the changes to the rule language. These rules define the contracts/request for proposal (RFP) process for AHCCCS' long term care program. The Administration is amending these rules to make the rules more clear, concise, and understandable by:

- grouping like concepts to provide clarity and conciseness to the rule language,
- deleting language that appropriately exists in contract rather than rule according to A.R.S. § 41-1005(A)(16),
- clarifying language that does not clearly present policies or procedures, and
- updating citations to documents incorporated in the rule, as needed.

It is anticipated that the private sector, including small businesses or political subdivisions will not be impacted since the proposed rule language changes are intended to streamline and clarify the existing rules. The Administration, contractors and providers will benefit because the changes provide greater flexibility and clarification of the rule language.

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

The only changes to the proposed rule, are grammatical and technical changes suggested by G.R.R.C. staff.

11. A summary of the principal comments and the agency response to them:

On October 2, 2001, the Administration simultaneously conducted public hearings in Phoenix, Yuma, and Sierra Vista. The Phoenix site was linked by videoconference with Tucson and Flagstaff. The Administration received no oral or written comments prior to close of record at 5 p.m. on October 2, 2001.

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:

42 CFR 488, Subpart F, May 17, 1999, R9-28-606(B)

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

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

**CHAPTER 28. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)
ARIZONA LONG-TERM CARE SYSTEM**

ARTICLE 1. DEFINITIONS

Section

R9-28-101. General Definitions

ARTICLE 6. ~~REQUEST FOR PROPOSALS~~ RFP AND CONTRACT PROCESS

Section

R9-28-601. General Provisions

R9-28-602. ~~Request for Proposals (RFP); Contract Award~~ RFP

R9-28-603. ~~Contract or Proposal Protests; Appeals~~ Contract Award

R9-28-604. ~~Contracts~~ Contract or Proposal Protests; Appeals

R9-28-605. ~~Subcontracts~~ Waiver of Contractor's Subcontract with Hospitals

R9-28-606. ~~Specialty Contracts~~ Contract Compliance Sanction

R9-28-607. ~~Contract Amendments; Mergers; Reorganizations~~ Repealed

R9-28-608. ~~Contract Suspension, Denial, Modification, Termination, or Sanction~~ Repealed

Arizona Administrative Register
Notices of Final Rulemaking

ARTICLE 7. STANDARDS FOR PAYMENTS

Section

- R9-28-701. Scope of ~~the~~ Administration's ~~liability~~ Liability
- R9-28-707. Contractor's Liability to Hospitals for the Provision of Emergency and Subsequent Care
- R9-28-710. ~~Capitation Payments to Program Contractors~~ Repealed
- R9-28-714. Payments to Providers
- R9-28-715. Specialty Contracts

ARTICLE 1. DEFINITIONS

R9-28-101. General Definitions

A. Location of definitions. Definitions applicable to Chapter 28 are found in the following:

Definition	Section or Citation
"210"	42 CFR 435.217
"217"	42 CFR 435.217
"236"	42 CFR 435.236
"Administration"	A.R.S. § 36-2931
"ADHS"	R9-28-111 <u>R9-22-112</u>
"Aggregate"	R9-22-107
"AHCCCS"	R9-22-101
"Algorithm"	R9-28-104
"ALTCS"	A.R.S. § 36-2932 <u>R9-28-101</u>
"ALTCS acute care services"	R9-28-104
"Alternative HCBS setting"	R9-28-101
"Ambulance"	R9-22-102
"Bed hold"	R9-28-102
"Behavior intervention"	R9-28-102
"Behavior management services"	R9-28-111 <u>R9-20-101</u>
"Behavioral health evaluation"	R9-28-111 <u>R9-22-112</u>
"Behavioral health medical practitioner"	R9-28-111 <u>R9-22-112</u>
"Behavioral health professional"	R9-28-111 <u>R9-20-101</u>
"Behavioral health service"	R9-28-111 <u>R9-20-101</u>
"Behavioral health technician"	R9-28-111 <u>R9-20-101</u>
"Billed charges"	R9-22-107
"Board-eligible for psychiatry"	R9-28-111 <u>R9-22-112</u>
"Capped fee-for-service"	R9-22-101
"Case management plan"	R9-28-101
"Case manager"	R9-28-101
"Case record"	R9-22-101
"Categorically-eligible"	A.R.S. § 36-2934 <u>R9-22-101</u>
"Certification"	R9-28-105
"Certified psychiatric nurse practitioner"	R9-28-111 <u>R9-22-112</u>
"CFR"	R9-28-101
"Clean claim"	R9-20-101
"Clinical supervision"	R9-28-111 <u>R9-22-112</u>
"CMS"	R9-22-101
"Community Spouse"	R9-28-104
"Contract"	R9-22-101
"Contractor"	A.R.S. § 36-2901
"County of fiscal responsibility"	R9-28-107
"Covered services"	R9-22-102
"CPT"	R9-22-107
"CSR D"	R9-28-104
"Day"	R9-22-101
"DES Division of Developmental Disabilities"	A.R.S. § 36-551
<u>"Department"</u>	<u>A.R.S. § 36-2901</u>
"De novo hearing"	R9-28-111 <u>42 CFR 431.201</u>
"Developmental disability"	A.R.S. § 36-551
"Diagnostic services"	R9-22-102
"Director"	R9-22-101

Arizona Administrative Register

Notices of Final Rulemaking

“Disenrollment”	R9-22-117
“DME”	R9-22-102
“EPD”	<u>R9-28-301</u>
“Eligible person”	A.R.S. § 36-2931
“Emergency medical services”	R9-22-102
“Encounter”	R9-22-107
“Enrollment”	R9-22-117
“Estate”	A.R.S. § 14-1201
“Facility”	R9-22-101
“Factor”	R9-22-101
“Fair consideration”	R9-28-104
“FBR”	R9-22-101
“Grievance”	R9-22-108
“GSA”	R9-22-101
“Guardian”	R9-22-116
“Home and community based services” (“HCBS”)	A.R.S. §§ 36-2931 and 36-2939
“Health care practitioner”	R9-28-111 <u>R9-22-112</u>
“Hearing”	R9-22-108
“Home”	R9-28-101
“Home health services”	R9-22-102
“Hospital”	R9-22-101
“Intermediate care facility for the mentally retarded” (“ICF-MR”)	42 CFR 435.1009 and 440.150
“IHS”	R9-28-101
“IMD”	42 CFR 435.1009 and R9-28-111
“Indian”	P.L. 94-437 <u>42 CFR 36.1</u>
“Institutionalized”	R9-28-104
“Interested Party”	R9-28-106
“JCAHO”	R9-28-101
“License” or “licensure”	R9-22-101
“Medical record”	R9-22-101
“Medical services”	R9-22-101
“Medical supplies”	R9-22-102
“Medically eligible”	R9-28-104
“Medically necessary”	R9-22-101
“Member”	A.R.S. § 36-2931
“Mental disorder”	R9-28-111 <u>A.R.S. § 36-501</u>
“MMMNA”	R9-28-104
“Nursing facility” (“NF”)	42 U.S.C. 1396r(a)
“Noncontracting provider”	A.R.S. § 36-2931
“Occupational therapy”	R9-22-102
“Partial care”	R9-28-111 <u>R9-22-112</u>
“PAS”	R9-28-103
“PASARR”	R9-28-103
“Pharmaceutical service”	R9-22-102
“Physical therapy”	R9-22-102
“Physician”	R9-22-102
“Post-stabilization services”	42 CFR 438.114
“Practitioner”	R9-22-102
“Primary care provider”	R9-22-102
“Primary care provider services”	R9-22-102
“Prior authorization”	R9-22-102
“Prior period coverage” (“PPC”)	R9-28-101 <u>R9-22-107</u>
“Private duty nursing services”	R9-22-102
“Program contractor”	A.R.S. § 36-2931
“Provider”	A.R.S. § 36-2931
“Prudent layperson standard”	42 U.S.C. 1396u-2
“Psychiatrist”	R9-28-111 <u>R9-22-112</u>
“Psychologist”	R9-28-111 <u>R9-22-112</u>

Arizona Administrative Register
Notices of Final Rulemaking

“Psychosocial rehabilitation”	R9-28-111 <u>R9-20-101</u>
“Quality management”	R9-22-105
“Regional behavioral health authority” (“RBHA”)	R9-28-111 <u>A.R.S. § 36-3401</u>
“Radiology”	R9-22-102
“Reassessment”	R9-28-103
“Redetermination”	R9-28-104
“Referral”	R9-22-101
“Reinsurance”	R9-22-107
“Representative”	R9-28-104
“Respiratory therapy”	R9-22-102
“Respite care”	R9-28-102
“RFP”	R9-22-106
“Room and board”	R9-28-102
“Scope of services”	R9-22-102
“Section 1115 Waiver”	A.R.S. § 36-2901
“Speech therapy”	R9-22-102
“Spouse”	R9-28-104
“SSA”	PL. 103-296, Title I <u>42 CFR 1000.10</u>
“SSI”	R9-22-101
“Subcontract”	R9-22-101
“Utilization management”	R9-22-105
“Ventilator dependent”	R9-28-102

B. General definitions. The following words and phrases, in addition to definitions contained in A.R.S. §§ 36-2901 and 36-2931, and 9 A.A.C. 22, Article 1, have the following meanings unless the context of the Chapter explicitly requires another meaning:

“~~AHCCCS~~” is defined in 9 A.A.C. 22, Article 1.

“ALTCs” means the Arizona Long-term Care System as authorized by A.R.S. § 36-2932.

“Alternative HCBS setting” means a living arrangement approved by the Director and licensed or certified by a regulatory agency of the state, where a member may reside and receive HCBS including:

For a person with a developmental disability (DD) specified in A.R.S. § 36-551:

Community residential setting defined in A.R.S. § 36-551;

Group home defined in A.R.S. § 36-551;

State-operated group home ~~defined in~~ under A.R.S. § 36-591;

Family foster home under 6 A.A.C. 5, Article 58;

Group foster home ~~defined in~~ under 6 A.A.C. 5, Article 59 R6-5-5903;

Licensed residential facility for a person with traumatic brain injury ~~specified in~~ under A.R.S. § 36-2939;

~~Adult Therapeutic Foster Home~~ therapeutic foster home defined in under 9 A.A.C 20, Articles 1 and 15; and ~~Behavioral health service agency specified in A.R.S. § 36-2939(B) and Level I and Level II behavioral health agencies under 9 A.A.C. 20, Articles 1, 4, 5, and 6 for Levels I, II, or III; and 9 A.A.C. 20, Articles 1 and 14 for Rural Substance Abuse Transitional Agency.~~

Rural substance abuse transitional agencies under 9 A.A.C. 20, Articles 1 and 14.

For a person who is elderly or physically disabled (EPD) under R9-28-301, and the facility, setting, or institution is registered with AHCCCS:

Adult foster care homes defined in A.R.S. § 36-401 and as authorized in A.R.S. § 36-2939; an assisted living home or ~~residential unit~~ assisted living center, units only, as defined in under A.R.S. § 36-401, and as authorized in A.R.S. § 36-2939.

Licensed residential facility for a person with a traumatic brain injury specified in A.R.S. § 36-2939;

~~Adult Therapeutic Foster Home~~ therapeutic foster home defined in under 9 A.A.C. 20, Articles 1 and 15; ~~Behavioral health service agency specified in A.R.S. § 36-2939(B) and Level I and Level II behavioral health agencies under 9 A.A.C. 20, Articles 1, 4, 5, and 6 for Levels I, II, or III; and 9 A.A.C. 20, Articles 1 and 14 for Rural Substance Abuse Transitional Agency.~~

Rural substance abuse transitional agencies under 9 A.A.C. 20, Articles 1 and 14.

Alzheimer’s treatment assistive living facility demonstration pilot project as specified in Laws 1999, Ch. 313, § 35.

“~~Capped fee for service~~” is defined in 9 A.A.C. 22, Article 1.

“Case management plan” means a service plan developed by a case manager that involves the overall management of a member’s care, and the continued monitoring and reassessment of the member’s need for services.

Arizona Administrative Register
Notices of Final Rulemaking

“Case manager” means a person who is either a degreed social worker, a licensed registered nurse, or a person with a minimum of two years of experience in providing case management services to a person who is elderly and physically disabled or has developmental disabilities.

“Case record” is defined in 9 A.A.C. 22, Article 1.

“CFR” means Code of Federal Regulations, unless otherwise specified in this Chapter.

“Contract” is defined in 9 A.A.C. 22, Article 1.

“Day” is defined in 9 A.A.C. 22, Article 1.

“DES Division of Developmental Disabilities” is defined in A.R.S. § 36-551.

“Director” is defined in 9 A.A.C. 22, Article 1.

“Disenrollment” is defined in 9 A.A.C. 22, Article 1.

“Eligible person” is defined in A.R.S. § 36-2931.

“Enrollment” is defined in 9 A.A.C. 22, Article 1.

“Facility” is defined in 9 A.A.C. 22, Article 1.

“Factor” is defined in 9 A.A.C. 22, Article 1.

“FBR” means Federal Benefit Rate and is defined in 9 A.A.C. 22, Article 1.

“HCBS” means home and community based services defined in A.R.S. §§ 36-2931 and 36-2939.

“Home” means a residential dwelling that is owned, rented, leased, or occupied at no cost to a member, including a house, a mobile home, an apartment, or other similar shelter. A home is not a facility, a setting, or an institution, or a portion and any of these, licensed or certified by a regulatory agency of the state as a:

Health care institution defined in under A.R.S. § 36-401;

Residential care institution defined in under A.R.S. § 36-401;

Community residential facility setting defined in under A.R.S. § 36-551; or

Behavioral health service facility setting defined in under 9 A.A.C. 20, Articles 1, 4, 5, and 6.

“Hospital” is defined in 9 A.A.C. 22, Article 1.

“ICF-MR” means an intermediate care facility for the mentally retarded and is defined in 42 CFR 435.1009 and 440.150.

“IHS” means the Indian Health Service.

“Indian” is defined in P.L. 94-437.

“JCAHO” means the Joint Commission on Accreditation of Healthcare Organizations.

“License” or “licensure” is defined in 9 A.A.C. 22, Article 1.

“Medical record” is defined in 9 A.A.C. 22, Article 1.

“Medical services” is defined in 9 A.A.C. 22, Article 1.

“Medically necessary” is defined in 9 A.A.C. 22, Article 1.

“Member” is defined in A.R.S. § 36-2931.

“NF” means nursing facility and is defined in 42 U.S.C. 1396r(a).

“Nonecontracting provider” is defined in A.R.S. § 36-2931.

“Prior period coverage” means the period of time from the first day of the month of application or the first eligible month whichever is later to the day a member is enrolled with the program contractor. The program contractor receives notification from the Administration of the member’s enrollment.

“Program contractor” is defined in A.R.S. § 36-2931.

“Provider” is defined in A.R.S. § 36-2931.

“Referral” is defined in 9 A.A.C. 22, Article 1.

“Reinsurance” is defined in 9 A.A.C. 22, Article 1.

“SSA” means Social Security Administration defined in P.L. 103-296, Title I.

“SSI” is defined in 9 A.A.C. 22, Article 1.

