NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

NOTICE OF PROPOSED EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

Editor's Note: The following Notice of Exempt Rulemaking was reviewed per Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 1508.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 9, 2011.

[R12-105]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) **Rulemaking Action**
R9-22-710 Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing statute: A.R.S. §§ 36-2903.01, 36-2907

Implementing statute: A.R.S. § 36-2904

3. The proposed effective date of the rules:
August 1, 2012

4. A list of all previous notices appearing in the *Register* addressing the proposed exempt rule:
None

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:
Please provide comments either by e-mail or mail to the contact listed below. The close of the comment period is July 9, 2012.

Name:	Mariaelena Ugarte
Address:	AHCCCS Office of Administrative Legal Services 701 E. Jefferson St., Mail Drop 6200 Phoenix, AZ 85034
Telephone:	(602) 417-4693
Fax:	(602) 253-9115
E-mail:	AHCCCSRules@azahcccs.gov
Web site:	www.azahcccs.gov

6. An explanation of the rule, including the agency's reasons for initiating the rule, including the statutory citation to the exemption from regular rulemaking procedures:
The Veterans Health Care Act of 1992 established the 340B program in section 340B of the Public Health Service Act (PHS Act). The 340B program requires drug manufacturers participating in Medicaid to provide discounted covered outpatient drugs to certain eligible health care entities, known as covered entities. Covered entities include disproportionate share hospitals, family planning clinics, and federally qualified health centers, among others as described under 42 U.S.C. 256b(a)(4). As of October 2010, approximately 15,000 covered-entity locations were enrolled in the 340B program.

The Health Resources and Services Administration (HRSA) administers the 340B program. In 2000, HRSA issued guidance directing covered entities to refer to State Medicaid agencies' policies for applicable billing policies in

regards to 340B claims. The Centers for Medicare and Medicaid Services (CMS), which administers the Medicaid program, does not require State Medicaid agencies to set 340B policies. The AHCCCS Administration recently promulgated a rule which describes the reimbursement methodology applicable to FQHCs and FQHC Look Alikes and their contacted pharmacies for drugs that are subject to 340B pricing. This rule became effective February 1, 2012. In response to questions regarding the scope of this rule, the AHCCCS Administration found that further clarification was needed to define an FQHC and FQHC Look-Alike pharmacy. Additionally, the proposed rule clarifies that contracted pharmacies shall not submit claims for drugs dispensed under an agreement with a 340B entity as part of the 340B drug pricing program.

Arizona Laws 2011, Ch. 31, § 34, authorized the agency to adopt rules necessary to implement a program within available appropriations, including making changes to reimbursement rates and methodologies, and to make changes to rules relating to cost sharing responsibilities of eligible persons.

Arizona Laws 2011, Ch. 31, § 34 exempts the Administration from the formal rulemaking requirements of A.R.S. Title 41, Chapter 6.

Arizona Law 2011, Ch. 31, § 34, which authorizes this exempt rulemaking, requires public notice with an opportunity for public comment of at least 30 days. Public notice of this rulemaking will be accomplished through publication of this rulemaking on the agency web site on May 31, 2012. A supplemental notice will also appear in the *Arizona Administrative Register* in advance of the close of the comment period. In addition, notice will be directed to those individuals who, prior to this proposed rulemaking have notified the agency of their desire to receive such notices directly pursuant to A.R.S. § 36-2903.01(B)(6).

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

The Department of Health and Human Services Office of Inspector General issued a report with the following recommendations: (1) inform states that they should incorporate 340B policies into their Medicaid State Plans, (2) inform states of alternative methods of identifying 340B claims that we identified in this report, and (3) facilitate communication between HRSA and states by providing a list of State Medicaid pharmacy directors to HRSA and instructing states to contact HRSA when errors in the Medicaid Exclusion File are found. CMS and HRSA concurred with the recommendations.

The study "Cost of Dispensing Study: An independent comparative analysis of U.S. prescription dispensing costs by Grant Thornton LLP" demonstrated a national median cost of dispensing.

Arizona used an adjustment factor using geographic practice cost indices resulting in the AZ cost of dispensing. The Administration has analyzed the data through the study and AHCCCS claims data at the NDC level for the 1st quarter of 2011; the results of the analysis demonstrated a net savings valued at approximately $7.1M annually.

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 AHCCCS Administration believes that the amendment to this rule defining an FQHC and FQHC Look-Alike pharmacy will provide clarity to those providers that are unsure of their participation in the 340B program and therefore include appropriate reimbursement for claims paid at the 340B pricing. Although no economic impact is associated with the revision proposed in this rulemaking, the estimated savings to the state associated with the prior rulemaking effective February 2012 is approximately $7.1M. It should be noted that these approximate savings and dispensing fee costs do not take into consideration the prescriptions filled at 340B contracted pharmacies which are not subject to this methodology.

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

Not applicable

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

No comments have been received yet. Please provide comments either by e-mail or mail by the close of the comment period July 9, 2012.

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

None

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

None

14. Was this rule previously made as an emergency rule? If so, please indicate the *Register* citation:

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

ARTICLE 7. STANDARDS FOR PAYMENTS

Section
R9-22-710. Payments for Non-hospital Services

ARTICLE 7. STANDARDS FOR PAYMENTS

R9-22-710. Payments for Non-hospital Services

A. Capped fee-for-service. The Administration shall provide notice of changes in methods and standards for setting payment rates for services in accordance with 42 CFR 447.205, December 19, 1983, incorporated by reference and on file with the Administration and available from the U.S. Government Printing Office, Mail Stop: IDCC, 732 N. Capitol Street, NW, Washington, DC, 20401. This incorporation by reference contains no future editions or amendments.

1. Non-contracted services. In the absence of a contract that specifies otherwise, a contractor shall reimburse a provider or noncontracting provider for non-hospital services according to the Administration's capped-fee-for-service schedule.
2. Procedure codes. The Administration shall maintain a current copy of the National Standard Code Sets mandated under 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004), incorporated by reference and on file with the Administration and available from the U.S. Government Printing Office, Mail Stop: IDCC, 732 N. Capitol Street, NW, Washington, DC, 20401. This incorporation by reference contains no future editions or amendments.
   a. A person shall submit an electronic claim consistent with 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004).
   b. A person shall submit a paper claim using the National Standard Code Sets as described under 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004).
   c. The Administration may deny a claim for failure to comply with subsection (A)(2)(a) or (b).
3. Fee schedule. The Administration shall pay providers, including noncontracting providers, at the lesser of billed charges or the capped fee-for-service rates specified in subsections (A)(3)(a) through ~~(A)(3)(d)~~ (d) unless a different fee is specified in a contract between the Administration and the provider, or is otherwise required by law.
   a. Physician services. Fee schedules for payment for physician services are on file at the central office of the Administration for reference use during customary business hours.
   b. Dental services. Fee schedules for payment for dental services are on file at the central office of the Administration for reference use during customary business hours.
   c. Transportation services. Fee schedules for payment for transportation services are on file at the central office of the Administration for reference use during customary business hours.
   d. Medical supplies and durable medical equipment (DME). Fee schedules for payment for medical supplies and DME are on file at the central office of the Administration for reference use during customary business hours. The Administration shall reimburse a provider once for purchase of DME during any two-year period, unless the Administration determines that DME replacement within that period is medically necessary for the member. Unless prior authorized by the Administration, no more than one repair and adjustment of DME shall be reimbursed during any two-year period.

B. Pharmacy services. The Administration shall not reimburse pharmacy services unless the services are provided by a pharmacy having a subcontract with a Pharmacy Benefit Manager (PBM) contracted with AHCCCS. Except as specified in subsection (C), the Administration shall reimburse pharmacy services according to the terms of the contract.

C. FQHC Pharmacy reimbursement.

1. For purposes of this ~~section~~ Section the following terms are defined:
   a. "340B Drug Pricing Program" means the discount drug purchasing program described in 42 U.S.C. 256b.
   b. "340B Ceiling Price" means the maximum price that drug manufacturers can charge covered entities participating in the 340B Drug Pricing Program as reported by the drug manufacturer to HRSA.
   c. "340B entity" means a covered entity, eligible to participate in the 340B Drug Pricing Program, as defined by the Health Resources and Human Services Administration.
   d. "Actual Acquisition Cost (AAC)" means the purchase price of a drug paid by a pharmacy net of discounts, rebates, chargebacks and other adjustments to the price of the drug. The AAC excludes dispensing fees.
   e. "Contracted Pharmacy" means an arrangement through which a 340B entity may contract with an outside phar-

macy to provide comprehensive pharmacy services utilizing medications subject to 340B pricing.

f. "Dispensing Fee" means the amount paid for the professional services provided by the pharmacist for dispensing a prescription. The Dispensing Fee does not include any payment for the drugs being dispensed.