“Subcontract” is defined in 9 A.A.C. 22, Article 1.

ARTICLE 6. REQUEST FOR PROPOSALS RFP AND CONTRACT PROCESS

R9-28-601. General Provisions

A. The Director has full operational authority to adopt rules for the RFP process and the award of contract under A.R.S. § 36-2944.

~~A-B.~~ The Administration shall follow the provisions specified in under 9 A.A.C. 22, ~~Articles 4 and 6~~ Article 6 for ALTCS members, subject to limitations and exclusions specified in under that Article, unless otherwise specified in this Chapter. All references to the Administration also shall apply to ALTCS.

~~B-C.~~ The Administration shall establish award contracts under A.R.S. § 36-2932 to provide services ~~as specified in under~~ A.R.S. § ~~36-2940~~ 36-2939.

D. The Administration is exempt from the procurement code under A.R.S. § 41-2501.

Arizona Administrative Register
Notices of Final Rulemaking

~~C.E.~~ All contract records shall follow the provisions of A.R.S. § 36-2932 and A.A.C. R9-22-603. The Administration and contractors shall retain all records relating to contract compliance for five years under A.R.S. § 36-2932 and dispose of the records under A.R.S. § 41-2550.

R9-28-602. Request for Proposals (RFP); Contract Award RFP

The ALTCS RFP for an ~~EPD~~ a program contractor serving members who are elderly or physically disabled ~~EPD~~ shall be in accordance with meet the requirements of A.R.S. §§ 36-2944, A.R.S. § 36-2939, A.A.C. R9-22-602, and A.A.C. R9-22-604 Articles 2 and 11 of this Chapter.

R9-28-603. Contract or Proposal Protests; Appeals Contract Award

The ALTCS ~~grievances~~ related to contract performance shall be in accordance with A.A.C. R9-22-602, and all references in that rule shall apply to ALTCS.

The Administration shall award a contract under A.R.S. § 36-2944 and A.A.C. R9-22-603.

R9-28-604. ~~Contracts~~ Contract or Proposal Protests; Appeals

All ALTCS contracts shall meet the requirements in accordance with A.R.S. §§ 36-2932 and 36-2944 and A.A.C. R9-22-402. In addition, the Administration may extend existing contracts as specified in the contract.

Contract or proposal protests or appeals shall be under A.A.C. R9-22-604 and Article 8 of this Chapter.

R9-28-605. Subcontracts Waiver of Contractor's Subcontract with Hospitals

All ALTCS subcontracts shall be entered in accordance with A.R.S. § 36-2932 and A.A.C. R9-22-403, and all references in that rule shall apply to ALTCS.

A contractor's subcontract with hospitals may be waived under A.A.C. R9-22-605.

R9-28-606. Specialty Contracts Contract Compliance Sanction

The Director shall negotiate specialty contracts under A.A.C. R9-22-716.

A. The Administration shall follow sanction provisions if criteria under A.A.C. R9-22-606 are met.

B. The Administration shall apply remedies found in 42 CFR 488, Subpart F, effective May 17, 1999, incorporated by reference and on file with the Administration and the Office of the Secretary of State, for a nursing facility that does not meet requirements of participation under 42 U.S.C. 1396r. This incorporation by reference contains no future editions or amendments.

R9-28-607. Contract Amendments; Mergers; Reorganizations Repealed

~~A. Any amendments, mergers or reorganizations regarding ALTCS shall be in accordance with A.A.C. R9-22-404.~~

~~B. If a program contractor or DES Division of Developmental Disabilities notifies the Administration in writing that it refuses to sign an amendment within 60 days from the date the Administration mails the amendment, the Administration may initiate contract termination proceedings for the program contractor. For DES Division of Developmental Disabilities the refusal will be considered a grievance and administered under 9 A.A.C. 28, Article 8.~~

~~C. If the Administration does not receive a signed amendment or a written refusal to sign the amendment by the 60th day from the date the Administration mails the amendment, the Administration shall consider the amendment as accepted by the program contractor or DES Division of Developmental Disabilities.~~

R9-28-608. Contract Suspension, Denial, Modification, Termination, or Sanction Repealed

~~A. The Administration shall follow the suspension, denial, modification, termination, or sanction provisions in accordance with A.A.C. R9-22-405 and R9-22-406, and all references in that rule.~~

~~B. The Administration shall apply remedies for a NF that does not meet requirements of participation under 42 U.S.C. 1396r(h) effective August 5, 1997, and 42 CFR 488, Subpart F, effective May 17, 1999, incorporated by reference and on file with the Administration and the Office of the Secretary of State. These incorporations by reference contain no future editions or amendments.~~

ARTICLE 7. STANDARDS FOR PAYMENTS

R9-28-701. Scope of ~~the~~ Administration's ~~liability~~ Liability

~~A. The Administration shall bear no liability for the provision of covered services or the completion of a plan of treatment to any member or eligible person beyond the date of termination of such individual's eligibility and enrollment.~~

~~B. The Administration shall bear no liability for subcontracts which the program contractor may execute with other parties for the provision of either administrative or management services, medical services, covered health care services or for any other purpose. The program contractor shall indemnify and hold the Administration harmless from any and all liability arising from these subcontracts and shall bear all costs of defense of any litigation over such liability and shall satisfy in full any judgment entered against the Administration in such connection.~~

The Administration shall bear no liability for providing covered services or completing a plan of treatment for a member beyond the date of termination of the member's eligibility.

R9-28-707. Contractor's Liability to Hospitals for the Provision of Emergency and Subsequent Care

- ~~A. The program contractor is responsible for providing emergency medical or acute behavioral health care to a member only until the time the member's condition is stabilized and the member is transferable, or until the member is discharged following stabilization subject to the requirements of A.R.S. § 36-2909(B) and Article 2 of this Chapter.~~
- ~~B. Subject to subsection (A), if a member cannot be transferred following stabilization to a facility that has a subcontract with a program contractor, the program contractor shall pay for all treatment that is appropriately documented, medically necessary treatment, and prior authorized in accordance with A.A.C. R9-22-705, provided to the member before the date of discharge or transfer in accordance with payment standards in A.A.C. R9-22-705.~~
- ~~C. If a member refuses transfer from a noncontracting provider institution to an institution affiliated with the member's program contractor, neither the Administration nor the program contractor shall be liable for any costs incurred subsequent to the date of refusal when:
 - 1. Subsequent to consultation with the member's program contractor, the member continues to refuse the transfer; and
 - 2. The member is provided and signs a written statement, before the date of transfer of liability, informing the member of the medical and financial consequences of refusing to transfer. If the member refuses to sign the written statement, a statement signed by 2 witnesses indicating that the member was informed may be substituted.~~

~~A contractor is liable to a hospital for the hospital's provision of emergency and subsequent care under A.A.C. R9-22-709, R9-28-705, and Article 2 of this Chapter.~~

R9-28-710. Capitation Payments to Program Contractors Repealed

- ~~A. The Administration shall make all payments to a program contractor in accordance with the terms and conditions of the contract executed between the program contractor and the Administration and this Chapter.~~
- ~~B. The Administration shall pay capitation monthly to a program contractor who has met the requirements in A.R.S. § 36-2942(8).~~
- ~~C. The Administration shall pay a program contractor a capitated amount per member per month. Administrative costs shall be incorporated into the capitation payment amount.~~

R9-28-714. Payments to Providers

~~The Administration shall pay providers under A.A.C. R9-22-714 and Article 2 of this Chapter.~~

R9-28-715. Specialty Contracts

~~The Director may negotiate specialty contracts under A.A.C. R9-22-716.~~

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

**CHAPTER 31. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)
CHILDREN'S HEALTH INSURANCE PROGRAM**

PREAMBLE

1. Sections Affected

Article 4
Article 6
R9-31-601
R9-31-602
R9-31-603
R9-31-604
R9-31-605
R9-31-606
R9-31-701
R9-31-709
R9-31-714
R9-31-716
R9-31-718

Rulemaking Action

Repeal
Amend
Amend
New Section
New Section
New Section
New Section
New Section
Amend
Amend
New Section
Amend
New Section

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

Authorizing statutes: A.R.S. §§ 36-2982 and 36-2986
Implementing statutes: A.R.S. §§ 36-2982 and 36-2986

3. The effective date of the rules:

January 10, 2002

Arizona Administrative Register
Notices of Final Rulemaking

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

Notice of Rulemaking Docket Opening: 7 A.A.R. 2527, June 15, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 3791, August 31, 2001

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

Name: Cheri Tomlinson, Federal & State Policy Administrator

Address: 801 East Jefferson
Mail Drop 4200
Phoenix, AZ 85034

Telephone: (602) 417-4198

Fax: (602) 256-6756

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

These rules define the contracts/request for proposal (RFP) process for AHCCCS' children's health insurance program. The Administration is amending these rules to make the rules more clear, concise, and understandable by:

- repealing Article 4 and relocating the provisions of Article 4 to Article 6,
- grouping like concepts to provide clarity and conciseness to the rule language,
- deleting language that appropriately exists in contract rather than rule according to A.R.S. § 41-1005(A)(16),
- clarifying language that does not clearly present policies or procedures, and
- updating citations to documents incorporated in the rule, as needed.

Following is an explanation of the changes:

9 A.A.C. 31, Article 4, Contracts, Administration, and Standards

This Article is repealed. The Administration believes that Chapter 31 needs to model Chapter 28 for which the Administration has combined the contract and RFP process as the two content areas are so intertwined. The provisions of Article 4 are grouped with like concepts in Article 6 or deleted because they are more appropriately housed in contract per A.R.S. § 41-1005(A)(16).

9 A.A.C. 31, Article 6, RFP and Contract Process

R9-31-601 The Administration amended R9-31-601 to include those provisions that were in R9-31-401.

The Administration added the following as new Sections to mirror 9 A.A.C. 22, Article 6:

- R9-31-602 "RFP", which refers to A.R.S. § 36-2986 and A.A.C. R9-22-602 for specificity.
- R9-31-603 "Contract Award", which refers to A.R.S. § 36-2986 and A.A.C. R9-22-603 for specificity
- R9-31-604 "Contractor Proposal Protests; Appeals", which refers to A.A.C. R9-22-604 for specificity.
- R9-31-605 "Waiver of Contractor's Subcontract with Hospitals", which refers to A.A.C. R9-22-605 for specificity.
- R9-31-606 "Contract Compliance Sanction", which refers to A.A.C. R9-22-606 for specificity.

9 A.A.C. 31, Article 7, Standards for Payments

The Administration revised those Sections in Article 7 that pertained to contract.

- R9-31-701 The Administration deleted subsection "D", "E", and "F" because the provisions are more appropriately housed in contract per A.R.S. § 41-1005(A)(16).
- R9-31-709 The Administration amended the Article to include the following citations: A.R.S. § 36-2989, A.A.C. R9-22-709, R9-31-705 and Article 2 of Chapter 31 for specificity.
- R9-31-714 The Administration added "Payments to Providers" as a new Section, which clarifies the prerequisite for provider payment and included the citation, A.A.C. R9-22-714, for specificity.
- R9-31-716 The Administration amended the language to improve the clarity and conciseness, deleted those areas that are already specified in contract and added a reference to A.A.C. R9-31-716 for specificity.
- R9-31-718 The Administration added "Contractor Performance Measure Outcomes" as a new Section, which includes a citation to A.A.C. R9-22-716 for specificity.

7. A reference to any study that the agency relied on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

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 contractors, members, providers, and AHCCCS are nominally impacted by the changes to the rule language. These rules define the contracts/request for proposal (RFP) process for AHCCCS' children's health insurance program. The Administration is amending these rules to make the rules more clear, concise, and understandable by:

- repealing Article 4 and relocating the provisions of Article 4 to Article 6,
- grouping like concepts to provide clarity and conciseness to the rule language,
- deleting language that appropriately exists in contract rather than rule according to A.R.S. § 41-1005(A)(16),
- clarifying language that does not clearly present policies or procedures, and
- updating citations to documents incorporated in the rule, as needed.

It is anticipated that the private sector, including small businesses or political subdivisions will not be impacted since the proposed rule language changes are intended to streamline and clarify the existing rules. The Administration, contractors and providers will benefit because the changes provide greater flexibility and clarification of the rule language.

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

The only changes made to the proposed rule are grammatical and technical changes suggested by G.R.R.C. staff.

11. A summary of the principal comments and the agency response to them:

On October 2, 2001, the Administration simultaneously conducted public hearings in Phoenix, Yuma, and Sierra Vista. The Phoenix site was linked by videoconference with Tucson and Flagstaff. The Administration received no oral or written comments prior to close of record at 5 p.m. on October 2, 2001.

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 adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 31. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)

CHILDREN'S HEALTH INSURANCE PROGRAM

ARTICLE 4. CONTRACTS REPEALED

Section

- R9-31-401. General Provisions Repealed
R9-31-402. Administration's Contracts with Contractors Repealed
R9-31-403. Subcontracts Repealed
R9-31-404. Contract Amendments; Mergers; Reorganizations Repealed
R9-31-405. Suspension, Denial, Modification, or Termination of Contract Repealed
R9-31-406. Contract: Sanction; Performance; and Solvency Repealed
R9-31-407. Contract or Protest, Appeal Repealed

ARTICLE 6. REQUEST FOR PROPOSAL (RFP) RFP AND CONTRACT PROCESS

Section

- R9-31-601. General Provisions for RFP
R9-31-602. RFP

Arizona Administrative Register
Notices of Final Rulemaking

- R9-31-603. Contract Award
- R9-31-604. Contract or Proposal Protests: Appeals
- R9-31-605. Waiver of Contractor's Subcontract with Hospitals
- R9-31-606. Contract Compliance Sanction

ARTICLE 7. STANDARDS FOR PAYMENTS

Section

- R9-31-701. ~~General~~; Scope of the Administration's Liability; ~~and Payment to a Contractor~~
- R9-31-709. Contractor's Liability to Hospitals for the Provision of Emergency and Subsequent Care
- R9-31-714. Reserved Payments to Providers
- R9-31-716. Specialty Contracts
- R9-31-718. Contractor Performance Measure Outcomes

ARTICLE 4. ~~CONTRACTS REPEALED~~

R9-31-401. ~~General Provisions Repealed~~

- ~~**A.** Administration and contract authority. The Administration shall administer the program as specified in A.R.S. § 36-2982.~~
- ~~**B.** Rule authority. The Director has full operational authority to use the appropriate rules adopted for contract administration and oversight of contractors as specified in A.R.S. § 36-2986.~~
- ~~**C.** For purposes of this Chapter, as specified in A.R.S. § 36-2981, contractor includes the following:
 - 1. A health plan as specified in A.R.S. § 36-2981; or
 - 2. A qualifying plan as specified in A.R.S. § 36-2981 and that provides services to members as specified in A.R.S. § 36-2989.~~
- ~~**D.** Exemption from procurement process. The Administration is exempt from the procurement code as specified in A.R.S. §§ 36-2988 and 41-2501.~~
- ~~**E.** Contractor's financial responsibility. The Administration shall specify in contract when a person who has been determined eligible will be enrolled with a contractor and the date on which the contractor will be financially responsible for health and medical services to the person as specified in A.R.S. § 36-2987.~~
- ~~**F.** Contract. A contract may be canceled or rejected in whole or in part as specified in contract if it is deemed by the Director to be in the best interest of the state. The reasons for cancellation or rejection shall be made part of the contract file.~~
- ~~**G.** Damages or claims. Offerors shall have no right to damages or basis for any claims against the state, its employees, or agents, arising out of any action by the Administration according to the provisions of subsection (F).~~
- ~~**H.** Ownership interest. A contractor shall not knowingly have a director, officer, partner, or person with ownership of more than 5% of the contractor's equity who has been debarred or suspended by any federal agency, as specified in 42 U.S.C. 1396u-2, as of August 5, 1997, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future additions or amendments.~~
- ~~**I.** Certification. The Administration shall certify a contractor as a risk-bearing entity as specified in 42 U.S.C. 1396b(m), as of August 5, 1997, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future additions or amendments.~~

R9-31-402. ~~Administration's Contracts with Contractors Repealed~~

- ~~**A.** Contracts with the Administration. The Administration shall use contractors that have a contract with the Administration to provide services to members who qualify for the program as specified in A.R.S. § 36-2988.~~
- ~~**B.** Conditions when the Administration is a contractor. The Director may require contract terms allowing the Administration to operate a contractor directly under circumstances specified in the contract according to A.R.S. § 36-2986.~~
- ~~**C.** Expansion or contraction of services or services areas. The Director may negotiate with any successful bidder for the expansion or contraction of services or service areas, after contracts have been awarded as specified in A.R.S. § 36-2988.~~
- ~~**D.** Amending contracts. The Administration has full authority to amend existing contracts awarded in compliance with A.R.S. § 36-2988.~~
- ~~**E.** Content of contract. Each contract between the Administration and a contractor shall be in writing and contain at least the following information:
 - 1. The method and amount of compensation or other consideration to be received by the contractor.
 - 2. The name and address of the contractor.
 - 3. The population to be covered by the contractor.
 - 4. The amount, duration, and scope of medical services to be provided, or for which compensation will be paid for Title XXI coverage.
 - 5. The term of the contract, including the beginning and ending dates, as well as methods of extension, renegotiation, and termination.
 - 6. A provision that the Director may evaluate, through inspection or other means, the quality, appropriateness, or timeliness of services performed under the contract.~~

Arizona Administrative Register
Notices of Final Rulemaking

7. A description of the eligibility requirements for a Title XXI member, medical and cost record-keeping systems, and a provision that the Director may audit and inspect any of the contractor's records that pertain to services performed and determinations of amounts payable under the contract. These records shall be maintained by the contractor for 5 years from the date of final payment or, for records relating to costs and the date of final payment or, for records relating to costs and expenses to which the Administration has taken exception, 5 years after the date of final disposition or resolution of the exception.
8. A provision that contractors maintain all forms, records, and statistical information required by the Director for purposes of audit and program management. This material, including files, correspondence, and related information pertaining to services rendered or claims for payments shall be subject to inspection and copying by the Administration or by the Department of Health and Human Services during normal business hours at the place of business of the person or organization maintaining the records.
9. A provision that the contractor safeguard information.
10. Any activities to be performed by the contractor affecting members that are related to 3rd party liability requirements prescribed in A.R.S. § 36-2986.
11. Functions that may be subcontracted, including a provision that any subcontract meets the requirements of 42 CFR 434.6, as of December 30, 1983, which is incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
12. A provision that the contractor arrange for the collection of any required copayment by the provider.
13. A provision that the contractor will not bill or attempt to collect from a Title XXI member for any covered service except as authorized by statute or these rules.
14. A provision that the contract will not be assigned or transferred without the prior approval of the Director.
15. Procedures for enrollment or re-enrollment of a covered population.
16. Procedures and criteria for terminating the contract.
17. A provision that any cost sharing requirements imposed for services furnished to members are in accordance with A.R.S. § 36-2982, and 42 CFR 447.50 through 447.58, as of December 19, 1990, which are incorporated by reference and on file with the Administration and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
18. Procedures for terminating enrollment and choice of health professional.
19. A provision that specifies the rates are actuarially sound.
20. A provision that a contractor provide for an internal grievance procedure that:
 - a. Is approved in writing by the Administration;
 - b. Provides for prompt resolution; and
 - c. Ensures the participation of individuals with authority to require corrective action.
21. A provision that the contractor maintain an internal quality management system consistent with A.R.S. § 36-2986 and Title XXI rule and policy as specified in R9-31-522.
22. A provision that the contractor submit marketing plans, procedures, and materials to the Administration for approval before implementation.
23. A statement that all representations made by contractors, or authorized representatives are truthful and complete to the best of their knowledge.
24. A provision that the contractor is responsible for all:
 - a. Tax obligations;
 - b. Worker's Compensation Insurance; and
 - c. All other applicable insurance coverage, for itself and its employees, and that the Administration has no responsibility or liability for any of the taxes or insurance coverage.
25. A provision that the contractor agrees to comply with all applicable statutes and rules.

R9-31-403. Subcontracts Repealed

- A:** Approval. A contractor entering into a subcontract to provide services to a Title XXI member must meet the requirements specified in the contract. Any amendment to a subcontract shall be subject to review and approval by the Director. No subcontract alters the legal responsibility of a contractor to the Administration to ensure that all activities under the contract are carried out.
- B:** Subcontracts. Each subcontract shall be in writing and include a:
1. Provision that the subcontract is to be governed by, and construed in accordance with all laws, rules, and contractual obligations of the contractor.
 2. Provision to notify the Administration in the event the subcontract is amended or terminated.
 3. Provision that assignment or delegation of the subcontract is voidable, unless prior written approval is obtained from the Administration.
 4. Provision to hold harmless the state, the Director, the Administration, and a Title XXI member in the event the contractor cannot or will not pay for covered services performed by the subcontractor.

Arizona Administrative Register
Notices of Final Rulemaking

5. ~~Provision that the subcontract and subcontract amendments are subject to review and approval by the Director as established in these rules and that a subcontract or subcontract amendment may be terminated, rescinded, or canceled by the Director for a violation of these rules.~~
 6. ~~Provision to hold harmless and indemnify the state, the Director, the Administration, or a Title XXI member against claims, liabilities, judgments, costs and expenses with respect to third parties, which may accrue against the state, the Director, the Administration, or a Title XXI member, through the negligence of the subcontractor.~~
 7. ~~Provision that a Title XXI member is not to be held liable for payment to a provider in the event of contractor's bankruptcy; and~~
 8. ~~Provision that the requirements contained in R9-31-402(E)(1) through (E)(10) and (E) (13), (14), (16), (20), (23), (24), (25) apply but substitute the term "subcontractor" wherever the term "contractor" is used.~~
- C.** ~~Waiver. A contractor may submit a written request to the Administration requesting a waiver of the requirement that the contractor subcontract with a hospital in the contractor's service area. The request shall state the reasons a waiver is believed to be necessary and shall state all efforts the contractor has made to secure a subcontract. For good cause shown, the Administration may waive the hospital subcontract requirement. The Administration shall consider the following criteria in deciding whether to waive the hospital subcontract requirement:~~
1. ~~The number of hospitals in the service area.~~
 2. ~~The extent to which the contractor's primary care physicians have staff privileges at noncontracting hospitals in the service area.~~
 3. ~~The size and population of, and the demographic distribution within, the service area.~~
 4. ~~Patterns of medical practice and care within the service area.~~
 5. ~~Whether the contractor has diligently attempted to negotiate a hospital subcontract in the service area.~~
 6. ~~Whether the contractor has any subcontracts in adjoining service areas with hospitals that are reasonably accessible to the contractor's members in the service area.~~
 7. ~~Whether the contractor's members can reasonably be expected to receive all covered services in the absence of a hospital subcontract.~~

R9-31-404. Contract Amendments, Mergers, Reorganizations Repealed

~~Any merger, reorganization, or change in ownership of a contractor shall require that the contractor submit the contract between the Administration and the contractor for amendment and prior approval by the Director. Additionally, any merger, reorganization, or change in ownership of a subcontractor that is related to or affiliated with the contractor shall constitute a contract amendment which requires the prior approval of the Director. To be effective, contract amendments shall be in writing and executed by the Director.~~

R9-31-405. Suspension, Denial, Modification, or Termination of Contract Repealed

- A.** ~~General. The Director may suspend, deny, refuse or fail to renew, or terminate a contract or subcontract for good cause as specified in contract.~~
- B.** ~~Modification and termination of the contract without cause. The Administration and contractor by mutual consent may modify or terminate the contract at any time without cause. Additionally, the Administration may terminate or suspend the contract in whole or in part without cause effective 30 days after mailing written notice of termination or suspension by certified mail, return receipt requested to the contractor.~~
- C.** ~~Notification:~~
1. ~~The Director shall provide the contractor written notice of intent to:~~
 - a. ~~Suspend;~~
 - b. ~~Deny;~~
 - c. ~~Fail to renew; or~~
 - d. ~~Terminate a contract or related subcontract.~~
 2. ~~The Administration shall provide a notice to an affected principal, an enrolled member and an other interested party, and shall include:~~
 - a. ~~The effective date; and~~
 - b. ~~Reason for the action.~~
 3. ~~The Administration shall immediately stop processing all applications and shall provide 30 days advance notice to a contractor that the program will terminate on the 1st day of the following month after notice is served, if the federal government:~~
 - a. ~~Eliminates federal funding for the program; or~~
 - b. ~~Significantly reduces the federal funding below the estimated federal expenditures according to A.R.S. § 36-2985.~~
- D.** ~~Records:~~
1. ~~All medical, financial, and other records shall be retained by a terminated contractor in accordance with state laws and rules. Medical records or copies of medical records may be required to be submitted to the Director, or designee, within 10 working days of the effective date of contract termination.~~

Arizona Administrative Register
Notices of Final Rulemaking

2. ~~All contract records shall be retained for a period of 5 years and disposed of as specified in A.R.S. § 36-2986.~~

R9-31-406. ~~Contract; Sanction; Performance; and Solvency~~ Repealed

- ~~A. The Director may impose a sanction upon a contractor that violates any provision of the rules as specified in contract.~~
- ~~B. Adequate performance. The Director shall require contract terms that are necessary to ensure adequate performance by the contractor as specified in A.R.S. § 36-2986 and 9 A.A.C. 31, Article 5.~~
- ~~C. Solvency. The Director shall establish solvency requirements in contract as specified in A.R.S. § 36-2986 and 9 A.A.C. 31, Article 5.~~

R9-31-407. ~~Contract or Protest, Appeal~~ Repealed

~~The contractor shall file a grievance as specified in A.A.C. R9-22-804.~~

ARTICLE 6. ~~REQUEST FOR PROPOSAL (RFP)~~ RFP AND CONTRACT PROCESS

R9-31-601. ~~General Provisions for RFP~~

- ~~A. The Director has full operational authority to adopt rules ~~or~~ and to use the appropriate rules for contract administration and oversight of contractors as specified in under A.R.S. § 36-2986. The Administration shall administer the program under A.R.S. § 36-2982.~~
- ~~B. The Administration shall award contracts under A.R.S. § 36-2986 to provide services under A.R.S. § 36-2989.~~
- ~~B.C. The Administration shall follow the provisions specified in under 9 A.A.C. 22, Article 6 for ~~offerors and are~~ members, subject to the limitations and exclusions specified in that Article, unless otherwise specified in this Chapter.~~
- ~~D. The Administration is exempt from the procurement code under A.R.S. § 36-2988 and § 41-2501.~~
- ~~E. The Administration and contractors shall retain all contract records for five years under A.R.S. § 36-2986 and dispose of the records under A.R.S. § 41-2550.~~

R9-31-602. RFP

The RFP for a contractor serving members who qualify for the program shall be under A.R.S. § 36-2986 and A.A.C. R9-22-602.

R9-31-603. Contract Award

The contract award shall be under A.R.S. § 36-2986 and A.A.C. R9-22-603.

R9-31-604. Contract or Proposal Protests; Appeals

Contract or proposal protests or appeals shall be under A.A.C. R9-22-604.

R9-31-605. Waiver of Contractor's Subcontract with Hospitals

A waiver of a contractor's subcontract with a hospital shall be under A.A.C. R9-22-605.

R9-31-606. Contract Compliance Sanction

The Administration shall follow sanction provisions under A.A.C. R9-22-606.

ARTICLE 7. STANDARDS FOR PAYMENTS

R9-31-701. ~~General; Scope of the Administration's Liability; and Payment to a Contractor~~

- ~~A. The Director has full operational authority to adopt rules ~~or~~ and to use the appropriate rules adopted for the development and management of a contractor payment system as specified in under A.R.S. §§ 36-2986 and 36-2987.~~
- ~~B. If the federal government eliminates federal funding for the program or significantly reduces the federal funding below the estimated federal expenditures, the Administration shall immediately stop processing all applications and shall provide at least 30 days advance notice to contractors and members that the program ~~shall~~ will terminate as specified in under A.R.S. § 36-2985.~~
- ~~C. The Administration shall bear no liability for providing covered services to or completing a plan of treatment for any member beyond the date of termination of the member's eligibility, ~~or enrollment~~ as specified in A.R.S. § 36-2987.~~
- ~~D. The Administration shall make all payments to a contractor in accordance with the terms and conditions of the contract executed between the contractor and the Administration and in accordance with these rules as specified in A.R.S. § 36-2986.~~
- ~~E. The Administration shall bear no liability for subcontracts that a contractor executes with other parties for the provision of administrative or management services, medical services, or covered health care services, or for any other purpose. A contractor shall indemnify and hold the Administration harmless from any and all liability arising from the contractor's subcontracts, shall bear all costs of defense of any litigation over the liability, and shall satisfy in full any judgment entered against the Administration in litigation involving the contractor's subcontracts.~~
- ~~F. The Administration shall make capitation payments monthly to a contractor who meets the requirements in A.R.S. § 36-2987.~~

Arizona Administrative Register
Notices of Final Rulemaking

R9-31-709. Contractor's Liability to Hospitals for the Provision of Emergency and Subsequent Care

- A.** For purposes of program and contractor liability, an emergency medical or acute mental health condition of a member shall be subject to reimbursement only until the member's condition is stabilized and the member is transferable, or until the member is discharged following stabilization subject to the requirements of A.R.S. § 36-2989 and Article 2 of this Chapter.
- B.** Subject to subsection (A), if a member cannot be transferred following stabilization to a facility that has a subcontract with the contractor of record, the contractor of record shall pay for all appropriately documented, prior authorized, and medically necessary treatment provided the member before the date of discharge or transfer in accordance with payment standards in R9-31-705.
- C.** If a member refuses transfer from a nonprovider or noncontracting hospital to a hospital affiliated with the member's contractor of record, neither the Administration nor the contractor shall be liable for any costs incurred after the date of refusal if:
1. After consultation with the member's contractor of record, the member continues to refuse the transfer; and
 2. The member has been provided and signs a written statement, before the date of transfer of liability, informing the member of the medical and financial consequences of refusing to transfer. If the member refuses to sign a written statement, a statement signed by 2 witnesses indicating that the member was informed may be substituted.