g. "Federally Qualified Health Center" means a public or private non-profit health care organization that has been identified by HRSA and certified by CMS as meeting the criteria under sections 1861(aa)(4) and 1905(l)(2)(B) of the Social Security Act and receives funds under Section 330 of the Public Health Service Act.

h. "Federally Qualified Health Center Look-Alike" means a public or private non-profit health care organization that has been identified by HRSA and certified by CMS as meeting the definition of "health center" under Section 330 of the Public Health Service Act, but does not receive grant funding under Section 330.

i. "FQHC or FQHC Look-Alike pharmacy" means a pharmacy that dispenses drugs to FQHC or FQHC-LA patients and that is owned and/or operated by an FQHC/FQHC-LA or by an entity that reports the costs of an FQHC/FQHC-LA on its Medicare Cost Report, whether or not collocated with an FQHC or an FQHC Look-Alike.

2. Effective the later of February 1, 2012, or CMS approval of a State Plan Amendment, an FQHC or FQHC Look-Alike shall:
   a. Notify the AHCCCS provider registration unit of its status as a 340B covered entity no later than:
      i. 30 days after the effective date of this Section;
      ii. 30 days after registration with the Health Resources and Services Administration (HRSA) for participation in the 340B program; or
      iii. The time of application to become an AHCCCS provider.
   b. Provide the 340B pricing file to the AHCCCS Administration upon request. The 340B pricing file shall be provided in the file format as defined by AHCCCS.
   c. Identify 340B drug claims submitted to the AHCCCS FFS PBM or the Managed Care Contractors' PBMs for reimbursement. The 340B drug claim identification and claims processing for a drug claim submission shall be consistent with claim instructions issued and required by AHCCCS to identify such claims.
3. The FQHC and the FQHC Look-Alike pharmacies shall submit claims for AHCCCS members for drugs that are identified in the 340B pricing file, whether or not purchased under the 340B pricing file, with the lesser of:
   a. The actual acquisition cost, or
   b. The 340B ceiling price.
4. The AHCCCS Fee-for-Service and Managed Care Contractors' PBMs shall reimburse claims for drugs which are identified in the 340B pricing file dispensed by FQHC and FQHC Look -Alike pharmacies, whether or not purchased under the 340B pricing file, at the amount submitted under subsection ~~(3)~~ (C)(3) plus a dispensing fee listed in the AHCCCS Capped Fee-For-Service Schedule unless a contract between the 340B entity and a Managed Care Contractor's PBM specifies a different dispensing fee.
5. Contracted pharmacies shall not submit claims for drugs dispensed under an agreement with the 340B entity as part of the 340B drug pricing program, and the ~~The~~ AHCCCS Administration and Managed Care Contractors shall not reimburse such claims ~~contracted pharmacies for drugs dispensed under an agreement with the 340B entity as part of the 340B drug pricing program~~.
6. The AHCCCS Administration and Managed Care Contractors shall reimburse contracted pharmacies for drugs not dispensed under an agreement with the 340B entity as part of the 340B program at the price and dispensing fee set forth in the contract between the contracted pharmacy and the AHCCCS or its Managed Care Contractors' PBMs. Neither the Administration nor its Managed Care Contractors will reimburse a contracted pharmacy that does not have a contract with the Administration or MCO's PBM.
7. The AHCCCS Administration and its Managed Care Contractors shall reimburse FQHC and FCHC Look-Alike pharmacies for drugs that are not eligible under the 340B Drug Pricing Program at the price and dispensing fee set forth in their contract with the AHCCCS or its Managed Care Contractors' PBMs.
8. AHCCCS may periodically conduct audits to ensure compliance with this Section.

NOTICE OF EXEMPT RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 18. NATUROPATHIC PHYSICIANS BOARD OF MEDICAL EXAMINERS

Editor's Note: The following Notice of Exempt Rulemaking was exempt from Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 1508.)

[R12-100]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) **Rulemaking Action**
R4-18-107 Amend

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

Authorizing statute: A.R.S. § 32-1527

Implementing statute: A.R.S. § 32-1527

Statute or session law authorizing the exemption: A.R.S. § 41-1005(A)(24)

3. The effective date of the rule and the agency's reason it selected the effective date:

The effective date of the rule is June 6, 2012. The Board is requesting an immediate effective date according to A.R.S. § 41-1032(A)(5) because almost all of the fees are being decreased or eliminated, thus the rule is less stringent than the rule that is currently in effect and does not have an impact on the public health, safety, welfare or environment and does not affect the public involvement and public participation process. The Board is amending its fees consistent with its statutory authority and the fees established by the Board at its September 8, 2011 Board meeting.