A contractor's liability to hospitals for the provision of emergency and subsequent care shall be under A.R.S. § 36-2989, A.A.C. R9-22-709, R9-31-705, and Article 2 of this Chapter.

R9-31-714. Reserved Payments to Providers

The Administration shall pay providers under A.A.C. R9-22-714.

R9-31-716. Specialty Contracts

The Director may at any time negotiate or contract on behalf of contractors for specialized hospital and medical services including, but not limited to, transplants, neonatology, neurology, cardiology, and burn care. If the Director contracts for specialized services, contractors of record may be required to include the services within their delivery networks and make contractual modifications necessary to carry out this Section. Specialty contractors shall take precedence over all other contractual arrangements between contractors of record and their subcontractors. Specialty contractors may require interim payments to specialty contractors on behalf of contractors of record for contract services received by members. Interim payments to specialty contractors may be deducted from capitation payments, performance bonds, or other monies for payment on behalf of contractors of record. If the Administration and a hospital that performed a transplant surgery on a member does not have a contracted rate, the system shall not reimburse the hospital more than the contracted rate established by the Administration. The Director may negotiate specialty contracts under A.A.C. R9-22-716.

R9-31-718. Contractor Performance Measure Outcomes

Contractor performance measure outcomes shall be under A.A.C. R9-22-719.

NOTICE OF FINAL RULEMAKING

TITLE 15. REVENUE

**CHAPTER 3. DEPARTMENT OF REVENUE
LUXURY TAX SECTION**

PREAMBLE

- | | |
|--|--|
| 1. <u>Sections Affected</u>
R15-3-302 | <u>Rulemaking Action</u>
New Section |
| 2. <u>The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):</u>
Authorizing statute: A.R.S. §§ 42-1005 and 42-3004
Implementing statute: A.R.S. § 44-7101 | |
| 3. <u>The effective date of the rule:</u>
January 10, 2002 | |
| 4. <u>A list of all previous notices appearing in the Register addressing the final rule:</u>
Notice of Rulemaking Docket Opening: 7 A.A.R. 3164, July 27, 2001
Notice of Proposed Rulemaking: 7 A.A.R. 4312, October 5, 2001 | |
| 5. <u>The name and address of agency personnel with whom persons may communicate regarding the rulemaking:</u>
Name: Christie Comanita, Manager | |

Arizona Administrative Register
Notices of Final Rulemaking

Address: Tax Research and Analysis Section
Arizona Department of Revenue
1600 W. Monroe
Phoenix, AZ 85007

Telephone: (602) 542-4672

Fax: (602) 542-4680

E-mail: ComanitaC@revenue.state.az.us

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

Background

In 1996, Arizona and other States initiated litigation against certain tobacco product manufacturers for damages arising out of the health costs caused by cigarettes. In November 23, 1998, the States entered into what has become known as the "Master Settlement Agreement" ("MSA") with four of the major manufacturers ("OPMs"). Pursuant to the MSA, the State can receive over \$80 million each year in settlement payments.

Although the settling States resolved their claims against the OPMs, they retained similar existing or potential claims against tobacco manufacturers who have not signed the MSA ("non-participating manufacturers" or "NPMs"), yet continue to sell cigarettes in the United States. Because of the health and financial concerns arising out of such sales,¹ each of the settling States, including Arizona, enacted a model statute, known as the "NPM Escrow Statute." Under the terms of Arizona's NPM Escrow Statute, an NPM whose cigarettes or roll-your-own tobacco ("RYO") are sold in this State must either: (i) become a "participating manufacturer" ("PM") or (ii) annually deposit certain funds into a "qualified escrow fund," the principle of which may be used to pay a judgment or settlement of a future claim brought against the NPM by the State or an individual residing in the State. [A.R.S. § 44-7101(3)] The amounts that must be deposited into escrow each year depend on the number of individual cigarettes/RYO cigarettes sold in Arizona during the preceding year "whether directly or through a distributor, retailer or similar intermediary or intermediaries." [A.R.S. § 44-7101(2)(j)]

[¹The Arizona Legislature's findings in the NPM Escrow Statute included:

- "Cigarette smoking presents serious public health concerns to the State and to the citizens of the State. The Surgeon General has determined that smoking causes lung cancer, heart disease and other serious diseases, and that there are hundreds of thousands of tobacco-related deaths in the United States each year. These diseases most often do not appear until many years after the person in question begins smoking." [A.R.S. § 44-7101(1)(a)];
- "Cigarette smoking also presents serious financial concerns for the State. Under certain health-care programs, the State may have a legal obligation to provide medical assistance to eligible persons for health conditions associated with cigarette smoking, and those persons may have a legal entitlement to receive such medical assistance. [] Under these programs, the State pays millions of dollars each year to provide medical assistance for these persons for health conditions associated with cigarette smoking." [A.R.S. § 44-7101(1)(b)-(c)]; and
- "It would be contrary to the policy of the State if tobacco product manufacturers who determine not to enter into [the Master Settlement Agreement] could use a resulting cost advantage to derive large, short-term profits in the years before liability may arise without ensuring that the State will have an eventual source of recovery from them if they are proven to have acted culpably. It is thus in the interest of the State to require that such manufacturers establish a reserve fund to guarantee a source of compensation and to prevent such manufacturers from deriving large, short-term profits and then becoming judgment-proof before liability may arise." [A.R.S. § 44-7101(1)(f)].

To enforce the terms of the NPM Escrow Statute, the State must, to the extent feasible, determine which of the hundreds of NPMs throughout the world are selling "cigarettes" (which includes RYO cigarettes) in Arizona, and how many of those cigarettes are sold in this State each year. To accomplish this, the NPM Escrow Statute contemplates that the necessary information will be obtained from licensed Arizona tobacco distributors, who already gather information about cigarettes/RYO in connection with their monthly excise tax reports. The Statute thus requires that the number of individual cigarettes sold ("Units Sold") by an NPM in Arizona would be "measured by the excise taxes collected by the State on packs (or 'roll-your-own' tobacco containers) bearing the excise tax stamp of the State," and that "the department of revenue shall promulgate such regulations as are necessary to ascertain the amount of State excise tax paid on the cigarettes of each such [NPM] for each year." [A.R.S. § 44-7101(2)(j)]

The Importance of Diligent Enforcement

Diligent enforcement of the NPM Escrow Statute is essential not only to ensure that there will be adequate funds in each NPM's escrow fund with which to respond to judgments and settlements against the NPM, but to protect the millions of dollars of settlement payments that the State receives each year from the Participating Manufacturers pursuant to the MSA. The MSA provides that if the OPMs can demonstrate (i) that their collective market share in any given year decreased by more than 2%, and (ii) that the MSA was a significant factor in the market share loss, then the PMs will be entitled to a *refund* of certain settlement payments (called an "NPM Adjustment") from all States that

Arizona Administrative Register
Notices of Final Rulemaking

failed to “diligently enforce” their NPM Escrow Statutes. Depending on the number of States that fall into this category, the NPM Adjustment could conceivably eat up the State’s entire annual settlement allocation, which in the year 2000 totaled over \$82 million. Simply put, if Arizona fails to “diligently enforce” the NPM Escrow statute during a particular year, it risks having to return every dime of the settlement amount it receives from the Participating Manufacturers for that year.

Description of the Rule

The rule will assist the State in enforcing the Statute by permitting the Department to ascertain the quantity of each NPM’s cigarettes sold in Arizona by each tobacco distributor and the amount of Arizona excise tax paid on those cigarettes. The rule requires tobacco distributors to provide: (i) the NPM name and address, brand name, and amount of all NPM cigarettes (including RYO) received in Arizona, sold in Arizona, and exported from Arizona without payment of excise taxes; (ii) the amount of excise taxes paid or to be paid on the NPM cigarettes reported as sold in Arizona; and (iii) the invoice number of each invoice relating to the tobacco distributor’s purchase, acquisition, or export of the reported cigarettes. The rule further provides that: (i) reports for cigarettes sold after April 24, 2000 and before the effective date of the rule are to be filed with the Department 60 days after the effective date of the Rule; (ii) tobacco distributors must maintain all records relating to their purchase and sale of NPM cigarettes for a period of 4 years and make those records available to the Department upon request; and (iii) the Department may revoke a license issued to a tobacco distributor for failure to comply with the rule.

Pursuant to A.R.S. § 42-2003(t), the information collected by the Department pursuant to the rule may be released to the Attorney General for purposes of determining compliance with the Statute and bringing enforcement actions against tobacco product manufacturers who have failed to comply.

7. Reference to any study that the agency relied on in its evaluation of or justification for the final rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

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:

It is expected that the benefits of the rule will be overwhelmingly greater than the costs. Certain tobacco distributors will incur minimal costs to comply with the reporting requirements of the rule. The Department will incur moderate costs in administering the rule and revising tobacco forms and instructions. The Department and certain tobacco distributors will benefit from the reduced need for the Department to audit the tobacco distributors to gather necessary information. The Department, the Governor’s Regulatory Review Council, and the Secretary of State’s Office will incur the costs associated with the rulemaking process. The State as a whole will benefit from enhanced enforcement of the NPM Escrow Statute and reduce the risk of losing over \$80 million in revenue for each year that this rule is enforced.

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

The word “taxes” that was inadvertently left off as the last word in the definition of “tobacco distributor” in subsection (A)(9) has been added.

In response to a comment received from an out-of-state distributor, the Department has modified Section C(9) by adding “(and if subsequently requested by the Department ...)” after the word “number”.

Otherwise, only minor grammatical and stylistic changes have been made.

11. A summary of the principal comments and the agency response to them:

The Department received comments from lawyers representing two NPMs, one of which presented oral comments at the public hearing. Written comments to a previous but similar version of the rule were received from one non-resident distributor. The NPM’s principle comments were that the rule creates an unnecessary burden on tobacco distributors, should require distributors to report the same information concerning PM cigarettes, may dissuade distributors from carrying NPM cigarettes, and does not address procedures for obtaining NPM refunds. The non-resident distributor commented that it may be difficult to identify the NPM of certain brands and that producing invoices and invoice numbers would be burdensome.

The Department’s response to all comments are set forth in detail in the Concise Explanatory Statement, submitted herewith. The Department contends that the rule is carefully limited to information that will assist the Department and the Attorney General in enforcing Arizona’s NPM Escrow Statute. The rule does not impose an unreasonable burden on distributors, who already must keep track of most of the requested information in connection with the Department’s current reporting requirements. The Department has received no suggestion from distributors that the rule will influence them to discontinue NPM products, and several distributors already are providing some of the requested information voluntarily. The rule does not contain procedures for NPM refunds because the rule addresses a completely separate topic and there is no direction in the NPM Escrow Statute that the Department promulgate such

Arizona Administrative Register
Notices of Final Rulemaking

a rule. As indicated above, the Department has modified the Rule to provide that invoices need not be submitted as a matter of course, and will be required only upon specific request by the Department.

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

None

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

None

14. Was the rule previously adopted as an emergency rule?

No

15. The full text of the rule follows:

TITLE 15. REVENUE

CHAPTER 3. DEPARTMENT OF REVENUE

LUXURY TAX SECTION

ARTICLE 3. TOBACCO

Section

R15-3-302. Repealed Tobacco from Manufacturers Not Participating in the Master Settlement Agreement

ARTICLE 3. TOBACCO

R15-3-302. Repealed Tobacco from Manufacturers Not Participating in the Master Settlement Agreement

A. For purposes of this Section, the following definitions apply:

1. “Cigarette” has the meaning prescribed in A.R.S. § 44-7101(A), Section 2(d).
2. “Department” means the Department of Revenue.
3. “Excise taxes” means taxes imposed on cigarettes under A.R.S. Title 42, Chapter 3.
4. “Master Settlement Agreement” has the meaning prescribed in A.R.S. § 44-7101(A), Section 2(e).
5. “Non-participating manufacturer” means a tobacco product manufacturer that is not a “participating manufacturer.”
6. “Original participating manufacturers” means Brown & Williamson Tobacco Corporation, Lorillard Tobacco Company, Philip Morris Incorporated, and R.J. Reynolds Tobacco Company, and the respective successors of each of them.
7. “Participating manufacturer” means the “original participating manufacturers” and “subsequent participating manufacturers.”
8. “Subsequent participating manufacturers” means tobacco product manufacturers that have become signatories to the Master Settlement Agreement but that are not original participating manufacturers, and the respective successors of each of them.
9. “Tobacco distributor” means a “distributor” as defined in A.R.S. § 42-3001(5) that has paid or is obligated to pay excise taxes.
10. “Tobacco product manufacturer” has the meaning prescribed in A.R.S. § 44-7101(A), Section 2(i).

B. The Department shall maintain a current list of participating manufacturers and make it available to tobacco distributors.

C. A tobacco distributor shall report monthly to the Department on a form provided by the Department:

1. The brand names of each non-participating manufacturer’s cigarettes received by the tobacco distributor in Arizona;
2. The brand names of each non-participating manufacturer’s cigarettes received by the tobacco distributor outside Arizona and sold by the tobacco distributor in Arizona;
3. The name and address of the non-participating manufacturer of each brand of cigarettes identified by the tobacco distributor;
4. The number of individual cigarettes of each brand of each non-participating manufacturer sold in Arizona by the tobacco distributor during the preceding month, separately stating:
 - a. The number of cigarette packages sold and the number of individual cigarettes in each package; and
 - b. The number of “roll-your-own” tobacco containers sold and the number of individual cigarettes in each container;
5. The amount of excise taxes paid or to be paid on the cigarettes addressed in subsection (4), separately stating:
 - a. The amount of excise taxes paid by purchasing and affixing tax stamps to cigarette packages;
 - b. The amount of excise taxes to be paid with the tobacco distributor’s tax return for “roll-your-own” tobacco containers; and
 - c. Any other amount of excise taxes paid or to be paid on the cigarettes not addressed in subsections (a) or (b);
6. The number of individual cigarettes of each brand of each non-participating manufacturer received by the tobacco distributor in Arizona, separately stating:

Arizona Administrative Register
Notices of Final Rulemaking

- a. The number of cigarette packages received and the number of individual cigarettes in each package; and
- b. The number of “roll-your-own” tobacco containers received and the number of individual cigarettes in each container;
7. The number of individual cigarettes of each brand of each non-participating manufacturer that the tobacco distributor exported from Arizona without payment of excise taxes, separately stating:
 - a. The number of cigarette packages exported and the number of individual cigarettes in each package; and
 - b. The number of “roll-your-own” tobacco containers exported and the number of individual cigarettes in each container;
8. The number of individual cigarettes of each brand of each non-participating manufacturer for which the tobacco distributor obtained a tax refund under A.R.S. § 42-3008, separately stating:
 - a. The number of cigarette packages for which the tobacco distributor obtained a tax refund and the number of individual cigarettes in each package; and
 - b. The number of “roll-your-own” tobacco containers for which the tobacco distributor obtained a tax refund and the number of individual cigarettes in each container; and
9. The invoice number (and if subsequently requested by the Department, a copy of each invoice) relating to the tobacco distributor’s:
 - a. Purchase or acquisition of any non-participating manufacturer’s cigarettes received or sold by the tobacco distributor in Arizona; and
 - b. Export, if any, of any non-participating manufacturer’s cigarettes from Arizona.
- D.** A tobacco distributor shall file the report required under subsection (C) with the Department by the 20th day of the month following the month for which the report is made. Reports for cigarettes sold in Arizona after April 24, 2000, and before the effective date of this Section are due 60 days after the effective date of this Section.
- E.** A tobacco distributor shall maintain all records relating to or reflecting its purchase and sale of non-participating manufacturers’ cigarettes after April 24, 2000, for a period of 4 years after the date of sale. The tobacco distributor shall make the records available to the Department upon request by the Department.
- F.** Subject to the requirements of R15-3-308, the Department may revoke a license issued to a tobacco distributor under A.R.S. § 42-3201 if the tobacco distributor fails to comply with this Section, based on the severity of the violations.

NOTICE OF FINAL RULEMAKING

TITLE 20. COMMERCE, BANKING, AND INSURANCE

CHAPTER 6. DEPARTMENT OF INSURANCE

PREAMBLE

- | | |
|------------------------------------|---------------------------------|
| 1. <u>Sections Affected</u> | <u>Rulemaking Action</u> |
| Article 18 | New Article |
| R20-6-1801 | New Section |
| R20-6-1802 | New Section |
| R20-6-1803 | New Section |
| R20-6-1804 | New Section |
| R20-6-1805 | New Section |
| R20-6-1806 | New Section |
| R20-6-1807 | New Section |
| R20-6-1808 | New Section |
| R20-6-1809 | New Section |
| R20-6-1810 | New Section |
| R20-6-1811 | New Section |
| R20-6-1812 | New Section |
| R20-6-1813 | New Section |
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 20-1001 through 20-1004, 20-1008, 20-1009, 20-1015(A)
Implementing statutes: A.R.S. §§ 20-142, 20-143, 20-106, 20-1001 through 20-1019, and 20-2510
 - 3. The effective date of the rules:**

January 10, 2002
 - 4. A list all previous notices appearing in the register addressing the proposed rules:**

Notice of Rulemaking Docket Opening: 6 A.A.R. 4512, December 1, 2000

Notice of Proposed Rulemaking: 7 A.A.R. 2132, May 25, 2001

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

Name: Margaret L. McClelland
Address: Arizona Department of Insurance
2910 North 44th Street, Second Floor
Phoenix, AZ 85018
Telephone: (602) 912-8456
Fax: (602) 912-8452

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

Prepaid dental plan organizations (Organizations) in Arizona have traditionally been subject to dual regulation by the Arizona Department of Health Services (ADHS) and the Arizona Department of Insurance (Department). The Department has been the licensing authority and oversees financial condition, certain aspects of market conduct, policy forms and advertising, and disciplinary matters. ADHS oversaw the health services aspect of the Organizations. During the 2000 Session, the Arizona Legislature passed SB 1172 which, effective July 1, 2001, placed all regulatory authority over Organizations with the director of the Department (director) and removed ADHS as a regulator of Organizations. The final rules provide the framework for regulation of Organizations by the Department.

The Department convened an informal advisory work group to assist the Department in developing these rules. The work group was made up of representatives of a wide spectrum of stakeholders interested in prepaid dental rules, including dentists, prepaid dental plans, and employers. The work group members had an opportunity to review and make comments on two drafts of the proposed rules. The Department considered each of those comments in drafting the proposed rules. Oral proceedings on the proposed rules were held in Tucson and Phoenix in June 2001. The record closed on June 29, 2001. The Department received written and oral comments on the rules and responded to the comments in this preamble and the Concise Explanatory Statement.

The final rules establish definitions, as well as requirements for application for certificate of authority, monitoring, program of compliance, dental care plans, geographic areas served, the chief executive officer, the dental director, maintenance of dental records, quality improvement, and other requirements necessary for regulation of prepaid dental plans. The rules incorporate many requirements that existed in the ADHS rules under 9 A.A.C. 23, Article 4.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

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 Department believes that the benefits of these rules will outweigh the costs.

In this economic impact statement minimum impact means \$5,000 or less. Moderate impact means more than \$5,000, but less than \$10,000. Maximum means \$10,000 or more.

When the regulatory authority previously exercised by ADHS passed to the Department on July 1, 2001, the Department absorbed economic impacts previously absorbed by ADHS, as prescribed in the controlling legislation. The Department transferred two FTEs from ADHS to the Department to carry out the program duties at the Department. The Department is also incurring the costs of administering the program.

The proposed rules will impose no burden on consumers. The rules will provide some intangible benefit through improved access to dental services and improved quality of services.

There was already a regulatory scheme at the Arizona Department of Health Services (ADHS) and the Department with which Organizations generally complied. Many of the requirements of the ADHS rules have been restated in these rules, so there are no new economic impacts to the Organizations for complying with previously existing requirements. Specifically, prior DHS rules required an Organization to have a chief executive officer (R9-23-404, repealed) and a dental director (R9-23-405, repealed).

An Organization may incur minimal costs under R20-6-1805 that requires reporting of some information to the Department not previously required.

An Organization could incur minimum to maximum costs for having to refer a member out-of-network under R20-6-1807(C), if the Organization cannot ensure that the member has an appointment within the required time-frame of nine weeks, as required in that rule. This requirement is essential to ensuring that members receive the benefits promised in their policies.

Arizona Administrative Register
Notices of Final Rulemaking

The Department believes that nine weeks is a reasonable amount of time in which the Organization should be able to schedule its members for initial, non-emergent, diagnostic visits, and that is a reasonable time-frame after which the Department may intervene, in the event that members are unable to access even initial appointments.

In setting the nine-week time-frame, the Department considered the changing dental care marketplace and the availability of the dental work force in the state. The Department also consulted an informal work group for their input on the time this time-frame, as well as the other requirements of this rule. The Department did not receive feedback that this nine-week time-frame is unreasonable. The Department believes that the nine-week time-frame neither imposes an excessive regulatory burden on an Organization, nor unduly compromises the access to dental care for the Organization's members. The Department determined that nine weeks is reasonable and emphasizes the accountability of the Organizations in providing and maintaining access to initial visits throughout a network of general dentists. The Organization can avoid cost by ensuring that it meets the wait time requirements of R20-6-1807(C), or it can mitigate the impact of this rule by keeping noncompliance with this rule at a minimum.

Additional impacts to an Organization may result from the requirement in R20-6-1813 for an assignment process that sets a time limit on assigning members and limits the number of members that may be unassigned at any time. Members of a prepaid dental plan must select a network general dentist at the time of enrollment. Under the former Department of Health Services rule, which did not set standards for the assignment process, Organizations were able to delay making assignments and hold premiums of about \$5.00 to \$12.00 per member, per month, that otherwise would have gone to dentists providing services. Under R20-6-1813, an Organization will be required to assign members to providers promptly and premiums will follow the member and be paid to the provider. The economic viability and network maintenance of this kind of prepaid insurance model depend on providers receiving the monthly premium payments to which they are entitled.

Membership in prepaid dental plans is somewhat fluid in that new members are continuously being enrolled in the plan. Thus, there will always be a small number of members who have not yet been assigned to a dentist. Even under this new rule, the Organization will still be able to hold a small percentage of premiums for members whose assignments have not yet been confirmed. Most Organizations currently comply with the requirements of this new rule and keep the number of unassigned members at a minimum. The rule is structured to give flexibility to each Organization to design its own process with as many efficiencies as possible. This requirement will result in an economic benefit to providers who will have additional members assigned to them and will receive the premiums for those additional members within 30 days.

An Organization could incur minimum to maximum costs to comply with the requirement of R20-6-1804 that requires that the Organization designate a dentist within the Arizona geographic area to act on matters that require immediate, onsite attention if the dental director is not or cannot be in Arizona on a timely basis. The amount of the cost incurred will be determined by the Organization based on how the Organization decides to manage this requirement. It is likely that four of the seven Organizations that have a Certificate of Authority and currently operate in Arizona will have no economic impact from this rule because they already have a dental director or a designee located in Arizona. The remaining Organizations have flexibility in complying with this requirement, such as the option to contract, as needed, on a retainer basis with a qualified dentist.

The Department has included a provision in R20-6-1804(F) that exempts Organizations with fewer than 2,000 members from compliance with the requirement of having a dental director designee located in the Arizona geographic area. The Department believes that the need to have a dental director designee in Arizona is largely volume driven. The greater the membership in Arizona, the larger the network and the greater the number of issues likely to require prompt onsite attention. When there are fewer than 2,000 members, the potential need for onsite attention is less and the benefits are less likely to outweigh the costs. In setting the fewer-than-2,000-member cut-off, the Department considered the exception established in A.R.S. § 20-488.08(D)(3), which governs risk-based capital requirements and exempts from risk-based capital requirements Organizations that cover fewer than 2,000 lives. R20-6-1804(F) could also reduce the economic burden on an Organization that might be a small business.

Other than the impacts discussed for Organizations and providers, the Department expects the rules to provide no additional burdens on private or public employees, businesses or political subdivisions, or the state. The Department expects no discernible effect on state revenues as a result of these rules.

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

The Department made changes to the rules in response to oral and written comments received, as described in section 11 below. The Department made changes to the rules based on comments from the staff of the Governor's Regulatory Review Council regarding public comments received, as well as G.R.R.C. staff suggested changes to grammar, style, format, and punctuation. Additional changes were made for clarity, conciseness, and understandability. The Department moved the requirements of R20-6-1815, Disclosure of Information to R20-6-1802(I). The Department deleted R20-6-1815, Annual Report and R20-6-1816, Application, Examination, and Licensing of Producers because the requirements are already in statute.

11. A summary of principal comments and the agency response to them:

R20-6-1802. Application for Certificate of Authority

Arizona Administrative Register
Notices of Final Rulemaking

R20-6-1802(B)

COMMENT: Two commenters expressed concern with the requirement that a fidelity bond required under A.R.S. § 20-1004 be issued by an insurer authorized to transact business in Arizona. One commenter stated that if a parent company is located in a state other than Arizona and has an umbrella policy that covers all locations, that should suffice. One commenter suggested the rule be revised to allow the fidelity bond be issued, at the appropriate and required levels, by an insurer licensed to transact insurance in any state.

RESPONSE: The Department agrees and the rule has been revised to allow the fidelity bond required under A.R.S. § 20-1004(A)(4) to be issued by any authorized insurer.

R20-6-1802(H)(2)

COMMENT: A commenter stated that the rule should require each plan dentist to state the number of hours the dentist intends to work for the plan, either hourly or a percentage. The commenter suggested that uppercase language be inserted at the end of (H)(2) that states "... AND INDICATES THE NUMBER OF HOURS PER WEEK, ON AVERAGE, THE DENTIST WILL DEVOTE TO PATIENTS WHO ARE MEMBERS OF THE PREPAID DENTAL PLAN". The commenter believes this will provide the Department with a tool for determining if the plan has sufficient number of dentists and if there are critical gaps in the network.

RESPONSE: The Department disagrees with this comment. The Department believes that this requirement would be overly burdensome to the provider and the provider would not be able to accurately predict the number of hours the provider would work for a plan over the contract period. Additionally, it would be burdensome to the Department to monitor and enforce such a requirement. The Department's interest in having a sufficient number of dentists in the network and in assessing and improving network adequacy is addressed under R20-6-1807, including R20-6-1807(C), that establishes a limit on the length of wait times for initial diagnostic appointments. The Department's related interest in having consumers provided with accurate information about dentists available in the network is addressed by R20-6-1811, which sets forth the requirements for the accuracy of provider directories.

No change to the rule.

R20-6-1802(H)(3)

COMMENT: Several commenters believe the requirement that the application include a list of clinical staff by classification for each general dentist is onerous and unnecessary. The commenters state dental practice clinical support staff change frequently; the data provided will not be accurate one day after it is collected. It was suggested clinical support staff should be licensed appropriately and that it be the duty of the owner dentist to ensure that only licensed personnel are employed and comply with regard to scope and function according to Title 4, Chapter 11, Articles 5,6,7,8, 9 & 10 of the Arizona Administrative Code.

RESPONSE: The requirement for listing support staff by classification will be deleted.

COMMENT: A commenter is unclear whether the requirement of R20-6-1802(H)(3) is a one-time requirement for filing of an initial certificate of authority, or will it be an ongoing requirement.

RESPONSE: The requirement for listing support staff by classification will be deleted.

R20-6-1803. Chief Executive Officer

R20-6-1803(B)

COMMENT: A commenter questions why it is necessary for a CEO to have an office in the Arizona service area and expressed concern that such a requirement imposed nationally would require 50 CEOs. Another commenter requests that the Department delete the requirement for the CEO to maintain, and be present at an office within Arizona at all times. Both commenters state that it is the responsibility of the CEO to maintain adequate staff within the state to assure compliance with required laws or statutes and regulations.

RESPONSE: It is not clear from these comments whether the commenters object to having to maintain an office in Arizona **and** to having the CEO available at that office or object only to having to have a CEO available in Arizona. If the commenters object to maintaining an office in Arizona, the Department is puzzled by their affirmative statements that "it is the responsibility of the CEO to maintain adequate staff within the state." Presumably, the staff would need to work at an office of some kind.

The Department believes that it would be optimum for the Organization to have an office in Arizona. However, the Department believes that without an Arizona office, the Organization could stay in compliance with the requirements of these rules and the controlling statutes, as long as there is adequate staff in Arizona. Having considered the comments, the Department has concluded that it will not require the Organization to have an office in the state. The rule is revised accordingly.

With regard to the commenters' objection to having the CEO available in Arizona, the Department recognizes that some Organizations have CEOs who are responsible for operations in more than one state, do not work full time on matters relating to any one state, and may do a significant amount of their work on Arizona matters while in another state. The concern the Department sought to address is the Organization's commitment to a reasonable amount of personal oversight by a CEO within the state and that the Organization has enough interest in Arizona members to be

Arizona Administrative Register
Notices of Final Rulemaking

available within the state to address high level management issues. However, the Department believes this concern can be adequately addressed by means other than the CEO's physical presence in the state, such as the use of electronic methods of communication.

Having considered the comments, the Department has deleted the requirement that there be a CEO available at an office in the Arizona geographic area, giving the Organization and the CEO the flexibility to determine the availability of the CEO in Arizona.

ISSUE: The G.R.R.C. staff commented that the Department cannot place education and experience requirements on the CEO of the Organization.

RESPONSE: Interested parties and the regulated community had opportunities to review and comment on the rule-making during informal and formal comment periods. The Department did not receive comment on the requirement that the CEO have education and experience or any expression of concern that the requirement is inappropriate or burdensome. Although the G.R.R.C. staff raised a question about the need for this provision, the Department kept the requirement, which has been in place since ADHS adopted this provision in 1996. The Department believes that it is a sound business and healthcare practice and essential for the Organization's governing authority to select a person who is capable of running the business. This requirement is directly related to the Department's statutory responsibility under A.R.S. 20-1004(A)(1) to determine that "the persons responsible for conducting the affairs of the prepaid dental plan are competent and trustworthy and are professionally capable of providing or arranging for the provision of services offered."

R20-6-1804. Dental Director

R20-6-1804(A)

COMMENT: A commenter expressed support for the provision that requires the dental director be licensed to practice dentistry in any state or territory of the United States or the District of Columbia.