4. A list of all notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the exempt rulemaking:

Not applicable

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

Name:	Dr. Craig Runbeck, Executive Director
Address:	1400 W. Washington St., Suite 300 Phoenix, AZ 85007
Telephone:	(602) 542-8242
Fax:	(602) 542- 8804
E-mail:	craig.runbeck@aznd.gov

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

Under A.R.S. § 32-1527, the Board by formal vote at an open public meeting is required to establish its fees. The Board is amending its fees rule to be current with the fees established by the Board at its September 8, 2011 Board meeting. The Board decreased many of its fees and is making this rule to be consistent with the fees published on its web site at www.aznd.gov. Under A.R.S. § 41-1005(A)(24), the Board is exempt from A.R.S. Title 41, Chapter 6 for rulemaking.

The Board is submitting this rulemaking to the Secretary of State's office in accordance with the exemption authorization in Executive Order 2011-05, State Regulatory Rulemaking Moratorium.

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

The Board did not review or rely on any study.

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

Not applicable

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

The Board is exempt under A.R.S. § 41-1005(A)(24).

10. A description of any changes between the proposed rules, including supplemental notices, and the final rulemaking package (if applicable)
Not applicable

11. A summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments (if applicable):
The Board did not receive any public or stakeholder comments.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. Additional matters include but are not limited to:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:
The Board issues a license, which falls within the definition of general permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:
Federal law is not applicable to the subject of the rule.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:
The Board did not receive such an analysis from any person.

13. A list of any incorporated material and its location in the rules:
None

14. Whether the rule was previously made, amended, repealed, or renumbered as emergency rule? If so, shall state where the text changed between the emergency and exempt rulemaking packages:
The Board did not make, amend, repeal, or renumber the rule as an emergency rule.

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 18. NATUROPATHIC PHYSICIANS BOARD OF MEDICAL EXAMINERS

ARTICLE 1. GENERAL PROVISIONS

Section
R4-18-107. Fees

ARTICLE 1. GENERAL PROVISIONS

R4-18-107. Fees

A. Application fees are as follows:
1. Medical license, ~~$300~~ $150
~~2. Specialist certificate, $300~~
~~3.~~2. Certificate to dispense, ~~$300~~ $150
~~4.~~3. Medical assistant certificate, $100
~~5.~~4. Clinical training certificate, ~~$150~~ $100
~~6. Internship certificate, $150~~
~~7.~~5. Preceptorship certificate, ~~$150~~ $100
~~8. Certificate to conduct a clinical training program, $150~~
~~9. Certificate to conduct an internship training program, $150~~
~~10. Certificate to conduct a preceptorship training program, $150~~

B. Arizona naturopathic jurisprudence examination, $60

C. Annual renewal fees are as follows:
1. Medical license, ~~$360~~ $110
2. Certificate to dispense, ~~$300~~ $150
3. Medical assistant certificate, $100
4. Clinical training certificate, $150
~~5. Internship certificate, $150~~
~~6.~~5. Preceptorship certificate, $150
~~7. Certificate to conduct a clinical training program, $396~~

~~8. Certificate to conduct an internship training program, $396~~
~~9. Certificate to conduct a preceptorship training program, $396~~

D. Late renewal fees are as follows:
1. Medical license, ~~$180~~ $55
2. Certificate to dispense, ~~$150~~ $75
3. Medical assistant certificate, $50
4. Clinical training certificate, $75
~~5. Internship certificate, $75~~
~~6.~~5. Preceptorship certificate, $75
~~7. Certificate to conduct a clinical training program, $200~~
~~8. Certificate to conduct an internship training program, $200~~
~~9. Certificate to conduct a preceptorship training program, $200~~

E. Other fees are as follows:
1. For a duplicate license or certificate, $20
2. For photocopying Board records, documents, letters, applications, or files, $5 or $0.25 per page, whichever is greater
3. For each audio tape or computer disk containing information requested, $25
4. For written verification of a license or certificate, ~~$10~~ $5
5. For the costs in locating a person who is licensed or certified, ~~Actual~~ actual cost incurred by the Board
~~6. For submitting a fingerprint card to the department of public safety, $24~~
~~7.~~6. For each insufficient fund check, $25