RESPONSE: The Department appreciates the comment in support of the rule. No response required.

COMMENT:A commenter stated that the rules should require that the dental director be an Arizona licensed dentist.

RESPONSE: The Department disagrees with this comment. All licensed dentists receive similar training and pass similar regional dental board examinations in order to receive their licenses. The general qualifications of those dentists are relatively equal. In order to serve as a dental director, a dentist must possess additional qualifications and experience to be effectively involved in the management decisions and quality improvement processes in an Organization. These additional qualifications and experiences are not gained through taking a dental board examination, but through participation in business management and quality improvement processes. Therefore, the director believes that an Arizona license for the dental director is less relevant than qualifications and experiences needed to be an effective dental director. As the commenter notes, if the dental director is responsible for direct denial of care on the basis of medical necessity, the dental director must be licensed in Arizona, as required in A.R.S. § 20-2510(B) and (C).

R20-6-1804(B)

COMMENT: A commenter stated that the Department is micro-managing the Organization by setting forth this requirement.

RESPONSE: The Department disagrees with this comment. The Department views this as part of its statutory obligation under A.R.S. § 20-1004(A)(2) to be satisfied that the Organization constitutes an appropriate mechanism to achieve a prepaid dental plan. The Department has an interest in ensuring that the Organization and dental director manage the provider network and be involved in network decisions. The Department feels that this is essential to providing quality services to the members served by the network.

No change to the rule.

COMMENT: A commenter suggests that the word "activities" is missing at the end of the sentence.

RESPONSE: The Department revised the rule to add "aspects of" for clarity.

R20-6-1804(C)

COMMENT: The Department received several comments that the requirement that the dental director be "physically present within the Arizona geographic area during normal business hours" is problematic and restrictive for plans with operational centers outside Arizona, and could add to administrative costs, especially for a dental director of a multi-state plan. Several commenters recommended technological or electronic availability instead of physical presence in the state. Two commenters stated that the dental director should visit the area regularly. Another commenter suggested a dental consultant acting as dental director can make clinical decisions as necessary during normal business hours and should have authority to make quality of care decisions for the plan. Two commenters objected to having to have a full time dental director in Arizona.

RESPONSE: As with the CEO, the Department recognizes that some Organizations have dental directors who are responsible for operations in more than one state. Those dental directors may not work full time on matters relating to

Arizona Administrative Register
Notices of Final Rulemaking

any one state and may do a significant amount of their work on Arizona matters while in another state. However, the Department believes strongly that the role of the dental director is different from the role of the CEO. Occasionally, there are urgent situations that will require immediate attention and decision-making authority from a dental director who is onsite in the Arizona geographic area. Some such situations include the need for prompt resolution for urgent patient care issues that require examination of dental records or prompt personal discussion with a provider of urgent, adverse problems relating to credentialing, disciplinary problems, access to care, or quality of care. If the dental director is not or cannot be onsite in the Arizona geographic area on a timely basis to address these concerns, there must be a qualified dentist who represents the dental director and is able to act on behalf of the dental director in the Arizona geographic area.

The Department believes that a dental director who functions as a strong professional liaison between the Organization and network providers will more effectively be able to resolve issues of quality of care, access to care, network development and management, and service concerns. This liaison role requires a personal working relationship with network dentists, understanding of dental standards and practices in the community, and knowledge of the Arizona Dental Practice Act and its impact on delivery of dental services in Arizona. Having a dentist representative available in Arizona will strengthen that liaison role.

The rule is revised to remove the requirement for maintaining an office in Arizona and to add a provision for a dental director designee.

R20-6-1805. ~~Changes to the Program of Compliance~~ Required Reporting

COMMENT: A commenter stated that this Section heading should be changed to "Required Reporting".

RESPONSE: The Department agrees and the heading will be changed accordingly.

COMMENT: A commenter stated that this Section should specify a maximum dentist: member ratio, and suggest that the ratio no more than 1:4,000.

RESPONSE: The Department disagrees that it is appropriate to establish such a ratio. The rate of growth of the population in Arizona has greatly exceeded the rate of growth of new dentists in the state. Therefore, establishing such a ratio could have a negative impact on the ability of members to receive services under a plan. The Department believes that the wait time requirements in R20-6-1807(A)(1)(c) and (C) will more effectively allow members to receive services within a reasonable time.

No change to the rule.

R20-6-1805(B)

COMMENT: A commenter requested that the requirement for providing the information listed in this subsection be changed from quarterly to semi-annually.

RESPONSE: The Department believes that semi-annual reporting of these requirements would not allow the Department to effectively monitor these Organization activities. Semi-annual reporting of this information would allow too much time to pass between reporting. This would make oversight by the Department less effective and could result in a serious decline in the quality and delivery of services going unnoticed. The Department also needs to review this information quarterly to determine whether the Organization continues to meet the requirements to retain its certificate of authority.

No change to rule.

R20-6-1805(B)(2).

COMMENT: A commenter stated that the electronic database would not need to be filed quarterly and that only the changes to it should be filed after the initial filing. The commenter suggests that each plan should have quarterly meetings of the Plan, Quality Improvement, Peer Review and Credentialing committees in which plans are required to report on aspects of QI Plan including:

1. Access measures included should be reported to assure adequacy of:
 - a. Network capacity;
 - b. Appointment availability; and
 - c. Geographic access
2. Credentialing and re-credentialing activity
3. Chart review and structural audit
 - a. Risk management
 - b. Chart reviews
 - c. Targeted reviews

Arizona Administrative Register
Notices of Final Rulemaking

d. The actions directed by committees and/or dental director should be reported that reflect the plan's activity to assure compliance with the plan's QI plan.

e. Grievance reporting – adequate to assure that plan member issues are resolved satisfactorily and in a timely manner.

Another commenter requested that the provision require an initial submission of the electronic database of providers and that submissions of revisions to the database would be filed on a quarterly basis.

Another commenter stated that (B)(2) is not clear as to whether the information provided is for the members or the dentists.

RESPONSE: The Department requires quarterly reporting of the aspects of the quality improvement program that the commenter lists. Quarterly reporting is necessary so that the Department can monitor the quality improvement plan and ensure that members are being provided quality services. However, the Department agrees that the requirement for filing of the electronic database in subsection (B)(2) should be changed from quarterly to annually, with quarterly filing of any changes to the database. Subsection (B)(2) will be deleted and a new subsection (C)(3) containing the database requirements is added.

COMMENT: A commenter requested that the following language be added to R20-6-1805(B)(10):

10. A list of each plan dentist and the number of hours per week, on average, devoted to the delivery of dental services to members of the plan.

RESPONSE: The Department disagrees with this comment. The Department does not require that a provider devote a set number of hours per week to the delivery of dental services to a plan and does not believe that this would be useful information. The Department believes that the underlying issue of concern here is the wait time for an initial dental appointment and that concern is adequately addressed in R20-6-1807(C) by requiring wait times be less than nine weeks.

No change to the rule.

R20-6-1806. Basic Dental Services

COMMENT: One commenter favors more flexibility in plan design and prefers that the members, employers, and carriers design and determine basic dental services.

RESPONSE: A.R.S. § 20-1004 mandates that the director establish basic dental services appropriate for dental plans. To allow each Organization to establish its own list of basic dental services would be contrary to statute. The director believes that the services set forth in R20-6-1806(B) are appropriate and that the services set forth meet the mandate of A.R.S. § 20-1004(A)(2).

No change to the rule.

COMMENT: A commenter states that this rule should specify that prepaid dental plans must provide basic dental services without any additional payment beyond the premium and that requiring copays is not prepaid dental insurance as authorized by Arizona law. The commenter further states that it is inconsistent with statutory intent for prepaid dental plan members to pay copays in addition to the monthly premium, for the basic dental services listed in this Section. The commenter cites A.R.S. §§ 20-1004(A)(2) and 20-1015.

RESPONSE: The Department disagrees with these comments. First, the Department disagrees that A.R.S. §§ 20-1004(A)(2) and 20-1015 are dispositive. These statutes require the director to establish a list of services an Organization must be competent to provide, or arrange for, as basic dental services, in order to obtain and maintain a certificate of authority. These statutes do not address copays or any other financial or economic aspect of providing prepaid dental services.

Second, allowing physicians to charge copays does not violate Title 20. Health insurance is “prepaid” if the provider receives a set periodic payment for each patient, regardless of whether the provider provides any care to that member. Patient copays, in addition to premiums, are a standard component of prepaid health insurance, whether for dental, medical, behavioral, vision, or any other health services. A copay is “partial payment of medical service expenses required in group health insurance, in addition to the membership fee”. Rubin, H., The Dictionary of Insurance Terms, 4th edition, 2000, at p. 112. In the case of prepaid dental insurance in Arizona, copays are flat fees that are set in advance. They are the maximum the dentist may charge, regardless of the actual cost of the services and they represent a discount from the usual, customary, and reasonable fees for the services. That discount is part of the value that members receive in exchange for the premium they pay to their prepaid dental plan.

The Department notes that prepaid dental insurance copays may be different from typical medical HMO copays, to the extent that the prepaid dental insurance copays may vary with the service being provided, and may be much larger than medical copays. For example, in some cases in Arizona, the prepaid dental insurance copay could be as much as \$365 for a porcelain-fused-to-metal crown, or \$375 dollars for a molar root canal. This copay structure is not a violation of Title 20, and does not take the arrangement out from under the prepaid dental insurance umbrella.

The copay structure is essentially dictated by the economics of providing dental insurance on a prepaid basis. For example, premiums of approximately \$9.00 per member, per month are paid to the organizations. These low premi-

Arizona Administrative Register
Notices of Final Rulemaking

ums are a key factor in making prepaid dental coverage available. The Organization may pay each participating dentist approximately \$5.00 per member, per month. To require that all basic dental service be provided solely for the cost of the monthly premium could have the result of: (1) inducing dentists to decline to participate in prepaid dental plans, resulting in fewer prepaid dental plan options, and higher costs to those seeking dental care; or (2) increased premiums, making prepaid dental coverage less affordable to consumers.

Despite disagreement with the commenter's interpretation of statutory intent and position regarding copays, the Department believes that R20-6-1806(C) should be revised to improve the Department's ability to monitor copays and assess whether in fact they represent a discount from the usual, customary, and reasonable fees for the services. R20-6-1805(C) is revised to add a new subsection (C)(4) accordingly.

R20-6-1806(A)(4)

COMMENT: In addition to the comment above, the commenter states that a clarification should be made to the text to make it clear that only amalgam fillings, and not composite fillings or crowns, are included within the concept of basic dental services. The commenter suggested changing the rule to read as follows:

Amalgam fillings.

RESPONSE: Department disagrees with this comment. The Department has determined that Organizations should include composite fillings and crowns as part of the restorative services they provide or arrange for. Because the Department recognizes that these services could be more expensive than amalgam fillings, a plan is allowed to charge a copay for the service.

No change to the rule.

R20-6-1807. System for Delivery of Service

COMMENT: A commenter expressed support of the requirements in subsections (B), (C) and (D).

RESPONSE: The Department agrees with this comment. No change required to the rule.

R20-6-1807

COMMENT: A commenter suggested that the Department clarify that the term "appointment" means "first available" appointment.

RESPONSE: The Department agrees. The definition is revised to delete the term "scheduled" and add "first available" to the definition.

R20-6-1807(A)(1)(c)

COMMENT: A commenter expressed concern about the requirement for reporting the percentage of members who are able to schedule an appointment within nine weeks. The commenter suggests that rather than using a set number of weeks, the Department should consider the average wait time of all dentists in a particular geographic area.

RESPONSE: The Department considered using average wait times of all dentists in a particular geographic area. However, the Department determined that that would be a fluctuating and inconsistent method for monitoring wait times. Also, the complexity of data gathering, compilation of data, and determination of average wait times quarterly would be extensive and not a cost-effective use of time for the Department or the Organizations. Also, the Department would have to constantly update the rules to establish and publish the current wait time, as determined by the average wait times for each geographic area established. This would be a burdensome process.

Wait time is only one factor that the Department considers in determining network adequacy. Geographic distribution of dentists, and current availability for all general dentists in Arizona are other factors considered under this Section.

No change to the rule.

R20-6-1807(A)(1)

COMMENT: A commenter questioned how the information in R20-6-1808(A)(1)(e) and (f) would be determined and whether there would be a uniform information source for all plans.

RESPONSE: The Department has many resources available for the information under (A)(1)(e), including state and federal census and BODEX. The information gathered would be uniformly applied to all plans.

R20-6-1807(A)(2)

COMMENT: The commenter states that if a plan does not provide specialty care, it should not have to cover out-of-network specialty care. Accordingly, if it does provide such coverage, an obligation to provide specialty care from a non-network dentist would be suitable in cases where the plan failed to contract with a network specialist in a given area.

RESPONSE: The rule is revised to clarify that this information is required only if such services are covered benefits. Subsection (3) is also stricken for further clarification.

R20-6-1807(C).

Arizona Administrative Register
Notices of Final Rulemaking

COMMENT: One commenter supports the requirement for plans to monitor appointment availability and arrange for members to seek care outside the network when network dentists do not provide timely appointments.

RESPONSE: The Department agrees with this comment; no change required.

COMMENT: The Department received a comment in support of the requirements in this Section.

RESPONSE: The Department agrees with this comment; no change required.

COMMENT: A commenter expressed concern that network dentists would not have an incentive to reduce wait-times if consumers could move to non-network dentists and not be required to return to the network regardless of improvement in wait-times. Another commenter expressed a similar concern that allowing the consumer to go, and remain, out-of-network, would have an adverse affect on the viability of provider participation in the plan, due to the loss of a patient.

RESPONSE: The Department believes that these are not valid concerns. Members are entitled to timely access to care, for which they pay premiums. It is the Organization's responsibility to provide and manage an adequate network and this requirement should not interfere with that. Presumably, if a member assigned to a particular plan provider is referred to an out-of-network provider, the plan provider no longer will receive a monthly capitation payment for that member unless or until the member is reassigned to that provider. Potential loss of capitation payments is itself an incentive for plan providers to maintain required wait times. Moreover, an Organization is free to provide positive incentives to plan providers to keep wait-times within the required time-frames and thereby enhance provider participation and strengthen overall network adequacy.

No change to the rule.

COMMENT: A commenter expressed a concern that quality management oversight can only be provided when care is provided by network dentists.

RESPONSE: This comment implies that that quality management oversight consists entirely of reviewing the qualifications of network dentists. Quality management oversight includes making sure that members have timely initial access to care and choice with regard to continuity of care. This rule balances the importance of choosing qualified network providers with the importance of getting in to see the dentist in the first place. Moreover, Organizations can choose the dentists to whom they refer patients and seek "overflow" contracts with those dentists. Such contracts could reduce the Organization's out-of-network costs and permit credentialing.

No change to the rule.

COMMENT: A commenter stated that it could not identify any clinical or administrative reason why the member would be better served by remaining with the out-of-network dentist for the period following the initial appointment and stated that the member's dental record would typically be with his or her primary care dentist.

RESPONSE: The Department has determined that the importance of continuity of care is a sound clinical basis for this requirement, and that minimizing disruption and inconvenience to members is a sound administrative basis. Members protected by this rule will typically not have records with a primary care dentist with the Organization, because they will be referred out-of-network for an appointment.

No change to the rule.

COMMENT: A commenter expressed concern that members receiving services from out-of-network providers might be balance-billed by those providers if the member was not required to return to the network before the end of the enrollment period.

RESPONSE: This rulemaking will not prevent balance-billing by an out-of-network provider who is not subject to the requirements of this rulemaking. The Department recognizes that it could be an inconvenience to the member to be balance-billed, but it would not create any additional financial liability, as the rule clearly requires that the Organization provide the services at no greater cost than the member would otherwise incur. The concern the Department seeks to address with this rule is access to care and the potential detriment to health that could result from a wait time of more than nine weeks to see a dentist for an initial appointment. The Department believes that the certainty of access to care that the rule provides far outweighs possible inconvenience of balance-billing from an out-of-network provider. The Department encourages Organizations to seek "overflow" contracts with non-plan dentists. Such contracts could reduce the Organization's out-of-network costs, permit credentialing, and prohibit balance-billing.

COMMENT: Two commenters expressed concern that this requirement will result in higher premiums if the referred patient remains with an out-of-network dentist for the remainder of the enrollment period.

RESPONSE: It is difficult for the Department to respond to these concerns with no specifics from the commenters about the basis for these concerns, and how much extra expense they perceive an Organization might incur, or how that extra expense would affect premiums.

If the out-of-network requirements are read in the context of all of R20-6-1807(C), it is clear that each Organization has ample control and opportunity to avoid sending even one member out-of-network. Specifically, before any member must be referred out-of-network, the Organization must have more than 15% of its offices not able to schedule "appointments" in less than nine weeks. Under R20-6-1801, "appointment" means a first available, initial, non-emer-

gent, diagnostic visit to the dentist. Careful management and oversight by the Organization would allow the Organization to avoid such a significant number of members having wait times that would require that they be referred out-of-network.

Even if the Organization does not manage its network to avoid having more than 15% of its offices not able to schedule appointments in less than nine weeks, the Organization has 90 days to cure the non-compliance by reducing the number of non-compliant offices to no more than 15%. This gives the network another significant opportunity to avoid referring a member out-of-network.

If the Organization cannot cure the non-compliance in 90 days, it can refer patients to a network office that is in compliance, again having ample opportunity to avoid referring the member out-of-network.

Only after failing to take advantage of and manage significant opportunities to avoid out-of-network referral is an Organization required to send patients out-of-network. Even then, only those patients who are waiting for "appointments," as defined above, would be referred out.

Once a member is referred out-of-network, the member may choose to remain out-of-network for the remainder of the enrollment period. Nothing prohibits the Organization from offering the member the choice to re-establish with a network dentist before the end of the enrollment period. Because enrollment periods are finite, usually lasting one year, the Department foresees few situations where, under all these circumstances, out-of-network costs occasioned by this rule should have a significant impact on premiums.

In the absence of specifics, and in light of the opportunities for an Organization to avoid referral out-of-network, the Department does not agree that this requirement is burdensome, or is very likely to result in higher premiums. An Organization that genuinely anticipates significant out-of-network costs has other means to avoid raising premiums. For example, an Organization could pay incentives to plan providers to meet or exceed the nine week availability standard, or, as noted above, negotiate discounted fee-for-service contracts with select non-plan providers.

No change to the rule.

COMMENT: Commenters suggested that the rule be revised to allow the plan to require the consumer to return to the consumer's network office or a replacement network office as soon appointment availability meets the required time-frames.

RESPONSE: The Department disagrees with this suggestion for several reasons. The rule is intended to create an incentive for an Organization to maintain a minimum wait time for an "appointment" as defined in R20-6-1801. It is a disservice to members who go outside the network for initial, non-emergent, diagnostic visits to be required to return to the network to start the process all over again, just to save the Organization money. For continuity of care and convenience, the patient should have the option of remaining with the out-of-network dentist.

The member may choose to remain out-of-network only for the remainder of the enrollment period. This would normally be for a period of less than a year. By implication, the Organization may have a process in place to offer the member the choice to re-establish with a network dentist before the end of the enrollment period.

No change to the rule.

COMMENT: A commenter suggests that the member should be allowed to go out-of-network only until the end of the "treatment episode" and not for the remainder of their enrollment.

RESPONSE: It is not clear what the commenter means by "treatment episode". Members who are protected by this rule are those who are waiting for an "appointment", defined under R20-6-1801 as a "first available, initial, non-emergent, diagnostic visit to the dentist". Not all of them will require immediate treatment but some may require treatment later in the enrollment period. The rule is designed to provide access and choice to members who have been inconvenienced and under-served by poor availability. It would be a disservice to members who go outside the network for initial, non-emergent, diagnostic visits to be required to return to the network to start the process all over again, just to save the Organization money. For continuity of care and convenience, the patient should have the option of remaining with the out-of-network dentist to whom they have been referred.

No change to the rule.

COMMENT: Commenters suggested that the rule allow plans to seek financial redress from, or backcharge, the network dentist who did not meet the required time-frames.

RESPONSE: The Department disagrees that such a provision should be included in this rule. The Department does not have the authority to promulgate a rule that may have the effect of establishing a fee without specific statutory authority for the fee. See A.R.S. § 41-1008.

No change to the rule.

COMMENT: R20-6-1807(C) seems to be in conflict with the standard, in that they only require 15% of network offices to have wait times less than nine weeks.

RESPONSE: The Department agrees that for clarity, the first sentence of R20-6-1807(C) should be stricken. Additionally, the Department revised the third sentence in R20-6-1807(C) to correct a typographical error. The text was

Arizona Administrative Register
Notices of Final Rulemaking

intended to require a wait time of less than “9 weeks” as stated in the previous sentence, rather than “90 days.” The rule is revised for clarity.

R20-6-1809. Contract Requirements

R20-6-1809(B)

COMMENT: A commenter stated that this subsection should require a recall system that includes, at least, discussion of the importance of regular checks-ups, an annual newsletter, each member receives a written reminder of periodic preventive dental services, and that there be follow-up in 30 days for those who do not respond.

RESPONSE: Department believes that there must be a recall system as required R20-6-1810(B)(2), but the dental office should determine how it will manage the details of a recall system.

No change to this subsection.

R20-6-1810. Records

R20-6-1810(A)

COMMENT: The plan should not be responsible for ensuring that the provider maintains proper records. These requirements should be under the purview of the Arizona Board of Dental Examiners (BODEX), in compliance with the Dental Practice Act.

RESPONSE: The Department agrees with this comment and subsection (A) has been deleted. Subsections (B) and (C) are renumbered accordingly.

R20-6-1810(B)

COMMENT: The Department received several comments stating that the requirement that records “shall not be removed from the provider’s premises” should read “shall not be removed from the provider’s possession.” A provider is not always able to store all records on premises. A commenter requests that the rules be revised to allow storage of the records off-site as appropriate.

RESPONSE: The Department agrees with this comment and the word “premises” is changed to “possession”. Additionally, the Department revised subsection (B)(2) to clarify that the records may be removed from the possession of the provider when subpoenaed by the BODEX.

R20-6-1811. Quality Improvement

COMMENT: The Department received a comment in support of the requirements in this Section.

RESPONSE: The Department agrees with this comment; no change required.

R20-6-1811(E)(1)

COMMENT: A commenter suggests that the regulatory trend for review of each contracted general dentist is to review every three years, instead of every two years and recommends that this requirement be changed accordingly.

RESPONSE: The Department agrees with this comment and the rule is revised to change “2” to “three,” to reflect the regulatory trend. The review every three years is the industry standard and the Department believes that standard is no less protective of the public and it does not affect quality of care.

COMMENT: A commenter stated that there are situations when a facility or chart review every two years is not necessary and recommends that all newly licensed plans audit all offices prior to contracting and within two years of contract initiation; thereafter, audits be scheduled based upon performance.

RESPONSE: The interval for review of charts has been revised from “2” to “three” years to reflect the regulatory trend.

R20-6-1811(E)(2)

COMMENT: Practice protocols should follow what is required of dentists by the BODEX under the Dental Practice Act.

RESPONSE: The Department agrees with this comment. The rule is revised to strike subsection (E)(2).

R20-6-1811(E)(7)

COMMENT: A commenter stated that the specialist providers under the commenter’s plan do not have Drug Enforcement Administration (DEA) numbers because they do not write prescriptions that require controlled substances. There are also some general dentists who do not have DEA numbers. The rule should require a DEA number “if applicable.”

RESPONSE: The Department agrees with the comment and the phrase “if applicable” will be added at the end of subsection (E)(7)(c).

R20-6-1811(E)(7)(e)

Arizona Administrative Register
Notices of Final Rulemaking

COMMENT: The commenter stated that not all specialists in dentistry are board eligible or board certified in dentistry and requests that this rule be revised to comply with the minimum standard of graduation from an accredited specialty graduate program as defined by the American Dental Association, as required by the BODEX.

RESPONSE: The Department agrees. The rule will be revised to require documentation that each specialist has graduated from an accredited specialty graduate program as required by the BODEX

R20-6-1811(E)(9)

COMMENT: Several commenters expressed concern about the requirement for “continuous recredentialing”, as opposed to recredentialing every two or three years. A commenter stated that the regulatory trend is to recredential every three years. A commenter expressed concern that the value in return for the additional cost is not clear and could result in an increase in premiums. Additionally, a commenter stated that it is unclear what “continuous” recredentialing means.

RESPONSE: The rule is revised to clarify that recredentialing will occur at least every three years.

R20-6-1812. Confidentiality of Records

COMMENT: A commenter stated that the commenter does not believe the Department has statutory authority to require confidentiality of records as set forth in this rule. The commenter questions why contract information is confidential and believes that patient records should not automatically be confidential, but the member should be able to choose confidentiality of only identifying information.

RESPONSE: The confidentiality of information submitted to the Department under this Article is governed under A.R.S. § 39-121, so, there is no need to address confidentiality of this information here. The rule is revised to remove the requirement of confidentiality of contracts with providers submitted under this Article.

R20-6-1813. Assignment of Members

COMMENT: The Department received a comment in support of the requirements in this Section.

RESPONSE: The Department agrees with this comment; no change necessary.

COMMENT: A commenter expressed concern about legal liability from having the Organization assign members to a provider if the member does not choose a dentist.

RESPONSE: As an operator of a prepaid dental plan, an Organization could have to address issues of legal liability that arise from such operation. However, the Department is not aware of additional liability that arises solely from the requirement of having the Organization assign unassigned members to a dentist.

The Department has an interest in requiring that plan members be assigned to a provider within a reasonable time, allowing them to access care. Subsection (B) provides that a member can choose a different dentist if the member does not choose to go to the provider chosen by the Organization.

R20-6-1813(B)

COMMENT: A commenter expressed concern about the requirement to assign a member to a dentist who is closest to the member’s home, and states that it is unclear exactly how it would be determined which dentist is closest to the patient’s home. The commenter thinks that quality improvement functions, not just distance, should be considered in making assignments.

RESPONSE: The Department’s key concern here is that the members be assigned. It is less critical for the Department to try to establish every criterion that an Organization could use to determine member assignment. After an assignment is made by the Organization, the member has the option of choosing another dentist that the member decides is more convenient. The rule is revised to delete text regarding assigning the member closest to the member’s home and clarify that the Organization shall allow the member to select their network provider.

R20-6-1815. Annual Report

COMMENT: The reference to A.R.S. § 20-1000 should be 20-1009.

RESPONSE: This Section is deleted because the requirement is contained in statute.

GENERAL COMMENTS:

COMMENT: Several commenters thanked the Department for the opportunity to give input in the drafting of this rulemaking.

RESPONSE: The Department appreciates the comments.

COMMENT: A commenter gave his perspective of the history of abuses in prepaid dental plans in Arizona and the legislative and administrative agency responses to those abuses.

RESPONSE: While those comments are not specific to the text of these rules, the Department appreciates these comments.

Arizona Administrative Register
Notices of Final Rulemaking

COMMENT: A commenter expressed concern that dentists who provide services under a plan will be subject to more scrutiny than non-plan dentists.

RESPONSE: The Department agrees that dentists who do not provide services under a prepaid dental plan would not be subject to requirements of these rules, while dentists who choose to be prepaid dental plan providers are. The Arizona legislature determined that regulation in this area is necessary to improve the quality of services provided by prepaid dental plans, especially in light of the closed networks operated by some Organizations. The Department believes these rules reasonably reflect the legislative intent.

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 the rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 20. COMMERCE, BANKING, AND INSURANCE

CHAPTER 6. DEPARTMENT OF INSURANCE

ARTICLE 18. ~~RESERVED~~ PREPAID DENTAL PLAN ORGANIZATIONS

Section

R20-6-1801. ~~Reserved~~ Definitions

R20-6-1802. ~~Reserved~~ Application for Certificate of Authority

R20-6-1803. ~~Reserved~~ Chief Executive Officer

R20-6-1804. ~~Reserved~~ Dental Director

R20-6-1805. ~~Reserved~~ Required Reporting

R20-6-1806. ~~Reserved~~ Basic Dental Services

R20-6-1807. ~~Reserved~~ System for Delivery of Services

R20-6-1808. ~~Reserved~~ Geographic Areas

R20-6-1809. ~~Reserved~~ Contract Requirements

R20-6-1810. ~~Reserved~~ Records

R20-6-1811. ~~Reserved~~ Quality Improvement

R20-6-1812. ~~Reserved~~ Confidentiality of Records

R20-6-1813. ~~Reserved~~ Assignment of Members

ARTICLE 18. ~~RESERVED~~ PREPAID DENTAL PLAN ORGANIZATIONS

R20-6-1801. ~~Reserved~~ Definitions

In this Chapter, the following definitions apply:

“Appointment” means a first-available, initial, non-emergent, diagnostic visit to a dentist.

“Board certified” means a dentist who is recognized by the appropriate specialty board of the Commission on Accreditation of Dental Education of the American Dental Association.

“Board eligible” means a dentist who successfully completes an approved training program in a specialty field recognized by the American Dental Association.

“Chief executive officer” means the person who has the authority and responsibility for the operation of a prepaid dental plan Organization according to applicable legal requirements and policies approved by the governing authority.

“Dental hygienist” means a person who is licensed to practice dental hygiene under A.R.S. § 32-1281 et seq.

“Dentist” means a person who is licensed to practice dentistry under A.R.S. § 32-1201 et seq.

“Department” means the Arizona Department of Insurance.

“Diagnostic service” means a dental service intended to identify a dental abnormality, and includes a radiograph and a clinical exam.

“Director” means the director of the Arizona Department of Insurance.

Arizona Administrative Register
Notices of Final Rulemaking

“Emergency dental service” means a dental service intended to evaluate and stabilize a dental condition of recent onset, control bleeding, and relieve pain, and includes the provision of local anesthesia, and elimination of acute infection, but does not mean a medication that is prescribed by the dentist.

“General dentist” means a dentist whose practice is not limited to a specific area and who is not board certified.

“Governing authority” means the persons, including a board of trustees or board of directors, who have the ultimate authority and responsibility for the direction of a prepaid dental plan Organization.

“Organization” means a prepaid dental plan organization as defined in A.R.S. § 20-1001.

“Patient” means a person who is being attended by a dentist or dental hygienist to receive an examination, diagnosis, or dental treatment, or a combination of an examination, diagnosis, and dental treatment.

“Preventive service” means dental care intended to maintain dental health and prevent dental disease, including any combination of oral hygiene education, routine prophylaxis, and application of fluorides.

“Prophylaxis” means cleaning the teeth of a patient with healthy tissue using mild abrasives and dental instruments to remove plaque, calculus, and stains above the gum line.

“Provider directory” means an Organization’s published listing of all contracted network dentists.

“Radiograph” means a picture produced on a sensitive surface by a form of radiation other than light, including x-ray.

“Restorative service” means the use of a metal or composite filling or crown.

“Specialist” means a dentist whose practice is limited to one of the nine specialty categories recognized by the American Dental Association: endodontics, oral and maxillofacial surgery, oral and maxillofacial radiology, orthodontics and dentofacial orthopedics, pediatric dentistry, periodontics, prosthodontics, oral pathology, or dental public health.

“Treatment plan” means a statement of the services to be performed to eliminate or alleviate a patient’s symptoms or disease, based on a dentist’s assessment of the patient’s dental history, the clinical examination, and the dentist’s diagnosis.

R20-6-1802. Reserved Application for Certificate of Authority

- A.** A person who wishes to operate as prepaid dental plan organization in Arizona shall file an application for certificate of authority under A.R.S. § 20-1003 for the director’s review and approval under A.R.S. § 20-1004. The application shall contain all the information required in A.R.S. § 20-1003 and R20-6-1802.
- B.** An authorized insurer shall issue the fidelity bond required under A.R.S. § 20-1004(A)(4).
- C.** An Organization shall not commence operation of, or service under, a prepaid dental plan without approval of the director under A.R.S. § 20-1004.
- D.** An application is deemed filed with the director when the director receives it. The applicant shall include fees under A.R.S. § 20-167 with the application.
- E.** An applicant not domiciled in this state shall file a power of attorney as required by A.R.S. § 20-1003(A)(11) on a Department-prescribed form, with the application.
- F.** Within 180 days after the director issues a certificate of authority to an Organization, the Organization shall notify the director in writing of each member appointed to the board of directors for the Organization under A.R.S. § 20-1003(A)(4).
- G.** At the time it submits its application for certificate of authority, an Organization shall submit a written program of compliance with supporting documents that specify how the Organization will comply with the provisions of this Article. The written program of compliance shall contain the following:
 - 1.** The responsibilities of and qualifications for the following positions:
 - a.** The Organization’s chief executive officer, and
 - b.** The Organization’s dental director;
 - 2.** A plan for provision of basic dental services required under R20-6-1806(A) and a copy of the schedule of benefits required under R28-6-1806(B);
 - 3.** A description of the system for delivery of services under R20-6-1807;
 - 4.** A description of the geographic area designated under R20-6-1808;
 - 5.** A plan for compliance with contract requirements under R20-6-1809 and a copy of a contract with a general dentist and a specialist;
 - 6.** A plan for compliance with records requirements under R20-6-1810; and
 - 7.** The Organization’s quality improvement plan under R20-6-1811.
- H.** An application shall include the following information:
 - 1.** The proposed number of members, and
 - 2.** A copy of a letter from each network dentist that documents the dentist’s intent to contract with the Organization to provide services to patients under the Organization’s prepaid dental plan.

Arizona Administrative Register
Notices of Final Rulemaking

- I.** The director may require that an applicant for a certificate of authority under A.R.S. § 20-1003(A)(14) submit information that discloses biographical, employment and business financial history, criminal activity, fingerprints, or any information that relates to the ability to operate a prepaid dental plan for principals, principal officers, controlling persons, and insurance producers of the applicant, if necessary for the protection of residents of this State.

R20-6-1803. Reserved Chief Executive Officer

- A.** The governing authority shall appoint a chief executive officer (CEO). The CEO shall have:
1. The education and experience to manage the Organization, and
 2. Responsibility for the geographic area in Arizona that the Organization serves, including:
 - a. Implementing the policies of the governing authority, and
 - b. Maintaining adequate personnel to ensure compliance with applicable Arizona statutes and rules.
- B.** The governing authority shall notify the Department within ten days after the effective date of a change in the appointment of the CEO.

R20-6-1804. Reserved Dental Director

- A.** The governing authority or CEO shall appoint as the Organization's dental director a dentist licensed to practice dentistry in any state or territory of the United States or the District of Columbia.
- B.** The dental director shall perform at least the following functions for the Organization's geographic area in Arizona:
1. Participate on the Organization's quality improvement committee required under R20-6-1811;
 2. Oversee the Organization's program and processes for:
 - a. Maintaining and improving clinical quality of care, including continuity of care;
 - b. Provider relations;
 - c. Facility and dental record reviews; and
 - d. Provider credentialing and recredentialing;
 3. Be knowledgeable about and participate in decisions regarding the Organization's operations;
 4. Comply with A.R.S. § 20-2510(B) and (C) when directly denying, on the basis of medical necessity, a health care provider's request for prior authorization; and
 5. Timely respond to matters within the Organization's Arizona geographic area that require personal onsite attention or ensure that a designee who meets the requirements specified in subsection (D) timely responds to those matters.
- C.** Matters that require personal onsite attention include:
1. Urgent patient care issues that require examination of dental records or X-rays;
 2. Prompt personal discussion with a provider of urgent concerns relating to credentialing, disciplinary problems, access to care, or quality of care.
- D.** Any designee acting under subsection (B)(5) shall:
1. Be a dentist licensed to practice dentistry in any state or territory of the United States or the District of Columbia;
 2. Have expedient access to the dental director, the CEO, and other organization management personnel as necessary to resolve any matter requiring personal onsite attention; and
 3. Have the education, experience, and Organizational knowledge required to address the matter requiring personal onsite attention.
- E.** The Organization shall notify the Department in writing within ten days after the effective date of a change in the appointment of the dental director or any designee.
- F.** The requirements for a designee under subsections (B)(5), (D), and (E) shall not apply to an Organization with fewer than 2,000 members in Arizona.

R20-6-1805. Reserved Required Reporting

- A.** An Organization shall submit to the Department in writing for review any proposed change to the program of compliance. The Department shall notify the Organization in writing within 30 days of receipt of the proposed change whether the submission is administratively complete. The Department shall complete its substantive review and notify the Organization of approval or disapproval of the proposed change within 60 days of notification of administrative completeness.
- B.** An Organization shall provide the following information about the prepaid dental plan to the Department quarterly:
1. The total number of members and the number of members assigned to each general dentist's office;
 2. A list of all contracted network general dentists and specialists that notes those who have been added or deleted since the previous quarterly report;
 3. Verification that each specialist added to the network since the last quarterly report has graduated from a specialty graduate program accredited by the American Dental Association; Documentation of the Organization's quality improvement activities, including the number of providers who have been credentialed or re-credentialed since the last quarterly report, the number of facility reviews, and the number of chart reviews;
 4. The average wait time measured in weeks for an appointment for each network dentistry office;
 5. A copy of the current provider directory; and
 6. A complaint log with a summary of Organization responses by complaint category.
- C.** An Organization shall submit the following information to the Department at least annually:

Notices of Final Rulemaking

1. Member satisfaction survey results and supporting data;
2. Results of a survey of network general dentistry offices with supporting data confirming a recall system under R20-6-1810(B)(2);
3. An electronic database that lists the name, address, and telephone number of each provider and whether the provider is accepting new members. The Organization shall submit the database for general dentists and specialists separately. The Organization shall submit any changes to this database to the Department quarterly; and
4. A report that compiles all the copays listed in all the schedules of benefits offered by the Organization, with comparisons of the copays to the usual, customary, and reasonable fees, as determined by the Organization, for the procedures listed on the schedule of benefits.

R20-6-1806. Reserved Basic Dental Services

- A.** A prepaid dental plan shall provide the basic dental services listed below:
1. Emergency dental services on a 24-hour-per-day basis,
 2. Diagnostic services,
 3. Preventive services, and
 4. Restorative services.
- B.** An Organization shall publish and make available to its members and purchasers a schedule of benefits that includes the dental plan's basic dental services and other available dental services and any associated copays.

R20-6-1807. Reserved System for Delivery of Services

- A.** An Organization shall have a system for delivery of services that includes:
1. An adequate network of general dentists. To determine network adequacy, the Department shall consider the following:
 - a. Geographic distribution of network general dentists' offices,
 - b. The number of dental offices accepting new members,
 - c. The percentage of all network members who are able to schedule an appointment within nine weeks,
 - d. The availability of trained clinical support staff in the Arizona geographic area,
 - e. The ratio of population growth to the increase or decrease in the number of dentists in the Arizona geographic area, and
 - f. Current availability for appointments in all general dentist practices in Arizona; and
 2. Provision for using specialists for dental services that cannot be provided by the Organization's network of contracted specialists, if the services are covered benefits.
- B.** If a network dental office that is open to new members has an appointment wait time of longer than nine weeks, for three consecutive calendar quarters, the director may require the Organization to close the office to new members until the wait time is less than nine weeks.
- C.** If more than 15% of the network offices that are open to new members have an appointment wait time of longer than nine weeks, the Organization shall submit a plan to the Department under which the Organization will, within 90 days, reduce the wait time to less than nine weeks. If the Organization does not reduce the wait time to less than nine weeks within the 90 day period the Organization shall refer the members who are waiting for an appointment to another network general dentist or a non-network general dentist who can schedule the member for an appointment in less than nine weeks. The member may choose to continue dental care under the prepaid dental plan with the referred dentist for the remainder of the member's enrollment period. The Organization shall provide the non-network services to the referred member at a cost that is no greater than if the services are provided by the member's assigned network dentist.
- D.** An Organization shall pay for emergency dental services provided to a member by a dentist licensed in the jurisdiction where the services are provided, subject to plan limitations disclosed in the dental care plan, including emergency dental services that occur:
1. Within the geographic area served by the member's designated provider but the provider is unavailable, or
 2. Occurs outside of the member's designated geographic service area.

R20-6-1808. Reserved Geographic Areas

- A.** An Organization shall designate the geographic areas in Arizona in which the Organization intends to provide dental services that are reasonably convenient to the prospective members. The Organization shall provide a description of the geographic areas and locations of all facilities in which dental care will be provided under the prepaid dental plan. This information shall accompany or be included in any advertisements or sales materials provided to prospective employer groups and prospective members.
- B.** An Organization shall define its geographic areas by citing at least one of the following:
1. Local government jurisdictions, such as cities or counties;
 2. Street boundaries; or
 3. Area within a specified radius of an intersection.

Arizona Administrative Register
Notices of Final Rulemaking

R20-6-1809. Reserved Contract Requirements

- A.** An Organization shall have a written contract with each provider that documents the requirements for providing services under the prepaid dental plan and the terms of the agreements between the parties. The Organization shall ensure that the provider complies with all contract requirements.
- B.** In addition to the requirements in subsection (A), an Organization shall ensure that its contract with a provider includes the following provisions:
1. That the Organization has authority to review the provider's records.
 2. That the provider is responsible to implement and maintain a process to inform assigned members of the need to schedule periodic preventive dental services based on the member's oral health status, and
 3. That the provider is responsible to complete any procedure undertaken upon a member if the contract is terminated or expires.

R20-6-1810. Reserved Records

- A.** Dental records are the property of the provider and shall not be removed from the provider's possession, except:
1. With the patient's permission, including for routing records to a dental or medical practitioner for consultation or evaluation; or
 2. When subpoenaed by a court or BODEX.
- B.** An Organization shall maintain at its principal office a copy of each issued or delivered advertising matter or sales material, letter of solicitation, evidence of coverage, provider directory, certificate, agreement, or contract. The Organization shall note the date each advertising matter or sales material is filed with the Department and the date of distribution to any person. The advertising matter or sales material shall be maintained for at least three years.

R20-6-1811. Reserved Quality Improvement

- A.** An Organization shall have a governing authority.
- B.** The governing authority shall appoint a quality improvement committee that consists of the chief executive officer or designee, the dental director, the person who manages the Organization's quality improvement process, and at least one dental health professional. The committee may also include network allied health professionals and members of the plan.
- C.** The quality improvement committee shall:
1. Meet at least quarterly.
 2. Review and evaluate dental services delivered under the Organization's plan, and
 3. Establish procedures for recordkeeping and distribution of committee reports.
- D.** An Organization shall provide the director with a copy of the minutes of each quality improvement committee meeting within 30 days of the quality improvement committee meeting.
- E.** An Organization shall maintain a written quality improvement plan that contains procedures for each of the following:
1. Ensuring that a dentist licensed in any state or territory of the United States or District of Columbia reviews and evaluates dental care and services provided by each contracted general dentist at least once every three years;
 2. Allocation of the Organization's resources to analyze a problem or any identified deficiency;
 3. Implementing a corrective action plan and methods for monitoring improvement;
 4. Notifying a member in writing of the member's responsibility to cooperate with those providing dental care services and of the member's rights to:
 - a. Voice concerns about the Organization or care provided;
 - b. Be provided with information about the Organization, its services, providers, and member rights and responsibilities;
 - c. Participate in decisions about the member's dental care; and
 - d. Be treated with respect and have the right to privacy recognized;
 5. Monitoring and improving membership satisfaction;
 6. Maintaining an accurate provider directory that meets at least the following requirements:
 - a. Lists only credentialed providers who are currently scheduling members for diagnosis and treatment; and
 - b. Clearly designates providers who are not accepting new members;
 7. Review by the dental director of the following for initial credentialing of network providers:
 - a. Query to the National Practitioner Data Bank;
 - b. Query to BODEX;
 - c. Valid United States Drug Enforcement Administration certificate, if applicable;
 - d. Evidence of current malpractice insurance; and
 - e. Documentation that each specialist has graduated from an accredited specialty graduate program as required by BODEX.
 8. Recredentialing, at least every three years, that updates information obtained in subsections (E)(7)(b) through (d), for the dental director's review.

R18-6-1812. Reserved Confidentiality of Records

An Organization shall not disclose information obtained pertaining to the diagnosis, treatment, or health of a member to any person except:

1. To the extent necessary to carry out this Article;
2. Upon the express written consent of the member, applicant, provider, or Organization, as appropriate; or
3. Under statute or court order for the production or discovery of evidence or as part of a civil or criminal investigation.

R20-6-1813. Reserved Assignment of Members

A. Within 30 days of enrollment, an Organization shall assign a member to the provider the member chooses. The Organization, however, shall choose and assign a provider to a member within 30 days of any of the following:

1. Receipt of a member enrollment form that does not designate a provider, or receipt of a member enrollment form that designates a provider who is unavailable;
2. The date of the notice that the member's assigned provider intends to cease providing services; or
3. The date the member's assigned provider becomes unavailable, for any reason.

B. An Organization shall give each member the option of selecting a network provider other than the provider assigned by the Organization under subsection (A).

C. An Organization shall maintain a continuous assignment process in compliance with subsection (A) and (B), allowing no more than 4% of members to be unassigned at any time.